POLICY AND PROCEDURE	
Title: Part D Formulary	
Primary policy owner: Pharmacy	**Policy #:** PH47
Impacted/Secondary policy owner: Select the department(s) that are responsible for compliance with all, or a portion of the policy or procedure as outlined	
1) ☐All Departments 2) ☐Behavioral Health & Social Services (BH/SS) 3) ☐ Benefits Administration (BA) 4) ☐ Case Management (CM) 5) ☐ Claims (CLMS) 6) ☐ Community Marketplace & Member Engagement (MAR) 7) ☐ Compliance (CMP/HPA) 8) ☐ Configuration (CFG) 9) ☐ Provider Contracting (CONT) 10) ☐ Cultural & Linguistics (CL) 11) ☐ Customer Service (CS)	12) ☐ Facilities (FAC) 13) ☐ Finance (FIN) 14) ☐ Human Resources (HR) 15) ☐ Information Technology / Core Systems (IT) 16) ☒ Pharmacy (PH) 17) ☐ Provider Networks (PRO) 18) ☐ QI Health Equity (GRV/HE/HEQ/PHM/QM) 19) ☐ Utilization Management (UM) 20) ☐ Procurement (PRM) 21) ☐ Administration (SAF/BC/EM) 22) ☐ Medical Management (MM)
Product Type: ☐Medi-Cal ☒D-SNP	**Supersedes Policy Number:** NA

I. PURPOSE

To ensure Health Plan of San Joaquin and Mountain Valley Health Plan ("Health Plan") is in compliance with all contractual requirements, applicable federal and state laws, and regulations for responding, preventing, reviewing, and investigating all reported and identified non-

compliance. Health Plan Workforce and Delegates uses a list of covered drugs (formulary) in compliance with federal and state regulations and other program requirements.

II. POLICY

Formulary Development

A. Health Plan must use a formulary that includes drug categories and classes that cover disease states, consistent with Part D program requirements.
B. The Pharmacy and Therapeutics (P&T) Committee must review and approve, annually, the formulary and the Utilization Management (UM) restrictions such as Prior Authorization (PA), Step Therapy (ST), Quantity Limitations (QL) and Age Restrictions, as well as, relevant policies and criteria.
C. The formulary must include at least 2 drugs in each category, or class of medication, identified by US Pharmacopeia (USP) drug classification system or other systems accepted by Centers for Medicare and Medicaid Services (CMS).
D. The formulary must include all, or substantially all, drugs in the 6 classes of medications considered by CMS to be "protected class drugs." They include: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics. (*CMS defines "substantially all" in section 3.2.25 of Chapter 6 of Part D Manual*).
E. The initial formulary, to be used in the benefit year, must be submitted to CMS in the preceding year, based on timelines established by CMS (generally early June) and must receive the appropriate approvals from CMS prior to being used.
F. The formulary, in a printable format, must be displayed on Health Plan's website along with the PA and ST criteria by October 15 of the year preceding the benefit year.

Formulary Maintenance

G. Once CMS approves the formulary, to be used for the benefit year, no negative changes must be made to it. Examples of negative changes are: removal of a drug from the list of covered drugs unfavorable tiered

cost-sharing status, or changes to the UM requirements to make access more stringent.

Exceptions to this rule include:

1. Negative Changes to the formulary for safety reasons: if a covered Part D drug is deemed unsafe by the Food and Drug Administration (FDA) or is removed from the market by the manufacturer, the affected drug(s) can be removed from the formulary.
2. Maintenance Negative Changes: such as removal of a brand name drug upon the availability and addition to the formulary of a newly approved "A" rated generic or removal of a biologic upon the availability of a biosimilar.
3. Non-Maintenance Negative Changes: only upon submission and approval of a Negative Change request to CMS.

Note: *Negative changes require specific notifications. See Procedure section of this policy*.

H. Throughout the benefit year, the formulary must be updated to allow for the addition of new drugs.
    1. Protected class medications must be reviewed by the P&T Committee within 90 days from their entry to the market.
    2. Non-protected class medications must be reviewed by the P&T Committee withing 180 days from their entry into the market.
I. The formulary updates must be submitted to CMS, monthly, based on a schedule released by CMS annually. These changes must not be implemented until CMS approves them.
J. The formulary displayed on Health Plan's website must be updated to reflect the latest CMS approved drugs and must be posted on the 1st of every month following CMS approval.

