Contract: **H0104, S1030**
Policy Name: **Medicare Formulary Transition**

Purpose:
This procedure describes the standard process the Plan Sponsor, its divisions and subsidiaries, and its pharmacy benefit manager (PBM), uses to develop and maintain the Medicare Transition Program.

Policy:
It is the policy of the Plan Sponsor to maintain a Transition Program that adheres to the Centers for Medicare & Medicaid Services (CMS) requirements, including the application of transition benefits to members obtaining medications in retail and Long-Term Care (LTC) settings, as well as temporary fills for all entitled members. A copy of the Medicare Transition Program Description (program description) is submitted to CMS upon request.

Relevant Law and/or Regulation and/or Guidance:
42 CFR § 423.120(b)(3)
42 CFR § 423.154
42 CFR §423.578(b)
42 CFR §423.154(a)(1)(i)
CMS Prescription Drug Benefit Manual: Chapter 6

Products Impacted:
☒ Medicare ☐ Medicaid ☐ Commercial

Scope:
Government Programs and Formulary Operations
Medicare Information Technology (IT)
Clinical Programs
Eligibility
Member Materials
Government Programs Compliance
Government Programs Client Engagement
Government Programs Regulatory and Audit

Definitions:

Formulary Exception (FE): An exception process which defines when a Non-formulary medication is covered (or has specific copay) under a closed formulary prescription drug benefit design. Examples may include:
• A dose restriction, including the number and/or dosage form, that causes a particular Part D drug not to be covered for the number of doses prescribed,
• A step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met,
• A therapeutic substitution requirement

• Continued coverage of drugs for which the plan is discontinuing coverage for reasons other than safety or because the prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

Prior Authorization (PA): A requirement that specific criteria be met before the drug is covered (or has a specific copay) under a prescription benefit. Medications are selected for PA because they have actual or potential misuse, overuse, or inappropriate use that could be of clinical concern, economic concern or both.

Quantity Limit (QL) Exception: A request from an enrollee, enrollee's appointed representative or physician or other authorized prescriber that requires that specific Medicare Part D sponsor approved clinical criteria be met before the medication requesting more than the defined quantity limit will be paid under an enrollee's prescription benefit.

Step Therapy (ST): A utilization management tool which requires use of one or more drugs in a step-wise, graduated manner for cost or quality reasons. If a member does not respond satisfactorily, progressively more or different therapy is prescribed as needed. Protocols for ST can govern which prescription drug claims adjudicate for a given member.

Utilization Management (UM): Utilization Management is the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and facilities under the provisions of the applicable health benefits plan; sometimes called "utilization review" (URAC definition).

Background:
The Plan Sponsor recognizes and works to maintain compliance with the dual goals of the Medicare Transition Program (Program), which are: (1) making certain that eligible Part D members receive their temporary transition supply of non-formulary Medicare Part D drugs, including Part D drugs that are on the Plan Sponsor's formulary but require Prior Authorization (PA), Step Therapy (ST), and/or Quantity Limits (QL) under the Plan Sponsor's Utilization Management (UM) rules, and (2) providing Part D members with sufficient time to work with their health care providers to switch to therapeutically-appropriate formulary alternatives or to request a PA or Formulary Exception (FE) on the grounds of medical necessity. The Plan Sponsor administers this Program consistent with CMS regulations and manual requirements, as amended from time to time.

This program description addresses the following elements:

1. Transition Requirements
2. General Transition Process
3. New Prescriptions vs. Ongoing Drug Therapy
4. Transition Timeframes and Temporary Fills
5. Timeframe and Transition Fills in Outpatient Settings
6. Timeframe and Transition Fills in LTC Settings
7. Transition Extensions
8. Transition Across Contract Years for Current Members
9. Emergency Supply for Current Members
10. Level of Care Changes

11. Edits for Transition Fills
12. Cost Sharing Considerations
13. Transition Notices
14. Public Notice of Transition Processes

Implementation Statement:
An automated transition benefit process is in place to systematically process transition claims for non-formulary Part D drugs (including Part D drugs that are on the Plan Sponsor's formulary but require PA, ST, or have QL under the Plan Sponsor's utilization management rules) appropriately.

Specific point-of-sale messaging is applied to non-formulary Part D drug claims. Specifically, the point-of-sale messaging provides an explanation for the claim being paid or rejected (e.g. due to the medication being non-formulary) as well as Plan Sponsor's toll-free Pharmacy Contact Center's phone number to call for more information on rejected transition claims.

Claim edits are applied during transition at point-of-sale regarding Part A or B versus Part D coverage where a coverage determination must first be made, to prevent coverage of a non-Part D drug, and to promote safe utilization of a Part D drug.

The transition fill process has been automated and does not require a dispensing pharmacist to enter an override code, or "hard edit," prior to paying the claim for the non-formulary drug.

