Policy/Procedure Name: **Control Number:**

MEDICARE PART D TRANSITION MANAGEMENT **1350/20.000186**

EFFECTIVE DATE: January 1, 2025

DESCRIPTION:

To provide a process for both new enrollees and current beneficiaries to Capital District Physicians' Health Plan, Inc. and CDPHP Universal Benefits, Inc. (collectively referred to as CDPHP or Plan Sponsor) to obtain coverage for non-formulary drugs (i.e., drugs not on the CDPHP formulary as well as Part D drugs that are on the formulary but require prior authorization, step therapy or quantity limits). The process also ensures that CDPHP meets all CMS requirements for new member transition into a CDPHP benefit plan or, for existing members who have a change in level of care or who enter a long-term care (LTC) facility.

This policy, as the overriding policy, works in conjunction with the standard transition policy and procedure used by the Delegated PBM, to allow CDPHP to meet CMS requirements. The purpose of this policy is to describe the Medicare transition process and ensure that continued drug coverage is provided to new and current Part D enrollees. The transition process allows for a minimum of a 1-month temporary supply of drugs providing sufficient time for enrollees to work with their health care providers to select a therapeutically appropriate formulary alternative, or to request a formulary exception based on medical necessity. Transition processes will be administered by the Plan and delegated PBM, in a manner that is timely, accurate and compliant with all relevant Centers for Medicare and Medicaid Services (CMS) guidance and requirements as per 42 CFR §423.120(b)(3). An applicable month's supply is determined as the number of days submitted to CMS for the Plan Benefit Package (PBP)'s applicable month's supply for the relevant plan year (30 days Non-LTC; 31 days LTC). CMS approval determines the approved month's supply for Beneficiaries in both the LTC and non-LTC settings.

POLICY:

CDPHP in conjunction with its pharmacy benefit manager (PBM) implements and maintains an appropriate transition process consistent with 42 CFR § 423.120(b)(3) that includes a written description of how, for enrollees who current drug therapies may not be included in their new Part D plan's formulary, it will effectuate a meaningful transition for the following beneficiaries:

- New enrollees into the Plan Sponsor's prescription drug plan following the annual coordinated election period,
- Newly eligible Medicare beneficiaries from other coverage,
- Enrollees who switch from one plan to another after the start of the contract year,
- Current enrollees affected by negative formulary changes across contract years, and
- Enrollees residing in long-term care (LTC) facilities

Annually, CDPHP submits a copy of this transition policy to CMS.

Policy/Procedure Name: **Control Number:**

MEDICARE PART D TRANSITION MANAGEMENT **1350/20.000186**

To be consistent with best practices, CDPHP maintains the same transition process for new and existing members. All beneficiaries will be treated as newly enrolled for the purpose of meeting CMS transition requirements.

PROCEDURES:

1. Implementation Statement

a. **Claims Adjudication System**: The delegated PBM has systems capabilities to provide a temporary supply of non-formulary Part D drugs to accommodate the immediate needs of an enrollee, as well as to allow CDPHP and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication on formulary or the completion of an exception request to maintain coverage of an existing drug based on medical necessity.

b. **Pharmacy Notification at Point-Of-Sale (POS)**: The delegated PBM utilizes the current NCPDP Telecommunication Standard to provide POS messaging. The delegated PBM reviews NCPDP reject and approval codes used during transition. Pharmacy messages are updated based on NCPDP and CMS standards and guidelines.

c. **Edits During Transition**: Only the following utilization management edits will apply during transition at point-of-sale:

i. Edits to help determine Part A or B versus Part D coverage,
ii. Edits to prevent coverage of non-Part D drugs (e.g., statutorily excluded drugs such as a drug used for erectile dysfunction, or formulary drugs being dispensed for an indication that is not medically accepted), and
iii. Edits to promote safe utilization of a Part D drug (e.g., opioid safety edits, quantity limits based on FDA maximum recommended daily dose such as acetaminophen, early refill edits).
iv. Note: Step therapy and prior authorization edits may be resolved at point-of-sale.

