MFC-MD May 2026 Annual Policy Review and Update Summary
200 Series – Pharmacy and Therapeutics Committee

Changes that apply to all policies:

- Updated all NCQA, MCO Standards, and COMAR to current year references.

Policy Number and Name	Description of Revision/Review
202: Pharmacy & Therapeutics Committee	• Updated all NCQA, MCO Standards, and COMAR to current references. • Update Approved by Director, Pharmacy • Added section 1.2.3 to acknowledge ad hoc meetings as necessary.
203: Drug Use Evaluation (DUE)	• Updated MCO Standards
204: Early Refill, Managed Drug Limitations, Lost Medication & Travel Supply Policy	• Updated all NCQA, MCO Standards, and COMAR to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy
205: Non-Formulary Policy	• Updated all NCQA, MCO Standards, and COMAR to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy • Added language 5.3 Alternative cost effective clinical appropriate non-formulary may be required than requested nonformulary medication
206: FDA Drug Recalls and Market Withdrawals	• Updated all NCQA to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy
208: P&T Policy & Procedure Review	• Updated all NCQA to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy
209: Formulary Management	• Updated all NCQA, MCO Standards, and COMAR to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy

	• Section 1.9.2.4 Updated address where request can be mailed • Section 3.4.3. HCLV must be approved by CMO • Section 6.1.1. Added addition medication changes can be at ad hoc meeting. •
213: Pharmacy Downtime Procedures	• Updated all NCQA to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy • Section 1.1. Updated account team escalation path
217: Corrective Managed Care	• Changed Approved from AVP Clinical Operations to Director, Pharmacy
218; Pharmacy Authorization Process	• Updated all NCQA, MCO Standards, and COMAR to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy • Section 4.1.2, changed maximum approval non-controlled medications to 6-12 months
219; Opioid Prescription Parameters and Limitations	• Updated MCO Standards to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy
220; Prevention of Fraud, Waste, and Abuse in Pharmaceutical Utilization	• Changed Approved from AVP Clinical Operations to Director, Pharmacy

MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**202**	
Subject:	**Pharmacy & Therapeutics Committee**	
Section:	**Pharmacy**	
Initial Effective Date:	**06/06/2000**	
Revision Effective Date(s):	**07/18, 07/19, 07/20, 7/21, 11/21, 07/22, 7/23, 7/24, 7/25, 07/26**	
Historical Revision Date(s):	**09/01, 04/03, 04/04, 10/04, 10/05, 10/06, 10/07, 10/08, 10/09, 10/10, 10/11, 09/12, 10/13, 10/14, 10/15, 10/16, 07/17, 11/17**	
Review Effective Date(s):		
Historical Review Date(s):		
Responsible Parties:	**Health Plan Pharmacist, P&T Committee**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**MDH Standards and Reporting Requirements of Drug Use Management Programs for MCOs March 2026edition Sections 1.0, 2.0. COMAR 10.67.06.04, NCQA 2026: UM 11A, 11B, 11D(2, 4) MD Medical Assistance Program MCO Transmittal No. 176, March 25, 2024**	
Approved:	**AVP Clinical Operations**	**Chief Medical Officer**

Purpose: **To standardize the structure and drug use management functions of the Pharmacy and Therapeutics (P&T) Committee to ensure compliance with regulatory requirements and NCQA standards.**

Scope: **MedStar Family Choice Maryland**

Policy: **The MedStar Family Choice P&T Committee oversees the management of the Pharmacy Benefit and medication formulary for Managed Care Organizations (MCO).**

Definition: **Medical Reviewer: Medical Director or Health Plan Pharmacist**

Procedure:

1. The P&T Committee manages the complete formulary.
    1.1. The Chairperson of the P&T Committee will be the Maryland Health Plan Pharmacist or other clinician appointed by the Chief Medical Officer.
    1.2. The P&T Committee meets five times per year.
        1.2.1. Quarterly in February, May, August, and November.
            1.2.1.1. Annual Policy Review is presented at the May P&T to approve policy updates that become effective July 1st.
        1.2.2. Annually in October for the full formulary review.
            1.2.2.1. Contents of the formulary preface are reviewed annually as part of the full formulary review.

1.2.3 Ad hoc meetings may be convened as necessary.

    1.3. The P&T Committee has final authority to approve or deny all proposed changes to the MedStar Family Choice Formulary, including all utilization management (UM):
        1.3.1. Managed Drug Limitations (MDL) and/or Quantity Limits (QL)
            1.3.1.1. Age-limitations
            1.3.1.2. Gender-limitations
        1.3.2. Prior Authorization (PA) criteria,
        1.3.3. Step Therapy (ST) protocols,
        1.3.4. Copay tier designations for Brand drugs not otherwise defined by MDH,
        1.3.5. Any other clinical protocols that will impact MedStar Family Choice members.
    1.4. Evaluation for inclusion on the Formulary will include, but is not limited to:
        1.4.1. Pharmaceutical drug class,
        1.4.2. Clinical guidelines,
        1.4.3. Drug cost,
        1.4.4. Drug safety,
        1.4.5. Drug efficacy,
        1.4.6. Drug availability,
        1.4.7. Volume of member utilization; and
        1.4.8. Comparison of therapeutically equivalent treatments.
    1.5. The MedStar Family Choice formulary has a three-tiered copay structure outlined by MDH:
        1.5.1. Tier descriptions are maintained in the Preface of the Formulary document.
        1.5.2. Tier designations appear next to individual products on the Formulary document.
        1.5.3. Tier 0 products have no copay/cost to the member.
            1.5.3.1. Tier 0 products include:
                1.5.3.1.1. Family planning medications and devices
                1.5.3.1.2. Vaccines
        1.5.4. Tier 1 products have a $1.00 copayment per prescription.
            1.5.4.1. Tier 1 products include:
                1.5.4.1.1. All generic medications regardless of formulary status.

1.5.4.1.2. All new and refill HIV/AIDS drugs.
1.5.4.1.3. Formulary preferred brand drugs. This is the default designation for formulary brand medications.

1.5.5. Tier 2 products have a $3.00 copayment per prescription.
1.5.5.1. Tier 2 products include:
1.5.5.1.1. Brand, formulary products when therapeutic equivalents are available on the formulary to promote lower-cost, formulary alternatives.
1.5.5.1.2. Brand, formulary products that are first-in-class medications where clinical guidelines establishing place in therapy are not yet available.
1.5.5.2. Assignment of a Tier 2 designation for a brand, formulary product shall be approved by the P&T Committee.

1.5.6. Non-formulary medications
1.5.6.1. Non-formulary medications that are brand-name, single-source products have a $3 copay requirement.
1.5.6.2. Non-formulary, generic products have a $1.00 copay requirement.

1.5.7. As defined by MDH, the following classes of individuals shall be exempt from any copay requirements described above:
1.5.7.1. Individuals under age 21.
1.5.7.2. Pregnant persons.
1.5.7.3. Individuals in hospice care or long-term care facilities.
1.5.7.4. Native American individuals.
1.5.7.5. Any individual who self-reports that they are unable to pay the copayment.

2. The P&T Committee will have representation from the network physicians, pharmacists, utilization management, nursing, pharmacy vendors and others as selected by MedStar Family Choice.
2.1. At least half of the voting members of the Committee shall be composed of healthcare practitioners with direct patient care responsibilities for MedStar Family Choice members including prescribing, dispensing, or administering medications.
2.1.1. This shall be recorded in the attendance section of the minutes.
2.2. Specialist practitioners will be consulted, as appropriate, for advice concerning medications being evaluated.
2.2.1. The content of such advice shall be reported into the minutes.

3. Voting will be by simple voice consensus unless there is a dissenting voice, in which case a formal vote shall take place with a simple majority to carry the vote.

4. Members of the P&T Committee will be expected to abide by MedStar Family Choice Policy 711: Conflict of Interest as it pertains to their role on the Committee.
4.1. When the P&T Meeting Agenda is distributed, the manufacturer of any drug or product to be reviewed will be published.

4.2. Any member of the P&T Committee with an interest or relationship to a manufacturer of a reviewed drug or product shall abstain from participating in any action or vote related to the proposed drug or product.

5. The Chairperson is responsible for overseeing MedStar Family Choice P&T Committee activities as described below:
   5.1. Prepare and disseminate the consent and meeting agendas at least one week prior to the scheduled P&T meetings.
   5.2. Develop meeting content, including DUE, drug utilization information, drug safety information, and recommendations for MDL, PA criteria, ST protocols, Copay Tier designation, and any other clinical updates that will impact members of MedStar Family Choice.
   5.3. Update and maintain the Prior Authorization and Step Therapy table.
      5.3.1. The P&T Committee shall review and approve the criteria.
      5.3.2. PA and ST criteria and protocols shall be reviewed at least annually.
   5.4. Create and maintain minutes for each meeting.
      5.4.1. Provide Minutes, along with Policies and Procedures, at the request of the Maryland Department of Health (MDH).
      5.4.2. Submit minutes for review and approval by Committee members via email within 45 days of the meeting date.
   5.5. Submit all Formulary changes monthly to MDH via the Formulary Navigator.
   5.6. Prepare for MDH approval all member and/or provider formulary change notification letters.
      5.6.1. Negative formulary change notification will occur not less than 30 calendar days prior to the effective date of the change.
         5.6.1.1. Communications may occur via secure email for network providers or via USPS for out-of-network providers.
   5.7. Collaborate with the MedStar Family Choice contracted pharmacy benefits manager (PBM) to:
      5.7.1. Update the MedStar Family Choice formulary coding.
      5.7.2. Obtain quarterly documents that capture all formulary information in JSON and PDF formats as required for MedStar Family Choice to post on its website.
         5.7.2.1. Interim formulary changes may not be reflected online until the next quarterly document update.
         5.7.2.2. The PBM will provide at least annually an opportunity to update the Formulary Preface statement. The updates may include, may not limited to:
            5.7.2.2.1. Copayment/coinsurance requirements and the products to which they apply.
            5.7.2.2.2. Definitions of UM requirements.
            5.7.2.2.3. List of preferred formulary products.
            5.7.2.2.4. Medications covered under the medical benefit but have PA requirements established by the P&T Committee.

5.7.3. Update all Specialty medication lists and associated MDL to post on the website.

5.8. May make urgent formulary change decisions e.g., additions, removals, changes to PA, ST or utilization management criteria without prior approval from the P&T Committee.

5.8.1. Interim decisions will be reviewed by the Committee at the next scheduled P&T Committee meeting.

5.8.2. The Committee has final authority to approve or modify the decision(s).

5.9. Ensure all current formulary information is posted publicly.

5.9.1. All pharmacy benefit UM requirements are indicated within the formulary document.

5.9.2. Criteria for all ST protocols and PA requirements are included on the MedStar Family Choice Prior Authorization and Step Therapy Tables.

5.9.3. A summary of upcoming formulary changes will be posted to the MedStar Family Choice website at least 30-days prior to the effective date of the change.

5.9.4. A summary of upcoming formulary changes will be included in the Quarterly Provider Newsletter.

5.10. Coordinate the annual review of policies and procedures in accordance with Policy 208: P&T Policy and Procedure Review.

Summary of Changes:	**07/26:** • **Updated all NCQA, MCO Standards, and COMAR to current references.** • **Added section 1.2.3 to acknowledge ad hoc meetings as necessary.** **07/25:** • Updated all NCQA, MCO Standards, and COMAR to current references. • Added section 1.2.2 to acknowledge annual policy updates. • Added subsections 1.3.1.1 and 1.3.1.2 to capture all UM features. • Section 1.4: removed the word “continued” for clarity. • Added “Pharmaceutical Drug class” as Section 1.4.1. • Section 2: Corrected “quality management” to “utilization management”. • Added sections 5.6.1 and 5.6.1.1 for clarity and completeness. • Added the clause “but are not limited to…” to section 5.7.2.2. • Added section 5.7.3 to capture publication of Specialty Drug quantity limits. • Added section 5.9.4 to capture required provider communications. **07/24:** • 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. • Clarified Purpose statement. • Removed “Review and Approve Drug Safety programs”. (6) • Replaced MFC abbreviations for standardized referencing. • Added references to annual update of formulary Preface. • Added time frames for P&T Communications. • Added Section 1.5 all references to Copays and Tier assignments due to new copay regulations eff. 5/1/2024. • Added Policy 711 reference for Conflicts of Interest. • Expanded listing of PBM related tasks for completeness. • Added references to maintaining Specialty medication info. • Added Formulary change letters to responsibilities of P&T Chairperson. • Added information regarding review and approval of PA/ST criteria. • Transferred procedures for communicating negative formulary changes to members to Pharmacy Policy 209, Section 5.3 • Transferred policy describing timing of formulary changes to Pharmacy Policy 209: Section 6. **07/23:** • Responsible Parties changed to Health Plan Pharmacist • Updated regulatory reference to March 2023 MDH Standards • Updated NCQA Reference to 2023 Standards • Updated Approved by to: Dr Wills and C. Attia • Updated Statement 6.f. to updated web location: https://dsd.maryland.gov/regulations/Pages/10.67.06.04.aspx • Reorganized Procedure section to align with current P&T Committee processes, including creating a section describing the role and responsibilities of the P&T Committee Chairperson. • Removed details about communication of Formulary information to providers and members, and added a reference to the policy that describes this process. **07/22:** • Removed reference to jurisdictions. • Removed Dr. Toye and Dr. Gerry as Responsible parties. Added Dr. Gregory Dohmeier as Responsible party. • Updated regulatory reference to April 2022 MDH Standards Updated NCQA Reference to 2022 Standards • Add Statement to 6f - Unless approved by the Department, an MFC will not require or utilize prior authorization or step therapy criteria for coverage of formulary drugs if such prior authorization or step therapy requires a participant to use a drug that is included in the pharmacy carve out program as stated in COMAR

	10.67.06.04(E)(6) (http://www.dsd.state.md.us/comar/comarhtml/10/10.67.06.04.htm) . **11/21:** • Changed meeting schedule from every other month/no less than 5X per year to meeting quarterly and October for a total of 5 meetings per year. **07/21:** • Added Maryland to scope. • Changed Case Management to Clinical Operations in Responsible Departments. **07/20:** • Updated Regulatory References to reflect 2020 NCQA Standards. • Added that the P&T Committee does an annual review of the formulary. • Removed references to paper formulary booklets. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed “Maryland” from scope. **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:** • Updated titles and regulatory references. Removed DC CAB as there is no group that is meeting, removed posting to DHCF website as that is not done. **10/16:** • Removed reference to ePocrates. **10/15:** • Under #5, added h. – regarding monthly report to DH.

MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**203**	
Subject:	**Drug Use Evaluation (DUE)**	
Section:	**Pharmacy**	
Initial Effective Date:	**06/04/2000**	
Revision Effective Date(s):	**07/19, 07/20, 07/21, 07/22, 07/23, 07/24, 7/25, 07/26**	
Historical Revision Date(s):	**09/01, 09/02, 04/03, 04/04, 10/05, 10/06, 10/07, 10/08, 10/09, 10/10, 10/11, 09/12, 10/13, 10/14, 10/15, 10/16, 07/17, 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:	**Code of Federal Regulations 42 Part 438.3(s) MDH Standards and Reporting Requirements of Drug Use Management Programs for MCOs March 2026, 4.0**	
Approved:	**Director, Pharmacy**	**Chief Medical Officer**

Purpose: **To establish a program, inclusive of prospective and retrospective components, that shall assess the medical appropriateness, safety, and effectiveness of prescribing, dispensing and patient drug use and to develop activities to educate practitioners and pharmacists on the inappropriate or medically unnecessary drug use within groups of patients and classes of drugs.**

Scope: **MedStar Family Choice Maryland**

Policy: **MedStar Family Choice will comply with 42 CFR Part 438.3(s) regarding coverage of outpatient drugs.**

Procedure:

1. Retrospective Drug Usage Review (DUR) reports are a standing P&T Consent agenda item.
   1.1. MedStar Family Choice Health Plan Pharmacist receives quarterly DUR data from the delegated Pharmacy Benefits Manager (PBM).
   1.2. The Health Plan Pharmacist reviews POS DUR data for opportunities to apply utilization management or appropriate coding guardrails to improve patient safety.
      1.2.1. All proposed DUR interventions are presented to the P&T Committee for approval.
   1.3. Drug Use Evaluation (DUE) tools will include indicators for drug appropriateness that are reported as DUR, criteria, and thresholds.
2. The Health Plan Pharmacist and/or the delegated Pharmacy Benefits Manager (PBM) select drug candidates for evaluation based on selected characteristics such as, but not limited to:
   2.1. Frequently prescribed drugs.
   2.2. Drugs with significant adverse reactions.
   2.3. Drugs with significant drug-drug, drug-food, or drug-disease interaction.
   2.4. Drugs that alter laboratory parameters that warrant attention.
   2.5. Drugs that are highly toxic.
   2.6. Drugs that require special monitoring.
   2.7. Drugs selected by the P&T Committee for formulary addition, deletion, or restriction of use.

