POLICY AND PROCEDURE

DEPARTMENT: Pharmacy Operations	REFERENCE NUMBER: CC.PHAR.03
EFFECTIVE DATE: 04/07	POLICY NAME: Drug Recall Notification
REVIEWED/REVISED: 02/08, 02/09, 02/10, 02/11, 02/12, 02/13, 02/14, 08/14, 08/15, 08/16, 11/16, 11/17, 08/18, 08/19, 08/20, 02/08/21	RETIRED DATE: N/A
PRODUCT TYPE: Medicaid	PAGE: Page 1 of 7

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 safety recalls and market withdrawals.

POLICY:
Centene's PBM, Envolve Pharmacy Solutions Drug Alert and Recall Team (DART), on behalf of each health plan, has the responsibility to identify and notify health plan members and prescribers affected by the FDA Class 1 and/or Class II safety recalls, and market withdrawals. Members and prescribers are notified via U.S. mail and health plans are notified via email. Communication to members and prescribers is not applicable if the recalls or withdrawals are unrelated to safety issues or if members cannot be identified from the batch or lot numbers of the withdrawn pharmaceuticals.

FDA Recall Classification:

The FDA classifies drug recalls as Class I, Class II, or Class III, based on the severity of the potential consequence to a patient's health, with Class I recalls having the most probable cause for a serious health event. Most recalls are initiated by the product manufacturer as voluntary market recalls with FDA knowledge and approval.

Class I Recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious, adverse health consequence or death.

Class II Recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequence or where the probability of serious adverse heath consequences is remote.

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

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PROCEDURE:

1. It is Envolve's responsibility to monitor the FDA MedWatch E-mail Alerts daily, FDA Enforcement Reports weekly, and FDA Drug Recalls Website on business days. This monitoring looks for and reviews the Class I and Class II drug recalls and market withdrawals that are safety related and affect an applicable product.

2. The DART will determine if the received FDA safety drug recall or market withdrawal is relevant to Centene's membership.
   a. Recalls are considered actionable if:
      i. it is a Class I recall, or
      ii. it is a Class II recall AND affects all lot numbers of the NDC being recalled.
   b. Market withdrawals are considered actionable if it affects all lot numbers of the NDC being withdrawn.

3. Per DART's Drug Recall Standards:
   a. Action will not be taken for recalled or withdrawn pharmaceuticals for which members cannot be identified from the batch or lot numbers.
   b. Action will not be taken for recalled or withdrawn pharmaceuticals which are not covered by the pharmacy benefit, though a utilization report will be run to determine if claims exists and whether appropriate action is warranted.
   c. Action will not be taken for wholesale-only drug recalls and withdrawals.
   d. Action will not be taken for withdrawals unrelated to safety issues.

4. In order to meet accreditation requirements, DART's turnaround time to mail out the member and prescriber notice letters from the date of the FDA recall classification (Class I or Class II) or the market withdrawal notification is as follows:
   a. Within 14 calendar days for Class I Drug Recalls
   b. Within 30 calendar days for Class II Drug Recalls
   c. Within 30 calendar days for Drug Market Withdrawals

5. The DART runs a Utilization Management (UM) report to identify and notify members who have received the recalled or withdrawn drug in the 120 calendar days prior to the date the notifications were discovered (unless another timeframe was specified in the FDA notification).
   a. The UM report contains the following data:

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     i. member ID number, member last name, member first name, and member address, member date of birth, prescriber NPI, prescriber last name, prescriber first name, prescriber address, pharmacy name, pharmacy address, pharmacy ID number, claim date, medication description name, NDC number, and prescription number.

