

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: Sept. 29, 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. Detailed information regarding each affected product is provided below.

Recall / Withdrawal #1

Drug: Lidocaine 5% ointment

Manufacturer: Sun Pharmaceuticals, Inc.

Reason for Recall / Withdrawal: failed content uniformity specifications. Out of specification for assay during analysis at the 24- month long term stability station.

Effective Date: Aug. 31, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Lidocaine	5%	Ointment	51672-3008-05	AD48154	April 30, 2027

FDA Recall / Withdrawal Notice:

<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=222500>

Manufacturer Communication: 1-800-818-4555 5 a.m. - 5 p.m. PST (Monday - Friday)

Recall / Withdrawal #2

Drug: Nystatin USP 100,000 units per gram cream

Manufacturer: Sun Pharmaceuticals, Inc.

Reason for Recall / Withdrawal: failed stability specifications

Effective Date: Sept. 14, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Nystatin	100,000 units per gram	Cream	51672-1289-01	AD49605 AD49606	May 31, 2027

FDA Recall/Withdrawal Notice:

<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=222791>

Manufacturer Communication: 1-800-818-4555 5 a.m. - 5 p.m. PST (Monday - Friday)

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.