PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY/ PROCEDURE

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<tr><td colspan="3">Policy/Procedure Number: MPRP4034 (previously RP100434)</td><td colspan="3">Lead Department: Health Services
Business Unit: Pharmacy</td></tr>
<tr><td colspan="3">Policy/Procedure Title: Pharmaceutical Patient Safety</td><td colspan="3">☒ External Policy
☐ Internal Policy</td></tr>
<tr><td colspan="2">Original Date: 02/16/2005</td><td colspan="4">Next Review Date: 05/13/2027
Last Review Date: 05/13/2026</td></tr>
<tr><td>Applies to:</td><td colspan="2">☐ Employees</td><td>☒ Medi-Cal</td><td colspan="2">☒ Partnership Advantage</td></tr>
<tr><td rowspan="2">Reviewing Entities:</td><td colspan="2">☒ IQI</td><td>☒ P & T</td><td colspan="2">☐ QUAC</td></tr>
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<tr><td>☐ CEO</td><td>☐ COO</td><td>☐ CREDENTIALS</td><td colspan="2">☐ DEPT. DIRECTOR/OFFICER</td></tr>
<tr><td colspan="3">Approval Signature: Robert Moore, MD, MPH, MBA</td><td colspan="3">Approval Date: 05/13/2026</td></tr>
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I. RELATED POLICIES:

A. MPXG5008 – Clinical Practice Guideline: Pain Management, Chronic Pain Management and Safe Opioid Prescribing
B. CMP09 - Investigating & Reporting Fraud, Waste and Abuse

II. IMPACTED DEPTS:

A. Health Services
B. Compliance

III. DEFINITIONS:

A. Class I Recall: A situation in which there is a reasonable probability that the use of, or exposure to, a product may cause serious adverse health consequences or death.
B. Class II Recall: A situation in which use of, or exposure to, a product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
C. Medi-Cal Rx: The program title established by the State of California Department of Health Care Services (DHCS) for the new system of administering Medi-Cal pharmacy benefits through the fee-for-service (FFS) delivery system effective January 1, 2022. Refer to All Plan Letter (APL) 22-012 *Revised* for more information.
D. Partnership Advantage: Effective January 1, 2026, Partnership HealthPlan of California will operate a Centers for Medicare & Medicaid Services (CMS)-approved Dual-Eligible Special Needs Plan (D-SNP) in specific counties as described in the Department of Health Care Services (DHCS) CalAIM Dual Eligible Special Needs Plan Policy Guide. This line of business will be known as Partnership Advantage and will be a Medicare Advantage plan offered to all full-benefit, dual-eligible beneficiaries 21 years of age or older who reside in the applicable counties. Partnership Advantage Members will be qualified to receive both Medi-Cal and Medicare services as described in the Partnership Advantage Member Handbook.
E. Physician-Administered Drug (PAD) or Medical Benefit Medications: A physician-administered drug is an outpatient drug that is typically administered by a health care provider in a physician's office or other outpatient clinical setting. For example, drugs that are infused or injected are typically physician- administered drugs. The provider bills the appropriate state Medicaid program (i.e. – fee-for-service, managed care plan, or county organized health system [COHS]) for the drug, using the appropriate national drug code (NDC) and Healthcare Common Procedure Coding System (HCPCS) code.

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IV. ATTACHMENTS:

A. Prescriber Letter
B. Member Letter

V. PURPOSE:

To describe Partnership HealthPlan of California's role in providing patient safety information to pharmacists, practitioners and patients for both the Medi-Cal and Partnership Advantage lines of business. Due to the implementation of Medi-Cal Rx on January 1, 2022, this policy does not apply to products billed through the Medi-Cal pharmacy benefit.

VI. POLICY / PROCEDURE:

A. Objectives:
   1. Identify and notify practitioners and members of product withdrawals, which include voluntary withdrawals by the manufacturer or those under Food and Drug Administration (FDA) requirement, for patient safety reasons or other reasons on a case-by-case basis.
   2. Identify and notify practitioners and members of entire product withdrawals from the market (all NDCs/Lots), which include voluntary withdrawals by the manufacturer or those under Food and Drug Administration (FDA) requirement, for patient safety reasons or other reasons on a case-by- case basis.