The delegated PBM will ensure that the transition process 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 up to the plan sponsors allowable transition month supply. For example, if an enrollee presents at a retail pharmacy with a prescription for 1 tablet per day for 30 days and the Plan Sponsor has a quantity limit edit in place that limits the days' supply to 14 per prescription for safety purposes, the enrollee would receive a 14-day supply (consistent with the safety edit). At the conclusion of the 14-day supply, the enrollee should be entitled to another

16-day supply while he/she continues to pursue an exception with the Part D plan, or a switch to a therapeutic alternative that is on the plan's formulary.

As outlined in 42 CFR §423.153(b), the delegated PBM has POS PA edits to determine whether a drug is covered under Medicare Parts A or B as prescribed and administered, is being used for a Part D medically accepted indication or is a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D.

d. **Pharmacy Overrides at POS**: During the enrollee's transition period, all edits (with the exception of those outlined in section 1.4(c)) associated with non-formulary drugs are automatically overridden at POS. Pharmacies can also contact the delegated PBM Pharmacy Help Desk directly for immediate assistance with POS overrides, including emergency fills as described in Emergency Supply for Current Enrollees. Please see section Six Protected Classes for specific information for the processing of non-formulary drugs in this category.

2. Transition Requirements

a. **Affected Enrollees**. An appropriate transition program consistent with 42 CFR § 423.120(b)(3) includes a description for enrollees whose current drug therapies may not be included in their new Part D plan's formulary on how it effectuates a meaningful transition for:

i. New enrollees into prescription drug plans following the annual coordinated election period;
ii. Newly eligible Medicare enrollees from other coverage;
iii. Enrollees who switch from one plan to another after the start of the contract year;
iv. Current enrollees affected by negative formulary changes across contract years; and
v. Enrollees residing in LTC facilities.

3. Applicable Drugs

a. This transition policy applies to non-formulary drugs. For the purposes of transition, non-formulary Part D drugs means the following:

i. Part D drugs that are not on the Plan Sponsor's formulary, and
ii. Part D drugs that are on the Plan Sponsor's formulary but require prior authorization or step therapy, or that have an approved QL lower than the enrollee's current dose, under the Plan Sponsor's utilization management requirements.

b. This transition policy includes procedures for medical review of non-formulary drug requests, and when appropriate, a process for enrollees to switch to therapeutically appropriate formulary alternatives, failing an affirmative medical necessity determination.

c. The Pharmacy & Therapeutics (P&T) Committee approves the non-formulary criteria that outlines the exception process. Criteria comprises of medication trial and failure (if applicable), appropriate diagnosis, contraindication or adverse event or harm to any formulary alternatives, and any formulary alternative likely to be less effective for the enrollee. During the exception process, the Plan Sponsor obtains medical information and issues a decision. If not deemed to be medically necessary, the Plan Sponsor will provide the enrollee and prescriber with a denial reason, including available formulary alternatives when appropriate.

d. System capabilities allow a temporary supply of no less than a 1 month supply (as defined in the Plan Sponsor's approved bid) of non-formulary Part D drugs to address the immediate needs of an enrollee. This allows the Plan Sponsor and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically-equivalent medication on formulary or to complete an exception request to continue coverage based on medical necessity.

e. Refills are allowed 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

f. The Six Protected Classes as identified by CMS in Chapter 6 Section 30.2.5 include: 1) Antidepressant; 2) Antipsychotic; 3) Anticonvulsant; 4) Antineoplastic; 5) Antiretroviral; and 6) Immunosuppressant (for prophylaxis of organ transplant rejection). Enrollees transitioning to a plan while taking a six protected class drug must be granted continued coverage for the duration of the treatment or up to the full duration of active enrollment in the plan. Utilization management (i.e., PA and/or Step Therapy) is not applied to enrollees transitioning to the Medicare Part D plan on six protected class agents, but may only be applied to new enrollees' naïve to therapy.

4. General Transition Process

a. Enrollees with transition fills are provided with the appropriate assistance and information to understand the purpose of the transition with the following steps:

i. The first transition fill of a Part D drug triggers a transition letter process that inform enrollees of the transition fill.
ii. CMS-approved transition letters provide guidance and options for enrollees on how to proceed after receiving temporary transition fill. Enrollees will have the necessary information to work with their health care provider to switch to an alternative drug on formulary if appropriate or to pursue an exception process.
iii. Call Centers are staffed to handle potential call volumes from affected enrollees as well as pharmacies during the transition period. In addition to answering any questions an enrollee or pharmacy has, Call Center agents will also handle any overrides as needed to provide necessary drugs to an enrollee by extending the transition period, on a case-by-case basis, if the enrollee's exception request or appeal has not been processed by the end of the minimum transition period.