3. Prospective DUE is the responsibility of the dispensing pharmacist and is a delegated function of the MedStar Family Choice contracted pharmacy benefit manager (PBM).
   3.1. The MedStar Family Choice PBM contracts with a clinical drug information database to provide clinical drug data products utilized in support of both prospective and retrospective Drug Utilization Review (DUR) processes and other clinical programs.
   3.2. Relevant product files are loaded and shared with multiple adjudication platforms.
      3.2.1. Representatives from the associated Drug File IT Support teams and/or Drug File Business teams are responsible for confirming that all file loads are successful.
   3.3. Point-of-Dispensing Safety:
      3.3.1. The MedStar Family Choice contracted PBM has a system in place to identify and classify drug-drug interactions by severity at the point of dispensing at the retail pharmacy.
      3.3.2. MedStar Family Choice's PBM's Point-of-Service DUR is a concurrent online editing system that electronically screens drug claims for several types of potential adverse drug interactions. These warnings include:
         3.3.2.1. Excessive Doses
         3.3.2.2. High or Low Dosages
         3.3.2.3. Duplicate Therapy
         3.3.2.4. Drug-Disease Interactions

3.3.2.5. Over and Under Utilization
3.3.2.6. Drug-age precautions.
3.3.2.7. Drug-gender precautions.
3.3.2.8. Drug-pregnancy precautions.

3.3.3. When potential safety issues are triggered, warning messages are transmitted to the dispensing pharmacy to provide an opportunity for the pharmacist to evaluate the issues and determine the need for intervention.

3.3.4. The Health Plan Pharmacist retrospectively reviews PBM provided POS DUR reporting to identify and mitigate trends based on patient safety and/or utilization concerns.

Summary of Changes:	**07/26:** • **Updated MCO Standards** **07/25:** • Previous Section 2 was reordered to Section 1 and edited for clarity with addition of subsections 1.1-1.3. • Previous Section 1 was reordered to Section 2 with adjustments: o Procedure Statement: updated to reflect current state, replaced P&T Committee with Health Plan Pharmacist and/or delegated PBM. o Section 2: Added the word “reports” and “Consent”. • Previous Section 3 removed, referenced in Policy 202. • Previous Section 4 removed. • Previous Section 5 incorporated into Section 1.1. o Section 5.1 removed. o Section 5.2 moved to become Section 1.2. • Section 5.3 reordered to Section 3.3. • Previous Section 6 moved and condensed into new Section 3.3.4. **07/24:** • Moved P&T Committee listing from “Responsible Department” to “Responsible Parties” section. • Reformatted font and procedures to improve readability. • Updated policy Approver titles; removed individual names. • Added reference to Code of Federal Regulations. • Removed incorrect NCQA reference. • Added Policy Statement to capture MDH MCO Standard 4.1. • Added Section 2.1, DUE tools and procedure. • Changed references of CVS-Caremark to MFC pharmacy benefit manager (PBM). • Added statement of P&T to maintain patient confidentiality.

	• Removed previous Sections 7 and 8 that described point-of-dispensing pharmacist DUE activities that are beyond scope of MFC-MD. • Added Section 6 to describe how MFC-MD uses PBM supplied POS DUR data, cadence, procedures. **07/23:** • Responsible Parties changed to Health Plan Pharmacist • Updated regulatory reference to March 2023 MDH Standards • Updated NCQA Reference to 2023 Standards • Updated Approved by to: Dr. Wills and C. Attia • Updated references to CVS Caremark to MFC contracted pharmacy benefit manager (PBM) throughout. • Removed description of PBM prospective DUR policy which is provided by the delegated PBM. • Added reference to current PBM's DUR policy. • Removed reference to Policy 206 – Pharmaceutical Patient Safety Issues which has been updated and no longer pertains to this policy. • Removed "DUE will include approximately 2 drugs for review per year". • Added Point-of-Dispensing Safety: from policy 206 as it was more appropriate for this policy. **07/22:** • Removed Dr. Toye and Dr. Gerry as Responsible parties. • Responsible party changed to Dr. Gregory Dohmeier • Updated regulatory reference to April 2022 MDH Standards 4.0 DUE • Updated NCQA Reference to 2022 UM 11 **07/21:** • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to scope. • Changed Case Management to Clinical Operations in Responsible Departments. **07/20:** • Updated Regulatory References to reflect 2020 NCQA Standards. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed "Maryland" from scope. **07/18:** • Updated NCQA regulatory references to reflect 2018 and changed Delmarva to Maryland EQRO. • 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:** • Updated titles and regulatory references. **10/16:** • No changes. **10/15:** • No changes.

MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**204**	
Subject:	**Early Refill, Lost Medication, & Travel Supply Policy**	
Section:	**Pharmacy**	
Initial Effective Date:	**05/21/2007**	
Revision Effective Date(s):	**07/18, 07/19, 07/21, 07/22, 7/23, 7/24, 7/25, 07/26**	
Historical Revision Date(s):	**10/08, 10/09, 10/10, 10/11, 09/12, 10/13, 10/14, 10/15, 07/17, 11/17, 01/18**	
Review Effective Date(s):	**07/01/2024**	
Historical Review Date(s):		
Responsible Parties:	**Health Plan Pharmacist, P&T Committee**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**Standards and Reporting Requirements of Drug Use Management Programs for MCOs Participating in the Maryland HealthChoice Program FFY2026, March 2026 version, 4.0** **COMAR: 10.09.03.06(D)(2), 10.67.06.04(J)(2), 10.09.03.01** **NCQA 2026 UM 11E**	
Approved:	**Director, Pharmacy**	**Chief Medical Officer**

Purpose: **To define the MedStar Family Choice Policy and Procedure for Early Refills, Lost Medications, and Travel Supply of Medications**

Scope: **MedStar Family Choice Maryland**

Definition: **Medical Reviewer: Medical Director or Health Plan Pharmacist**

1. A request for an early refill due to lost medication, travel supply, or any other reason may be initiated by the member, prescriber, or dispensing pharmacy. Requests may be initiated by phone, fax, or website.

2. The authorization process is initiated by the receipt of a request. The pharmacy preauthorization staff will take the member's name, telephone number,

prescribing practitioner's name, contact information, and the requested medication name, dose, and directions.

2.1. Requests for travel authorization shall include the requested travel dates,location, purpose and confirmed proof of travel with dates (Example: paid plane, train, lodging, etc) along with any relevant documentation to support request before forwarding to the Medical Reviewer for a decision.

2.2. The preauthorization staff will contact the prescribing practitioner and request clinical information supporting the clinical justification for the request if needed to determine medical necessity.

2.2.1. Requests for replacement of lost supply or travel supplies may not require clinical documentation to support the request.

3. The request will then follow the procedures and timelines as outlined in Pharmacy Policy 218: Pharmacy Authorization Process.

4. MedStar Family Choice will not authorize an early refill, lost/stolen medication, or travel supply of controlled medications.

4.1. An exception may be approved when:

4.1.1. A member is receiving controlled medication(s) for cancer treatment, sickle cell disease, or is in hospice or receiving palliative care.

4.1.2. The request is pursuant to a stolen supply of medication, an exception may be approved, and MedStar Family Choice Maryland may require confirmation of a completed police report prior to approval.

4.1.3. A dose change depletes the previous supply sooner than the allowable refill date.

5. Any other request for authorization of a prescription for an early refill may be approved only by a Medical Reviewer and will be based on a determination of the medical necessity for the individual member. This determination of medical necessity may include, but is not limited to, confirmation of medical need for early or additional medication by the prescriber.

6. MedStar Family Choice reserves the right to deny requests for early medication refills or reimbursements for previous early medication refills paid for by members with cash if sufficient medical necessity is not present.

7. Requests for early prescription fills for members solely because their enrollment span is ending are not considered an example of medical necessity.

8. Requests for early prescription fills for members with plans for extended travel outside of the United States will require an override in the PBM clinical software system.

8.1. Early refill requests for travel within the United States shall be redirected to fill at another network pharmacy once the utilization threshold is met.
8.2. The prior authorization entry for the early prescription refill will be limited to a total supply of no more than 30-days in a running 6 month period. The authorization for an early fill shall be entered into the PBM clinical software as a one-time override to prevent unintended extension of approval.
8.3. Prescriptions may be filled for international travel providing the member has an enrollment segment that extends and covers the travel period. In other words, if a request is received in May to fill medications for use in June, the clinical software system must show the member will be an active member during June. If the clinical software system shows a May 31st disenrollment date, the prescription will not be authorized.
8.4. Exceptions may be made for members with restricted pharmacy access under Policy 217: Corrective Managed Care at the discretion of the Medical Reviewer.

Summary of Changes:	**07/26:** • Updated all NCQA, MCO Standards, and COMAR to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy **07/25:** • Updated all NCQA, and MCO Standards to current year references. • Updated title to remove “Managed Drug Limitation”. • Removed all references to “Managed Drug Limitation” from policy. • Updated wording to clarify scope of types of early refill requests. • Section 4.1: Added clause “an exception may be approved when”. • Re-numbered subsections 4.1 and 4.2 to 4.1.1. and 4.1.2. • Added subsection 4.1.3 to capture common scenarios. • Section 5: Simplified wording • Subsection 5.1: Rolled up into Section 5. • Section 5.2: Removed (addressed in 4.1.3). **07/24:** • 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 definition of Medical Reviewer. • Transferred section 10, describing medications eligible for 90-day supplies to Pharmacy Policy 209, Section 2. • Clarified that clinical documentation to support review will be requested by the preauthorization staff unless the request is for a vacation supply or to replace lost meds. • Clarified that a Medical Reviewer will review all requests for an early refill, MDL exception or travel supply. • Modified reference to CVS to PBM. • Added that MedStar may request a copy of a police report when requested to replace stolen medications. (4.2.) • Clarified that travel within the USA must adhere to utilization thresholds. • Added exceptions for Corrective Managed Care patients. **07/23:** • Responsible Parties changed to Health Plan Pharmacist • Updated Approved by to Dr. Wills and C. Attia • Updated reference to Standards and Reporting Requirements of Drug Use Management Programs for MCOs Participating in the Maryland HealthChoice Program FFY2022, March 2023 version • Updated NCQA reference to NCQA 2023 UM 11E • Updated COMAR to COMAR 10.09.03.06(D)(2), 10.67.06.04(J)(2), and 10.09.03.01 • Added Pharmacist to all references to Medical Director. **07/22:** • Removed Dr. Toye and Dr. Gerry as Responsible parties. • Responsible parties changed to Dr. Gregory Dohmeier • Updated COMAR citations 10.67.06.04 I (d) and 10.9.03.06 (D) (2) • Updated regulatory reference to reflect April 2022 MDH Standards • Updated NCQA Reference to 2022 Standards • Added clarification on 90-day supply to exclude carved out drugs • Changed title by adding Maintenance Medication (90 Day Supply)" to more accurately reflect contents of policy **07/21:** • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to scope. • Changed Case Management to Clinical Operations in Responsible Departments. **07/20:** • Updated Regulatory References to reflect COMAR recodification and 2020 NCQA Standards.

	• Edited/condensed description of how precertification staff acquires information for the sake of clarity. • Changed “will” be to “may” be limited to a 30-day supply of medications not listed in COMAR 10.09.03.01. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed “Maryland” from scope. **11/18:** • Added controlled vs. non-controlled distinction and set limits for controlled medication early refills. **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. **01/18:** • Removal of timeline information (moved to a new Pharmacy Process Policy which was made to comply with decision timeframe specified in updated COMAR 10.09.71.04). **11/17:** • Revisions to comply with decision timeframe specified in updated COMAR 10.09.71.04. **07/17:** • Major revision. Split Policy 204 into 204A&B (previous policy included MD & DC). Updated regulatory references and NCQA, clarified language to indicate documentation requirements, decision and notification tables, changed Physician Advisor to Medical Director, added definitions to align with NCQA UM 5, updated titles, major changes to align with NCQA definitions of level of review. **10/16:** • No changes. **10/15:** • Added denial notice to the DHCF per contract: When a medication request is denied, MFC will make the contractually required notification to the DHCF within 2 business days.

MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**205**	
Subject:	**Non-Formulary Medications**	
Section:	**Pharmacy**	
Initial Effective Date:	**06/06/2000**	
Revision Effective Date(s):	**11/18, 07/19, 07/20, 07/21, 07/22, 07/23, 07/24, 7/25, 07/26**	
Historical Revision Date(s):	**09/01, 09/02, 04/03, 04/04, 10/04, 10/05, 10/06, 10/07, 10/08, 10/09, 10/10, 10/11, 09/12, 10/13, 10/14, 10/15, 06/17, 10/16, 11/17, 01/18, 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:	**MDH Standards and Reporting Requirements of Drug Use Management Programs for MCOs March 2026 version 3.0 Standards 2.0, 3.0 NCQA 2026: UM 11E COMAR 10.09.03.06(D) and 10.67.06.04J(2).**	
Approved:	**Director, Pharmacy**	**Chief Medical Officer**

Purpose: **To ensure that members shall have access to Non-Formulary pharmaceuticals when medically necessary and in the absence of therapeutically equivalent formulary-preferred alternatives.**

Scope: **MedStar Family Choice – Maryland**

Policy: **In accordance with the organization's dedication to provide quality health care services, this policy will allow members to receive medically necessary, Non-Formulary pharmaceuticals if no therapeutically equivalent formulary-preferred alternative option is available.**

Definition: **Medical Reviewer: Medical Director or Health Plan Pharmacist**

Procedure:

1. An emergency, 72-hour supply of the prescribed medication shall be allowed:
   1.1. In an emergency determined by the prescriber.
   1.2. In an emergency determined by the pharmacist, when possible, in consultation with the prescriber; or
   1.3. If the prescriber does not provide a response to preauthorization request within 24 hours.
   1.4. The dispensing pharmacist can process an Emergency Override for a 72-hour supply of medication without contacting MedStar Family Choice.
      1.4.1. The 72-hour emergency procedure should not be used for routine or continuous overrides.
      1.4.2. The pharmacist should use their professional judgement regarding whether there is an immediate need every time the emergency supply option is used.

2. The request for a non-formulary prescription authorization may be initiated by the member, prescribing practitioner, or the dispensing pharmacy staff. Requests can be initiated by phone, fax, or website.
   2.1. The requesting party of a non-formulary pharmaceutical shall be allowed the opportunity to speak with a Medical Reviewer upon request.

3. The authorization process is initiated by the receipt of a request. The pharmacy preauthorization staff will take the member's name, telephone number, prescriber's name, contact information, the requested medication name, strength, dose, and directions for use. The date and time of the request must be recorded.

