POLICY AND PROCEDURE	
Policy # and TITLE: PH14 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 (BH) 3) ☐Benefits Administration (BA) 4) ☐Care 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) ☐Health Equity (HEQ) 15) ☐Human Resources (HR) 16) ☐Information Technology / Core Systems (IT) 17) ☒Pharmacy (PH) 18) ☐Provider Networks (PRO) 19) ☐Quality Management (QM/GRV/HE) 20) ☐Utilization Management (UM)
PRODUCT TYPE: ☒Medi-Cal	**Supersedes Policy Number:** Policy # and Policy Title

I. PURPOSE

To establish 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 of San Joaquin (HPSJ) shall:

1. Identify and notify affected practitioners and members of product recalls and withdrawals that have been issued by the FDA or pharmaceutical manufacturers for patient safety reasons, or other reasons on a case-by-case basis.
2. Identify and notify practitioners of other potential patient safety issues with regards to the use of physician administered medications.

III. PROCEDURE

A. Drug recalls and withdrawals from the market

1. The Director of Pharmacy, Staff Pharmacists, and Pharmacy Technician Specialists (PTS) will sign up to receive FDA Enforcement Updates as soon as they become available and will review 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 When a drug is withdrawn from the market or is subject to a Class I or II recall due to patient safety reasons, an urgent notice will

be sent out to all providers within two business days to ensure that use of the physician administered drug is discontinued.

3. Drugs may be withdrawn from the market under the following categories with differing levels of urgency:
    a. Class I Recall: A situation in which there is a reasonable probability that the use of or exposure to a product will cause serious adverse health consequences or death.
    b. 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.
    c. Class III Recall: A situation in which use of or exposure to a product is not likely to cause adverse health consequences
    d. 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.
4. When a Class I Recall is issued, the Pharmacy Department identifies members and prescribing practitioners affected by the recall and notifies them by letter within three business days of the FDA notice.

a. Affected members are those who have a medical claim for the recalled physician administered drug within the 180 days prior to the recall.

b. Affected prescribing practitioners are those who prescribed the recalled physician administered drug within the 180 days prior to the recall.

c. Affected members and prescribing practitioners are identified from current medical claims data.

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

5. When a Class II Recall or Market Withdrawal is issued, the Pharmacy Department identifies members and prescribing practitioners affected by the recall and notifies them by letter within 30 calendar days of the FDA notice.

    a. Affected members are those who have a medical claim for the recalled physician administered drug within the 180 days prior to the recall.

    b. Affected prescribing practitioners are those who prescribed the recalled physician administered drug within the 180 days prior to the recall.

    c. Affected members and prescribing practitioners are identified from current medical claims data.

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

B. Other potential drug safety issues

1. On a quarterly basis, HPSJ identifies members receiving excessive medications inappropriately. Please refer to PH21 for details.
2. These members are reviewed by the Director of Pharmacy, Quality Improvement Nurse and Medical Director and may be placed on Restricted Status requiring a Prior Authorization Request (PA) 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. NCQA Standard UM 13 – Procedures for Pharmaceutical Management
C. PH21 – Drug Utilization Review

VI. REVISION HISTORY

*Version 001 as of 01/01/2023

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	04/21/2023
002		
002		
Initial Effective Date: 02/02/1996		

VII. Committee Review and Approval

Committee Name	Version	Date
Compliance Committee	001	
• Privacy & Security Oversight Committee (PSOC)	N/A	
• Risk Management	N/A	
• Delegation Oversight	N/A	
• Policy Review	001	
Quality and Utilization Management	001	
• Quality Of Care	N/A	
• Grievance	N/A	

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