Upper Peninsula Health Plan
Policy & Procedure

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Index #: 300-025 Effective: 2/16/05

Title: Pharmaceutical Safety – Drug Withdrawals or Recalls

Scope: Pharmacy

Revised: 2/14/07, 11/29/12, 3/11/14, 1/1/15, 9/27/16; 8/3/18, 10/30/20, 11/7/2021

Reviewed: 10/28/22

Authorized By: _____ Date: 11/18/21 Title: CEO

Product Type(s): ☐ All Products ☒ Medicaid ☐ Healthy Michigan Plan

☐ Medicare ☒ MIChild ☐ MI Health Link

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# FDA-REQUIRED OR VOLUNTARY DRUG WITHDRAWALS OR RECALLS

*Purpose*

To describe the sequence of events used to inform clients, members, provider networks, and prescribers, or as contract stipulations or other regulations dictate, when Class I Recalls, Class II recalls (when not lot-specific), or safety-related market withdrawals of Food and Drug Administration (FDA)-regulated pharmaceutical products have been issued by the FDA or pharmaceutical manufacturers

*Policy*

The Upper Peninsula Health Plan (UPHP) will use due diligence in notifying members and prescribers when they are affected by withdrawals or recalls of pharmaceuticals. UPHP maintains an appropriate process, consistent with the Medicare Prescription Drug Benefit Manual, any other Centers for Medicare and Medicaid (CMS) guidance, URAC Consumer Safety procedures and National Committee for Quality Assurance (NCQA) standards to provide retrospective notice of drugs deemed unsafe by the FDA or for drugs removed from the market by their manufacturers for safety reasons.

This policy applies to products covered under the pharmacy benefit (i.e. where a prescription is required for processing and payment by a client; examples may include prescription and over-the-counter (OTC) products and devices):

- Class I or patient-/member-level product recalls
- Class II product recalls that are not lot-specific
- Market withdrawals where a specific product is completely removed from the market secondary to serious safety issues

This policy does not apply in the following circumstances:

- Withdrawals unrelated to safety issues
- Class II product recalls that are specific lots for which UPHP is unable to identify affected members
- Class III drug recalls
- Wholesale-only withdrawals

*Definitions*

Class I Recalls: 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.

Class II Recall: 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.

Class III Recall: Situation in which use of, or exposure to, a product is not likely to cause adverse health consequences.

Lot-specific Recall: Situation in which specific lots are recalled due to safety issues, while other lots are safe and available for use. Company is unable to identify which specific lot(s) a member may have received.

Market Withdrawal: Situation in which product has a minor violation that would not be subject to FDA legal action.

*Procedure*

1. The UPHP in conjunction with the Pharmacy Benefit Manager (PBM) will identify members receiving the affected products.
2. The PBM will provide UPHP with a description of the recall and a report summary identifying impacted beneficiaries and providers:
    a. Class I recall reports within 14 days
    b. Class II recalls reports within 21 days
    c. Market withdrawal reports within 21 days
3. Reports may also be generated by UPHP. The Director of Pharmacy or Pharmacist designee – in conjunction with the PBM and Medical Director – determines which method will provide accurate and timely information allowing for prompt member identification and notification regarding the recall.
4. Notification may be by telephone, mail or social media dependent on the recall or withdrawal type.
5. Depending on the urgency and/or volume of notification, personnel will be utilized in the following order:
    a. Pharmacy services
    b. Customer service
    c. Clinical services
6. The Pharmacy Director, Pharmacist, or Medical Director will prepare a scripted message to be relayed to prescribers and/or members. The message will contain information regarding the course of action that should be taken. UPHP may utilize

letter templates prepared by the PBM. These notices will be sent within the following timeframes:

a. Class I recall reports within 21 days
b. Class II recalls reports within 30 days
c. Market withdrawal reports within 30 days

Exception to this policy may be made with the approval of the Chief Executive Officer or an authorized designee.

END OF POLICY & PROCEDURE