POLICY AND PROCEDURE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Drug Recall Notification Process
PAGE: 1 of 6	**REPLACES DOCUMENT:**
APPROVED DATE: 7/08	**RETIRED:**
EFFECTIVE DATE: 7/08	**REVIEWED/REVISED:** 01/2018, 03/2018
PRODUCT TYPE: All	**REFERENCE NUMBER:** GA.PHAR.08

SCOPE:
Peach State Health Plan Pharmacy Department, Envolve Pharmacy Solutions.

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

POLICY:
Peach State 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 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 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, 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 Peach State 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 Peach State 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 Corporate Pharmacy and Peach State.

4. Envolve Pharmacy Solutions sends member utilization reports to the Peach State 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 Peach State Pharmacy Director is responsible for coordinating member mailings or phone communications and tracking the process.

6. Once Peach States 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. The process for communications which are delivered via website or written letters includes submission and approval by Georgia Department of Community Health (DCH).

REFERENCES:
NCQA UM 11: 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:

DEFINITIONS: N/A

REVISION:	DATE
Removed the Health Plan Notification Attachment and reordered attachments to reflect this change.	07/2011
Annual Review. No changes made.	03/2012
Annual Review. No changes made.	03/2013
Annual Review. No changes made.	03/2014
Added language to address prescriber notification.	03/2015
Revisions to the timing of member and provider communications to align with the PBM's timeline and NCQA standards.	03/2015
Changed #2 in Procedure from "within 6 business days" to "within 4 business days" for Envolve Pharmacy Solutions to make the recommendation for notifications to be sent on Class 1 recalls. Added to References: NCQA UM 12: Element C: Pharmaceutical Patient Safety Issues. Policy and Procedure GA.PHAR.03	03/2016
Removed Attachment B: Workflow	10/2016

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Added Attachment B: Prescriber Notification Template (Draft) and Attachment C: Pharmacy Notification Template	10/2016
Updated reference of US Script to Envolve Pharmacy Solutions	10/2016
Added USS.PHARM.02 to References section. Annual review replaced US Script with Envolve Pharmacy Solutions and added US Script may be designated to carry out member and prescriber notification (#8)	01/2017
Removed attachments. Updated name of EPS policy to EPS.PHARM.02 FDA Drug Alert and Recall Team. Changed timeframe for DART to notify Health Plan on Class I recalls. Updated data elements on Excel file that Envolve will provide. Added recall materials would need to be approved by DCH.	01/2018
Annual review. No changes made.	03/2018

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file
Sr. Director, Pharmacy Operations: Approval on file
Sr. Medical Director: Approval on file

NOTE: The electronic approval is retained in Compliance 360.

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IMPORTANT <DRUG NAME> RECALL NOTICE!

<Date>

Dear <Member>,

You are receiving this letter because our records indicate that you may have used your pharmacy benefit to fill a prescription for <drug name>.
On <Date> The US Food and Drug Administration (FDA) announced that <describe the nature of the recall[1]>.

<A = general drug recall OR B= drug recall limited to specific lots >

A.) If you are still taking <drug name>, we encourage you to contact your doctor to discuss other treatment options. It is important that you do not make any changes in therapy without first consulting your doctor. Your doctor is in the best position to recommend alternative therapies based on your specific treatment needs.

B.) You should call your pharmacy to determine if the medication that you received could be included as a part of this drug recall. Normally, the pharmacist will replace the medication. **It is important that you do not make any changes in therapy without first consulting your doctor.**

This letter is based on information currently known to us. This information is being provided for general information purposes only and not meant to interfere with the independent medical judgment of a treating physician. Only your treating physician can determine what medications are appropriate for you.

Sincerely,
<Plan> Pharmacy Department
1. >FDA reference>

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[Insert Health Plan Logo]

[Provider Name]
[Address]
[Address]
[Address]

[Date]

Dear [Provider],

The Federal Drug Administration (FDA) released a <insert the type of recall and the affected drug>.

As your partner in member safety, the Envolve Pharmacy Solutions FDA Alert and Recall Team met to review this voluntary recall notice. The FDA press release states the following:

- GlaxoSmithKline (GSK) Consumer Healthcare is voluntarily recalling all Alli weight loss products from U.S. and Puerto Rico retailers as the company believes that some packages of the product were tampered with and may contain product that is not authentic Alli.
- GSK received inquiries from consumers in seven states about bottles of Alli that contained tablets and capsules that were not Alli.
- A range of tablets and capsules of various shapes and colors were reported to be found inside bottles. Additionally, some bottles inside the outer carton were missing labels and had tamper-evident seals that were not authentic. These tampered products were purchased in retail stores.

GSK is requesting consumers who have product they are unsure or concerned about not use it. Instead, they should call GSK promptly at (800)-671-2554, and a representative will provide further instructions. If they have consumed questionable product, they should also contact their healthcare providers.

By reviewing claim data from the past six months, Envolve Pharmacy Solutions has determined which <Health Plan Name> members processed a prescription for this drug. These members should return the drug to the place where it was obtained (i.e. doctor's office, pharmacy, etc.).

If you have any questions or concerns about Envolve Pharmacy Solutions' response to the product recall, please contact Debra Jacks, Clinical Pharmacist, at (559)244-3724 or e-mail at Debra.Jacks@EnvolveHealth.com.

Best Regards,

Envolve Pharmacy Solutions FDA Alert and Recall Team