4. Requests for a non-formulary pharmaceutical will be redirected to a formulary alternative whenever possible.
   4.1. The Medical Reviewer will evaluate the request and identify available formulary alternatives and document the alternative(s) in the clinical software.
   4.2. The preauthorization staff may relay any redirection recommendation(s) to the prescriber only as identified and documented by the Medical Reviewer.
   4.3. If the prescriber agrees that the alternative formulary medication is appropriate, this will be captured within the clinical software documentation.
      4.3.1. The request will be considered void and captured as redirected.
      4.3.2. The preauthorization staff will communicate the decision to the requestor.
   4.4. If redirection to a formulary alternative is not successful, or if no therapeutically equivalent formulary alternative is available, then the non-formulary request will be evaluated for medical necessity by a Medical Reviewer.

5. Non-formulary medications will be approved by the Medical Reviewer if medical necessity can be established. This determination of medical necessity may include, but is not limited to, the following:
   5.1. Absence of any formulary alternatives and the member's condition warrants the non-formulary medication; and

5.2. Confirmation by the Medical Reviewer that the requested dose, formulation, directions for use, and treatment duration is appropriate based on the requested indication; and
5.3. The health plan reserves the right to require use of a clinically appropriate, more cost-effective non-formulary alternative in lieu of the requested non-formulary medication.
5.4. Documentation from the member's prescriber of a clinically significant therapeutic concern that justifies the use of a non-formulary medication instead of **all** clinically appropriate formulary alternatives.
    5.4.1. Confirmation that any failed pre-requisite therapies were dosed according to clinical guidelines and patient adherence to therapy is not contradicted by the pharmacy claims data when available.
        5.4.1.1. Failure to trial of formulary medications should be documented in the medical record including dates of active treatment.
    5.4.2. Adverse or allergic reaction
    5.4.3. Adverse drug-drug interaction between the preferred formulary alternative and then member's concurrent therapy, if the drug-drug interaction cannot be resolved.
    5.4.4. Adverse drug-disease interaction between proposed Formulary medications and a documented disease state.
    5.4.5. Documentation of a member's visual or other physical impairment that would result in medication administration, compliance, and/or safety issues.
    5.4.6. Documentation of a member's swallowing or gastrointestinal absorption impairment that would result in medication administration, compliance, and/or safety issues.

6. Requests for Non-Formulary, Brand Name Medication when a generically equivalent is available:
    6.1. Will be reviewed following the same criteria as any other non-formulary request, and;
    6.2. To align with amendments to COMAR 10.09.03.07 H (3), prescribers are required to complete a Maryland Department of Health (MDH) MedWatch form.
    6.3. A copy of the form must be included with the request to MedStar Family Choice for review before coverage of a brand name medication with a generic equivalent will be approved.
    6.4. Mere submission of the form is no guarantee that the request will be honored. When a generic version of the drug made by a different manufacturer is available, a trial with another therapeutically equivalent formulary drug may be required before approval of a brand name product.
    6.5. In the event of a market shortage for generic products, a brand drug may be approved through the duration of the anticipated drug shortage.
    6.6. Links to the MedWatch form and instructions for completion are found on the MDH website, on the Pharmacy Prior Authorization and Step Therapy Table, and are linked here:
        - **Instructions for Completing MDH MedWatch Form**

- **MDH MedWatch Form**

7. Requests for non-formulary medications follow the procedures and timelines as outlined in Policy 218: Pharmacy Authorization Process.

Summary of Changes:	**07/26** • **Updated all NCQA, MCO Standards, and COMAR to current references.** • **Changed Approved from AVP Clinical Operations to Director, Pharmacy** • **Added language 5.3 Alternative cost effective clinical appropriate non-formulary may be required than requested nonformulary medication** **07/25:** • Removed references to NCQA 5C and 5E because they specifically relate to timeliness which is addressed in Policy 218. • Purpose Statement: Replaced “medications” with “pharmaceuticals”. • Policy Statement: Replaced “prescription medications” with “pharmaceuticals”. • Moved previous Section 4 into subsection 2.1. • Section 4: • Combined • Section 4.3: • Section 4.3.1: • Inserted • Previous • Section 5.3.3: • Inserted subsection 6.1, all others moved down one. • Former subsection 6.3: Removed “and approval”. • Section 6.4: clarified wording to reflect that formulary alternatives should be exhausted before approving a brand, non-formulary product. **07/24:** • 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. • Refined the Purpose Statement. • Expanded the Policy Statement.

	• Added definition of Medical Reviewer. • Clarified that all clinically appropriate formulary alternatives should be exhausted before approving a non-formulary request. • Restricted action of redirection to occur only under the supervision of a Medical Reviewer. • Incorporated all of Policy 201; clarified and expanded procedures for brand-name medication requests. • Aligned requirement for a completed MedWatch form with COMAR standards. • Included MedWatch form and directions for reference. **07/23:** • Responsible Parties changed to Health Plan Pharmacist • Updated regulatory reference to March 2023 MDH Standards • Updated NCQA Reference to 2023 Standards • Updated Approved by to: Dr. Wills and C. Attia • Updated Section 6 COMAR reference to 10.67.06.04J • Added Health Plan Pharmacist as possible deciding party in addition to a Medical Director. **07/22:** • Removed Dr. Toye and Dr. Gerry as Responsible parties. Added Dr. Gregory Dohmeier as Responsible party. • Updated regulatory reference to April 2022 MDH Standards • Updated NCQA references to reflect 2022 NCQA Standards • Updated COMAR references to reflect changes to MDH Standards **07/21:** • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to scope. • Changed Case Management to Clinical Operations in Responsible Departments. **07/20:** • Updated Regulatory References to reflect COMAR recodification and 2020 NCQA Standards. • Updated “visual impairment” to “visual or other physical impairment” in letter f. • Corrected #7 to read medical necessity of the Non-Formulary drug (it previously stated Brand Name drug) • Regarding redirection efforts, clarified “Formulary generic alternative” to just “Formulary alternative” as redirection may not always be to a generic drug. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed “Maryland” from scope.

	10/18: • Addition in Policy Section: “Members have the option to submit an exception request based on medical necessity by calling MFC directly or submitting a request online via the MFC website. • Added “member” in #1 of Procedure. **07/18:** • Updated NCQA regulatory references to reflect 2018 and changed DHMH to MDH. • Modified Effective Date to Initial Effective Dates; added Historical Revision Dates and Revision Effective Dates; and added Historical Review Dates and Review Effective Dates. **01/18:** • Removal of timeline information (moved to a new Pharmacy Process Policy which was made to comply with decision timeframe specified in updated COMAR 10.09.71.04). **11/17:** • Revisions to comply with decision timeframe specified in updated COMAR 10.09.71.04. **07/17:** • Major revision. Split Policy 205 into 205A&B (previous policy included MD & DC). Updated regulatory references and NCQA, clarified language to indicate documentation requirements, decision and notification tables, changed Physician Advisor to Medical Director, added definitions to align with NCQA UM 5, updated titles, major changes to align with NCQA definitions of level of review. **10/16:** • No changes. **10/15:** • Added denial notice to the DHCF per contract: When a medication request is denied, MFC will make the contractually required notification to the DHCF within 2 business days.

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:**

	• 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.

	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.

MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**208**	
Subject:	**Pharmacy Policy & Procedure Review**	
Section:	**Pharmacy**	
Initial Effective Date:	**04/01/2006**	
Revision Effective Date(s):	**07/18, 07/19, 07/20, 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, 7/17, 11/17**	
Review Effective Date(s):		
Historical Review Date(s):		
Responsible Parties:	**Health Plan Pharmacist, P&T Committee**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**MDH Standards and Reporting Requirements of Drug Use Management Programs for MCOs 1.8 March 2026 version** **NCQA 2026: UM 11 A (4), 11D(1,3)**	
Approved:	**Director, Pharmacy**	**Chief Medical Officer**

Purpose: **To ensure that the Medstar Family Choice Pharmacy policies and procedures are updated annually.**

Scope: **MedStar Family Choice Maryland**

Policy: **The P&T Committee Chairperson is responsible for coordinating the review and revision of all MedStar Family Choice Pharmacy Policies annually.**

Procedure:

1. The annual review of policies and procedures occurs in the second quarter of the calendar year.
   1.1. Both physicians and pharmacists shall be involved in developing policies and procedures of the formulary management program.

1.2. Annual updates will be brought to the May MedStar Family Choice Pharmacy & Therapeutics (P&T) Committee for review, discussion, and approval.
1.3. Draft versions of the updated policies will be disseminated electronically to the P&T Committee voting members at least one week before the scheduled meeting.
    1.3.1. Questions, comments, or feedback about the proposed updates may be incorporated into the policy updates before the P&T meeting. All changes will be shared during the meeting and captured in the minutes for posterity.
1.4. Approval of new policies and/or proposed policy revisions will occur by simple voice consent unless there is a dissenting voice, in which case a formal vote shall take place with a simple majority to carry the vote.
1.5. The effective date of annually approved policies and procedures will be July 1st of the corresponding calendar year to align with the timing of NCQA Standards updates.
1.6. Interim policy and procedure revisions may be made if needed to address changes to NCQA Standards, Maryland Department of Health (MDH) regulations, changes to workflow or any identified business need.
    1.6.1. Interim policy and procedure revisions shall be communicated to the voting members of the P&T Committee for review via email once the draft is finalized.
    1.6.2. The interim policy will be reviewed with all other policies during the regularly scheduled annual review.
    1.6.3. Questions, comments, or feedback about the proposed updates may be incorporated into the policy updates before the P&T meeting. All changes will be shared during the meeting and captured in the minutes for posterity.
    1.6.4. The effective date for interim policies will be the first of the month following approval by the P&T Committee.

2. The P&T Committee shall make available its meeting minutes, policies, and procedures at the request of the Maryland Department of Health (MDH).

3. Relevant pharmacy policy and procedure updates will be posted to the MedStar Family Choice website within 30 days of approval.

4. Updates to the Pharmacy Policies and Procedures are communicated to the practitioner network in various ways, including but not limited to:
    4.1. As “Frequently Asked Questions” on the MedStar Family Choice website.
    4.2. Written notification of the availability of the information on the website will be mailed to the practitioner network annually.
    4.3. Printed copies of Policies and Procedures will be available upon request.
    4.4. Information about pharmacy policies and procedures is available in the MedStar Family Choice Provider Manual.
    4.5. A summary of the annual updates made to the policies and procedures is posted on the MedStar Family Choice website.

of Changes:	**07/26:** • Updated all NCQA to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy **07/25:** • Updated NCQA References and MCO Standards to current year • Simplified wording of Purpose and Policy statements to show review occurs annually instead than annually". • Section 4: Wording simplified. • Subsection 4.5: Added for completeness. **07/24:** • Moved P&T Committee listing from "Responsible Department" to "Responsible Parties" sectio • Reformatted font and procedure to improve readability. • Updated all NCQA and MCO Standards to current references. • Updated policy Approver titles and removed individual names. • Removed Policy Background statement. • Added: Physicians and Pharmacists develop policies. • Added: Procedures for policy reviews, feedback, and voting. • Added: Timelines and procedures for Policy changes. • Added: Timelines and procedures for interim Policy updates. **07/23:** • Responsible Parties changed to Health Plan Pharmacist • Updated regulatory reference to March 2023 MDH Standards • Updated NCQA Reference to 2023 Standards • Updated Approved by to: Dr. Wills and C. Attia **07/22** • Responsible Parties changed to Dr. Gregory Dohmeier • Updated Regulatory Reference to April 2022 MDH Standards • Updated NCQA Reference to 2022 Standards **07/21:** • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to scope. • Changed Case Management to Clinical Operations in Responsible Departments. **07/20:** • Updated Regulatory References to reflect 2020 NCQA Standards. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed "Maryland" from scope. **07/18:** • Updated NCQA regulatory references to reflect 2018. • Modified Effective Date to Initial Effective Dates; added Historical Revision Dates and Revisio Dates; and added Historical Review Dates and Review Effective Dates. **11/17:** • Removed District references, changed DHMH to MDH

	07/17: • Updated titles and regulatory references. Changed policy review to first quarter calendar year annual review to be completed before July 1 each year. Added contract modifications to the D sentence. **10/16:** • No changes. **10/15:** • No changes.

MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**209**	
Subject:	**Pharmacy Benefits Management**	
Section:	**Pharmacy**	
Initial Effective Date:	**06/04/2000**	
Revision Effective Date(s):	**7/19, 7/20, 5/21, 7/21, 7/22, 7/23, 7/24, 7/25, 7/26**	
Historical Revision Date(s):	**09/01, 04/03, 04/04, 10/05, 10/06, 10/07, 10/08, 10/09, 10/10, 10/11, 09/12, 10/13, 10/14, 07/17, 11/17, 7/18**	
Review Effective Date(s):		
Historical Review Date(s):		
Responsible Parties:	**Health Plan Pharmacist, P&T Committee**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**MDH Standards and Reporting Requirements of Drug Use Management Programs for MCOs 2.0, 3.0, 4.0 March 2026. 2021 MDH High-Cost, Low-Volume Drug Risk Mitigation Policy COMAR 10.34.10.01C (2), COMAR 10.67.06.04, COMAR 10.09.03.05(14) and C (3) NCQA 2026: UM 11A: 1, 2, 4, UM 11B 1, 2, 3, 5; UM 11D, ME 5D United States Code of Federal Regulations 1396r-8(d)(2)**	
Approved:	**Director, Pharmacy**	**Chief Medical Officer**

Purpose: To ensure that the MedStar Family Choice has standard processes in place for Pharmacy Benefits Management, as overseen by the Pharmacy & Therapeutic (P&T) Committee.

Scope: MedStar Family Choice Maryland

Policy: MedStar Family Choice P&T Committee oversees the Pharmacy Benefit; including management of the closed formulary, utilization management, and implementation of all approved changes. To ensure that all members and providers have the most current Pharmacy Benefit information, MedStar Family Choice Maryland

adheres to standard processes for communicating all formulary updates per NCQA and Maryland state requirements.

Definition: Medical Reviewer: Medical Director or Health Plan Pharmacist

Procedure:

1. FORMULARY MANAGEMENT

1.1. The MedStar Family Choice P&T Committee is responsible for managing the formulary.

1.1.1. The P&T Committee will ensure that formulary coverage encompasses all required pharmaceuticals as mandated by any regulatory entity, i.e. Maryland Department of Health (MDH), Centers for Medicare and Medicaid (CMS).

1.2. Medications and Durable Medical Equipment and supplies that are administered in an outpatient setting or dispensed from a retail pharmacy may be considered for inclusion on the formulary.

1.2.1. Exceptions to the scope of the formulary may be made to apply utilization management (UM) criteria to medications administered through the medical benefit whereas criteria could not otherwise be applied but are clinically or fiscally prudent.

1.3. MedStar Family Choice may exclude from coverage any medication ordered for an excluded benefit, as limited in COMAR 10.09.03.05 or the United States Code of Federal Regulations 1396r-8(d)(2)(h).

1.3.1. Pharmacy benefit exclusions include but are not limited to:

1.3.1.1. Medications ordered for weight management.

1.3.1.2. Experimental or investigational drugs.

1.3.1.3. Medications ordered to treat sexual or erectile dysfunction.

1.3.1.4. Medications ordered for cosmetic purposes.

1.3.1.5. Medications ordered for off-label indications.

1.3.1.6. Over-the-counter pharmaceuticals coverage is not mandated. The coverage provided by MedStar Family Choice is discretionary and may be cost and/or quantity limited.

1.3.2. Medications that are only Food and Drug Administration (FDA)-approved for an excluded benefit will be excluded from the MedStar Family Choice formulary.

1.4. Medications carved out by MDH.

1.4.1. MDH maintains a list of medications that are excluded from coverage by the MCO and are covered under the MDH with their own separate formulary and utilization management. These medications include:

1.4.1.1. Behavioral Health (Mental Health and Substance Abuse)

1.4.1.2. Anticonvulsants

1.4.1.3. Antiparkinsonian Agents

1.4.1.4. Attention Deficit Hyperactivity Disorder for members aged 6-17 years.

1.4.1.5. Fibromyalgia

1.4.1.6. Movement Disorders
1.4.1.7. Musculoskeletal Therapy Agents
1.4.1.8. Alcohol Deterrents
1.4.1.9. Opioid Antagonists
1.4.1.10. Partial Opioid Antagonists
1.4.1.11. Partial Opioid Agonist/Antagonist combinations
1.4.1.12. Smoking Deterrents

1.5. MedStar Family Choice prefers generic and biosimilar medications when available.
1.5.1. Innovator products on the formulary may be replaced automatically when interchangeable generic or biosimilar products become available.

