



**MedStar Family
Choice**

ADMINISTRATIVE POLICY AND PROCEDURE

Policy #:	206	
Subject:	FDA Drug Recalls and Market Withdrawals	
Section:	Pharmacy	
Initial Effective Date:	07/01/2007	
Revision Effective Date(s):	07/19, 07/20, 10/20, 07/21, 07/22, 07/23, 07/24, 7/25, 07/26	
Historical Revision Date(s):	10/07, 10/08, 10/09, 10/10, 10/11, 09/12, 10/13, 10/14, 10/15, 10/16, 07/16, 11/17, 07/18	
Review Effective Date(s):		
Historical Review Date(s):		
Responsible Parties:	Health Plan Pharmacist, P&T Committee	
Responsible Department(s):	Clinical Operations	
Regulatory References:	NCQA 2026 UM, Element 11C	
Approved:	Director, Pharmacy	Chief Medical Officer

Purpose: To define the MedStar Family Choice pharmaceutical safety procedures for United States Food and Drug Administration (FDA)-classified drug recalls and market withdraws.

Scope: MedStar Family Choice Maryland

Procedure:

1. Oversight of monitoring, evaluation, and follow-up member notification for FDA-classified drug recalls and market withdrawals is delegated to MedStar Family Choice's contracted Pharmacy Benefits Manager (PBM).
2. The PBM will monitor the FDA Enforcement Report, FDA website, drug manufacturer communications, and other sources as appropriate at least weekly to identify new drug recalls or market withdrawals.

3. For a newly identified Class I, II, or voluntary recall, or market withdrawal, the PBM will evaluate whether any MedStar Family Choice members received potentially recalled medication.
 - 3.1. If any MedStar Family Choice members are identified as being impacted, the PBM will draft a letter in patient-friendly language and submit it to MedStar Family Choice for review.
 - 3.2. MedStar Family Choice will review the letter, submit edits as needed to ensure accuracy and clarity and give final approval to the PBM.
 - 3.3. The approved notification letters will be mailed to impacted members by the PBM.
4. Drug Recall notification process:
 - 4.1 Class I recall letters will be mailed out in an expedited manner, not to exceed 25 calendar days from the FDA notification of the Class I recall.
 - 4.2 Class II recall notification letters will be mailed out within 30 calendar days from the FDA notification of the Class II recall.
 - 4.3 In the event a drug recall is initially unclassified and then subsequently classified by the FDA as Class I or Class II, the time frames described in 4.1 and 4.2 will begin on the first day of the recall classification.
5. Market withdrawal notification process:
 - 5.1. The PBM will provide MedStar Family Choice with a list of members who are potentially impacted by the market withdrawal.
 - 5.2. MedStar Family Choice will review the list and determine if notification is appropriate.
 - 5.3. The PBM will use the notification letter template pre-approved by Maryland Department of Health for Member notification.
 - 5.4. The PBM will process and mail Member notification letters within 30 days of the FDA notification and may be completed more urgently if MedStar Family Choice determines the reason for market withdrawal poses a clinically significant patient safety risk.
6. The contracted PBM will maintain a list of all drug recalls and market withdrawals where Member notification was required, including turnaround time information. This list will be shared with MedStar Family Choice staff on a regular cadence, and available on request.

Summary of Changes:	07/26 • Updated all NCQA to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy 07/25: • No changes 07/24:
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	• Moved P&T Committee listing from “Responsible Department” to “Responsible Parties” section. • Reformatted font and procedure to improve readability. • Updated all NCQA, MCO Standards, and COMAR to current year references. • Updated policy Approver titles and removed individual names. • Added “market withdraws” to Purpose Statement. • Clarified wording in Section 3 to include all types of recalls to align with 2024 NCQA standards. • Added section 4.3 to address unclassified drug recalls. • Corrected Section 5 to identify the PBM as responsible party for recall mailings. 07/23: • Updated the policy name from Pharmaceutical Patient Safety Issues to “Drug Recalls and Market Withdrawals” • Updated the NCQA regulatory reference. • Moved drug-drug interactions/prospective DUR of the policy to Policy 203.MD. • Clarified that enrollee notification is delegated to the contracted PBM. • Updated “CVS Caremark” to “PBM” throughout the policy. • Updated drug recalls/market withdrawals process descriptions to align with current state. • Added bullet #6 to capture how this delegated service is monitored by the PBM and MFC-MD 07/22: • Removed Dr.Toye and Dr. Gerry as Responsible parties. • Responsible parties changed to Dr. Gregory Dohmeier • Updated policy around Level II recalls to reflect 2022 NCQA Standards 07/21: • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to scope. • Changed Case Management to Clinical Operations in Responsible Departments. 10/20: • Revised Section B. #2 and #3 and consolidated it into #2. 07/20: • Updated Regulatory References to reflect 2020 NCQA Standards. 07/19: • Updated NCQA Reference to reflect 2019 Standards. • Removed “Maryland” from scope.
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	07/18: • Updated NCQA regulatory references to reflect 2018. • Modified Effective Date to Initial Effective Dates; added Historical Revision Dates and Revision Effective Dates; and added Historical Review Dates and Review Effective Dates. 11/17: • Removed District references, changed DHMH to MDH. 07/17: • Title changes. 10/16: • No changes. 10/15: • No changes.
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