PLAN POLICY AND PROCEDURE	
SHARP HEALTH PLAN make life better. **Title: Pharmacy Management Procedure for Pharmaceutical Patient Safety**	**Product Line** (check all that apply)**:** ☒ All ☐ Group HMO ☐ Individual HMO ☐ PPO ☐ POS ☐ N/A
Division(s): Health Services	
Department(s): Pharmacy	
Owner (Title): Pharmacy Manager	
Relevant Regulatory/Accrediting Agencies/Citations (specify): ☐ CMS: _____ ☐ DMHC: _____ ☒ NCQA-HP: UM 13C, QI 1A3 ☐ NCQA-WHP: _____ ☐ OTHER: _____	
Approved by: (Signature of VP, Compliance Officer, or CEO)	**Approval date:** 3/6/2016

I. PURPOSE:

This Policy and Procedure establishes Sharp Health Plan's (Plan) policy and procedure for Pharmaceutical Patient Safety.

II. POLICY:

It is the policy of Sharp Health Plan (Plan) to maintain a multifaceted program to improve the safety of the pharmaceutical benefits program for all its members.

III. PATIENT SAFETY ACTIVITIES AND PROCEDURES:

A. Drug Use Review (DUR) edits

The Plan or its vendor (MedImpact) employs drug interaction screening software to check for seven different DUR edits (Drug Interaction, Drug Dosage, Ingredient Duplication, Age Precaution, Pregnancy Precaution, Gender conflict, and Therapeutic Duplication). When dispensing providers utilize point-of-service electronic claims processing, the DUR information is communicated electronically to the dispensing provider who shares it directly

with the member at the time of dispensing, when appropriate. These 7 DUR edits are soft edits and send advisory information to the pharmacist. The National Council for Prescription Drug Programs (NCPDP) format for DUR errors allow up to three review messages to be returned to the pharmacy.

Point of Service/Dispensing software screening includes:

1. Ingredient duplication
2. Quantity limits
3. Dose checking edits
4. Drug-drug interaction screening
5. Duplicate therapy screening
6. Age precaution
7. Pregnancy precaution
8. Gender conflict

B. Drug-Drug Interactions

The Plan's vendor (MedImpact) subscribes to First Data Bank, NDDF Plus, National Drug Data File. The Drug-Drug Interaction Module identifies drug-drug interactions based on three (3) severity levels and is supported by references. The severity threshold for communicating drug interactions is determined by the Plan or their vendor with approval by the Plan's P&T Committee. The current Drug-Drug Interaction severity levels used by MedImpact are:

Level 1: Contraindicated Drug Combination
Action: This drug combination is clearly contraindicated in all cases and should not be dispensed or administered to the same patient.

Level 2: Severe Interaction
Action: Action is required to reduce risk of severe adverse interaction.

Level 3: Moderate Interaction
Action: Assess risk to patient and take action as needed.

Levels 1 and 2 Drug-Drug Interactions are communicated to the pharmacy.

C. Drug Recalls

The Plan uses a claims database report to identify claims processed during the look-back period to identify members and practitioners affected by FDA-required recalls or voluntary drug withdrawals from the market and notifies them in writing by mail.

Class I Recalls

Class I recalls are situations where there is reasonable probability that the use or exposure to the product will cause serious adverse health consequences or death.

An expedited process is used to notify members and prescribers of Class I recalls

as soon as possible, but no later than 25 calendar days after the formal FDA notification.
Notification to the affected members may include:

- Name of the pharmaceutical
- Date of the recall or withdrawal
- Reason for the recall or withdrawal
- Actions needed such as returning pharmaceutical to the pharmacy or seeing the prescribing practitioner for instructions or a new prescription.

Notification to the affected practitioners may include:

- Name of the pharmaceutical
- Date of the recall or withdrawal
- Members affected (if known)

Class II Recalls

Class II recalls or voluntary drug withdrawals are situations 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.

The Plan or its vendor has a mechanism in place for notifying members and prescribing practitioners within 30 calendar days of the Class II Recalls, Market Withdrawals and Safety at http://www.fda.gov/safety/recalls/default.htm.
Notification to the affected members may include:

- Name of the pharmaceutical
- Date of the recall or withdrawal
- Reason for the recall or withdrawal
- Actions needed such as returning pharmaceutical to the pharmacy or seeing the prescribing practitioner for instructions or a new prescription.