5. New Prescriptions vs. Ongoing Drug Therapy

a. The transition processes are applied to a brand-new prescription for a non-formulary drug if a distinction cannot be made between a brand-new prescription for a non-formulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale.

b. CMS approved PA, ST, or QL requirements are applied after the enrollee has exhausted their transition supply, if appropriate. For drugs with PA or ST on new starts only, the Plan Sponsor shall treat such enrollees as current utilizers if the initial fill is allowed because POS determination cannot determine current use is ongoing. Therefore, any PA or ST requirements for new starts are no longer applicable after the first fill has been provided.

6. Transition Timeframes and Transition Fills

a. Timeframe and Transition Supply in Outpatient Settings

i. In the retail setting, the Plan Sponsor's transition process provides at least a month's supply (based on the Plan Sponsor's approved bid) anytime during the first 90 days of an enrollee's enrollment in a plan, beginning on the enrollee's effective date of coverage.

If the enrollee presents with a prescription written for less, in which case, multiple fills up to a total of a month's supply is allowed, or a larger days' supply for prescription products that cannot be broken and:

1. the smallest package size available exceeds a month's supply,
2. require multiple packages to achieve a therapeutic dose or use and

exceeds a month's supply.

b. Timeframe and Transition Supplies in LTC Settings

i. In the LTC setting, the Plan Sponsor's transition program provides:

1. A temporary fill of at least a month's supply or a larger days' supply for prescription products that cannot be broken and: (i) the smallest unit available exceeds a month's supply, (ii) require multiple packages to achieve a therapeutic dose or use and exceeds a month's supply, with refills provided as needed, consistent with the applicable dispensing increment under 42 CFR §423.154 in the LTC setting (unless the enrollee presents with a prescription written for less) during the first 90-days of an enrollee's enrollment in a plan, beginning on the enrollee's effective date of coverage.

2. After their transition period has expired, a 31-day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days), or a larger days' supply for prescription products that cannot be broken and: (i) the smallest unit available exceeds a 31 day supply, (ii) require multiple packages to achieve a therapeutic dose or use and exceeds a 31 day supply, to allow time to request an exception or prior authorization.

3. For enrollees being admitted or discharged from a 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.

7. Transition Extension

The Plan Sponsor makes arrangements to 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 has been made).

8. Transition Across Contract Years for Current Enrollees

a. For current enrollees whose drugs will be affected by negative formulary changes from one contract year to the next, the delegated PBM will effectuate a meaningful transition by either:

i. Providing a transition process at the start of the new contract year, if the enrollee

has history of paid claim(s) for the drug within a designated lookback period which is a minimum of 108 days;

ii. Effectuating a transition prior to the beginning of the new contract year.

b. The transition process is extended to transition supplies across contract years, for enrollees who enroll into a plan with an effective enrollment date of either November 1 or December 1.

9. Emergency Supply for Current Enrollees

An emergency supply of non-formulary Part D drugs is supplied for LTC facility residents as part of the Plan Sponsor's transition program. During the first 90 days after an enrollee's enrollment, the Plan Sponsor's transition program provides a transition supply. However, if an enrollee's transition period has expired and they are in an LTC facility, the enrollee may still receive an emergency supply of non-formulary Part D drugs while an exception or PA is requested. These emergency supplies of non-formulary Part D drugs are for at least 31 days of medication, unless the prescription is written by a prescriber for less than 31 days, or a larger days' supply for prescription products that cannot be broken and: (i) the smallest unit available exceeds a 31 day supply, or (ii) require multiple packages to achieve a therapeutic dose or use and exceeds a 31 day supply.

10. Treatment of Re-enrolled Enrollees

In some cases, enrollees may leave one plan for a period of time to enroll in a different plan and then re-enroll in their original plan. Enrollment dates are tracked so that these enrollees are treated as new enrollees for purposes of receiving transition benefits. That is, the date of the enrollee's re-enrollment in their original plan is used for purposes of applying the transition benefits.