1.6. Medications may be identified to bring to a P&T committee meeting for formulary consideration based on:
1.6.1. New FDA approval of a medication or new indication for use.
1.6.2. Discussion with MedStar Family Choice staff members.
1.6.3. Maryland State Department of Health (MDH) transmittals.
1.6.4. Recommendations from pharmacy vendors or vendors associated with MedStar Family Choice Maryland.
1.6.5. Suggestions from MedStar Family Choice Staff.
1.6.6. Recommendations from other MedStar Family Choice Committees.
1.6.7. Non-formulary emergency override reports.
1.6.8. Newly released generic medications if the brand is non-formulary.
1.6.9. Prior Authorization request trend reports.

1.7. Medications are selected for inclusion or exclusion on the closed Formulary based upon discussion within the MedStar Family Choice P&T Committee. Discussion may include the following types of information about a medication:
1.7.1. Drug monograph information including generic name, brand name(s), manufacturer, dosage forms and strengths, FDA approved/labeled indication, mechanism of action, pharmacokinetics and pharmacodynamics, adverse effects, drug interactions, monitoring parameters, dosage, schedule, and administration.
1.7.2. Evaluation of clinical trials
1.7.3. Comparison of clinical therapeutics
1.7.4. Evaluation of available pharmacoeconomic studies
1.7.5. Comparative cost information to clinically equivalent formulary alternatives
1.7.6. Current utilization, if any.
1.7.7. Formulary recommendations, including any associated utilization management restrictions.

1.8. The P&T Committee will consider relevant findings from government agencies, medical literature and journals, national guidelines, MedStar Health practice guidelines, MedStar Health subject matter experts, and other sources such as large commercial insurance carriers, as applicable when considering a medication for formulary inclusion.

1.9. Formulary change requests should be submitted to the Chairperson of the P&T Committee.

1.9.1. Criteria and rationale for additions or deletions must be supplied to the Committee by a requesting party.
1.9.2. Requests can be made:
1.9.2.1. Via email at MFC-FormularyFeedback@MedStar.net
1.9.2.2. Via phone at 410-933-2200
1.9.2.3. Via fax at 410-933-2274 or
1.9.2.4. Via postal mail: Chairperson, P&T Committee, MedStar Family Choice, 10980 Grantchester Way, 5th Fl, Columbia, MD 21044
1.9.3. All formulary requests will be brought to the P&T Committee within two meeting cycles from receipt by the Chairperson.
1.10. All medications included in the closed Formulary are reviewed annually by the P&T Committee, as described in Pharmacy Policy #202: Pharmacy & Therapeutics Committee.
1.10.1. Annual formulary review encompasses a complete review of all utilization management requirements as described in Sections 3 and 4 of this Policy.

2. PRESCRIPTION PLAN COVERAGE (DAY SUPPLY LIMITS)

2.1. A 30-day supply of medication is the standard covered benefit.
2.2. A 90-day supply of medication is the standard covered benefit for maintenance medications as defined in COMAR 10.09.03.01. "Maintenance medication" means medication in chronic therapeutic categories corresponding to the following American Hospital Formulary Service (AHFS) classification numbers:
2.2.1. Cardiac drugs (24:04)
2.2.2. Antilipemic agents (24:06)
2.2.3. Hypotensive agents (24:08)
2.2.4. Vasodilating agents (24:12)
2.2.5. Sclerosing agents (24:16)
2.2.6. Alpha-adrenergic blocking agents (24:20)
2.2.7. Beta-adrenergic blocking agents (24:24)
2.2.8. Calcium-channel blocking agents (24:28)
2.2.9. Renin-angiotensin-aldosterone system inhibitors (24:32)
2.2.10. Hydantoins (28:12:12), excluding carveout.
2.2.11. Oxazolidinediones (28:12:16)
2.2.12. Succinimides (28:12:20)
2.2.13. Anticonvulsants, miscellaneous (28:12:92); (excluding carveout)
2.2.14. Replacement solutions (40:12) (potassium supplements only)
2.2.15. Diuretics (40:28)
2.2.16. Lipotropic agents (56:24)
2.2.17. Contraceptives (68:12)
2.2.18. Estrogens and antiestrogens (68:16)
2.2.19. Antidiabetic agents (68:20)
2.2.20. Antihypoglycemic agents (68:22)
2.2.21. Parathyroid (68:24)
2.2.22. Progestins (68:32)
2.2.23. Thyroid and antithyroid agents (68:36)

2.2.24. Vitamins (88:00)
2.2.25. Sodium fluoride (92:00), and
2.2.26. Iron preparations, oral (20.04.04) (oral products in which ferrous sulfate is the only active ingredient and chewable tablets of any ferrous salt if combined with vitamin C, multivitamins, multivitamins and minerals, or other minerals in the formulation).

2.3. Members may obtain 90-day supplies of maintenance medication from any in-network retail pharmacy or through the Pharmacy Benefit Manager's (PBM) Mail Order Pharmacy.
2.3.1. Members are not required to use Mail Order Pharmacy Services for any reason.
2.3.2. If a non-formulary medication request is approved for a maintenance medication as defined in Section 2.2 of this policy, then the entered override will allow a 90-day supply to be dispensed.

2.4. Exceptions to standard 30- or 90-day supply limits:
2.4.1. The P&T Committee may adjust the covered benefit day supply for certain medications to align with clinically appropriate use and/or product package sizes.
2.4.2. Oral contraceptive medications may be dispensed for up to a 365-day supply.

3. HIGH-COST, LOW-VOLUME MEDICATIONS

3.1. High-cost, low-volume medications (HCLV) have an expected annual cost greater than $500,000 per member.

3.2. MedStar Family Choice is responsible for authorizing, managing, and paying all claims related to medications in this category.
3.2.1. MedStar Family Choice shall invoice MDH for incurred expenses on a quarterly basis.

3.3. MedStar Family Choice is expected to develop and adhere to medical necessity criteria to ensure that all instances of utilization of HCLV medications follow clinical best practices.
3.3.1. Clinical criteria for PA are maintained in a separate document titled "MedStar Family Choice High-Cost Medication PA Criteria" which is posted on the MedStar Family Choice - Maryland website.

3.4. MedStar Family Choice may be asked to evaluate a request for a HCLV medication before such criteria are established.
3.4.1. A Prior Authorization (PA) is required regardless of formulary status to comply with MDH expectations.
3.4.2. All requests for authorization of a HCLV medication must be reviewed by a Medical Reviewer.
3.4.3. Chief Medical Officer must make final approval.
3.4.4. The duration of a PA for HCLV medications may be limited to a maximum of 3 months to facilitate the quarterly collection of updated clinical documentation required by MDH.
3.4.4.1. The duration of authorization may be reduced based on clinical appropriateness.

3.4.5. HCLV medications may be presented to P&T with a recommendation to add to formulary with PA requirements even when outside of the scope of the outpatient formulary, i.e., when covered under the Medical Benefit, to establish standardized criteria in the absence of a Medical Benefit formulary.

4. UTILIZATION MANAGEMENT

4.1. The P&T Committee will determine which formulary medications will have utilization management (UM) requirements, which may include but are not limited to:

- 4.1.1. Step Therapy (ST) protocols,
- 4.1.2. Prior Authorization (PA) criteria,
- 4.1.3. Managed Drug Limitations (MDL) and/or Quantity Limits (QL),
- 4.1.4. Age, gender
- 4.1.5. Copay tier designations for Brand drugs not otherwise defined by MDH,
- 4.1.6. Any other clinical protocols that will impact MedStar Family Choice members.
- 4.1.7. Therapeutic Duplication or Drug-Drug Interaction screenings.

4.2. Step therapy is a process that requires members to trial one or more formulary medications prior to accessing the medication prescribed by the provider.

- 4.2.1. Specific ST criteria are included in the “Prior Authorization and Step Therapy Table” found on the MedStar Family Choice website.
  - 4.2.1.1. Application of ST requirements may be automated by the pharmacy benefits manager (PBM).
  - 4.2.1.2. If the claims history does not support an automatic approval of the medication, a manual PA request will be required.
    - 4.2.1.2.1. The request will be processed as described in pharmacy Policy 218: Prior Authorization Process.

4.3. Prior authorization is a prospective process that requires prescribers to obtain approval from MedStar Family Choice before a specific medication is dispensed to the member.

- 4.3.1. Specific PA criteria are maintained in the “Prior Authorization and Step Therapy Table” and posted on the MedStar Family Choice website.
- 4.3.2. The PA criteria are approved by the P&T Committee.
- 4.3.3. Criteria are reviewed at least annually to evaluate and update the content.
- 4.3.4. Aggregate PA data will be reviewed annually to determine the clinical utility of the requirements and may be brought to P&T for evaluation.
- 4.3.5. PA criteria include, but are not limited to:
  - 4.3.5.1. Medication name (brand, generic, dosage form, and strengths)
  - 4.3.5.2. Any MedStar Family Choice specific requirements, including covered indications.
  - 4.3.5.3. Duration of authorization.
  - 4.3.5.4. Renewal Criteria – continuation of therapy beyond first approval.

4.3.6. MedStar Family Choice reserves the right to consult clinical resources in addition to the PA table to determine medical necessity for indications that are not directly addressed by the PA criteria.
4.3.7. When a formulary medication is FDA-approved for an indication that is an excluded benefit as described in Policy 205: Non-Formulary Medications, MedStar Family Choice will require PA to validate the ordered indication.

4.4. Managed drug limitations (MDL) and Quantity limits (QL) are limits that may be applied to formulary medications to promote appropriate utilization for reasons including, but not limited to:
4.4.1. FDA-labelled maximum daily doses.
4.4.2. FDA-labelled maximum therapy durations.
4.4.3. Clinical guidelines for use.
4.4.4. To identify and prevent clinical inertia.
4.4.5. Potential safety or utilization concerns.

4.5. Age, gender, or other limitations are UM features that may be applied to formulary medications to align with FDA-approved product labelling.

4.6. Specialty medications are defined by MDH based on cost, complexity of therapy, unusual storage requirements, and/or limitations on distribution channels.
4.6.1. Due to the complexity of Specialty medications, MedStar Family Choice reserves the right to delegate formulary and/or utilization management to the contracted PBM.
4.6.2. MedStar Family Choice – Maryland participates in the PBM-managed Specialty Drug Quantity Limits Program, which manages QL for many Specialty Medications.
4.6.2.1. An updated version of this list is maintained on the MedStar Family Choice – MD pharmacy web pages and also within the formulary document for all formulary Specialty Medications.

5. COMMUNICATION OF PHARMACEUTICAL UTILIZATION CHANGES

5.1. Formulary changes will:
5.1.1. Be posted quarterly to the MedStar Family Choice website.
5.1.1.1. Negative formulary changes (e.g., removal from the formulary or addition of PA or ST requirements) will be posted to the MedStar Family Choice website no less than 30 days prior to implementation of the change.
5.1.2. Be disseminated in the MedStar Family Choice Provider Newsletter.
5.1.3. Be disseminated in the MedStar Family Choice Member Newsletter, if applicable.
5.1.4. Be submitted monthly to MDH via email (i.e. the Formulary Navigator).
5.1.4.1. A copy of any formulary-change letters sent to providers and/or members must be included with the monthly submission.

5.2. Current PA and/or ST requirements will be posted quarterly to the MedStar Family Choice website.

5.3. Members impacted by negative formulary changes e.g., removals, addition of PA or ST criteria, MDL etc., shall be notified by U.S. postal mail no less than 30 days before the change becomes effective.

5.3.1. The content of the provider and/or member notification letters shall be submitted to MDH, and approval received prior to mailing.
5.3.1.1. This requirement may be waived when a templated letter format is utilized.
5.4. Prescribers of medications impacted by negative formulary changes e.g., removals, addition of PA or ST criteria, MDL, etc., shall be notified via electronic or U.S. postal mail no fewer than 30 days before the change becomes effective.
5.4.1. Prescribers will be provided with the names of individual patients affected by the formulary change.
5.5. The Formulary Preface is maintained as part of the Formulary Document.
5.5.1. Is updated annually.
5.5.2. The current formulary document is maintained on the MedStar Family Choice website and is updated quarterly.
5.5.3. Includes information describing how to use the pharmaceutical management procedures and utilization requirements:
5.5.3.1. Generic substitution processes.
5.5.3.2. Process for initiating medical exception, prior authorization, and non-formulary requests.
5.5.3.3. Prescription copayments.
5.6. A printed copy of any and all pharmaceutical management procedures, policies, protocols, etc., will be made available upon request.
5.7. Written notification of the availability of the updated information will be made at the time of member enrollment and annually.
5.8. "Frequently Asked Questions" resources for navigating the Pharmacy Benefits are available on the MedStar Family Choice website for both members and providers.
5.8.1. Topics addressed include, but are not limited to:
5.8.1.1. Explanation of medication limits,
5.8.1.2. How prescribers must provide information to support an exception request,
5.8.1.3. Process for generic substitution, therapeutic interchange, and step therapy protocols.
5.8.1.4. Prescription copayments.
5.9. MedStar Family Choice updates member pharmacy benefit information on its website and in materials used by telephone staff, prior to the effective date of a formulary change.
5.9.1. Quarterly summaries of all formulary changes are posted on the website.
5.9.2. A representative of the P&T Committee will attend quarterly Member Service meetings to convey notice of changes and support member-facing staff whose responsibilities include communicating with members regarding formulary content.

6. TIMING OF FORMULARY CHANGE IMPLEMENTATION

6.1. Additions of medications may be implemented at any time.

6.1.1. Interim additions of medications will be reviewed at the next occurring P&T meeting, or at ad hoc meetings as necessary.
6.1.2. The Committee has final authority to approve or change the addition.

6.2. Changes or additions to PA criteria, ST protocols, MDL, and copay tier designations are implemented following the regular schedule of P&T meetings.
6.2.1. Relaxation of PA criteria or ST protocols may be implemented at any time to respond to updates of Standards of Care or changes to the availability of formulary alternatives.
6.2.1.1. Interim adjustments to PA or ST requirements will be reviewed at the next occurring P&T meeting.
6.2.1.2. The Committee has final authority to approve or change the modifications.

6.3. Removals of medications from the formulary are implemented following the regular schedule of P&T meetings.
6.3.1. Removals become effective on the first day of the second full month following the meeting date.
6.3.2. Exceptions listed below may be removed on an interim basis:
6.3.2.1. Brand drugs when a generic equivalent becomes available.
6.3.2.2. Innovator biologics when a biosimilar therapeutic equivalent becomes available.
6.3.2.3. Upon FDA removal of a medication from the marketplace.
6.3.2.4. Upon manufacturer withdrawal of a drug product.
6.3.3. The P&T Committee may elect to permit continued coverage of medications removed from the formulary for current utilizers.
6.3.3.1. If current utilizers are permitted access to medication, no member-specific notification of the formulary change is required.

Summary of Changes:	**07/26:** • Updated all NCQA, MCO Standards, and COMAR to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy • Section 1.9.2.4 Updated address where request can be mailed • Section 3.4.3. HCLV must be approved by CMO • Section 6.1.1. Added addition medication changes can be at ad hoc meeting. **07/25:** • Updated all NCQA, MCO Standards, and COMAR to current year references. • Added Subsections: 1.1.1, 1.3.1.6, 1.6.9, 4.1.7, 4.6.2, 4.6.2.1, 5.3.1.1, 5.5.3.3, 5.8.1.4. • Subsection 1.6.3 changed “requirements” to “transmittals”.