B. Class II drug recall or voluntary withdrawals from the market:
   1. Physician-Administered Drug (PAD) or Medical Benefit Medications: When a drug in its entirety (all NDCs/Lots) is withdrawn from the market due to patient safety reasons Partnership identifies those members who have recently received the drug and those practitioners who have administered the drug, to the best of the plan's ability based on claim submissions received for dates of service lookback extending to 120 days prior to the recall notification. The members and practitioners are then both notified by mail of the drug withdrawal within thirty (30) calendar days of FDA notification.
   2. Medicare Part D Medications: When a drug is withdrawn from the market due to patient safety reasons, Partnership identifies those members who have recently received the drug and those practitioners who have prescribed the drug. The members and practitioners are then both notified by mail of the drug withdrawal within thirty (30) calendar days of FDA notification.

C. Class I drug recall or withdrawals:
   1. Physician-Administered Drug (PAD) or Medical Benefit Medications: When a drug in its entirety (all NDCs/Lots) is withdrawn from the market due to patient safety reasons, Partnership identifies those members who have recently received the drug and those practitioners who have prescribed the drug, to the best of plan's ability based on claim submissions received for a date of service lookback period of 120 days prior to the recall notification. The members and practitioners are then informed by mail of the drug withdrawal within (5) working days of FDA notification.
   2. Medicare Part D Medications: When a drug is withdrawn from the market due to patient safety reasons, Partnership identifies those members who have recently received the drug and those practitioners who have prescribed the drug. The members and practitioners are then both notified by mail of the drug withdrawal within five (5) working days of FDA notification.

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VII. REFERENCES:

A. DHCS APL 22-012 (revised) Governor's Executive Order N-01019, Regarding Transitioning Medi-Cal Pharmacy Benefit from Managed Care to Medi-Cal Rx (Dec. 30, 2022 supersedes APL 20-020)
B. SSA 1927(k)(2): CMS Definition of Covered Outpatient Drug
C. Food and Drug Administration (FDA) Enforcement Reports at www.fda.gov

VIII. DISTRIBUTION:

A. Partnership Provider Manual
B. Partnership Department Directors

IX. DEPARTMENT RESPONSIBLE FOR IMPLEMENTING PROCEDURE: Pharmacy Services

X. REVISION DATES:

Partnership Advantage (Program effective January 1, 2026)
05/14/25

Medi-Cal
09/21/05; 07/24/08; 10/28/10; 01/16/14; 10/01/15; 04/07/16; 04/06/17; *02/14/18; 02/13/19; 02/12/20; 05/12/21; 05/11/22; 05/10/23, 05/08/2024, 05/14/2025

*Through 2017, Approval Date reflective of the Pharmacy Therapeutics Committee meeting date. Effective January 2018, Approval Date reflects that of the Physician Advisory Committee's meeting date.

PREVIOUSLY APPLIED TO:

Healthy Families:
MPRP4034 - 10/28/2010 to 03/01/2013

Healthy Kids
07/24/2008; 10/28/10; 01/16/14; 10/01/15; 04/07/16 to 12/01/16 (Healthy Kids program ended 12/01/2016)

IX. POLICY DISCLAIMER:

A. In accordance with the California Health and Safety Code, Section 1363.5, this policy was developed with involvement from actively practicing health care providers and meets these provisions:
   1. Consistent with sound clinical principles and processes;
   2. Evaluated and updated at least annually;
   3. If used as the basis of a decision to modify, delay or deny services in a specific case, the criteria will be disclosed to the provider and /or enrollee upon request.
B. The materials provided are guidelines used by Partnership to authorize, modify, or deny services for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under Partnership.
C. Partnership's authorization requirements comply with the requirements for parity in mental health and substance use disorder benefits in 42 CFR 438.910.