11. Level of Care Changes

Unplanned transitions for current enrollees may arise such as level of care changes in which an enrollee is changing from one treatment setting to another. Enrollees may be admitted to a hospital or LTC facility or they may be discharged home. Early refill edits are not used to limit access to an enrollee's Part D benefit and will be suppressed during level of care changes. Additionally, specific NCPDP pharmacy submission clarification codes may be used for these unplanned transitions and allow for transition fills for each level of care change.

12. Edits for Transition Fills

a. The Plan Sponsor verifies that its PA and ST edits are overridden with the exception of scenarios where:

i. Determination of Part A/B versus Part D coverage is needed
ii. To prevent coverage of non-Part D drugs
iii. To Promote safe utilization of a Part D drug (e.g., a beneficiary-level opioid claim edits; quantity limits based on FDA maximum recommended daily dose such as APAP; early refill edits) during transition at point-of-sale.

b. An automated transition fill process is in place that does not require a dispensing pharmacist to enter an override code, or "hard edit," to permit payment of the claim for the non-formulary drug.

c. Regardless of the type of transition, all the above edits are subject to exceptions and appeals. Exception requests are expeditiously processed so that enrollees are not experiencing unintended interruptions in medically necessary Part D drug therapies and/or are not inappropriately paying additional cost-sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.

d. The Plan Sponsor retains the authority to deny access to quantities or doses during transition when it exceeds FDA safety limits or based upon the same peer reviewed medical literature or well-established clinical practice guidelines used by the Pharmacy & Therapeutics (P&T) committee in formulary management have been exceeded. Prior to implementing such a denial, the Plan Sponsor verifies and tracks that both: (1) an initial transition supply has been provided up to the maximum limit, and (2) the enrollee or prescriber was assisted in filing an exception or that an exception has been processed.

13. Cost Sharing Considerations

The Plan Sponsor verifies that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for Low-Income Subsidy (LIS) eligible enrollees. For non-LIS eligible enrollees, the Plan Sponsor will charge the same cost sharing for non-formulary Part D drugs provided during the transition process 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 process that would apply if the utilization management

criteria are met (i.e., whatever tier the drug is assigned to)

14. Transition Notices

a. The Plan Sponsor provides enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of nonformulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules).

b. Written notice via U.S. first class mail is sent to the enrollee within three (3) business days of adjudication of the temporary transition fill submit date. For LTC 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 sent within three business days of adjudication of the first temporary fill submit date. This turnaround is necessary to provide an affected enrollee with sufficient time -- especially considering CMS' month supply transition fill policy in the retail setting -- to work with his or her prescriber to switch to a therapeutically equivalent drug that is on the plan's formulary or to process an exceptions request. The notice must include the following elements:

i. An explanation of the temporary nature of the transition supply an enrollee has received.
ii. Instructions for working with the Sponsor and the enrollee's prescriber to satisfy utilization management requirements or identify appropriate therapeutic alternatives that are covered on the Sponsor's formulary.
iii. An explanation of the enrollee's right to request a formulary exception, the timeframes for processing the exception, and the enrollee's right to request an appeal if the sponsor issues an unfavorable decision; and.
iv. A description of the procedures for requesting a formulary exception.
v. As indicated above, Capital Rx utilizes the current NCPDP Telecommunication Standard to provide POS messaging. Capital Rx reviews NCPDP reject and approval codes used during transition. Pharmacy messages are updated based on NCPDP and CMS standards and guidelines.

c. Reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice, as noted above. A cover letter and confidential patient profile, which includes the patient's name, address, the drug filled and the reason for notification, are

sent directly to the prescriber of record via U.S. first class mail or to the prescribers' s facsimile.

d. The Plan Sponsor uses the CMS model Transition Notice via the file-and-use process or submits a non-model Transition Notice to CMS for marketing review subject to a 45-day review.

e. Prior authorization (PA) or exceptions request forms are made available upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on the Plan Sponsor's and/or PBM's website.

15. Public Notice of Transition Processes

a. CDPHP makes this program description available to enrollees via a link to our website and a link from Medicare Prescription Drug Plan Finder to the CDPHP website and includes it in pre- and post-enrollment materials as directed by CMS.

b. This information assures enrollees that procedures are in place to assist them in switching to therapeutic alternatives or in obtaining a formulary exception where appropriate when switching plans or switching medications at the start of a plan year. The information may be useful to educate other parties about Plan Sponsor's transition processes.

