POLICY AND PROCEDURE

DEPARTMENT: Pharmacy Operations	**DOCUMENT NAME:** Drug Recall Notification
PAGE: 1 of 5	**REPLACES DOCUMENT:**
APPROVED DATE: 04/07	**RETIRED:**
EFFECTIVE DATE: 04/07	**REVIEWED/REVISED:** 02/08, 02/09, 02/10, 02/11, 02/12, 02/13, 02/14, 08/14, 08/15, 08/16, 11/16, 10/17
PRODUCT TYPE: Medicaid	**REFERENCE NUMBER:** OH.PHAR.03

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

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

POLICY:
Centene Health Plan 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 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.

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1. See Envolve Pharmacy Solutions policy, EPS.PHARM.02 FDA Drug Alert and Recall Team, for more detailed process.
2. Centene Corporate Pharmacy Solutions Department and Envolve Pharmacy Solutions receive drug alerts and review 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/Preferred Drug List changes or restrictions.
3. Centene Corporate Pharmacy Solutions, in coordination with Envolve Pharmacy Solutions, determine an action plan depending on the level of safety concern. Notification of Class I recalls will be sent to the client, or the client's designee, 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 client, or the client's designee, within 2 business days of an ad hoc meeting of DART.
4. Envolve Pharmacy Solutions will send a summary of the FDA alert/recall/market withdrawal, a template member and a template prescriber notification letter to Centene Corporate Pharmacy Solutions and the Health Plan Director of Pharmacy (see Attachment A: Member Notification Template and Attachment B: Prescriber Notification Template).
5. Envolve Pharmacy Solutions will send applicable utilization reports to the Health Plan Director of Pharmacy. 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.
6. The Health Plan Director of Pharmacy is responsible for coordinating member and provider mailings or phone commnications and tracking the process.

7. Once the Health Plan recieves the template letters and utilization reports the plan will inititiate member and provider communications within 1 business day for Class I recalls and 5 business days for Class II or Class III recalls.
8. Envolve Pharmacy Solutions may be designated by external client(s) to carry out member and prescriber notification. If Envolve is the client's designee, Envolve will notify members and prescribers directly. In all situations, notification of affected members and prescribing practitioners must be expedited for Class I recalls, and must be completed within 14 days of receiving the FDA notice. Class II, Class III recalls, or other equivalent severity safety alerts must be completed within 30 days of receiving the FDA notice.

REFERENCES: EPS.PHARM.02 FDA Drug Alert and Recall Team

ATTACHMENTS:
Attachment A: Member Notification Template
Attachment B: Prescriber Notification Template

DEFINITIONS: N/A

REVISION LOG

REVISION	**DATE**
Removed from "Practitioners and Members" from "SCOPE" as those are external parties and are not to be included per template definition of "SCOPE".	05/07
Revise "SCOPE" to include Centene Corporate Pharmacy Solutions department.	02/08
Revise "PROCEDURE" to reflect the updated procedure among the PBM, Corporate Pharmacy Department, and the Health Plan Pharmacy Departments.	02/08
Add the Centene Health Plan Notification Letter as an attachment.	02/08
Addressed the Class II and Class III recalls in the POLICY section with a better definition of those requiring action in terms of safety concerns.	02/09
Coordinated the US Script policy and procedure to sync with	02/09

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health plan P&P language.	
Detailed PROCEDURE to define timing on notification of drug recalls aligning with NCQA standards.	02/09
Added the Member Notification Letter Template as an attachment.	02/09
Revised a sentence in the POLICY section from "Centene Corporation Health Plan will identify all members affected by an FDA drug recall" to "Centene Corporation Health Plan will identify all members affected by an FDA drug recall, when there is a potential to result in serious adverse health consequences".	02/10
Removed the Health Plan Notification Attachment and reordered attachments to reflect this change.	02/11
No changes were deemed necessary.	02/12
No changes were deemed necessary.	02/13
No changes were deemed necessary.	02/14
Added language to address prescriber notification.	08/14
Revisions to the timing of member and provider communications to align with the PBM's timeline and NCQA standards.	08/14
No revisions	08/15
Changed #3 in Procedure from "within 6 business days" to "within 4 business days" for US Script to make the recommendation for notifications to be sent on Class 1 recalls.	11/15
Annual Review; added US Script policy, USS.PHARM.02 FDA Drug Alert and Recall Team, for reference; added that US Script may be designated to carry out member and prescriber notification (#8).	08/16
Changed US Script to Envolve Pharmacy Solutions	11/16
Updated name of EPS policy to EPS.PHARM.02 FDA Drug Alert and Recall Team; Updated #3 to match EPS policy of when notifications of recalls will be sent to clients; Updated #8 to match EPS policy for sending notifications if EPS is designated to send out.	10/17

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POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

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

NOTE: The electronic approval is retained in Compliance 360.