	• Section 3.4.4: Added “in the absence of a Medical Benefit formulary”. • Subsection 4.3.2: Removed “established and”. • Removed Subsection 5.5 (duplicative of 5.3.1). • Subsection 5.5.2: removed “but no less than annually”. **07/24:** • Changed title from “Review, Selection & Evaluation of Meds Included in the Closed Formulary” to “Pharmacy Benefit Management” to reflect all current content. • 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. • Aligned the Purpose statement and Policy statement with the updated content. • Incorporated the content of retired policies: 200: Additions and Deletions to the Formulary (1) 204: Section re: 90-day supplies (2.2, 2.3) 210: Step Therapy (2.5) 212: Prior Authorization (2.6) 214: P&T Website Update (3) 215: PA Table Review (1.10.1; 2.6; 3.1, 3.2) 222: Specialty Pharmacy (2.9) • Added description of benefit excluded medications (1.3) and medications carved out to FFS (1.4) • Established that brand product coverage converts to generic once available (1.5.1) • Added statement that all formulary requests will be brought to P&T within 2 meeting cycles (1.9.3). • Included description of MDL/QL as part of UM (3.4) • Added that provider notification may occur via electronic mail (4.4) • Consolidated redundant content. **07/23:** • Responsible Parties changed to Health Plan Pharmacist • Updated regulatory reference to March 2023 MDH Standards • Updated NCQA Reference to 2023 Standards • Updated Approved by to: Dr. Wills and C. Attia **07/22:** • Responsible Parties changed to Dr. Gregory Dohmeier

	• Removed from Responsible Parties: Dr. Gerry and Dr. Toye • Updated Regulatory Reference to April 2022 MDH Standards • Updated NCQA Reference to 2022 Standards **07/21:** • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to scope. • Changed Case Management to Clinical Operations in Responsible Departments **05/21:** • Updated expert process for evaluating new medications. **07/20:** • Updated Regulatory References to reflect 2020 NCQA Standards. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed “Maryland” from scope. **07/18:** • Revised #6 to more precisely reflect which medications are chosen for review (outpatient administration and/or from retail pharmacy). • 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. **07/17:** • Updated titles and regulatory references. **10/16:** • No changes. **10/15:** • No changes.

MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**213**	
Subject:	**Pharmacy Downtime Procedures**	
Section:	**Pharmacy**	
Initial Effective Date:	**04/01/2002**	
Revision Effective Date(s):	**09/18, 07/19, 07/20, 07/21, 07/22, 07/23, 07/24, 07/25, 07/26**	
Historical Revision Date(s):	**09/02, 10/03, 09/04, 10/05, 12/06, 10/07, 09/08, 11/09, 09/10, 09/11, 10/12, 10/13, 10/14, 04/16, 10/15, 10/16, 07/17, 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:	**COMAR 31.01.02.06 A (3)** **NCQA 2026: UM 5C Factors 2, 4 and 7**	
Approved:	**Director, Pharmacy**	**Chief Medical Officer**

Purpose: **To ensure that standard processes are in place to allow members to maintain access to medications in the event of downtime of prescription processing systems or a declared State of Emergency.**

Scope: **MedStar Family Choice Maryland**

Policy: **MedStar Family Choice follows an established workflow to facilitate prescription processing when standard procedures are unavailable and will appropriately escalate claims processing to ensure uninterrupted member access to their medications.**

Procedure:

1. In the event of system failure or any situation where the pharmacy preauthorization staff cannot access the CVS Caremark Client Operating system occurs during business hours, MedStar Family Choice should contact the CVS Account Manager

(Level 1) via email. If no response within one hour, then MedStar Family Choice should move to the next level contact.

1.1. MedStar Account Management team escalation path:

Level 1 – Michelle Murphy, Account Manager 860-280-8678

Level 2 – Grady Doughty, Sr Manager 847-313-0709

Level 3 – David Bailey, Lead Director 224-517-6154

Level 4 – Bryan Sintic, Executive Director, 708-674-3598

2. In the event of a system failure after business hours, MedStar Family Choice should contact the CVS Help Desk and IT Services Help Desk at 877-493-9909 for assistance.

3. If the Governor of Maryland declares a State of Emergency, pharmacy edits may be lifted to allow early refills at the discretion of Maryland Department of Health (MDH). If directed by MDH, the Pharmacy Benefits Management (PBM) provider will be notified to suspend edits on early refills and instruct the pharmacy network to dispense a 30-day or 90-day supply for the refill in accordance with COMAR 31.01.02.06 A (3). The suspension of edits will remain in place until the State of Emergency is lifted by the Governor of Maryland or until otherwise directed by MDH.

4. PRIOR AUTHORIZATION DOWNTIME PROCEDURE
   4.1. Upon receipt of a medication request via telephone, the pharmacy precertification team will verify the identification of the requestor and their authority to discuss clinical information.
      4.1.1. Once confirmed, the staff member will collect the following information using the “Prior Authorization/Non-Formulary Medication Request” form. (Appendix 1)
         4.1.1.1. Member name and date-of-birth
         4.1.1.2. Requestor’s telephone number
         4.1.1.3. Prescriber name and contact number.
         4.1.1.4. Pharmacy name and contact number.
         4.1.1.5. Medication name, strength, dosage form, directions for use, and quantity requested.
         4.1.1.6. Date and time of receipt of request.
         4.1.1.7. Requests will be marked as “urgent” if specified by the requestor.
      4.1.2. Any paper documentation collected during this process shall be retained in a locked environment until entered into the clinical software system to protect Patient Health Information (PHI).
         4.1.2.1. The pharmacy pre-certification staff will document the request in the clinical software system once available.

4.1.2.2. Once documentation is completed in the clinical software system, the paper forms will be placed in the locked shred bin for disposal.

4.1.3. The pharmacy requests will be processed in the order received and may be escalated to address clinical urgency as described below:

4.1.3.1. Hospital discharge medications.

4.1.3.2. Medications prescribed for potentially life-threatening illnesses or diseases (e.g., insulins, anticoagulants, antibiotics).

4.1.3.3. Pain Medications

4.1.3.4. Medication for chronic conditions (e.g., hypertension, asthma/COPD, diabetes).

4.1.4. Requests will be processed per the procedures described in Policy 218: Pharmacy Authorization Process Policy.

4.1.4.1. If the PBM system is also down, refer to section 1 of this policy for approved requests.

4.1.4.2. If MedStar Family Choice is unable to comply with standard processing timelines as outlined in Policy 218: Pharmacy Authorization Process Policy, the member shall be informed of the estimated time frame within 24 hours of receipt of initial request and advised that the pharmacy may provide a 3-day emergency supply of the requested medication.

4.2. Once a decision is rendered by the Medical Reviewer, the precertification staff shall record the date and time that the member was notified.

Summary of Changes:	**07/26:** • Updated all NCQA to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmac • Section 1.1. Updated account team escalation path **07/24:** • Changed title from “Pharmacy Plan/Pharmacy Crisis Plan” to “Pharma • Moved P&T Committee listing from “Responsible Department” to “Resp • Reformatted font and procedure to improve readability. • Updated all NCQA, MCO Standards, and COMAR to current year refer • Updated policy Approver titles removed individual names. • Updated Purpose to include Statewide Emergency systems. • Updated Policy scope. • Updated Procedure scope. • Added escalation pathway for PBM support. • Reorganized the processes for prior authorization during downtime. • Added Appendix 1: PA/NF Medication Request form. **07/23:** • Responsible Parties changed to Health Plan Pharmacist • Updated regulatory reference to March 2023 MDH Standards • Updated NCQA Reference to 2023 Standards • Updated Approved by to: Dr. Wills and C. Attia

	• Removed 7-day quantity limit, changed to allow for dispensing quantity • Updated CVS pharmacy contact phone number **07/22:** • Responsible Parties changed to Dr. Gregory Dohmeier • Updated NCQA Reference to 2022 Standards **07/21:** • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to scope. • Changed Case Management to Clinical Operations in Responsible Dep **07/20:** • Updated Regulatory References to reflect 2020 NCQA Standards. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed “Maryland” from scope. **09/18:** • Revised Statewide Declaration of Emergency section to reflect MDH d edits. **07/18:** • Updated NCQA regulatory references to reflect 2018. • Modified Effective Date to Initial Effective Dates; added Historical Revi Effective Dates; and added Historical Review Dates and Review Effect **11/17:** • Removed District references, added regulatory reference, Updated PA **07/17:** • Updated titles, regulatory references and software designation. **10/16:** • No changes. **04/16:** • Addition of the section called Statewide Declaration of Emergency. **10/15:** • No changes.

APPENDIX I. Prior Authorization/Non-Formulary Medication Request form

Prior Authorization/Non-Formulary Medication Request

MedStar Family Choice

All requests must be accompanied by MEDICAL RECORDS to support the request. MFC-Maryland MUST RENDER A DECISION WITHIN 24 HOURS. If MEDICAL RECORDS are INCOMPLETE, the request is subject to DENIAL. Return by fax to MedStar Family Choice-Maryland at: 410-933-2274

Patient Name:	**Patient DOB:**
MedStar Family Choice ID # (begins with 91):	**Medicaid ID#:**

Reason for Medication Request:

☐ Prior Authorization	☐ Non-Formulary Medication Request
☐ Increase in Dosage/Frequency	☐ Vacation Supply
☐ Medication Lost/Stolen	☐ Out of Medication
☐ New Diabetic Device	☐ Yearly renewal of Diabetic Device

Medication Requested (*Dose and Frequency*) **or Diabetic Device Requested** (*list all components needed*):

_____

****Is the member currently on this medication:** ☐ **Yes** ☐ **No**

Please check that the following clinical has been included with medication request:

☑	Requirement(s)
	Last Clinical/Office visit note
	Pertinent Laboratory Findings (if applicable)
	List of Previous Medications Used to Treat Condition:_____
	Prior Authorization Table has been checked for medication criteria and submission requirements on: medstarfamilychoice.com/providers/pharmacy
	MedStar Family Choice – Maryland Drug Formulary has been reviewed for alternatives

Diagnosis Code(s) /ICD-10:_____

Pharmacy Name:_____ **Phone:** _____

*****Please provide all clinical notes to support the request and fax to the number above*****

By signing below, I certify that the information provided is accurate and that all the relevant medical records listed above are included in this submission.

Prescriber Signature: _____ **Date:** _____

Provider Name/Office:_____ **NPI#**_____

Provider Phone:_____ **Provider Fax:** _____

Contact Person Name: _____

Contact Phone w/ext:_____ **Contact Fax:** _____

MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**217**	
Subject:	**Corrective Managed Care**	
Section:	**Pharmacy**	
Initial Effective Date:	**02/10/16**	
Revision Effective Date(s):	**07/18, 09/18, 01/19, 07/19, 07/20, 07/21, 7/22, 7/23, 7/24, 7/25, 07/26**	
Historical Revision Date(s):	**07/17, 05/18**	
Review Effective Date(s):		
Historical Review Date(s):	**10/16, 10/17, 11/17, 07/18**	
Responsible Parties:	**Health Plan Pharmacist, P&T Committee**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**COMAR 10.09.24.14, COMAR 10.67.12, COMAR 10.67.12.02, COMAR 10.67.05.05A, 10.67.05.07C2, 10.67.05.06B, COMAR 10.67.06.04, 10.67.09.05 Maryland EQRO Systems Performance Review: Standard 7.11**	
Approved:	**Director, Pharmacy**	**Chief Medical Officer**

Purpose: **The purpose of this policy is to provide an outline of the MedStar Family Choice - Corrective Managed Care (CMC) Program.**

Scope: **This policy applies to members of MedStar Family Choice - Maryland meeting program eligibility requirements as stated below, or otherwise identified as misusing the plan pharmacy benefit.**

Background: **The Corrective Managed Care (CMC) Program was established as an effort to monitor and promote appropriate use of controlled substances, specifically opioids and benzodiazepines. Members receiving multiple prescriptions, using multiple prescribers and/or pharmacies to obtain controlled substances are identified. In April 2023, The Maryland Department of Health (MDH) expanded the purpose of this program to encompass any member abuse of Medicaid**

Pharmacy Benefits, regardless of controlled/scheduled designation.

Policy: **The Corrective Managed Care (CMC) program is defined by COMAR 10.67.12.**

Definition: **Medical Reviewer: Medical Director or Health Plan Pharmacist**

Procedure:

1. General criteria for enrollment in CMC are identified as member abuse of benefits when:
    1.1 The member engages in fraud as defined by COMAR 10.09.24.14
    1.2 The member utilizes an inappropriate type of provider for care.
    1.3 The member utilizes an appropriate type of provider at an inappropriate frequency for care.
    1.4 The member utilizes an appropriate provider in an inappropriate manner.
    1.5 The member utilizes a Medical Assistance card in an inappropriate manner.

2. MedStar Family Choice's CMC plan will mainly cover member abuse of pharmacy benefits but may also cover member abuse of non-pharmacy medical assistance benefits when appropriate.

3. Cases may be reviewed on the basis of statistical reports, outside complaints, referrals from other agencies, or other appropriate sources.

4. A Medical Reviewer or designee will identify and enroll members who have abused pharmacy benefits specific to controlled substances by reviewing pharmacy claims data supplied by the contracted Pharmacy Benefits Manager (PBM) monthly.
    4.1. Criteria for enrollment in CMC specific to controlled substances is when a review of claims shows that within a 30-day period, the member received:
        4.1.1. Six (6) or more prescriptions for controlled medications; and
        4.1.2. Used three (3) or more pharmacies; or
        4.1.3. Used three (3) or more prescribers. All prescribers in a group practice are considered a single prescriber.
    4.2. Candidates identified by a designee (e.g., PBM report or Health Plan Pharmacy technician) will have appropriateness verified by a Medical Reviewer.

5. The member will be required to obtain prescribed drugs only from a single designated provider and/or pharmacy that is in network with MedStar Family Choice unless the provider renders services in the context of, or the prescription is pursuant to:
    5.1. An emergency department visit; or
    5.2. Hospital inpatient treatment.

5.3. The medication is a Specialty product as defined in COMAR 10.67.06 and cannot be dispensed from the regularly assigned pharmacy.

6. The effective date of enrollment will be 20 days from the date of the notice. If a member determined to have abused benefits requests a redetermination of the decision, the effective date of the enrollment into CMC will be postponed pending the outcome of the request.

7. The duration of a member's enrollment in a plan will not be altered because of changes in how the individual receives medical assistance, including but not limited to a change in the member's MCO enrollment.

8. Members found to have abused benefits will be enrolled in the program for 24 months. Members who demonstrate continued abuse of MCO benefits while enrolled in the CMC program will be enrolled in the plan for an additional 36 months.

9. MedStar Family Choice will allow members enrolled in CMC the ability to suggest a pharmacy and/or provider.
    9.1. MedStar Family Choice will not accept the member's suggestion if MedStar Family Choice determines that the recipient's choice of provider would not serve the member's best interest in achieving appropriate use of the health care systems and benefits available through the MCO or if the suggested pharmacy is out-of-network.
    9.2. MedStar Family Choice will provide for the designation of a new pharmacy provider at the member's request.
10. Data Transfer between MedStar Family Choice and Maryland Department of Health (MDH):
    10.1. Once a month, by close of business of the 6th business day, MDH will create a file for MedStar Family Choice with all members currently locked in. The file will include patient info, lock-in span, and pharmacy NPI. This file will be posted on the Medicaid portal that MedStar Family Choice will be able to access and utilize to manage patients.
    10.2. The Medical Reviewer or designee(s) will:
        10.2.1. Review files received from MDH.
        10.2.2. Review reports received from the MedStar Family Choice PBM to identify individuals who meet the criteria for CMC. Final decisions will be made by the Medical Reviewer.
        10.2.3. Reconcile files from MDH and the list identified from the PBM reports each month.
        10.2.4. Update MedStar Family Choice records/systems accordingly by contacting PBM and arranging to have the identified members locked into a single designated pharmacy provider based on the information from MDH.
        10.2.5. Communicate discrepancies with UMBC and/or HealthChoice staff.
11. Submit a spreadsheet via secured encrypted email with information on MedStar Family Choice members that are new to lock-in since the previous report to the

HealthChoice staff by the close of business on the 8th business day of every month, including:

11.1. Member First and Last name
11.2. Member Date of Birth
11.3. Member's Medicaid ID
11.4. Pharmacy NPI
11.5. Member's Lock-in Begin and End Date
11.6. MedStar Family Choice ID

12. MedStar Family Choice will provide a member determined to have abused MCO benefits a written notice that includes the following:
    12.1. A statement that the member will be in the CMC program including:
        12.1.1. The effective date and duration of enrollment.
        12.1.2. An explanation of the reason(s) for the determination that the member abused benefits.
        12.1.3. The name, address, and phone number of the provider and/or pharmacy assigned to the patient.
        12.1.4. A statement that the member may identify a preference for an assigned primary care provider, specialty care provider and/or pharmacy.
        12.1.5. A statement that the member has 20 days to request a redetermination of the decision by providing additional information for MedStar Family Choice before enrollment will become effective and the address where the additional information should be sent.
            12.1.5.1 An explanation that the effective date will be postponed pending the review of any additional information the member provides.

