Department:	Pharmacy	**Original Approval:**	09/12/2007
Policy #:	PM509	**Last Approval:**	11/13/2019
Title:	Pharmaceutical Patient Safety		
Approved By:	Medical Management Leadership Team		
Dependencies:	None		

Purpose

Community Health Plan of Washington (CHPW) is committed to ensuring pharmaceutical patient safety. For this reason, in conjunction with its pharmacy benefit manager (PBM), CHPW has established the following programs for all lines of business:

- Concurrent Drug Utilization Review (DUR)
- Retrospective Drug Utilization Review (DUR)
- Drug Recall Safety Alerts

Policy

CHPW, in conjunction with its PBM, maintains a Concurrent Drug Utilization Review (DUR) at the point-of-dispensing. The goal of the Concurrent DUR is to serve as a secondary source of pharmaceutical information designed to enhance patient safety and to identify the most relevant drug interactions that could impact patient care and potentially result in an adverse drug reaction.

In addition, CHPW alerts physicians and members about significant patient-safety related issues including, but not limited to, market withdrawals[1], black box warnings[2], and class I recalls[3].

CONCURRENT DUR

The Concurrent DUR system is a clinically-based real-time process. The Concurrent DUR system that CHPW and its PBM use follows criteria standards found in 42 C.F.R 456.703(f)(1). It takes place during the claims adjudication process and is designed to identify important patient- specific pharmaceutical care concerns through the use of the following 13 modules:

1. Drug-age Consideration
2. Adverse Drug Disease Consideration
3. Adverse Drug Interaction

[1] Market withdrawal occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation.
[2] A black box warning is designed to warn of serious adverse reactions that may lead to death or serious injury.
[3] Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

4. Drug-gender interaction
5. Drug-pregnancy interaction
6. Excessive Dosing
7. Additive Toxicity
8. Drug Therapy duplication
9. Medication under dosing
10. Drug Allergy
11. Potential Drug Name Confusion
12. Prescriber Consultation
13. Refill Too Soon/Stockpiling Prevention
14. Suboptimal Patient Drug Adherence

When a claim is processed by a pharmacy, the Concurrent DUR system compares this claim to other previous claims for that member received by the PBM, as well as to the member's eligibility profile (age and gender). The Concurrent DUR system, then provides a response at the point-of-dispensing which identifies the type of conflict, if any; its severity, the data source which identifies the conflict, information about the conflicting drug (if a potentially harmful drug interaction is the issue) and the quantity of the conflicting drug

The primary data source for the Concurrent DUR modules is First Data Bank (FDB). When there are emerging issues as identified by the U.S. Food and Drug Administration Advisory Board recommendations, published literature, etc., these are communicated to the PBM's Concurrent DUR workgroup, which is responsible for the ongoing evaluation of potential patient safety concerns which occur at the point-of-dispensing.

FDB classifies drug-drug interactions into three severity levels.

- Severity one interactions are those where the drug combination is contraindicated and generally should not be dispensed or administered to the same patient.
- Severity two interactions are those where action is required to reduce the risk of severe adverse interaction.
- Severity three interactions are those where the provider needs to assess the risk to the patient and take action as needed.

All FDB severity one drug-drug interactions are included in the PBM's list of drug-drug interactions. New severity one drug-drug interactions or existing drug-drug interactions experiencing a severity upgrade to severity one are automatically included in the PBM's list of drug-drug interactions. FDB severity two or three drug-drug interactions are also included in the drug-drug interaction list if upon PBM's Concurrent DUR workgroup review a determination is made the interaction is immediate, clinically significant, and often results in an adverse event. When any severity one drug-drug interaction or identified severity two or three drug-drug interaction is detected a message is sent to the provider at the point-of-dispensing.

CHPW provides oversight over the PBM's Concurrent DUR process which monitors the overall success rate of a claim not being processed once the pharmacist is notified of a drug interaction. In the absence of a national benchmark, CHPW has established a threshold of 97% for not processing claims when drug interactions have been identified. On a regular basis, CHPW downloads reports from the PBM system TrendCentral. Further details can be found in Desk Procedure *DP130 – Procedure for Concurrent DUR*

RETROSPECTIVE DUR

The Retrospective DUR system that CHPW and its PBM use follows criteria standards found in 42 C.F.R 456.703(f)(1). The PBM provides CHPW the data to review. The data is reviewed to determine:

- Patterns of FWA
- Overutilization
- Underutilization
- Therapeutic appropriateness
- Drug-disease contraindications
- Drug-drug interactions
- Incorrect dosage or duration
- Clinical abuse/misuse

When necessary, CHPW provides outreach to providers through provider newsletters, pharmacy roundtables, P&T Committee, or educational webinars.