6. After the Marketing & Communications Department (MarComm) approves the letter templates, the DART mail-merges the member and prescriber drug recall or withdrawal notification letters using the information from the UM report. The letter templates include the drug name, strength, dosage form, manufacturer, the reason for the recall, date of the recall and actions to be taken such as talking to the doctor (see Attachment A: Member Recall Letter Template and Attachment B: Prescriber Recall Letter Template). A Frequently Asked Questions (FAQ) document for internal customer representatives is also produced.
   a. After the mail-merged letters are sent to Communication Distribution Services (CDS) for mailing, the DART will email the health plan representatives via the DUR_DART email distribution list to notify them that the completed mail-merged letters are uploaded on the Sharepoint site to view.
   b. The DART processes and completion dates for each actionable recall and withdrawal are documented in the DART Tracker on the DART SharePoint site.

7. If additional action is needed (e.g., market withdrawal), an ad-hoc DART meeting or a survey will be convened for the team to review the FDA notice(s), available supporting documentation, and utilization reports to determine appropriate communication measures. If approved by the Medicaid team, these measures may include, but are not limited to:
   a. Notifications to members and prescribers by mail;
   b. Application of system edits and point of service (POS) messaging to help prevent retail pharmacies from filling prescriptions for the drug of concern;
   c. Implementation of formulary changes or restrictions.

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      d. DART will also notify the Prior Authorization Operational Team and Medication Therapy Management (MTM) Team.

8. DART reports to the Clinical Services Quality Committee.

REFERENCES:
EPS.PHARM.02 FDA Drug Alert and Recall Team
https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program
https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions

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ATTACHMENTS:
Attachment A: Member Recall Letter Template

DART Member Letter
   Template.docx

Attachment B: Prescriber Recall Letter Template

  DART Prescriber
Recall Letter Template

Attachment C: ATC Member Recall Letter Template

SC Medicaid Member
Template & NDNMLI

Attachement D: ATC Prescriber Recall Letter Template

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SC Medicaid Provider letter 2020.docx

Attachment E: NH Member Recall Letter Template

CC.PHAR.03_Attach ment E_NH Member

DEFINITIONS:

Market withdrawal: Removal or correction of a product with a minor violation that would not be subject to legal action by the FDA.

Medication safety alert: A situation where an alert may warrant notification due to potential for life-threatening occurance or substantial health care cost impact to the plans.

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 health plan P&P language.	02/09
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	02/10

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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".	
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 #7 to match EPS policy for sending notifications if EPS is designated to send out.	11/17
Removed "Centene Corporate Pharmacy Solutions in coordination with" from #3; Added "and alerts" in #3; Added #8: Notification of Class I, II or III recalls or other equivalent severity voluntary market withdrawals and alerts will be sent to pharmacy providers within 3 business days of an ad hoc meeting of DART. Updated template and recall letters.	08/18
Extensive edits to the policy made per Accreditation/QI department for NCQA compliance. Updated DART process to match EPS Policy. Clarified timeframes for each step of the recall notification process. Included Attachments C and D to include Absolute Total Care letter templates.	08/19
Updated DART process to match EPS Policy. Updated the market withdrawal	08/20

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definition to match with the FDA's definition. Updated Attachments A, B, C, and D to include current letter templates. Added Attachment E- New Hampshire Member Recall Letter template.	
Updated and simplified EPS policy with best practices to align with WellCare, Meridian, and NCQA's policies. DART will monitor the weekly FDA Enforcement Reports and recall website on a regular basis and only start acting on the recalls after they have been classified as Class I or Class II. A recall is considered actionable if it is a Class I recall, or it is a Class II recall AND affects all lot numbers of the NDC being recalled. Turnaround timeframe to mail out the member and prescriber notice letters from the date of the FDA recall classification or the market withdrawal notification has also been updated to 14 calendar days for Class I Drug Recalls and 30 calendar days for Class II Drug Recalls and Drug Market Withdrawals. DART will run a Utilization Management (UM) report to identify and notify members who have received the recalled or withdrawn drug in the 120 calendar days prior to the date the notifications were discovered (unless another timeframe was specified in the FDA notification). Changed Envolve's membership to Centene's membership in Procedure #2. Added FDA websites to References section. Added definitions for Market Withdrawal and Medication Safety Alert to Definitions section.	02/08/21

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.