13. Member Redetermination and Appeals:
    13.1 Members determined to have abused benefits will have 20 days from the date of the notice to present additional documentation to explain the facts that serve as the basis for the MedStar Family Choice's determination of benefit abuse.
        13.1.1 MedStar Family Choice will review the additional information submitted for redetermination to evaluate the appropriateness of the member's enrollment in CMC.
        13.1.2 MedStar Family Choice will notify the member of its decision whether it is affirming or reversing its determination to enroll the member in CMC.
            13.1.2.1 If MedStar Family Choice confirms its determination to enroll the member in CMC, the notice will identify the effective date and duration of that enrollment and information on how to initiate an appeal.
            13.1.2.2 The date of the notice of action will be the date on the final letter after the redetermination.
    13.2 Outside of the 20-day window to initiate the redetermination process, the request becomes an appeal and will be handled in standard fashion as specified in COMAR 10.67.09.05.

13.3 If the appeal results in a State Fair Hearing, MedStar Family Choice - will attend the hearing and provide justification for enrollment in the program.

14. The member letter will follow the format of the MDH-approved template for the level of the appeal and shall be individually reviewed and approved by MDH prior to mailing.

15. The initial notification letters to the member will follow the MDH-approved template in Appendix I and shall be individually reviewed and approved by MDH prior to mailing.

Summary of Changes:	**07/26:** • Changed Approved from AVP Clinical Operations to Director, Pharmacy **07/25:** • Section 4: simplified wording to state “monthly”, instead of “on a monthly basis”. • Section 4.2: added “PBM report” to indicate other methods of identifying candidates for CMC. • Section 9.2 incorporated in Section 9.1, Section 9.3 renumbered as Section 9.2 for clarity. **07/24:** • 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. • Expanded Scope to include all misuse of plan pharmacy benefit, align with COMAR updates. • Expanded and aligned criteria for program selection. • Added references throughout policy to define the misuse of inappropriate filling of medications or use of providers. • Added Appendix I, letter template. **07/23** • Responsible Parties changed to Health Plan Pharmacist • Removed from Responsible Parties: Dr. Gregory Dohmeier • Updated Approved by to: Dr Wills and C. Attia • Updated Regulatory References • Included role of the Health Plan Technician to the process. • Removed References to old COMAR, Medicaid Advisory and Corrective Managed Care Program at the end of this policy. All pertinent references are found in the

	Administrative Policy and Procedure Regulatory References section. **07/22:** • Responsible Parties changed to Dr. Gregory Dohmeier • Removed from Responsible Parties: Dr. Gerry and Dr. Toye • Updated COMAR references to align with Corrective Managed Care COMAR 10.67.12 **07/21:** • Changed Case Management to Clinical Operations in Responsible Departments. **07/20:** • Updated Section from Care Management to Pharmacy to reflect appropriate policy series. • Updated Regulatory References to reflect COMAR recodification. • Updated Regulatory References to include all COMAR references found in Procedure section: COMAR 10.09.72.05, COMAR 10.67.12, COMAR 10.67.05.05A, COMAR 10.67.06.04, 10.67.09.05. **07/19:** • Policy subject has read Corrective Case Management but referred to as Corrective Managed Care. Changed Subject to reflect that. **01/19:** • Changed Pain Disease Management Case Manager to Case Manager to reflect titles post- reorganization. **09/18:** • Changed CM description to include Social Worker. **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. **05/18:** • Added “Exception for Specialty Medications.” **11/17:** • Removed A from policy number, Changed DHMH to MDH. **07/17:** • No changes. **10/16:** • No changes. **02/16:** • New policy.

5233 King Ave., Ste. 400
Baltimore, MD 21237
P 800-905-1722
F 410-933-2274
MedStarFamilyChoice.com

Appendix I.

Date:

Name:
Address:

This letter is to inform you that you are being enrolled in MedStar Family Choice's Corrective Managed Care Program. This means you must have all your prescriptions filled at a single (one) pharmacy.

Reason for Lock-in: **Example:** You are being enrolled in this program because you have continued to fill prescriptions for (name medication(s) within a 30-day period at (number of pharmacies) different pharmacies for the past year. These medicines are very similar and should not be taken together. MedStar Family Choice contacted both doctors giving you these medicines. Each doctor said that you told them you were not getting your prescriptions from any other provider.

We have assigned you to the following pharmacy:
Pharmacy name:
Pharmacy address:
Pharmacy phone:

MedStar Family Choice will not pay for prescriptions at any pharmacy except the one
listed above. If you would like to select/choose a different pharmacy in the MedStar Family Choice network, contact MedStar Family Choice Corrective Managed Care Program at 1-800-905-1722. If your selection is approved, MedStar Family Choice will pay for your prescriptions at the pharmacy you select/choose.

Additionally, if you need prescription drugs that are covered by the State and not MedStar Family Choice, you must also have those prescriptions filled at the pharmacy identified above or a pharmacy you have selected, and which has been approved. The State will not pay for prescriptions at any other pharmacy.

Unless you provide additional information explaining your use of pharmacy benefits, your enrollment will begin (date), and will be effective for 24 months.

If you do not agree with this decision, you, or your provider(s), with your permission, can file an appeal or provide information that explains why the use of multiple medicines of the same type and pharmacies or providers is medically necessary. This information must be received within 20 days from the date of this letter. You will not be enrolled in the Corrective Managed Care Program while the appeal or additional information is reviewed. We will notify you of our decision once the review

is complete. If you choose to file an appeal, mail your request or additional information to:

MedStar Family Choice
Corrective Managed Care Program
5233 King Avenue, Suite 400
Baltimore, MD 21237

You may also contact the State's HealthChoice Help Line at 1-800-284-4510. If they do not resolve your case within 10 days, you will receive a letter from them about how to file an appeal and obtain a fair hearing.

Unless you file an appeal or provide additional information explaining your use of pharmacy benefits, your enrollment will begin May 10, 2024, and will be effective for 24-months.

If you have questions about your enrollment in the Corrective Managed Care Program, please contact our MedStar Family Choice Corrective Managed Care Program at 1-800-905-1722.

Sincerely,

Samantha M Blunt, CPHT-ADV
Health Plan Pharmacy Technician
MedStar Family Choice
Corrective Managed Care Program
(443)692-1167
(410)350-7639 (fax)
Samantha.M.Blunt@medstar.net

MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**219**	
Subject:	**Opioid Prescription Prior Authorization**	
Section:	**Pharmacy**	
Initial Effective Date:	**05/01/2019**	
Revision Effective Date(s):	**07/19, 07/20, 07/21, 07/22, 07/23, 07/24, 07/25, 07/26**	
Review Effective Date(s):		
Responsible Parties:	**Health Plan Pharmacist, P&T Committee**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**MDH Standards and Reporting Requirements of Drug Use Management Programs for MCOs 2.14 March 2026 Standards** **Maryland Controlled Dangerous Substances Act Criminal Law Article, §§5-501-5-505, Annotated Code of Maryland, Section 1004 of Support Act** **Maryland Medicaid Pharmacy Advisory No. 94**	
Approved:	**Director, Pharmacy**	**Chief Medical Officer**

Purpose: **To ensure clinically appropriate access to opioid medications for MedStar Family Choice Members in accordance with Federal and State regulations.**

Scope: **MedStar Family Choice Maryland**

Policy: **MedStar Family Choice establishes and follows standard processes for evaluating requests for opioid medications to align with current best practices and regulatory requirements.**

Definitions: **Medical Reviewer: Medical Director or Health Plan Pharmacist**

Opioid naïve: Members who have not been dispensed any opioid prescriptions through the pharmacy benefit in the previous 30 days.

Procedure:

1. MedStar Family Choice evaluates all requests for opioid medications to monitor and manage the appropriate utilization and patient safety.
    1.1. Timelines and Procedures for request evaluation are found in Pharmacy Policy 218: Pharmacy Authorization Process
    1.2. Prior Authorization is required for all opioids.
        1.2.1. Prior authorization review of opioid prescriptions is automated by the Pharmacy Benefits Manager (PBM) to screen for compliance with SUPPORT ACT minimum standards:
            1.2.1.1. ≤ 50 morphine milligram equivalents (MME) per day, AND
            1.2.1.2. Limits of a seven-day supply for adults, or a three-day supply for Members under 18 years of age.
        1.2.2. Prior authorization review by a Medical Reviewer is required for opioid medication requests, including:
            1.2.2.1. Any immediate-release opioid prescription or combination of prescriptions exceeding:
                1.2.2.1.1. 50 MME per day.
                1.2.2.1.2. A seven-day supply for adults, or a three-day supply for Members under 18 years of age.
                1.2.2.1.3. Opioid naïve Members may not be dispensed more than allowed per the SUPPORT ACT limitations, i.e., 50 MME per day and a day supply limit of seven days for adults and three days for persons under age 18.
            1.2.2.2. Extended-release opioids are reserved for patients on an established opioid regimen as confirmed by prescription claims history or clinical documentation. Review by a Medical Reviewer will be completed for:
                1.2.2.2.1. All extended-release opioids, including buprenorphine products indicated for chronic pain treatment.
                1.2.2.2.2. Methadone for pain
                1.2.2.2.3. Concentrated oral dosage forms.
                1.2.2.2.4. All fentanyl dosage forms.
            1.2.2.3. Any request that exceeds formulary quantity limits (QL).
            1.2.2.4. All non-formulary opioids.

2. Exceptions:
    2.1. The following patients are exempt from the Opioid Prior Authorization requirements:
        2.1.1. Patients undergoing active cancer treatments.
        2.1.2. Patients with sickle cell disease who have <u>not</u> received gene therapy (e.g., Casgevy (exagamglogene autotemcel), Lyfgenia (lovotibeglogene), or similar).
        2.1.3. Patients receiving hospice care.
        2.1.4. Patients receiving palliative care.
        2.1.5. Patients in long-term care facilities or skilled nursing facilities.

2.1.6. Opioid naïve Members if the ordered opioid prescription is for:
2.1.6.1. No more than 50 MME per day; AND.
2.1.6.2. No more than a cumulative seven-day supply for adults, or a three-day supply for members under 18 years of age.

3. MedStar Family Choice may deny a request for an opioid medication if:
3.1. A clinical or safety concern is identified and unable to be resolved even when other authorization parameters described in this policy are met.
3.2. Unable to validate the prescription is issued in the usual course of professional treatment within the intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§5-501-5-505, Annotated Code of Maryland.
3.2.1. This applies to prescriptions written for an indication out of scope of the prescriber, i.e. an oncologist prescribing opioids for the treatment of pain not related to a cancer-related diagnosis.

4. Opioid Prior Authorization Requirements
4.1. All requests for review must be accompanied by medical records to support the request.
4.2. A completed Opioid Prior Authorization form is required for all opioid prior authorization requests.
4.2.1. The form is available on the MedStar Family Choice provider website at https://www.medstarfamilychoice.com/-/media/project/mho/mfc/maryland-healthchoice-physicians/pharmacy-materials/opioid-pa-form_fillable_effective-7-1-22-updated-2-27-23.pdf
4.2.2. Incomplete prior authorization forms, and/or forms submitted without supporting clinical documentation may result in a denial.
4.2.3. The form requires that the prescriber attest to:
4.2.3.1. Review of the Controlled Substance Prescription Drug Management Program (PDMP) in CRISP.
4.2.3.2. Patient has/will have a random Urine Drug Screen at least annually.
4.2.3.2.1. When documentation of urine drug screen results show that a patient may not be taking the medication as prescribed, MedStar Family Choice reserves the right to deny such requests as not medically necessary.
4.2.3.2.2. The patient is exempt from the requirement for urine drug screening when:
4.2.3.2.2.1. The prescription is pursuant to a discharge from a hospital, emergency department. or ambulatory surgery center, and
4.2.3.2.2.2. The total anticipated therapy duration is for a supply of no more than 30-days of medication.
4.2.3.3. Prescriber has provided or offered a prescription for naloxone to the patient or patient's household.
4.2.3.4. A signed contract between the patient and prescriber is complete and included in the medical record.

4.2.3.4.1. The pain management agreement has been renewed or updated within the last one year.
4.2.3.4.2. The member is exempt from the requirement for a signed patient-provider contract when:
4.2.3.4.2.1. The prescription is pursuant to a discharge from a hospital, emergency department, or ambulatory surgery center, and
4.2.3.4.2.2. The total anticipated therapy duration is for a supply of no more than 30-days of medication.

5. Opioid Prior Authorizations requested by out-of-network (OON) outpatient physicians are not covered by MedStar Family Choice.
   5.1. An exception to this may be granted by the Medical Reviewer for a one-time, 30-day supply if a continuity relationship can be established between the member and OON prescriber The purpose of this one-time exemption is to allow the member time to obtain future services/prescriptions from an in-network provider without incurring a gap in care.
   5.2. Patients will be referred to a Care Manager for assistance in establishing care with an in-network provider.

6. MedStar Family Choice will not authorize an early refill of controlled medications except as outlined in Pharmacy Policy 204: Early Refill, Lost Medication, & Travel Supply, Section 4.

7. According to the Maryland Medicaid Pharmacy Program Advisory No. 94: Medicaid patient should not be paying cash for any prescriptions under normal circumstances, especially prescriptions for controlled substances. Recipients insisting to pay cash for prescriptions for controlled substances should be referred to the Medicaid recipient Fraud and Abuse Department.
   7.1. To report concerns, call the Office of the Inspector General Recipient Fraud/Abuse Hotline at 866-770-7175 or www.dhmh.state.md.us/oig

Summary of Changes:	**07/26:** • Updated MCO Standards to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy **07/25:** • Updated references to MCO Standards and COMAR to current year references. • Purpose Statement: removed unnecessary reference to NCQA. • Section 1.2.2: Reworded for clarity. • Section 1.2.2.2.1: Added buprenorphine to reflect formulary update.

	• Section 1.2.2.3: Removed “managed drug limits” because duplicative with quantity limits. • Section 6: Updated reference to Policy 204 (renamed). • Sections 6.1 and 6.2 which are detailed in Policy 204. **07/24:** • Changed Policy name from “Opioid Prescription Parameters and Limitations to “Opioid Prescription Prior Authorizations.” • Moved P&T Committee listing from “Responsible Department” to “Responsible Parties” section. • Reformatted font and procedure to improve readability and align with MedStar standards. • Removed incorrect NCQA references. • Updated MCO Standards • Removed incorrect COMAR references. • Added MD Medicaid Advisory Reference • Added definition of Opioid Naïve • Added definition of Medical Reviewer • Added reference to Federal Support Act • Updated policy Approver title; removed references to individuals. • Added definition of Opioid Naïve • Added definition of Medical Reviewer • Added web address to Opioid Prior Authorization form. • Added that negative urine screens may be grounds for a denied request. • Added statement that an executed pain contract must be dated within one year to be valid. • Added verbiage that all opioid PA requests are reviewed by a Medical Reviewer. • Added clarifying statement that the exception for sickle cell disease does not apply if the patient has received gene therapy. • Added Section 4 to align with MCO Standard 2.14 at recommendation of MDH. • Added requirement that a referral to Care Management will be made to assist member with finding a network provider if needed. • Added that MedStar Family Choice may request documentation (police report) if patient reports stolen medications.