SAFETY ALERTS

CHPW alerts members for a Class I recall, Class II recall, and market withdrawal at the discretion of a CHPW clinical pharmacist. For Class I recalls, Class II recalls, and market withdrawals notifications are sent according to the following procedure:

1. When there is a Class II recall or market withdrawal, notices are mailed within 30 days of the FDA notification to all members who have received that drug in the last 120 days from any participating pharmacies.
2. When there is a Class I recall expedited notices are mailed within 25 days of the FDA notification to all members who have received that drug in the last 120 days from any participating pharmacies.

Additionally, CHPW provides members and prescribers notifications of drug recalls which may affect members in an outpatient setting via its Drug Recall Report on the website https://www.chpw.org/for-providers/pharmacy/drug-recall-report and https://medicare.chpw.org/member-center/member-resources/prescription-drug-coverage/drug-recall-report/ for Medicare Advantage members. Pertinent

drug recalls and withdrawals are posted to the website within 25 days of a Class I and 30 days of Class II & Market Withdrawal FDA notifications and maintained on the list for 365 calendar days.

All Class I recalls, Class II recalls, and market withdrawals are tracked by CHPW on the Drug Recall Log spreadsheet to ensure appropriate actions have been taken (Appendix A).

List of Appendices

A. Recalls and Withdrawals mailing monitoring template for all lines of business.

Citations & References

CFR	42 C.F.R. § 438.608(a), 42 C.F.R § 455.2, 42 C.F.R. Part 456,	
WAC		
RCW		
Contract Citation	☒ WAH	2019- 11.2, 12.5, 14.5.7, 17.3.4, 17.3.8.2
	☒ IMC	2019, 1.1651.168, 11, 12.5, 16.12.4- 16.12.8.1,
	☒ MA	Medicare Prescription Drug Manual Chapter 7;
Other Requirements		
NCQA Elements	2019 NCQA UM 11	

Revision History

Revision Date	Revision Description	Revision Made By
09/12/2007	Original	Rachel Koh
04/25/2008	Added detailed description of the process and turnaround time	Rachel Koh
01/08/2009	Review for style and formatting	Sunny Otake
6/25/2009	Content Update	Eric Guyette
05/28/2010	Review and no change	Maria Chan
06/08/2010	Approval	MMLT
03/09/2011	Approval	MMLT
05/13/2011	Content Update	Maria Chan
06/08/2011	Approval	MMLT
03/26/2012	Review and no change	Maria Chan
04/04/2012	Approval	MMLT
03/28/2013	Updated Citations Table	Reid Yamamoto
04/19/2013	Approval	MMLT
04/16/2014	Content Update Addition of Appendix	Steven Zona
04/23/2014	Approval	MMLT
03/26/2015	Content Update	Nonye Connor

04/07/2015	Approval	MMLT
03/04/2016	Updated citations table. Minor text updates.	Mary Eckhart
03/18/2016	Approval	MMLT
08/10/2016	Updated citations table to include the HBE	Mary Eckhart
03/01/2017	Moved to new template. Merged all lines of business.	Mary Eckhart
03/14/2017	Approval	MMLT
11/27/2017	Added additional DUR details	Mary Eckhart
11/28/2017	Approval	MMLT
03/02/2018	Moved to new template	Mary Eckhart
03/13/2018	Approval	MMLT
03/12/2019	Reviewed, no changes	Rashelle Heath
03/13/2019	Approval	MMLT
09/27/2019	Reviewed, minor updates	Rashelle Heath
10/03/2019	Reviewed	Omar Daoud
11/13/2019	Approval	MMLT

APPENDIX A: Recalls & Withdrawals mailing monitoring template for Medicare & Medicaid

Date of FDA notification	Type of notification	Drug Name	# of Medicaid Members affected	# of Medicare Members affected	Date of Medicare Member notification	Date of medicaid member Notification	Date of Webposting	Webposting within 25 (Class 1) or 30 days (Class 2 or market withdrawal) of FDA recall notification	Responsible party for prescriber notification	Letters adhere to NCQA timeframe?	Member list saved in Recalls and Withdrawals folder?	Reviewed date and Name of Reviewer for ESI MD letter mailing report