Plan Sponsor's transition program identifies new members in an outpatient setting and allows a one-time, temporary fill for at least a month's supply (unless the member presents with a prescription written for less, in which case multiple fills are permitted to provide up to a total of a month's supply of medication), or a larger days' supply for prescription products that cannot be broken and: (i) the smallest package available exceeds a month's supply, or (ii) require multiple packages to achieve a therapeutic dose or use and exceeds a month's supply, anytime during the first 90 days of a member's enrollment in a plan, beginning on the member's effective date of coverage under the Contract & Plan Benefit Package (PBP). If a member has received their one-time transition fill (or up to the allowed day supply) for that non-formulary or UM drug, the TBO logic does not apply to that drug and the claim rejects unless the member has obtained authorization.

The Plan Sponsor also verifies that the transition program identifies new members in a LTC setting and allows a temporary one month's supply consistent with the dispensing increment (unless the member presents with a prescription written for less) with refills provided if needed, of non-formulary Part D drugs anytime during the first 90-days of a member's enrollment in a plan, beginning with the member's effective date of coverage under the contract and PBP.

To confirm that the claims adjudication system is processing correctly, Quality Assurance Specialists and Audit representatives monitor claims for accuracy.

An extension of the transition period is provided on a case-by-case basis if the member's exception request or appeal has not been processed by the end of the minimum transition period and only until the member has switched to an appropriate formulary drug or a decision on an exception request has been made.

For current members whose drugs are removed from the Plan Sponsor's formulary from one contract year to the next, or has formulary drugs that remain on formulary, but to which a new PA, ST, or QL restriction is added from one contract year to the next, or who might otherwise be denied access to current therapy of a non-formulary drug, a meaningful transition is effectuated by either:

1. Providing a transition process at the start of the new contract year, if the member has history of paid claim(s) for the drug within a designated lookback period which is a minimum of 108 days; or
2. Effectuating a transition prior to the beginning of the new contract year.

This transition policy is extended across contract years if a member enrolls into a plan with an effective enrollment date of either November 1 or December 1 and needs access to a transition supply.

1.0 Transition Requirements

1.1 Affected Members. An appropriate transition program consistent with 42 CFR § 423.120(b)(3) is maintained that includes this description of how, for members whose current drug therapies may not be included in their new Part D plan's formulary, it effectuates a meaningful transition for:
(1) New members into prescription drug plans following the annual coordinated election period;
(2) Newly eligible Medicare members from other coverage;
(3) Members who switch from one plan to another after the start of the contract year;
(4) Current members affected by negative formulary changes across contract years; and
(5) Members residing in LTC facilities.

1.2 Applicable Drugs. This transition policy applies to non-formulary drugs, including:
(1) Part D drugs that are not on the Plan Sponsor's formulary, and
(2) 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 beneficiary's current dose, under the Plan Sponsor's utilization management requirements.

This transition policy includes procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new Part D plan members to therapeutically appropriate formulary alternatives, failing an affirmative medical necessity determination.

The non-formulary criteria (approved by the Pharmacy & Therapeutics (P&T) Committee) outlines the process that the patient has tried and failed formulary (any formulary tier) alternatives (if applicable) for the diagnosis being treated with the requested drug or that the prescriber has indicated that available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the

patient. During the coverage determination process, the Plan Sponsor obtains information pertaining to the medical necessity of the requested non-formulary drug and issues a decision. If not deemed to be medically necessary, the Plan Sponsor will provide the member and prescriber with the rationale for denial, including alternatives available on the formulary when appropriate.

System capabilities allow a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of a member. This allows the Plan Sponsor and/or the member sufficient time to work with the prescriber to make an appropriate switch to a therapeutically-equivalent medication or complete an exception request to maintain coverage of an existing drug based on medical necessity reasons.

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.

2.0 General Transition Process

Members who have used a transition benefit are provided with the appropriate assistance and information necessary to enable them to understand the purpose of the transition. In order to provide a meaningful transition, the following steps are taken:

1. Analysis of claims data within the claims adjudication system to determine which members require information about their transition supply.
2. Contacting those identified members through transition mailings to provide them with the necessary information to enable them to switch to a formulary product or, as an alternative, to pursue a necessary prior authorization.
3. Identification of staffing requirements necessary to process transition requests prior to the new benefit plan year. In particular, this includes increasing Contact Center capacity (including pharmacy help lines) to respond to an anticipated increase in call volume from affected members regarding the transition process.
4. Arrangements to continue to provide necessary drugs to a member by extending the transition period, on a case-by-case basis, if the member's exception request or appeal has not been processed by the end of the minimum transition period.

As a part of this policy members are provided with clear guidance regarding how to proceed after a temporary fill is provided by utilizing CMS-approved Transition Letters to apprise members of their options.

3.0 New Prescriptions versus Ongoing Drug Therapy

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.

CMS approved PA, ST, or QL requirements are applied after the transition fill has been satisfied, when appropriate. For protected class drugs that are subject to PA or ST on new starts only, the Plan Sponsor shall treat such members as current utilizers if the initial fill is allowed because point of sale determination cannot be made regarding current use/ongoing therapy for protected class drugs. Therefore, any protected class PA or ST requirements for new starts are no longer applicable after the first fill has been provided.

