POLICY AND PROCEDURE	
Title: Pharmaceutical Safe Use Monitoring of Physician Administered Drugs	
Primary Policy owner: Pharmacy	**Policy#:** PH14
Impacted/Secondary policy owner: Select the department(s) that are responsible for compliance with all, or a portion of the policy or procedure as outlined	
1) ☐All Departments 2) ☐Behavioral Health & Social Services (BH/SS) 3) ☐ Benefits Administration (BA) 4) ☐ Case Management (CM) 5) ☐ Claims (CLMS) 6) ☐ Community Marketplace & Member Engagement (MAR) 7) ☐ Compliance (CMP/HPA) 8) ☐ Configuration (CFG) 9) ☐ Provider Contracting (CONT) 10) ☐ Cultural & Linguistics (CL) 11) ☐ Customer Service (CS)	12) ☐ Facilities (FAC) 13) ☐ Finance (FIN) 14) ☐ Human Resources (HR) 15) ☐ Information Technology / Core Systems (IT) 16) ☒ Pharmacy (PH) 17) ☐ Provider Networks (PRO) 18) ☐ QI Health Equity (GRV/HE/HEQ/PHM/QM) 19) ☐ Utilization Management (UM) 20) ☐ Procurement (PRM) 21) ☐ Administration (SAF/BC/EM) 22) ☐ Medical Management (MM)
Product Type: ☒Medi-Cal ☐D-SNP	**Supersedes Policy Number:** N/A

I. PURPOSE

To establish Health Plan of San Joaquin and Mountain Valley Health Plan ("Health Plan") policies and procedures for notifying providers and

patients of any potential harm as discovered via drug recalls and any other drug safety alerts in relation to physician administered drugs.

II. POLICY

A. Health Plan :
   1. Identifies and notifies affected practitioners and members of product recalls and withdrawals that have been issued by the Food and Drug Administration (FDA) or pharmaceutical manufacturers for patient safety reasons, or other reasons on a case-by-case basis.
   2. Identifies and notifies practitioners of other potential patient safety issues with regards to the use of physician administered medications.

B. Drugs may be withdrawn from the market under the following categories with differing levels of urgency:
   1. Class I Recall: A situation in which there is a reasonable probability that the use of or exposure to a product that causes serious adverse health consequences or death.
   2. Class II Recall: A situation in which use of or exposure to a product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
   3. Class III Recall: A situation in which use of or exposure to a product is not likely to cause adverse health consequences.
   4. Market Withdrawal: A firm's removal or correction of a distributed product that involves a minor violation that would not be subject to legal action by the FDA.

C. Affected members and providers of drug recall or drug safety alerts are identified in the following manner:

1. Affected members are those who have a medical claim for the recalled physician administered drug within the 180 days prior to the recall.
2. Affected prescribing practitioners are those who prescribed the recalled physician administered drug within the 180 days prior to the recall.
3. Affected members and prescribing practitioners are identified from current medical claims data.

D. The letter contains the specific details of the recall, including, but not limited to, drug name, strength, lot number, NDC, and specific safety concerns.

III. PROCEDURE

A. Drug recalls and withdrawals from the market:

1. Health Plan's Director of Pharmacy, Staff Pharmacists, and Pharmacy Technician Specialists (PTS) sign up to receive FDA Enforcement Updates as soon as they become available and reviews them within 24 hours.
2. When a drug is withdrawn from the market or is subject to a Class I or II recall due to patient safety reasons, Health Plan sends an urgent notice out to all providers within three business days to ensure that use of the physician administered drug is discontinued.
3. When a Class I Recall is issued, Health Plan's Pharmacy Department identifies members and prescribing practitioners affected by the recall and notifies them by letter within three (3) business days of the FDA notice.
4. When a Class II Recall or Market Withdrawal is issued, Health Plan's Pharmacy Department identifies members and prescribing practitioners affected by the recall and notifies them by letter within thirty (30) calendar days of the FDA notice.

B. Other potential drug safety issues:

1. On a quarterly basis, Health Plan identifies members receiving excessive medications inappropriately. Please refer to PH21 – Drug Utilization Review for details.
2. These members are reviewed by Health Plan's Director of Pharmacy, Quality Improvement Nurse and Medical Director and may be placed on Restricted Status requiring a Prior Authorization (PA) Request for all medications and/or restricted to the use of one provider.

IV. ATTACHMENT(S)

A. DHCS Medi – Cal Managed Care Plans Definitions (Exhibit A, Attachment I, 1.0 Definitions)
B. Glossary of Terms Link
C. Medi-Cal Managed Care Contract Acronyms List (Exhibit A, Attachment I, 2.0 Acronyms)

V. REFERENCES

A. DHCS Contract, Exhibit A, Attachment 10, Provision F. 1
B. Health Plan Policy PH21 – Drug Utilization Review

VI. REVISION HISTORY

Version*	Revision Summary	Date
000	10/08, 05/12, 09/15, 02/16, 02/17, 02/18, 05/19, 11/19, 12/20, 09/21, 03/23	N/A
001	Moved PH14 onto new 2023 template	4/21/2023
002	Updated content to include Mountain Valley Health Plan. Reviewed content annually, no changes.	3/15/2024
003	Abbreviations and policy references were written out. Synced the sections for class I recalls so the time for mailers is consistent at three business days. Reorganized existing	5/2/2025

	content into relevant policy vs. procedure sections.	
004	Formatting edits were made. Reviewed with no further changes.	3/4/2026
Initial Effective Date: 2/2/1996		
Published Date:08/20/2026		

VII. Committee Review and Approval to be Completed by Compliance

Committee Name	Version	Date
Compliance Committee (CC)	004	8/14/2026
• Privacy & Security Oversight Committee (PSOC)		
• Program Integrity Committee (PIC)		
• Audits & Oversight Committee (AOC)		
• Policy Review Committee (PRC)	002	6/19/2024
Quality Improvement Health Equity Committee (QIHEC)	004	05/20/2026
• Quality Operations Committee (QOC)		
• Grievance Committee (GC)		

VIII. REGULATORY AGENCY APPROVALS

Department	Reviewer	Version	Date
Department of Healthcare services (DHCS)			

Department of Managed Care (DMHC)			

IX. *Approval* signature*

Signature	Name Title	Date
	PRC Chairperson	
	Policy Owner	
	Department Executive	
	Chief Executive Officer	

*Signatures are on file, will not be on the published copy