Policy and Procedure		
SUBJECT: **Medicare Part D Transition Policy (New And Current Members)**	DEPARTMENT: **Pharmacy**	
ORIGINAL EFFECTIVE DATE: **12/06**	DATE(S) REVIEWED/REVISED: **04/08, 08/09, 04/10, 08/10, 08/11, 06/12, 10/12, 02/13, 02/14, 06/14, 05/15, 05/16, 07/16, 09/16, 03/17, 07/17, 05/18, 07/18, 05/19 AH/KJ, 04/20 AH**	
APPROVED BY: **Oregon Region Pharmacy and Therapeutics Committee**	NUMBER: **ORPTCOPS060.0619**	PAGE: **1 of 4**

SCOPE:
Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Medicare

POLICY:
The Company will maintain an appropriate transition process consistent with 42 CFR 423.120(b)(3) that includes a written description of how, for enrollees whose current drug therapies may not be included in their new Part D plan's formulary, it will effectuate a meaningful transition for: (1) new enrollees into prescription drug plans following the annual coordinated election period; (2) newly eligible Medicare beneficiaries from other coverage; (3) enrollees who switch from one plan to another after the start of the contract year; (4) current enrollees affected by negative formulary changes across contract years; and (5) enrollees residing in long-term care (LTC) facilities. Members who change plan benefit packages (PBPs) within the same Contract are not eligible for a transition fill since the formularies between the PBPs do not differ.

The Company submits a copy of its transition process policy to the Centers for Medicare and Medicaid Services (CMS) for approval.

The Company will ensure that its transition policy will apply to non-formulary drugs, meaning both (1) Part D drugs that are not on the plan's formulary, and (2) Part D drugs that are on the plan's formulary but require prior authorization or step therapy, or that have an approved quantity limit (QL) lower than the beneficiary's current dose, under the plan's utilization management rules. The Company ensures medical review of non-formulary drug requests and redirects, when appropriate, new Part D enrollees and prescribing providers to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. Non-formulary drug requests are reviewed through the coverage determination process. The Company notifies the member and provider of any adverse determination. This notification includes covered formulary alternatives and/or medical necessity criteria.

The Company has claims processing system capabilities that allow a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to

allow the Company and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity.

The Company will ensure that in the retail setting, the transition policy provides for a one-time, temporary 30-day fill of medication (unless the enrollee presents with a prescription written for less than 30 days in which case the Company will allow multiple fills to provide up to a total of a 30 day supply of medication) anytime during the first 90 days of a beneficiary's enrollment with the Company, beginning on the enrollee's effective date of coverage.

The Company cost-sharing for a temporary supply of drugs provided under the transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS enrollees, the Company charges the same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with 42 CFR § 423.578(b) and the same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply if the utilization management criteria are met.

In the long-term care setting: (1) the transition policy provides for a one time temporary fill of 31 days (unless the enrollee presents with a prescription written for less) which is dispensed incrementally as applicable under 42 CFR §423.154 and with multiple refills provided if needed during the first 90 days of a beneficiary's enrollment in the plan, beginning on the enrollee's effective date of coverage; (2) after the transition period has expired, the transition policy provides for a 31-day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) while an exception or prior authorization is requested; and (3) for enrollees being admitted to or discharged from an LTC facility, early refill edits are not used to limit appropriate and necessary access to their Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge.

IMPLEMENTATION:
In order to assure that new enrollees are able to leave a pharmacy with a temporary supply of non-formulary Part D drugs without unnecessary delays, the Company's claims processor is set up to adjudicate (pay) the claim without blocks (unless for edits approved by CMS). As described in the policy above, the Company's claims processor is set up to apply at least a one-time, temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days), with multiple refills as necessary for up to a 30 day supply anytime during the first 90 days of a beneficiary's

enrollment with the Company, beginning on the enrollee's effective date of coverage. When the claim is paid in transition, a message is delivered on that claim that informs the pharmacy that the claim processed automatically under the transition benefit. No further action is required from the pharmacy. The Company only applies the following utilization management edits during transition at point-of-sale: (1) edits to determine Part A or B versus Part D coverage; (2) edits to prevent coverage of non-Part D drugs (e.g., excluded drugs such as a drug that may be used for sexual dysfunction, or formulary drugs being dispensed for an indication that is not medically accepted); and (3) edits to promote safe utilization of a Part D drug (e.g., a beneficiary-level opioid claim edit; quantity limits based on Food and Drug Administration (FDA) maximum recommended daily dose; early refill edits). Step therapy and prior authorization edits are resolved at point-of-sale.

For new enrollees, the Company prevents any unintended interruptions in pharmacologic treatment with Part D drugs during their transition into the Part D benefit. This includes ensuring that enrollees have timely access to their medically necessary Part D drug therapies for opioid dependence.

This transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limit safety edits or drug utilization edits that are based on approved product labeling.

The Company will apply all transition processes to a brand-new prescription for a non-formulary drug if it cannot make the distinction between a brand-new prescription for a non-formulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale.

The Company will send a written notice via U.S. first class mail to each enrollee within three (3) business days of adjudication of a temporary transition fill. The notice includes: (1) an explanation of the temporary nature of the transition supply an enrollee has received; (2) instructions for working with the Company and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the plan's formulary; (3) an explanation of the member's right to request a formulary exception, the timeframes for processing the exception, and the member's right to request an appeal if the plan issues an unfavorable response; and (4) a description of the procedures for requesting a formulary exception. For long-term care residents dispensed multiple supplies of a Part D drug in increments of 14 days or less, consistent with the requirements under 42 CFR 423.154(a)(1)(i), the written notice will be provided within 3 business days after adjudication of the first temporary fill. The Company will use the Centers for Medicare & Medicaid Services (CMS) model Transition Notice via the file-and-use process or submit a non-model Transition Notice to CMS for marketing review subject to a 45-day

review. The Company will ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice. Prescribers of record are either (1) directly provided a copy of the written transition notice labeled as the "PROVIDER COPY" via U.S. first class mail, fax, or electronic means or (2) notified via a phone call or individualized or batch fax/electronic notification.

The Company's prior authorization or exceptions request forms are available upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on the the Company's website.

The Company will extend its transition policy across contract years should a beneficiary enroll in the plan with an effective enrollment date of either November 1 or December 1 and needs access to a transition supply.

The transition policy is available to enrollees via a link from the Medicare Prescription Drug Plan Finder to the Company's website, and transition information will be included in pre-and post-enrollment marketing materials as directed by CMS.

The Company will continue to provide necessary Part D drugs to enrollees via an extension of the transition period, on a case-by-case basis, to the extent that their exception requests or appeals have not been processed by the end of the minimum transition period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request).

For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the Company will effectuate a meaningful transition by either: (1) providing a transition process at the start of the new contract year or (2) effectuating a transition prior to the start of the new contract year.

REFERENCES:

1. Medicare Prescription Drug Benefit Manual, Chapter 6- Part D Drugs and Formulary Requirements, Section 30.4-Transition, Rev.18, 01-15-16 (accessed 4/28/20)
2. 42 CFR 423.120 (b)(3) (accessed 4/28/20)
3. CY 2019 Final Rule [CMS-4182-F] (accessed 4/28/20)