PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY/ PROCEDURE

<table>
<tr><td colspan="3">Policy/Procedure Number: MPRP4062</td><td colspan="3">Lead Department: Health Services
Business Unit: Pharmacy</td></tr>
<tr><td colspan="3">Policy/Procedure Title: Drug Wastage Payments</td><td colspan="3">☒ External Policy
☐ Internal Policy</td></tr>
<tr><td colspan="2">Original Date: 01/21/2016</td><td colspan="4">Next Review Date: 08/12/2027
Last Review Date: 08/12/2026</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>
<tr><td colspan="2">☐ OPERATIONS</td><td>☐ EXECUTIVE</td><td>☐ COMPLIANCE</td><td>☐ DEPARTMENT</td></tr>
<tr><td rowspan="2">Approving Entities:</td><td colspan="2">☐ BOARD</td><td>☐ COMPLIANCE</td><td>☐ FINANCE</td><td>☒ PAC</td></tr>
<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: 08/12/2026</td></tr>
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I. RELATED POLICIES:

A. MCRP4068 – Medical Benefit Medication TAR Policy
B. CMP09 – Investigating & Reporting Fraud, Waste and Abuse

II. IMPACTED DEPTS:

A. Claims
B. Provider Relations
C. Compliance

III. DEFINITIONS:

A. Drug Waste means the remainder of drug or biological that has been discarded from a single use vial or other single use package after administering a dose/quantity of the drug or biological to a patient.
B. Fraud, Waste, and Abuse (FWA):
   1. Fraud: In general, Medicaid fraud involves making a false statement or misrepresentation of material facts to obtain a payment to which the provider is not otherwise entitled. The rules governing Medicaid define "fraud" as follows: "… an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law." An example of fraud is knowingly billing for services not furnished or supplies not provided.
   2. Waste: Waste is not defined in the rules, but is "generally understood to encompass over-utilization or inappropriate utilization of services and misuse of resources, and typically is not a criminal or intentional act." Examples of waste by a beneficiary could include making excessive office visits or accumulating more prescription medications than necessary for the treatment of specific conditions. Waste by a provider could include ordering excessive laboratory tests.
   3. Abuse: Abuse is defined in the Medicaid rules as follows: "… provider practices that are inconsistent with sound fiscal, business, or medical practices, and 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. It also includes beneficiary practices that result in unnecessary cost to the Medicaid program."

IV. ATTACHMENTS:

A. Allowable Waste Drug List

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V. PURPOSE:

To define the process on how to bill for discarded drugs and biologicals in an appropriate manner that falls within the guidelines of Healthcare Fraud, Waste, and Abuse and the Plan's reporting of potential findings. This policy only applies to drugs given by a provider (medical benefit), not pharmacy drugs covered under Medi-Cal Rx.

A. This policy shall apply in scope and pursuant to APL 22-012, Governor's Executive Order N-01-19 regarding Transitioning Medi-Cal Pharmacy Benefit from Managed Care to Medi-Cal Rx (the pharmacy benefit carve-out to Medi-Cal Fee-for-Service)
    1. Any & all policy items pertaining to pharmacy prescription claims &/or pharmacy drug Treatment Authorization Requests (TARs) shall not apply upon implementations of Medi-Cal Rx.

VI. POLICY / PROCEDURE:

A. Policy:
    1. Partnership HealthPlan of California (Partnership) encourages physicians, hospitals, and other providers to care for and administer to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. Providers should administer medications in the most cost-effective manner, utilizing the most cost-effective vial and/or combination of vial sizes in order to minimize waste.

