Memorandum

To: Gold Coast Health Plan Providers

From: Lily Yip, Pharm.D., MBA, APh, CDCES, BCACP, CPHQ, Director of Pharmacy

Re: FDA Drug Recall/Voluntary Market Withdrawal

Date: Aug. 5, 2026

This is a notification regarding a Food and Drug Administration (FDA) recall involving **cetirizine hydrochloride tablets USP 5 mg** manufactured by **Unique Pharmaceutical Laboratories**.

Reason for Recall/Withdrawal:
Unique Pharmaceutical Laboratories (a division of J.B. Chemicals and Pharmaceuticals Limited) is voluntarily recalling four lots of cetirizine hydrochloride tablets USP 5 mg to the consumer level due to cross contamination with ranitidine.

Effective Date: July 18, 2026

Affected Product Information

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Cetirizine	5 mg	Tablet	16571-401-10	GY825029 GY825030 GY825031 GY825031	10/2028 10/2028 10/2028 10/2028

Risk Statement
For consumers with a hypersensitivity to the ingredients in ranitidine, there is a reasonable probability that ingestion of cetirizine tablets contaminated with ranitidine could result in serious adverse events, including severe hypersensitivity reactions and anaphylaxis that manifests as hypotension, dyspnea, difficulty swallowing, throat and facial edema, generalized pruritic, urticaria, and loss of consciousness, which are all life-threatening. To date, Unique Pharmaceuticals has not received any reports of adverse events related to this recall.

Clinical Considerations
Providers should:

- Review patient records to identify individuals receiving affected product(s).
- Evaluate patients for potential clinical impact related to the recall or withdrawal.
- Discontinue use of affected lots/products as appropriate.
- Transition patients to an appropriate alternative therapy when clinically indicated.
- Monitor patients for adverse events or treatment interruptions.

Member Notification
Gold Coast Health Plan (GCHP) has identified and notified potentially affected members by letter regarding this recall/withdrawal.

Additional Information
For additional details regarding this recall/withdrawal, please refer to:

- FDA Recall Notice
- Manufacturer Communication: Rising Pharma Holdings, Inc., 1-844-874-7464, 8 a.m. to 5 p.m. (EST) (Monday-Friday) or email pv@risingpharma.com or qa@risingpharma.com
- FDA Drug Safety Communications:https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications
- FDA Recalls, Market Withdrawals, & Safety Alerts
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- The FDA Weekly Enforcement Report:

For additional questions, please email GCHP Pharmacy Services at Pharmacy@goldchp.org.