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. 18, 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: Dicyclomine HCl 10 mg capsule
Manufacturer: Aurobindo Pharma, USA, Inc.
Reason for Recall/Withdrawal: Shortfill; reports of empty capsules
Effective Date: July 23, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Dicyclomine HCl	10mg	Capsule	59651-0719-99	DMC125018A	July 2027

FDA Recall/Withdrawal Notice:
https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=221718
Manufacturer Communication: 1-866-850-2876 or email at pvg@aurobindousa.com

Recall/Withdrawal #2
Drug: Mirabegraon extended release 25 mg tablet
Manufacturer: Zydus Pharmaceuticals (USA), Inc.
Reason for Recall/Withdrawal: Due to out of specification (OOS) result for N-Nitroso Mirabegron impurity
Effective Date: Aug. 5, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Mirabegraon extended release	25 mg	tablet	70710-1159-03	E408618	Nov. 30, 2026

FDA Recall/Withdrawal Notice:
https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=221880
Manufacturer Communication: 1-877-993-8779 8:30 a.m. – 5 p.m. EST (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.