B. Procedure:
    1. When a physician, hospital, or other provider must discard the remainder of a single use vial or other single use package after administering a dose/quantity of a drug or biological.Partnership will provide payment for the amount of the drug or biological discarded, as well as the dose administered listed on the Allowable Waste Drug List (Attachment A), up to the amount of the drug or biological as indicated on the vial or package label.
    2. When submitting claims for drugs and biologicals, the JW modifier (drug amount discarded/not administered to any patient) and National Drug Code (NDC) are required to identify unused drug or biologicals from single use vials or single use packages that are appropriately discarded.
        a. The JW modifier is billed on a separate line and will provide payment for the amount of discarded drug or biological.
        b. The NDC of the drug or biological used must be submitted in conjunction with the JW modifier.
        c. The JW modifier is only applied to the amount of the drug or biological that is discarded. When there is no discarded amount from a single-dose container, the JZ modifier (no discarded drug or biological) must be reported in accordance with billing requirements, consistent with CMS requirements effective July 1, 2023.
        d. The JW modifier is not permitted when the actual dose of the drug or biological administered is less than the billing unit.
    3. The Allowable Waste Drug List (Attachment A) is not an exclusive list and will undergo review and revision as needed throughout the year, due to the Healthcare Common Procedure Coding System (HCPCS) code changes and market availability of single-dose vs multi-dose vials.
        a. When the JW modifier is used for a drug or biological which is *not* listed on the Allowable Waste Drug List (Attachment A), a TAR must be submitted for

consideration of approval of drug waste. Pharmacy department will review the request to determine if waste reimbursement is allowable based on the drug used, amount wasted, and standard billing rules for discarded drugs outlined in this policy.

4. Partnership will not reimburse for discarded drugs or biologicals under the following situations:
   a. The drug or biological is administered from a multi-dose vial
   b. The drug or biological is not administered to the patient
   c. An inappropriate vial size or combination of vials is used to deliver the administered dose
   d. The drug or biological is contaminated, or is compromised due to improper storage.
   e. If a second or subsequent vial that is used to complete a wight or body surface area (BSA_-based dose, and less than 5% of the dose is in the last vial prescribed (i.e., exact dose not rounded down to nearest whole vial, when the dose used from the partial vial is within range of drug being ordered)
5. The patient's medical record must document the following items:
   a. The physician's order for the drug. If the order is written based on patient specific factors (weight, body surface area, etc.), current measurement of those factors must also be documented.
   b. The date and time that the drug or biological was administered to the patient
   c. The amount of the drug or biological administered to the patient
   d. The route of administration of the drug or biological.
   e. The amount of the drug or biological that was discarded or wasted and the reason for wastage.
   f. The name and credentials of the person administering the drug
   g. How much of the drug was given and how much was wasted for that specific patient.
6. TAR requests for non-formulary drugs and biologicals should include the following information:
   a. The amount of drug or biological to be administered to the patient per treatment.
   b. The amount of drug or biological that will be wasted per treatment, listed separately.
   c. The NDC of the drug or biological that will be used.
   d. Note: if a drug or biological *is on* the allowable waste list, medication TAR approval will NOT include additional units for waste. The TAR is ONLY to include the dose necessary for administration and should NOT include additional units for waste. Please see billing procedure VI.B.2. above for claims billing.

C. Reporting:
   1. Pharmacy department clinical staff, in conjunction with Claims department staff, may identify claims after payment is rendered with billing errors as described above.
   2. All claims identified by Pharmacy department staff for recovery of overpayment will be reviewed quarterly for accuracy and reported annually to the Chief Compliance Officer via RAC_Inbox by the Pharmacy Director or his/her designee.
   3. All potential FWA cases identified will be reported by the Pharmacy department staff immediately via RAC Reporting as described by Policy #CMP0

VII. REFERENCES:

A. CMS. Medicare Claims Processing Manual, Chapter 17-Drugs and Biologicals, § 40.
B. California Department of Health Services (DHCS) All Plan Letter (APL) 22-012 Governor's Executive Order N-01-19, Regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal Rx (*revised* 12/30/22) (supersedes APL 20-020)
C. CA Welf & Inst Code § 14185 - Drug Utilization Under Medi-Cal Managed Care Programs

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VIII. DISTRIBUTION:

A. PHC Provider Manual
B. PHC Department Directors

IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE: Director Pharmacy Services

X. REVISION DATES:

Medi-Cal
01/12/17; 04/06/17; *06/13/2018; 05/08/19; 05/13/20; 11/11/20; 11/10/21, 11/09/22, 11/08/23, 11/13/24; 08/13/25; 08/12/26

Partnership Advantage (effective Jan. 1, 2028)
N/A

*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 Kids
01/21/2016 to 12/01/2016 (Healthy Kids Program ended 12/01/16)

XI. 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.