BACKGROUND

The Centers for Medicare and Medicaid Services (CMS) requires Part D sponsors to ensure that members have adequate access to covered Part D drugs dispensed at Out-of-Network (OON) pharmacies when a member cannot reasonably be expected to obtain Part D drugs at a network pharmacy and when such access is not routine. Medicare Advantage Prescription Drug (MA-PD) plans must develop policies and procedures governing reasonable rules for appropriately limiting OON access. This policy supports Kaiser Foundation Health Plan of Washington (KFHPWA) MA-PD plan’s commitment to meet the CMS requirements in the Prescription Drug Benefit Manual, Chapter 5, Benefits and Beneficiary Protections, Chapter 6, Part D drugs and Formulary Requirements and Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance.

POLICY

KFHPWA MA-PD plans shall ensure that KFHPWA Medicare Advantage Prescription Drug (MA-PD) members have adequate access to covered Part D drugs and vaccines. This includes obtaining Part D drugs and vaccines from out-of-network (OON) pharmacies and providers when necessary.

KFHPWA MA-PD plans reimburse members for coverage charges on Part D drug expenses incurred at OON pharmacies or providers, provided such members do not access Part D drugs at an OON pharmacy or a provider on a routine basis.

CMS does not allow coverage for medications purchased outside of the United States. Part D plans must exclude Part D drugs from qualified prescription drug coverage if they are not used and sold in the United States. In addition, Part D sponsors may only pay for drugs that satisfy the definition of Part D drug. In general, such definition requires FDA approval for sale in the United States. Therefore, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all the requirements of the U.S. approval, and thus it is considered to be unapproved.

KFHPWA MA-PD members are guaranteed out-of-network access when:

- Traveling outside the plan’s service area and unable to obtain a needed covered Part D drug from a network pharmacy.
- Receiving covered Part D drugs dispensed by an OON institution-based pharmacy while a member is in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting and as a result cannot get the prescriptions filled at a network pharmacy.
- Prescription claims for members in an outpatient observation status at a hospital are covered under Part D. If a member receives a denial for these claims he or she should send a reimbursement request to KFHPWA. The request should include a list of medication(s), including NDC, quantities and prescribing doctor.
Unable to reasonably access pharmacy services or covered Part D drugs from a network pharmacy in a timely manner because:

- There is no network pharmacy within a reasonable driving distance that provides services 24 hours per day/7 days per week.
- A network pharmacy is having stocking/distribution problems for a particular Part D drug, and/or
- Part D drug is an orphan drug or other specialty pharmaceutical typically shipped directly from manufacturers or other vendors and is not regularly stocked at accessible network retail or mail order pharmacies.
- Receiving covered Part D drugs appropriately dispensed and administered at OON physician offices (e.g. Part D-covered vaccines).

If a member is unable to reasonably obtain covered Part D drugs from a network pharmacy where a Federal or State disaster declaration or other public health emergency has caused the member to be evacuated or otherwise displaced from the member’s place of residence. KFHPWA emergency declaration protocol is governed by the National Kaiser Permanente Pharmacy Access During Declared Emergencies Policy (NATL.PHARM.MPD.013).

**Payment Exclusions**

KFHPWA MA-PD plans do not reimburse members for Part D medications obtained from an “excluded provider” as defined by 42 U.S.C. 1320a-7 and 42 U.S.C. 1320c-5. (See the List of Excluded Individuals/Entities, available at: http://oig.hhs.gov/fraud/exclusions.asp. Based upon guidance supported in the CMS Memo dated November 2, 2018 and the CY2018 Call Letter KFHPWA will not reimburse pharmacy claims furnished by providers who are listed on the CMS Preclusion list effective April 1, 2019.

KFHPWA MA-PD plans do not allow more than a 30 days’ supply of medication to be dispensed at the OON pharmacy. This one-month limit will be overridden on a case by case basis when warranted by extraordinary circumstances.

KFHPWA MA-PD plans do not reimburse for any compounding fee assessed for Multi-Ingredient Compound (MIC) claims. Ingredients that are considered to be Part D exclusions are not reimbursed.

KFHPWA MA-PD plans may require members accessing OON covered Part D drugs and services to assume financial responsibility for any differential between the OON provider’s usual and customary price and the KFHPWA MA-PD negotiated in-network pharmacy service charge.

**How to Request Reimbursement for OON Services**

All requests for reimbursement for OON services must be submitted in writing and must include:

- Member’s name, address and phone number;
- Prescriber name and address;
- A receipt for services that includes:
  - Date of service
  - Drug name
  - Strength
  - National Drug Code (NDC) number
  - Quantity
  - Days Supply
  - Paid Amount (by member and/or primary insurer)
  - Receipts from medications filled on cruise ships should include the flag the ship is operating under. (The cruise ship line can provide you with this information if it is not included on your original receipt.) Prescription medications dispensed on cruise ships are covered only if the ship is within 6 hours of a U.S. port, is a Part D covered drug, has a valid National Provider Identifier (NPI) number and a valid National drug code (NDC) number.
  - For prescriptions dispensed at a pharmacy, please include the Pharmacy name, address and NPI or NCPDP number. (The pharmacist at the dispensing location can provide you with this information.)
To ensure requests for reimbursement contain all required information, KFHPWA encourages members to submit these requests with the Part D Claim Member Reimbursement Request Form. The use of the Part D Claim Member Reimbursement Form is not required.

Requests for reimbursement for Part D claims should be sent to:

OptumRx  
PO BOX 650287  
Dallas, TX 75265-0287

**Review of Member Reimbursement Requests**

KFHPWA Pharmacy Benefits Manager (PBM), OptumRx reviews all requests for reimbursement and either approves (and makes payment) OR denies (and sends notification) the requests within fourteen (14) calendar days after the receipt of the request as required by CMS. Any claim submitted with a date of service prior to 01/01/2017 will be forwarded to the KFHPWA Pharmacy group for processing.

KFHPWA, or any organization operating on behalf of KFHPWA, notifies members that the request for reimbursement has been approved or denied using approved notices. Adverse decisions (denials) are provided to beneficiaries using the CMS approved template.

**Records Retention**

KFHPWA MA-PD plans comply with the CMS requirement for records retention for the current contract period and 10 prior contract periods to ensure the availability to CMS, Department of Health and Human Services (DHHS), the Comptroller General, or their designee, access to Medicare Advantage Organization facilities and records to evaluate through inspection or other means.

**Internal Audit Process**

KFHPWA MA-PD plans comply with the CMS requirement for conducting internal audits and reporting internal audit results and findings as required by CMS. All KFHPWA operational areas with responsibility for ensuring compliance with CMS requirements must complete internal audits as directed by the KFHPWA Medicare Contract Compliance Manager and the Kaiser Permanente National Compliance Office (NCO).

KFHPWA Medicare Programs and Compliance and NCO report internal audit results to CMS Regional office as required.

**Corrective Action**

Corrective actions are self-identified by operational departments or identified by Ethics and Compliance Office and are implemented by operational areas. Correction Action Plan (CAP) implementation is initiated with oversight by the regional Ethics and Compliance Office, Medicare Contract Compliance Manager and National Compliance Office (for issues with national impact).

The Medicare Contract Compliance manager escalates issues to the National Compliance office for CMS disclosure is needed.

**APPLICABILITY**

This policy is reviewed and updated annually and supports the requirements stated in this document.