POLICY AND PROCEDURE

DEPARTMENT: Ambetter Health Plans	**DOCUMENT NAME:** Drug Recall Notification
PAGE: 1 of 4	**REPLACES DOCUMENT:**
APPROVED DATE: 02/14	**RETIRED:**
EFFECTIVE DATE: 02/14	**REVIEWED/REVISED:** 02/15, 02/16, 02/17, 02/18
PRODUCT TYPE: Health Insurance Marketplace	**REFERENCE NUMBER:** HIM.PHAR.13

SCOPE:
Envolve Pharmacy Solutions and Centene Health Insurance Marketplace (Ambetter) Pharmacy Departments.

PURPOSE:
To identify and notify prescribers and members affected by FDA-required or voluntary drug withdrawals from the market.

POLICY:
Envolve Pharmacy Solutions will identify all members affected by an FDA drug recall, when there is a potential to result in serious adverse health consequences. The process will provide rapid response to drug recalls and other safety concerns and will provide information to those impacted by: Class I drug recalls, Class II or Class III recalls deemed to have serious safety concerns, or market withdrawal of drugs for safety reasons.

PROCEDURE:
The FDA provides notification of FDA- or voluntary drug product recalls. The guidelines categorize all recalls into one of three classes according to the level of hazard involved.

- Class I: Recalls are for dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are: mislabeling a life saving drug, or drugs found to be subpotent that are used to treat life threatening conditions.
- Class II: Recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. One example is a subpotent drug not used to treat life-threatening situations.
- Class III: Recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations.

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PROCESS:

1. Envolve Pharmacy Solutions receives drug alerts and reviews the FDA notices and available supporting documentation to determine appropriate communication measures. These measures may include, but are not limited to:
   a. Notifications to pharmacies and/or members and prescribers by mail, website, or fax;
   b. Application of system edits and POS messaging to help prevent retail pharmacies from filling prescriptions for the drug of concern;
   c. Implementation of formulary changes or restrictions.

2. Envolve Pharmacy Solutions determines an action plan depending on the level of safety concern. Envolve Pharmacy Solutions' Drug Alert and Recall Team (DART) makes a final recommendation for member notification within one (1) business day for a Class I recall, two (2) business days for a Class II recall, and within 30 days for all other lower-severity situations.

3. Envolve Pharmacy Solutions will send a summary of the FDA alert/recall/market withdrawal, a template member and a template prescriber notification letter to local Marketing Department(see Attachment A: Member Notification Template and Attachment B: Prescriber Notification Template).

4. Envolve Pharmacy Solutions will send applicable utilization reports to the local Pharmacy Director. The reports are provided in an Excel file and include the following data elements: prescriber last name, prescriber first name, prescriber NPI, prescriber address, member last name, member first name, member address, member date of birth, member ID number, pharmacy name, pharmacy ID number, claim date, label name, NDC, and prescription number.

5. Once local Marketing Department provides versioned and approved member and provider letters, Health plan Pharmacy Director is responsible for coordinating member and provider mailings or phone communications and tracking the process. Class I recall member

notifications are completed within 1 business day and, if deemed necessary, Class II or Class III member notifications are completed within 5 business days.

6. Notification of Class I recalls to pharmacy providers is delegated to Envolve Pharmacy Solutions (EPS.PHARM.02).

REFERENCES: N/A

ATTACHMENTS:

Attachment A: Member Notification Template

HIM.PHAR.13_Drug Recall Notification_At

Attachment B: Prescriber Notification Template

HIM.PHAR.13_Drug Recall Notification_At

DEFINITIONS: N/A

REVISION LOG

REVISION	**DATE**
Grammatical changes and rewording	02/15
Changed responsibility for mailing to corporate pharmacy director	02/15
Revisions to the timing of member and provider communications to align with the PBM's timeline and NCQA standards.	02/15
Changed reference from Corporate Pharmacy Department to US Script Utilization Management Pharmacy Department. Added attachments to the document.	02/16
Changed reference from US Script to Envolve Pharmacy Solutions	02/17
Changed section #3. Letter templates will be sent from Envolve to local Marketing Department. Changed section #5 and added:	02/18

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"Once local Marketing Department provides versioned and approved member and provider letters," Changed responsibility of letter mailing from Ambetter Director of Pharmacy to Health Plan Director of Pharmacy to allow for better operationalization of recalls.	

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

EPS Director, Marketplace Approval on file

Sr. V.P., Chief Medical Officer: Approval on file

NOTE: The electronic approval is retained in Compliance 360.