16. Quality Assurance and Monitoring

Pursuant to CMS guidance, necessary quality assurance checks are performed, such as running test claims for all the types of scenarios on the adjudication system, prior to the start of the plan year. It is the Plan Sponsor's policy to monitor the delegated PBM computer and software systems continually to maintain the timely delivery of transition fills for entitled enrollees. Performance is tracked regarding transition services, and immediate action is taken when problems are identified related to adherence to this CMS Part D Transition Policy.

CDPHP delegates the operational functions of transition fills to its PBM. As a part of the delegation monitoring agreement between CDPHP and the Delegated PBM, CDPHP may elect to identify and monitor a sample of up to 25 transition fill letters that have been mailed to beneficiaries by Delegated PBM during the previous 12 months and request in writing that Delegated PBM produce copies of such sample of transition fill letters. The Delegated PBM will then have 45 days to provide copies of these letters to CDPHP to ensure that the proper CMS turnaround times have been met.

In addition, call center representatives report to the pharmacy department any transition concerns that they receive through either phone calls or working through the coverage determination process. Through daily resolution of CMS issues (and working with the Appeals and Grievance Department), CDPHP may receive issues concerning transition. A CDPHP pharmacist works with the Delegated PBM to solve any transition concerns (including those brought to the attention of CDPHP by the Appeals and Grievance department) and resolve the member's concern within required timeframes.

REFERENCES: Federal Register, Vol. 76, No. 73, Part II, 42 CFR, §423.120(b)(3), §423.153(b), §423.154, § 423.578(b), Chapter 6 Medicare Prescription Drug Benefit Manual, Chapter 3, Medicare Communications and Marketing Guidelines (MCMG)

DEFINITIONS:

Centers for Medicare and Medicaid Services (CMS) – The agency within the US Federal Government that is charged with the execution and maintenance of the law defining the prescription drug program for senior citizens, the disabled, and the infirm.

Emergency Supply - An Emergency Supply is defined by CMS as a one-time transition fill that is necessary with respect to enrollees that are outside of their initial transition period and that are in the LTC setting.

Level of Care Changes - Level of care changes include the following changes from one treatment setting to another:

- Enter LTC facility from hospitals or other settings;
- Leave LTC facility and return to the community;
- Discharge from a hospital to a home;
- End a skilled nursing facility stay covered under Medicare Part A (including pharmacy charges), and revert to coverage under Part D;
- Revert from hospice status to standard Medicare Part A and B benefits; and
- Discharge from a psychiatric hospital with medication regimens that are highly individualized.

LTC - Long Term Care

National Council for Prescription Drug Programs (NCPDP) – a 501(c)(3) nonprofit charitable organization that comprises of subject matter experts that provides guidance and standards on health information technology such as pharmacy claim adjudication.

Prior Authorization (PA) - The process undertaken to make a benefit determination that is made prior to the intended delivery of the healthcare service, treatment, or supply under review (e.g., a Pre-Service

Claim). Prior Authorization includes requests for coverage determination for medications that are designated on the client part D formulary as "Prior Authorization Required", "Step Therapy", "Quantity Restrictions" or for requests for exception for non-formulary medications or co-insurance amount.
Plan - Medicare Part D Plan Sponsors who are PBM clients.
Point-of-Sale (POS) - The acronym given to the PBM's point-of-sale prescription transaction processing computer system. Also indicates that the actual retail transaction occurs when the claim is submitted electronically by the pharmacy.
Policy Administration - The Medicare Advantage and Medicare Prescription Drug Compliance Officer is responsible for the oversight regarding the performance under this policy.
Quantity Limit (QL) – Type of utilization management that limits the quantity of a medication an enrollee may receive.
Step Therapy (ST) – Type of utilization management that requires a trial(s) of other medication(s) before another medication may be covered.
Utilization Management (UM) - a technique is used by insurance companies, health plans, managed care entities, payers, etc., to manage the cost of health care benefits by assessing its appropriateness before covering a drug or service by using evidence-based criteria or guideline. These techniques are typically prior authorization (PA), step therapy (ST), and quantity limits (QL).

Sean P. Roche, MD

Medical Director

Revision Log	**Date**
Initial Policy Creation	5/17/2022
Reviewed- no changes	5/15/2023
Reviewed-no changes	5/16/2024
Reviewed-no changes	7/25/2024