Notification to the affected practitioners may include:

- Name of the pharmaceutical
- Date of the recall or withdrawal
- Members affected (if known)

D. Poly-Pharmacy

Sharp Health Plan performs several quality assurance programs, one of which is retrospective Drug Use Evaluation (DUE). The objective of DUE is to promote quality, cost- effective drug therapy for members.

1. Annually, SHP reviews medication profiles to identify Sharp Health Plan members whose medication history contains prescription claims for more than 10 unique, chronic medications from 3 or more prescribers during a 3-month period.
2. When a member reaches a threshold, the member's PCP is sent a letter and a profile of the member's prescription history and is asked to take steps to reduce polypharmacy where appropriate.

E. Controlled Substance Program

The purpose of the Controlled Substance Program DUE is to identify controlled substance utilization that may indicate overuse, dependence or drug seeking behavior. It is impossible to identify addictive behavior from pharmacy claims history alone. Chronic debilitating diseases may require the use of large doses and combinations of very potent analgesics, sedative-hypnotics, and anti-anxiety medications. However, patterns may emerge that are indicative of drug dependence. These patterns include the use of:

- multiple physicians and/or emergency care centers to obtain controlled substance prescriptions
- multiple pharmacies to fill controlled substance prescriptions
- a large number of controlled substance prescriptions
- a wide variety of controlled substance medications in large doses over long periods of time

1. Sharp Health Plan reviews the medication profiles of members who received 10 or more prescriptions for DEA schedule II, III, IV, or V controlled substances (excluding steroid hormones and drugs used to treat attention deficit hyperactivity disorder), and agents containing tramadol or carisoprodol during a 3 month period.

2. The last prescribing physician on record is sent a report listing the prescriptions for controlled substances filled by their patients who meet the criteria, the dates obtained, the dispensing pharmacies, and the names of physicians prescribing these medications.
3. Physicians are asked to review the controlled substance prescribing patterns for the patient(s) listed in this DUE and consider additional follow-up where medically needed.

F. Pharmacy Contracting Procedures

To optimize the safe distribution of medications, The Plan includes the following requirements in the pharmacy network contracts:

1. Ensure counseling is offered to members at point of dispensing when indicated.

2. Implement a method for maintaining up-to-date member information such as, but not limited to: member demographic information, member allergy information (drug and food)

3. Meet the minimum standards for pharmacy practice as established by the State.

4. Implement a Concurrent Drug Utilization Review System to review the prescribed drug therapy prior to dispensing the prescription to an enrollee at the point of sale or distribution. Screening should include but not be limited to the following:

    a. Therapeutic duplication

b. Age/gender-related contraindications

c. Over-utilization and under-utilization
d. Drug-drug interactions
e. Incorrect drug dosage or duration of drug therapy
f. Drug-allergy contraindications
g. Clinical abuse/misuse

G. Retrospective Drug Utilization Review System

The Plan or its vendor employs a system designed to ensure on-going periodic examination of claims data and other records. Computerized drug claims processing and information retrieval systems will be utilized to identify patterns of inappropriate or medically unnecessary care among enrollees, or risks associated with specific drugs or groups of drugs.

IV. REPORTING:

Reports of medication errors received by the Plan are processed according to the Quality Improvement Department's policy entitled "Identification of Quality of Care Issues" (HS-QI-101) to address each case, identify trends in medication errors and opportunities for improvement.

V. ATTACHMENTS: N/A

VI. REFERENCES:

A. SHP Pharmacy Management Procedure for Prior Authorization Required for Prescription Drugs (HS-RX-102)
B. SHP Pharmacy Management Procedure for Step-Therapy for Prescription Drugs (HS-RX111)
C. SHP Identification of Potential Quality of Care Issues (HS-QI-101)
D. MedImpact DUR Documentation 2008

VII. REVISION HISTORY:

Date	Modification (Reviewed and/or Revised)
06/08/2011	Original Document
03/14/2012	Approved by P&T Committee
03/13/2013	Approved by P&T Committee
03/19/2014	Approved by P&T Committee
03/18/2015	Approved by P&T Committee
09/09/2015	Approved by P&T Committee
03/09/2016	Approved by P&T Committee