POLICY AND PROCEDURE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Drug Recall Notification Process
PAGE: 1 of 6	**REPLACES DOCUMENT:**
APPROVED DATE: 08/18	**RETIRED:**
EFFECTIVE DATE: 08/18	**REVIEWED/REVISED:**
PRODUCT TYPE: All	**REFERENCE NUMBER:** MS.PHAR.30

SCOPE:
Centene Corporate Pharmacy, Magnolia Health Plan Pharmacy Department, and Envolve Pharmacy Solutions.

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

POLICY:
Magnolia Health Plan, in conjunction with Centene Corporate Pharmacy Department and Envolve Pharmacy Solutions, will identify all providers and members affected by a 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
- Market withdrawals of drug for safety reasons

PROCEDURE:
The FDA provides notification of FDA mandated 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 a label mix-up on a lifesaving drug, or drugs found to be sub-potent 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 drug that is under-strength but that is 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. Examples might be a container defect (plastic material delaminating or a lid that does not seal); off-taste, color, or leaks in a

bottled drink, and lack of English labeling in a retail food.

See Envolve Pharmacy Solutions policy, EPS.PHARM.02 FDA Drug Alert and Recall Team, for more detailed process.

1. Centene Corporate Pharmacy Department and Envolve Pharmacy Solutions receive drug alerts and review the FDA notices and available supportive documents to determine appropriate safety and communication measures needed. These measures may include but are not limited to:
    a. Notifications to pharmacies and/or members and providers via letter, website, phone call, or fax;
    b. Application of edits and online messaging to help prevent retail pharmacies from filling prescriptions for the drug of concern; and/or
    c. Implementation of Formulary/Preferred Drug List changes or restrictions.

2. Centene Corporate Pharmacy, in coordination with Magnolia Health Plan and Envolve Pharmacy Solutions determine an action plan depending on the level of safety concern. Notification of Class I recalls will be sent to the Magnolia Health Plan Pharmacy Department, within 1 business day of an ad hoc meeting of the Envolve Pharmacy Solutions Drug Alert and Recall Team (DART). Notification of Class II or III recalls or other equivalent severity voluntary market withdrawal will be sent to the Health Plan, within 2 business days of an ad hoc meeting of DART.

3. Envolve Pharmacy Solutions will send a summary of the FDA alert/recall/market withdrawal and a template member notification letter to Centene Corporate Pharmacy and to the Magnolia Health Plan Pharmacy Department.

4. Envolve Pharmacy Solutions sends member utilization reports to the Magnolia Health Plan Pharmacy Director. These 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. The Magnolia Health Plan Pharmacy Director is responsible for coordinating member mailings or phone communications and tracking the process.

6. Once the Magnolia Health Plan receives the template letters and utilization reports the plan will initiate member and provider communications within 1 business day for Class I recalls and 5 business days for Class II or Class III recalls.

7. Envolve Pharmacy Solutions may be designated to carry out member and prescriber notification.

REFERENCES:

NCQA UM 12: Element C: Pharmaceutical Patient Safety Issues

Policy and Procedure CC.PHAR.03 Drug Recall Notification
Policy and Procedure EPS.PHARM.02 FDA Drug Alert and Recall Team

ATTACHMENTS:

Attachment A: Member Notification Template

Attachment B: Prescriber Notification Template

Attachment C: FDA Alert and Recall Master Tracking Form

DEFINTIONS: N/A

REVISION:	DATE

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111 E. Capitol St.
Suite 500
Jackson, MS 39201

«Member_First_Name»«Member_Last_Name»
«Member_Address1» «Member_Address2»
«Member_City», «Member_State» «Member_Zip_Code»

IMPORTANT [DRUG NAME] RECALL NOTICE

August 28, 2018

Dear [Member First Name],

Your health is important to us. The U.S. Food and Drug Administration (FDA) announced a drug recall from [Manufacturer]. The recall is [voluntary/mandatory/other]. It is for [drug name and strength]. The FDA issued the recall due to [recall reason] on [Month/Day/Year].

The recall affects [number of lots] lot[s] of [drug name and strength] currently [on/off] the market. This includes lot number [lot number]. This lot expires [expiration month/year].

Our files show that you may have filled a prescription for this drug.

Please call your pharmacy to find out if your drug could be part of the recall. The pharmacy may replace the drug. **Please do not stop taking your drug. Talk to your doctor before making changes including stopping your medication.**

We are writing you for your information. This does not take the place of your doctor's advice. Only your doctor can decide what drugs are right for you.

Thank you,

«TPA_Name»

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magnolia health

111 E. Capitol St.
Suite 500
Jackson, MS 39201

<Date>
<Prescriber Name>
<Address >
<Address>

Dear <Prescriber Name>,
On <date>, the U.S. Food and Drug Administration (FDA) announced that [Description of Recall].This recall has been initiated as [Cause of Recall].

The FDA press release states the following:

- [Recall Details]
- [Recall Details]

By reviewing claim data from the past [# of Months] months, Envolve has determined which members processed a prescription for this drug. These members have been sent similar written notification of this recall.

If you have any questions or concerns about Envolve Pharmacy Solutions' response to the product recall, please contact Nelson Aragon, Pharm D, Drug Utilization Review Clinical Pharmacist, at (800) 225-2573, ext. 809-3034 or e-mail at Nelson.Aragon@envolvehealth.com, or contact Taline Jaghasspanian, Pharm D, Manager, Clinical Pharmacy Operations, at (818) 676-6959, or email at Taline.Jaghasspanian@centene.com.

Best Regards,

Envolve Pharmacy Solutions FDA Alert and Recall Team

FDA Alert

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Date Notification Received	Drug/Device	Alert/Recall/ Market Withdrawal	Overview/Link	Envolve DART Review Date	Ad Hoc Meeting/ Date	Action Recommended	Health plan email notification/ Date	MSCAN/ CHIP Member Letter Sent/Date	AMBETTER Member Letter Sent/Date	ALLWELL Member Letter Sent/Date	Prescriber Letter Sent/Date	Frequently Asked Questions/ Date	Reason No Action
7/16/2018, 7/27/18 (update)	Valsartan and valsartan-hctz recall from Solco Pharm, Major Pharm, and Teva; AvKARE, Remedy Repack, A-S Medication Solutions	Class I Recall	Presence of impurity that may be carcinogenic. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM613532.htm?utm_campaign=Untitled%20Email&utm_medium=email&utm_source=Eloqua	7/16/2018, 7/27/18	7/17/2018	member, prescriber letters, FAQ							Significant member utilization