Memorandum

To: Gold Coast Health Plan Providers

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

Re: FDA Drug Recall and Voluntary Market Withdrawal

Date: Aug. 26, 2026

This is a notification regarding multiple Food and Drug Administration (FDA) drug recalls/voluntary manufacturer withdrawals that may impact Gold Coast Health Plan (GCHP) members. Please see below for detailed information regarding each affected product.

Recall/Withdrawal #1
Drug: Clindamycin palmitate HCl for oral solution 75 mg/5 ml, 100ml bottle
Manufacturer: Heritage Pharmaceuticals, Inc.
Reason for Recall/Withdrawal: Presence of foreign substance - presence of particles and white flakes in the reconstituted bottles.
Effective Date: July 30, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Clindamycin palmitate HCl	75 mg/5 ml	Oral solution	23155-0603-51	2411550	Nov. 2026

FDA Recall/Withdrawal Notice
Manufacturer Communication: 1-866-901-1230 9 a.m. – 5 p.m. EST (Monday – Friday)

Recall/Withdrawal #2
Drug: Acetylcysteine solution 20% (200 mg/4 ml) vial
Manufacturer: American Regent
Reason for Recall/Withdrawal: Presence of particulate matter- product contaminated with particulate matter identified as hair.
Effective Date: July 24, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Acetylcysteine	20% (200 mg/ 4ml)	Solution (vial NOT for injection)	00517-7604-01 00517-7604-25	24426 25220	Nov. 30, 2026 May 31, 2027

FDA Recall/Withdrawal Notice
Manufacturer Communication: 1-800-645-1706 8 a.m. – 6 p.m. EST (Monday – Thursday), 8 a.m. – 4 p.m. EST (Friday) or email pv@americanregent.com

Clinical Considerations

Providers should:

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

Member Notification

GCHP has identified and notified potentially affected members by letter regarding this drug recall/withdrawal.

Additional Information

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

- FDA 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 Department at Pharmacy@goldchp.org.