	• Added state requirement and reference stating that patients paying cash for controlled substances shall be referred for FWA. (8) • Added Appendices I and II to show prior authorization forms, removed embedded files. **07/23**: • Responsible Parties changed to Health Plan Pharmacist • Updated regulatory reference to March 2023 MDH Standards • Updated NCQA Reference to 2023 Standards • Updated Approved by to: Dr. Wills and C. Attia • Corrected Policy 218 title; added Authorization • Removed table under 1.f. • Added workflow process for opioid prior authorization initiated by an MedStar Family Choice Maryland member. (5.e.) **07/22:** • Responsible Parties changed to Dr. Gregory Dohmeier • Removed from Responsible Parties: Dr. Gerry and Dr. Toye • Updated Regulatory Reference to April 2022 MDH Standards • Updated NCQA Reference to 2022 Standards • Removed embedded pdfs and concatenated to the end of the policy (Analgesic Opioid Prior Authorization Form and MDH Opioid Prior Authorization Form) **07/21:** • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to Scope. • Changed Case Management to Clinical Operations in Responsible Departments. **07/20:** • Updated Regulatory References to reflect COMAR recodification and 2020 NCQA Standards. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • General formatting. **05/19:** • New Policy.

Appendix I:

All requests must be accompanied by MEDICAL RECORDS to support the request. MFC MUST RENDER A DECISION WITHIN 24 HOURS. If MEDICAL RECORDS are INCOMPLETE, the request is subject to DENIAL.

Fax completed form to MFC MD 1-888-243-1790 or 410-933-2274

ANALGESIC OPIOID PRIOR AUTHORIZATION FORM

Patient's Information:

NAME: DOB:

SEX: ❑ M ❑ **F**

Prescriber's Information: **Name of Facility/Clinic:**

NAME: NPI #

Phone # Fax #

Contact Person for this Request:

NAME: Phone: Fax:

**** Prior authorization is approved for 6 months only****
□ New Prescription □ Refill (Patient has been taking this medication)

Please check the appropriate box for the Opioid Prior Authorization request.
□ Quantity Limit □ High Dose □ Long-Acting Opioid □ Non-Preferred
□ Methadone for Pain □ Fentanyl □ Other_____

Use a separate form for EACH medication request:
Medication:_____Strength: _____Quantity: _____

SIG: _____Length of Treatment_____months

Clinical Consideration:

Y	N	
❑	❑	Patient receiving opioid due to cancer treatment. Cancer type:_____
❑	❑	Patient receiving opioid due to sickle cell disease.
❑	❑	The patient is in hospice or is receiving palliative care.
❑	❑	Patient is Pregnant (where applicable)
Attestation required for each of the following:		
❑		Prescriber has reviewed Controlled Substance Prescriptions in PDMP (CRISP).
❑		Patient has/will have random Urine Drug Screens.
❑		Naloxone prescription was provided or offered to patient/patient's household.
❑		Patient-Prescriber Pain Management/Opioid Treatment Agreement/Contract signed and in Medical record?

I certify that the benefits of Opioid treatment for this patient outweigh the risks of treatment.

Prescriber's Signature_____ Date_____

Fax completed form to 1-888-243-1790 or 410-933-2274

(DHMH 11-2016 MFC 6-29-2017) Page **1** of **1**

Appendix II:

MARYLAND Department of Health

Page 1 of 4

OPIOID PRIOR AUTHORIZATION FORM

Managed care organizations listed and Medicaid fee-for-service use this form for opioid prior authorization.

Updated October 2017

Fax completed forms to the number corresponding to the patient's plan:

MCO and Fee-for-Service	Telephone	Fax
Aetna Better Health of Maryland (ABHM)	(866) 827-2710	(877)-270-3298 or www.aetnabetterhealth.com/maryland
Jai Medical Systems (JMS)	(800) 555-8513	(800) 583-6010
Kaiser Permanente Health Choice (KP)	(866) 331-2103	(866) 331-2104
Maryland Medicaid Fee-for-Service (FFS)	(800) 932-3918	(866) 440-9345
Maryland Physicians Care (MPC)	(800)-753-2851	(877)-328-9799
MedStar Family Choice (MFC)	(410) 933-2200 or 800-905-1722 After hours: (410)-999-5525	(888) 243-1790 or (410) 933-2274
Priority Partners (PP)	(888) 819-1043, option 4	(410)-424-4751
University of MD Health Partners (UMHP)	(877) 418-4133	(855) 762-5205 or www.covermymeds.com/epa/caremark

For Amerigroup and UnitedHealthCare forms visit:
https://mmcp.health.maryland.gov/healthchoice/opioid-dur-workgroup/Pages/pa-information.aspx

ALL prescribers must complete SECTION 1, SECTION 2 and SECTION 3.
Prescribers must complete either SECTION 4 or SECTION 5 as appropriate.

TO AVOID DELAYS in processing this request, please ensure that contact information is accurate in case additional information is required.

Duration of prior authorization is determined by Medicaid fee-for-service of managed care organizations.

For additional information about individual managed care organizations opioid prescribing requirements, visit: http://mmcp.health.maryland.gov/healthchoice/opioid-dur-workgroup/pages/pa-information.aspx.

MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**220**	
Subject:	**Management of Pharmacy Benefit Fraud, Waste, and Abuse**	
Section:	**Pharmacy**	
Initial Effective Date:	**05/27/2020**	
Revision Effective Date(s):	**07/20, 07/21, 07/22, 07/23, 07/24, 07/25, 07/26**	
Review Effective Date(s):		
Responsible Parties:	**Health Plan Pharmacist, P&T Committee**	
Responsible Department(s):	**Clinical Operations, Compliance**	
Regulatory References:	**COMAR: 10.09.24.14** **Maryland Medicaid Pharmacy Advisory No. 94**	
Approved:	**Director, Pharmacy**	**Chief Medical Officer**

Purpose: **To define the MedStar Family Choice Policy for Identification, Sanctioning, and Reporting of Fraud, Waste, and Abuse (FWA) in pharmaceutical utilization.**

Scope: **MedStar Family Choice Maryland members, network and non-network prescribers, dispensing pharmacies.**

Policy: **MedStar Family Choice monitors and responds to pharmaceutical FWA on an ongoing basis by using processes outlined in this policy and in the MedStar Family Choice 700 Series Policies.**

Definitions:

Medical Reviewer: Medical Director or Health Plan Pharmacist

Abuse: When a provider, pharmacy, or member demonstrates practices that are inconsistent with sound fiscal, business, and/or medical practices, that result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary, or that fail to meet professionally recognized standards for health care.

Procedure:

1. FWA in Pharmaceutical Utilization
   1.1. MedStar Family Choice will monitor for FWA in all pharmaceutical utilization in compliance with COMAR 10.09.24.14
   1.2. Any potential cases of FWA identified will be referred to the MedStar Family Choice Compliance who will investigate the cases for FWA according to Compliance Policies.
   1.3. A Medical Reviewer will assist MedStar Family Choice Compliance with any part of the investigation.
      1.3.1. MedStar Family Choice staff will collaborate with the Pharmacy Benefits Manager (PBM) and other contracted vendors as necessary to determine the full scope of the identified FWA.
   1.4. Health Plan Pharmacist will work to identify and implement system supports to help prevent FWA.
   1.5. MedStar Family Choice must report to the Maryland Department of Health, Office of the inspector General health who will refer any credible allegations of fraud to the Office of the Attorney General, Medicaid Fraud and Vulnerable Victims Unit.

2. Additional FWA Monitoring of Controlled Substances
   2.1. Controlled substance prescriptions dispensed for MedStar Family Choice members are evaluated at least quarterly for prescribing trends concerning for FWA.
   2.2. Providers are identified via FWA analytic reports which include, but are not limited to:
      2.2.1. Controlled substance prescriptions without an associated medical visit.
      2.2.2. High number of Controlled Substances.
      2.2.3. Unusual number of prescriptions for Schedule II Drugs
   2.3. Quarterly, MedStar Family Choice identifies, minimally, the top 5 providers in each measure below for further review.
      2.3.1. Total number of opioid prescriptions by provider.
      2.3.2. Total number of members receiving opioids by provider.
      2.3.3. The average Morphine Milliequivalent (MME) per member by provider.
      2.3.4. The average MME per claim paid by provider.
   2.4. Members found to be paying cash for controlled substances will be referred to the Medicaid recipient fraud and abuse department as described in the Maryland Medicaid Pharmacy Program Advisory No. 94.
      2.4.1. To report concerns, call the Office of the Inspector General Recipient Fraud/Abuse Hotline at 866-770-7175 or www.dhmh.state.md/us/oig.

3. MedStar Family Choice Medical Reviewers use all available resources to obtain comprehensive clinical details, including but not limited to:
   3.1. MedStar Family Choice's clinical software system.
   3.2. MedStar system EMR.

3.3. PBM prescription claims database.
3.4. Chesapeake Regional Information System Portal (CRISP) ***excluding*** the Prescription Drug Monitoring Program (PDMP).
3.5. Non-network or external medical records.

4. Indicators of potential pharmaceutical FWA include, but are not limited to:
   4.1. Failure of a provider to produce medical records for MedStar Family Choice review when requested.
   4.2. A trend of members traveling long distances to see a provider, defined as:
      4.2.1. Greater than 15 minutes/10 miles in urban areas.
      4.2.2. Greater than 30 minutes/20 miles in suburban areas.
      4.2.3. Greater than 40 minutes/30 miles in rural areas.
   4.3. Provider accepting cash for medical visit(s).
   4.4. Provider initiates controlled-substance therapy at a dose higher than the recommended starting dose. Starting doses are defined in the FDA Prescribing information for each medication.
   4.5. Provider prescribes mostly short-acting opioids for chronic pain, i.e., there is a paucity of utilization of extended-release opioids in their prescribing history for the last 3 months.
   4.6. Provider prescribes outside of specialty or scope of practice.
   4.7. Patterns of pharmacy dispensing the deviate from the norm, including but not limited to:
      4.7.1. Accepting cash payments for prescriptions.
      4.7.2. Dispensing disproportionately high amounts of a specific drug or product.
      4.7.3. Concurrent dispensing of multiple drugs in the same therapeutic class.
      4.7.4. Dispensing a quantity that exceeds the recommended dose or frequency of a drug or product.
      4.7.5. Patterns of dispensing that are indicative of pharmaceutical waste.
      4.7.6. Abuse of the 72-hour Emergency Supply Override functionality.
   4.8. When potential pharmacy FWA is identified:
      4.8.1. An internal audit will be completed by the Health Plan Pharmacist or designee(s).
         4.8.1.1. If the Health Plan Pharmacist confirms FWA, then the case will be referred to Compliance with a recommendation for further investigation.
         4.8.1.2. If Compliance validates the FWA, the Health Plan Pharmacist will present the case to the CMO and include an assessment of disruption to the plan membership.
         4.8.1.3. The CMO will make the final decision to report the pharmacy to the Maryland Department of Health (MDH) Office of Inspector General-Health (OIG-H).
            4.8.1.3.1. If the CMO agrees that the case should advance, Compliance will be notified to coordinate with the OIG-H for review.
            4.8.1.3.2. If the OIG-H agrees that the pharmacy may be excluded from network:

4.8.1.3.2.1. The Health Plan Pharmacist or designee will coordinate with the PBM to implement any necessary limitations of coverage or network participation.
4.8.1.3.2.2. The PBM will provide a 30-day notice to the impacted pharmacy of the decision to remove them from the network.
4.8.1.3.2.3. The PBM will be responsible for providing a 30-day notice to the impacted members of the decision to remove a pharmacy from the network.

5. After review by the Medical Reviewer if a provider meets any of the criteria listed in this policy and/or deviates from generally accepted standards of care, the case is referred to the MedStar Family Choice Quality of Care Committee (QOC).
   5.1. The QOC is comprised of all MedStar Family Choice Medical Directors, the Chief Medical Officer, the Health Plan Pharmacists, and several nursing staff for further disposition.
   5.2. The QOC cases are reviewed by all Medical Directors and the Chief Medical Officer.
      5.2.1. When the QOC Committee unanimously agrees that misconduct has occurred:
         5.2.1.1. Network Providers:
            5.2.1.1.1. Will receive a letter outlining the findings of the QOC.
            5.2.1.1.2. QOC will review the prescribing patterns of the identified prescriber for two additional quarters.
            5.2.1.1.3. If this review shows no inappropriate activity, then no additional monitoring will be required at this time.
            5.2.1.1.4. Continued monitoring of the identified prescriber for the two quarters.
            5.2.1.1.5. The QOC will review the new data.
               5.2.1.1.5.1. If the QOC determines that the generally accepted standards of care are not followed, then the prescriber will be referred to Credentialling, Provider Relations, and/or Compliance for further action.
         5.2.1.2. Out of Network Providers:
            5.2.1.2.1. Will receive a letter outlining the findings of the QOC.
            5.2.1.2.2. The PBM will be notified to implement a Point-of-Sale denial effective 30 days from notification.
            5.2.1.2.3. Affected members will be notified via U.S Mail that prescriptions written by the provider will not be covered by MedStar Family Choice effective 30-days from date of notice.
      5.2.2. If the QOC does not unanimously agree that misconduct has occurred, then the QOC will review the prescribing patterns for two additional quarters.
         5.2.2.1. The name(s) of providers being surveilled for misconduct shall be shared with Compliance, Credentialling and Provider Relations.

5.2.2.2. If a unanimous decision is not reached following two quarters of review, then the deciding action shall be determined by simple majority.

Summary of Changes:	**07/26:** • Changed Approved from AVP Clinical Operations to Director, Pharmacy **07/25:** • No changes. **07/24:** • Changed Title from “Prevention of FWA in Pharmaceutical Utilization” to Management of Pharmacy Benefit FWA”. • 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. • Removed references to NCQA and COMAR 10.67.09.04 which are not applicable to this policy. • Updated references to MDH Departments and workflow for reporting suspected fraud. • Added reference and content to align with MD Medicaid Pharmacy Program Advisory No. 94 regarding cash payments for opioid prescriptions. • Added Section 4 to describe procedures related to pharmaceutical FWA of non-controlled substances. • Transitioned figure 1 flow-chart into descriptive text outlined in Section 5. **07/23:** • Responsible Parties changed to Health Plan Pharmacist • Removed from Responsible Parties: Dr. Gregory Dohmeier • Updated COMAR, NCQA, and MDH Standards to current references. • Added Section A. Fraud, Waste, and Abuse in Pharmacy Utilization. • Added CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 reference and link. **07/22** • Responsible Parties changed to Dr. Gregory Dohmeier • Removed from Responsible Parties: Dr. Gerry and Dr. Toye • Updated Regulatory Reference to April 2022 MDH Standards • Updated NCQA Reference to 2022 Standards

	07/21: • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to Scope. • Changed Case Management to Clinical Operations in Responsible Departments. **09/20:** • Period of re-review changed from 90 to 180 days. • Updated to whom and when MFC must report. **07/20:** • Updated COMAR regulatory reference to reflect recodification and NCQA 2020 Standards. **05/20:** • New policy.

MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**218**	
Subject:	**Pharmacy Authorization Process**	
Section:	**Pharmacy**	
Initial Effective Date:	**01/01/2018**	
Revision Effective Date(s):	**07/18, 07/19, 07/20, 07/21, 07/22, 07/23, 07/24, 07/25, 07/26**	
Historical Revision Date(s):		
Review Effective Date(s):		
Historical Review Date(s):		
Responsible Parties:	**Health Plan Pharmacist, P&T Committee**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**MDH Standards and Reporting Requirements of Drug Use Management Programs for MCOs March 2026 version, 2.12, 3.0. COMAR 10.67.09.04 I (d), COMAR 10.67.09.04(A)(3) NCQA 2026:UM 5C: 2, 4, 7, 8, and Extension Conditions, UM 7G-I, UM 11B(4), UM 11E**	
Approved:	**Director, Pharmacy**	**Chief Medical Officer**

Purpose: **To define a process to ensure that members receive medically necessary medication promptly when the medication(s) are non-formulary or formulary with a prior authorization requirement.**

Scope: **MedStar Family Choice – Maryland**

Policy: **MedStar Family Choice follows standard processes for evaluating requests for medications requiring prior authorization in a timely fashion, consistent with MD COMAR and NCQA standards.**

Definitions:

Request: When a member, prescriber, or dispensing pharmacy staff asks for coverage of a specific pharmaceutical product.

- Includes concurrent and pre-service requests as defined by NCQA 2026 standards.

Urgent Request: A request for pharmaceutical services where application of the time frame for making routine or non-life-threatening care determinations:

- Could seriously jeopardize the life, health, or safety of the member or others, due to the member's psychological state, or
- In the opinion of a practitioner with knowledge of the member's medical or behavioral condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request.

Decision Extension: A one-time extension, by up to 14 calendar days may be granted, under the following conditions:

- The member requests an extension, or
- The organization needs additional information, provided it documents that it made at least one attempt to obtain the necessary information
- Medical reviewer has determined that the information provided is insufficient to render a decision

Retrospective or Post-Service Request: A request for coverage of pharmaceutical services that has been received, such as if a member paid out-of-pocket for a prescription and is now seeking reimbursement.

Medical Reviewer: Medical Director or Health Plan Pharmacist

Procedure:

1. A request for a medication authorization may be initiated by the prescriber, member, or the dispensing pharmacy staff via telephone, fax or on the MedStar Family Choice website.
   - 1.1. Requests may be submitted by telephone or fax using the corresponding submission form (see 1.2).
     - 1.1.1. Fax numbers: 410-933-2274, 410-350-7492, or
     - 1.1.2. Phone to 410-933-2200 or 800-905-1722
   - 1.2. Forms are located on the MedStar Family Choice pharmacy website: https://www.medstarfamilychoice.com/maryland-providers/pharmacy-prescription-information
     - 1.2.1. General Medication Prior Authorization form
     - 1.2.2. Hepatitis C Medication Prior Authorization form
     - 1.2.3. Opioid Prior Authorization form
     - 1.2.4. Wegovy Prior Authorization form
   - 1.3. For phone requests, preauthorization staff will record the date and time of the request, the member's name, telephone number, prescriber's name, details about the medication being requested.
   - 1.4. Requests must include clinical documentation to support medical necessity.
   - 1.5. After-hour pharmacy requests:
     - 1.5.1. Requests submitted outside of the normal business hours of Monday through Friday, 8:30 am to 5 pm, will be reviewed by the on-call Medical Reviewer.
     - 1.5.2. A preauthorization staff member is also on-call to receive requests, enter the data into the clinical software system, and forward them to a Medical Reviewer to

evaluate for a decision. The preauthorization staff will process Medical Reviewer decisions by entering any needed overrides into the PBM system and communicating the decision to the requestor, member, and/or pharmacy as needed.

2. Preauthorization staff will enter all requests into the clinical software system and forward them to a Medical Reviewer to evaluate and render a decision.
   2.1. Categorize the reason for the request, e.g. non-formulary exception, prior authorization required, early refill or vacation request, quantity limits exceeded, etc.
   2.2. Document the formulary status of the requested product.
   2.3. Specify if requested product appears on the High Cost Medications list.
   2.4. Collate any clinical documentation that supports the request.
   2.5. Document if the prescriber is a network or non-network provider.
   2.6. Summarize associated clinical documentation.
   2.7. Forward preliminary request to Medical Reviewer (at this time).
   2.8. If additional information is needed to supplement the request, the preauthorization staff may obtain the resources, which may include, but are not limited to:
      2.8.1.1. Direct provider outreach,
      2.8.1.2. MedStar Family Choice's clinical software system,
      2.8.1.3. MedStar system EMR,
      2.8.1.4. LabCorp data
      2.8.1.5. PBM Claims reporting database.
   2.9. Documentation of all provider outreach attempts must be recorded in the clinical software system and include:
      2.9.1. Date and Timestamp of outreach attempt.
      2.9.2. Type of outreach (e.g. fax, phone, email, etc.).
      2.9.3. Contact details (e.g. fax, phone or email address) used for outreach and name of recipient.
      2.9.4. Description of information requested.

3. The Medical Reviewer evaluates requests received in the clinical software system for medical necessity and clinical appropriateness.
   3.1. If additional clinical information is needed at least one attempt to obtain that information will occur within the first 24-hours of request receipt.
      3.1.1. The Medical Reviewer may ask preauthorization staff to procure the needed information.
      3.1.2. The Medical Reviewer may contact the prescriber for additional information.
      3.1.3. The Medical Reviewer may access the Chesapeake Regional Information System (CRISP), *excluding* the of the Prescription Drug Monitoring Portal (PDMP) portion of the data base.
   3.2. For non-formulary medication requests, the Medical Reviewer determines the medical necessity as described in pharmacy Policy 205: Non-Formulary Medications, Sections 6 and 7.
   3.3. The Medical Reviewer makes a decision to approve, deny, or otherwise action any request deemed to require clinical review.
      3.3.1. The timeline for rendering a decision is described in Section 6 of this policy.

3.3.2. For cases where the full information is not available, the Medical Reviewer evaluates available information to make a decision.
3.3.3. Requests may be redirected by the Medical Reviewer or withdrawn if original requestor agrees.
3.3.4. If the Medical Reviewer successfully redirects a request to a formulary alternative that requires PA or ST, the initial request may be converted to a request for the redirected medication.
3.3.4.1. Preauthorization staff may update the request when the Medical Reviewer has successfully redirected the request.

4. The default length of the approval period is the duration requested by the provider.
4.1. Approval durations may have drug-specific limitations.
4.1.1. Maximum 6-month approval for controlled medications.
4.1.2. Maximum 6 to 12-month approval for non-controlled medications.
4.1.3. Length of the approval period may be shorter as identified on the PA and ST table.
4.2. Approval periods may differ for initial versus renewal authorizations.
4.3. Medical Reviewers may use their clinical judgement to render partial approvals or shorter approval duration when clinically appropriate.
4.4. MedStar Family Choice reserves the right to discontinue an existing authorization when the new authorization would create a duplication of therapy; this may result when the prescriber has discontinued the previously authorized medication.

5. Preauthorization staff process and complete notification for all completed requests.
5.1. Notification of a decision complies with the timelines as described in Table 1 of this policy.
5.2. Approved request processing:
5.2.1. Preauthorization staff will enter an override in the Pharmacy Benefits Management (PBM) claims system so the prescription will adjudicate for the approved duration, and
5.2.2. Notify the dispensing pharmacy to reprocess the claim, and
5.2.3. Communicate the approval to the requestor by phone, fax, or electronic portal.
5.3. Denied request processing:
5.3.1. Preauthorization staff notify the member and prescriber of the denial in writing. The denial letter includes:
5.3.1.1. The specific reason(s) for the denial, in easily understood language.
5.3.1.2. A reference to the benefit provision, guideline, protocol, or other criterion upon which the denial decision is based.
5.3.1.3. Formulary alternatives, if applicable.
5.3.1.4. Directions to access the Formulary and/or PA & ST Table if applicable.
5.3.1.5. Name and credentials of the Medical Reviewer.
5.3.1.6. Option to discuss the denial with the Medical Reviewer, if desired.
5.3.1.7. The process and timeline for initiating an appeal.
5.3.1.8. Any additional information needed for the appeal.

5.3.1.9. A statement that Members may obtain, upon request, a copy of the actual benefit provision, guideline, protocol, or other criterion on which the denial decision is based.

5.3.1.10. Any forms required e.g., if requesting a Brand medication and a MedWatch form is required for approval, MedStar Family Choice will include the form with the denial.

5.3.2. The appeal process is described in Member Services policies:

5.3.2.1. Policy 301: Member Appeals; and

5.3.2.2. Policy 307: Provider Appeals.

5.4. Partially approved request notification follows processes described in Section 6.2 and Section 6.3 of this policy.

6. Pharmacy requests are processed in accordance with NCQA Standards, the Maryland Department of Health Standards and Reporting Requirements for Drug Use Management Programs for MCOs, and the Code of Maryland Regulations (COMAR).

6.1.1. Timelines for decision-making and notification are described in Table 1 below.

6.2. Requests confirmed to be clinically urgent will be prioritized for processing, and notification of the decision will occur no more than 24 hours from the date of receipt.

6.3. Requesting prescribers may speak to a Medical Reviewer at any time during request processing.

6.4. Members may initiate a retrospective coverage request up to 180 calendar days after the date of service.

6.4.1. If request approval occurs within three (3) days of the date of service, the member will be instructed to return to the pharmacy for a refund.

6.4.2. If request approval occurs more than three (3) days after the date of service, members will be instructed to mail their pharmacy and cash register receipts using the form and instructions described in Appendix I.

6.5. Requests that are redirected to a formulary-preferred alternative, or otherwise determined to be withdrawn will be processed within 24 hours from the date of receipt.

Table 1. Pharmacy request timelines and notification processes.

Request Type	Timeline for UM Decision Making	Timeline for Notification	Notification Method	Who Must Be Notified
All Requests other than Retrospective or Post-service • Non-Urgent Preservice Requests • Urgent Requests* • Urgent concurrent requests	Within 24 hours of the receipt date of the Request for Authorization. MedStar Family Choice MD will approve, deny, or request further information. If further clinical information is not received within 24 hours, an	Notification of the decision within 24 hours of the receipt date. A decision is made within 24 hours of the receipt date regardless of whether clinical information is received, Unless an extension is	Notice by telephone or another telecommunication device. Electronic or written (required for denials)	Telephone or Other Telecommunication Device (required): - Requesting practitioner/provider Written (required for denials): - Requesting facility - Requesting physician or clinician - PCP -Member or Member's authorized representative

	extension may be granted up to 14 calendar days	granted. Once the clinical is received the decision will be made within 24 hours of receiving the additional clinical.		
Retrospective/ Post-Service Pharmacy Requests	Within 30 calendar days of the receipt date of the request.	Electronic or written within 30 calendar days of the initial receipt date of the request.	Electronic or written	-Member or Member's representative (verbal approval or written denial) -Treating physician or clinician or requesting provider - PCP (denial only)

***Urgent requests will be processed as expediently as feasible, not to exceed 24 hours from date of receipt.**

Summary of Changes:	**07/26:** • Updated all NCQA, MCO Standards, and COMAR to current references. • Changed Approved from AVP Clinical Operations to Director, Pharmacy • Section 4.1.2, changed maximum approval non-controlled medications to 6-12 months **07/25:** • Updated all NCQA, MCO Standards, and COMAR references to current year. • Added Decision Extension section. • Added section 1.2.4-to include Wegovy PA form • Section 2 Added Clarification to categorize the reason for the request • Section 2.8 added the avenues the team may reach out to the providers and receive documentation • Section 3.1 added clarification on one attempt within the first 24 hours. • Section 3.2-specified for Non-formulary medication request • Section 3.3 removed "final" **07/24:** • 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. • Incorporated Policy 212: Pharmacy Prior Authorization • Reworded the Purpose statement for clarity and to remove references to policies that cite this policy as a reference. • Clarified the process for redirecting to formulary preferred alternative medications, with emphasis that this may be done only by a Medical Reviewer or under the direct supervision of a Medical Reviewer. • Added additional fax number for initiating an authorization request. • Removed obsolete references to the 2017 Hepatitis-C PA timeline and all references, obsolete. • Added Appendix I: Prescription Reimbursement Claim Form **07/23:** • Responsible Parties changed to Health Plan Pharmacist • Health Plan Pharmacist added with Medical Director throughout Policy • Updated regulatory reference MDH Standards to March 2023 • Updated NCQA reference to 2023 Standards • Updated Approved by to: Dr. Wills and C. Attia • Updated COMAR references • Removed Table: Medication Request from Patient, Prescriber or Pharmacy **07/22** • Responsible Parties changed to Dr. Gregory Dohmeier • Removed from Responsible Parties: Dr. Gerry and Dr. Toye • Updated Regulatory Reference to April 2022 MDH Standards • Updated NCQA Reference to 2022 Standards • Updated tables to reflect changes to UM5C for pharmacy 24-hour response time • Embedded MDH Memorandum 12/07/2017 expanded and concatenated to pdf **07/21:** • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to Scope. • Changed Case Management to Clinical Operations in Responsible Departments. **07/20:** • Updated Regulatory References to reflect COMAR recodification and 2020 NCQA Standards. • Added the following COMAR references found in Procedure Section to Regulatory References COMAR 10.67.11.04, COMAR 10.67.09.04(A)(3).

	• Revised timeline for Urgent Concurrent requests from 72 hours to 24 hours, regardless of the presence or absence of complete clinical information. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed “Maryland” from scope. • Removed “A” from any policy reference, as applicable. • Updated Urgent Concurrent timeframe to 72 hours from previous 24 hours. **07/18:** • Procedure 1. Updated to reflect methods of making requests (MFC PA form and MFC Non-Formulary Request form). • Procedure 2. Requests are sent to the medical director via the clinical software system. • Notification methods and who must be notified updated for all urgent timeframes. • Urgent pre-service and non-urgent notifications were revised to say that decision will occur within 24 hours of complete clinical. • Added “MDH Memorandum dated 12/07/2017: Re: Hepatitis C Medication Approval Timeline” as a reference and embedded it at end of policy. • Modified Effective Date to Initial Effective Dates; added Historical Revision Dates and Revision Effective Dates; and added Historical Review Dates and Review Effective Dates. **01/18:** • New Policy.

Appendix I: Prescription Reimbursement Claim Form

CVS caremark

14423-STANDARD-0816

Prescription Reimbursement Claim Form

Important!

- Always allow up to 30 days from the time you receive the response to allow for mail time plus claims processing.
- Keep a copy of all documents submitted for your records.
- Do not staple receipts or attachments to this form.
- Reimbursement is not guaranteed and other contractor will review the claims subject to limitations, exclusions and provisions of the plan.

STEP 1 Card Holder/Patient Information

This section must be fully completed to ensure proper reimbursement of your claim.

Card Holder Information

Identification Number (refer to your prescription card)

Group Number/Group Name

Last Name

First Name MI

Address

Address 2

City

State Zip Country

Patient Information–Use a separate claim form for each patient

Last Name

First Name MI

Date of Birth Male Female Phone Number

Relationship to Primary Member

Member Spouse Child Other _____

Pharmacy Information

Pharmacy Name

Address

City State Zip

REQUIRED: Please check appropriate box for submitting a paper claim. Claim will be returned if incomplete. (tape receipts or itemized bills on the back)

Reason I am filing this form is:

- ❑ Out of the country
- ❑ Pharmacy does not accept insurance
- ❑ Compound
- ❑ No insurance coverage at the time
- ❑ Other–provide reason below

_____

_____

❑ Medication purchased outside of the United States (tape receipts or itemized bills on the back)

PLEASE INDICATE:

Country: _____

Currency used: _____

Other Insurance Information

Coordination of Benefits (COB)

Are any of these medicines being taken for an on-the-job injury? ❑YES ❑NO

Is the medicine covered under any other group insurance? ❑YES ❑NO

If YES, is other coverage:
❑PRIMARY ❑SECONDARY
❑MEDICARE PART D

If other coverage is PRIMARY, include the Explanation of Benefits (EOB) with this form.

Name of Insurance Company:

_____

_____

ID#: _____

Continued