III. PROCEDURE

Formulary Development and Maintenance

A. Pharmacy Benefit Manager (PBM) has a P&T Committee that is responsible for reviewing and approving the Part D formulary that is used by Health Plan.

1. The P&T Committee is comprised of voting members who are healthcare professionals with unrestricted licenses to practice in their profession. At least one actively practicing physician and one actively practicing pharmacist shall be experts in elder care.
2. The Committee members are free of conflict regarding Health Plan.
3. The Committee meets at least quarterly.
4. Clinical decisions made by the PBM's P&T committee are based on scientific evidence and standards of practice, which include peer reviewed medical literature, well-established clinical practice guidelines and pharmacoeconomic studies, as well as other sources of information, as appropriate.
5. The P&T Committee minutes and formulary decisions are made available to Health Plan after each meeting.

B. PBM ensures that the formulary meets all CMS requirements regarding inclusion of drug categories and classes that cover all disease states and provides access to a wide range of Part D drug choices.

C. PBM performs all submissions of the Part D formulary, and associated PA/ST, and, if applicable, supplemental files - to CMS, via the Health Plan Management System (HPMS) web site on behalf of Health Plan.

D. PBM generates and provides Health Plan Part D formulary documents in CMS approved formats for Health Plan website posting.

E. PBM provides Health Plan its formulary drug list and Pre-Processing Drug Lists (PPDLs) containing detailed medication information for its internal use.

F. PBM provides Health Plan annually list of changes to the formulary from year to year as well as the list of continuing members that may be affected by them.

Formulary Display and Oversight

G. Health Plan's Marketing Department creates the Plan information, explanation of the formulary benefit/copayment document, and adds it to the printable formulary document before posting it on the website.

H. Health Plan ensures that the updated formulary is displayed on its website along with the correct formulary number, update date, and version number.

I. The negative change notifications adhere to the following rules:

    1. The Explanation of Benefits document informs the beneficiaries of maintenance negative changes.

    2. For CMS approved non-maintenance negative changes including changes due to safety reasons or market withdrawals:

        a. PBM notifies the pharmacy network.

        b. Health Plan notifies the affected members via letter and State Pharmaceutical Assistance Programs (SPAPs) and other entities providing prescription coverage via website posting.

J. Health Plan ensures that beneficiaries, affected by formulary changes from year to year, receive an annual notice of change (ANOC)by September 28 ahead of the benefit year as well as a printed formulary.

IV. ATTACHMENT(S)

A. Glossary of Terms Link

V. REFERENCES

A. Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements: Section 30 – Formulary Requirements and 30.3.4 - Provision of Notice Regarding Formulary Changes
B. Medicare Prescription Drug Benefit Manual, Chapter 6 section 3.2.25
C. Notification Guidance: 42 CFR 423.120(b)(5)
D. Access to Covered Part D overall guidance: 42 CFR 423.120 (b)(5)(iv)
E. Notice of Formulary Change Guidance: 42 CFR 423.120 (f)(5)
F. State Medicaid Agency Contract (SMAC)
G. Health Plan Contract with Centers for Medicare & Medicaid Services (CMS)

VI. REVISION HISTORY

Version*	Revision Summary	Date
001		
002		
003		
004		
Initial Effective Date: 09/24/2025		
Published Date:09/29/2025		

VII. Committee Review and Approval To Be Completed by Compliance

Committee Name	Version	Date
Compliance Committee	001	09/24/2025
• Privacy & Security Oversight Committee		
• Program Integrity Committee		
• Audits & Oversight Committee		
• Policy Review Committee		
Quality Improvement Health Equity Committee (QIHEC)		
• Quality Operations Committee		
• Grievance Committee		

VIII. REGULATORY AGENCY APPROVALS

Department	Reviewer	Version	Date

Department of Healthcare Services (DHCS)			
Department of Managed Care (DMHC)			

IX. *Approval signature**

Signature	Name Title	Date
	PRC Chairperson	
	Policy Owner	
	Department Executive	
	Chief Executive Officer	

*Signatures are on file, will not be on the published copy