HEALTH PLAN OF SAN JOAQUIN						
Subject: **Pharmaceutical Safe Use Monitoring**						
Department: Medical Management		**Unit:** Pharmacy		**Policy #: PH14**		
Effective Date: 02/01/1996	**Committee/Approval Date:** P&T 02/13/2018	**Review/Revision Dates:** 10/08, 05/12, 09/15, 02/16, 02/17, 02/18				
Applies To:	Medi-Cal	Yes	**X**	No		

POLICY

A. Health Plan of San Joaquin (HPSJ) shall:

1. Identify and notify dispensing providers of potential drug interactions, dosing and duration precautions, age precautions, ingredient duplications, gender conflicts, therapeutic or ingredient duplications, and compliance monitoring of refills too early.
2. Identify and notify affected practitioners and members of product recalls and withdrawals have been issued by the FDA or pharmaceutical manufacturers for patient safety reasons, or other reasons on a case by case basis.
3. Identify and notify practitioners of other potential patient safety issues with regards to the use of prescription medications.

PROCEDURE

A. **Drug Utilization Review**

1. HPSJ has adopted the Point of Sale (POS) Drug Utilization Review system of its Pharmacy Benefit Manager (PBM).
   a. The PBM performs POS (point of sale) Drug Utilization Review for claims submitted by pharmacy providers.
   b. These reviews are based on data and algorithms provided by First Data Bank or Medi-span's Drug Therapy Monitoring System and the results are returned to the pharmacy with the claim response.
2. The following types of Drug Utilization Review are conducted.
   a. Drug Interaction: Drugs categorized into the following 3 severity levels are communicated to the dispensing pharmacy:
      i. Severe: the interaction may be life threatening or cause permanent damage.
      ii. Moderate severity: the patient's condition may deteriorate due to the interaction, requiring additional care or extended hospitalization.
      iii. Minor severity: an interaction that is bothersome, but otherwise not medically detrimental.

b. Dosing/Duration Screening: Checks for dosages that are too high or too low based upon pediatric, adult, or geriatric age group.

c. Drug-Age Caution Screening: Identifies contraindications, such as a symptom or condition, that make a particular treatment or procedure inadvisable based on the member's age.

d. Gender Conflict: This review checks for drugs that are used either exclusively in males or females.

e. Duplicate Rx Screening: Performs two edits. The first checks for therapeutic duplications; the second checks for ingredient duplications.

B. **Drug recalls and withdrawals from the market**

1. The Director of Pharmacy and Staff Pharmacists will sign up to receive FDA Enforcement Updates 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 II recall due to patient safety reasons, the Director of Pharmacy or Staff Pharmacist will block the drug from being processed online and will notify all pharmacies in the network within 24 hours of announcement.

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 filled a prescription for the recalled drug within the 180 days prior to the recall.

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

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

   d. The Pharmacy Department performs a mail merge of the lists with the Drug Recall Notice letter.

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 filled a prescription for the recalled or withdrawn drug within the 180 days prior to the recall.

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

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

   d. The Pharmacy Department performs a mail merge of the lists with the Drug Recall Notice letter.

C. **Other potential drug safety issues**

1. On a quarterly basis, HPSJ identifies members receiving excessive medications inappropriately, especially narcotics.

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 pharmacy provider.

REFERENCE

A. DHCS Contract, Exhibit A, Attachment 10, Provision F. 1

B. NCQA Standard UM 13 – Procedures for Pharmaceutical Management

Health Plan of San Joaquin
Approval: Signatures on File

DHCS Contract Deliverables

Contract Reference	*Date of Approval*	*DHCS Unit*		*Contract Reference*	*Date of Approval*	*DHCS Unit*