4.0 Transition Timeframe and Transition Supply

4.1 Timeframe and Transition Supply in Outpatient Settings

In the retail setting, the Plan Sponsor's Program provides for at least a month's supply (unless the member presents with a prescription written for less, in which case multiple fills are permitted to provide at least a month's supply of medication), or a larger days' supply for prescription products that cannot be broken and: (i) the smallest package available exceeds a month's supply, or (ii) require multiple packages to achieve a therapeutic dose or use and exceeds a month's supply, anytime during the first 90 days of a member's enrollment in a plan, beginning on the member's effective date of coverage.

4.2 Timeframe and Transition Supplies in LTC Settings

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 package available exceeds a month's supply, or (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 in the LTC setting (unless the member presents with a prescription written for less) during the first 90-days of a member's enrollment in a plan, beginning on the member'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 member 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 package available exceeds a 31 day supply, or (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 members 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 members are allowed to access a refill upon admission or discharge.

4.3 Transition Extension

The Plan Sponsor makes arrangements to continue to provide necessary Part D drugs to members 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).

5.0 Transition Across Contract Years

For current members whose drugs will be affected by negative formulary changes from one contract year to the next, our program allows for effectuation by either of the two methods noted below:

1. Providing a transition process at the start of the new contract year, if the member has history of paid claim(s) for the drug within a designated lookback period which is a minimum of 108 days;
2. Effectuating a transition prior to the beginning of the new contract year.

The Program is extended across contract years, if a member enrolls into a plan with an effective enrollment date of either November 1 or December 1 and needs access to a transition supply.

6.0 Emergency Supply for Current Members in the LTC Setting

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 a member's enrollment, the Plan Sponsor's transition program provides a transition supply. However, if a member's transition period has expired and they are in a LTC facility, the member still receives 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 package available exceeds a 31 day supply, or (ii) require multiple packages to achieve a therapeutic dose or use and exceeds a 31 day supply.

7.0 Treatment of Re-Enrolled Members

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

8.0 Level of Care Changes

In addition to circumstances impacting new members who may enter a plan with a medication list that contains non-formulary Part D drugs, other circumstances exist in which unplanned transitions for current members could arise and in which prescribed drug regimens may not be on the Plan Sponsor's formulary. These circumstances usually involve level of care changes in which a member is changing from one treatment setting to another.

For these unplanned transitions, members and prescribers must avail themselves of the Plan Sponsor's exceptions and appeals processes. Coverage determinations are processed and redeterminations are made as expeditiously as the member's health condition requires.

In order to prevent a temporary gap in care when a member is discharged to home, members are permitted to have a full outpatient supply available to continue therapy once their limited supply provided at discharge is exhausted. This outpatient supply is available in advance of discharge from a Part A stay.

When a member is admitted to or discharged from an LTC facility, and does not have access to the remainder of the previously dispensed prescription, a one-time override of the "refill too soon" edits is processed for each medication which would be impacted due to a member being admitted to or discharged from a LTC facility. Early refill edits are not used to limit appropriate

and necessary access to a member's Part D benefit, and such members are allowed to access a refill upon admission or discharge.

9.0 Edits for Transition Fills

The Plan Sponsor will only apply the following utilization management edits during transition at point-of-sale:

1. Determine Part A/B versus Part D coverage
2. Prevent coverage of non-Part D drugs
3. 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.

Step therapy and prior authorization edits must be resolved at point-of-sale.

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.

Regardless of the type of transition, all of the above edits are subject to exceptions and appeals. Exception requests are expeditiously processed so that members 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.

The Plan Sponsor retains the authority to deny access to quantities or doses during transition (e.g., where clearly articulated safety limits established by the FDA 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 member or prescriber was assisted in filing an exception or that an exception has been processed.

10.0 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 members. For non-LIS eligible members, 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.

11.0 Transition Notices

Written notice via U.S. first class mail is sent to the member within three (3) business days 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 the first temporary fill submit date.

The notice must include:

1. An explanation of the temporary nature of the transition supply a member has received.
2. Instructions for working with the Sponsor and the member's prescriber to satisfy utilization management requirements or identify appropriate therapeutic alternatives that are covered on the Sponsor's formulary.
3. An explanation of the member's right to request a formulary exception.
4. A description of the procedures for requesting a formulary exception.

Reasonable efforts are made to notify prescribers of affected members 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.

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.

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

The claims adjudication system utilizes the current NCPDP Telecommunication Standard to provide POS messaging so that appropriate transition claims (for non-formulary Part D drugs) receive transition-specific POS messaging.

12.0 Public Notice of Transition Processes

The Plan Sponsor makes this program description available to members via a link from Medicare Prescription Drug Plan Finder to the Plan Sponsor's web site and include it in pre- and post-enrollment marketing materials as directed by CMS.

The purpose of this information is to reassure members that there are procedures in place to assist them in switching to therapeutic alternatives or in obtaining a formulary exception, as appropriate. In addition, the information may be useful to educate advocates and other parties about Plan Sponsor's transition processes. Where available, the Plan Sponsor uses CMS model language and standardized formatting for transition process information and communications.

13.0 Quality Assurance

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 its computer and software systems continually in order to maintain the timely delivery of transition fills for entitled members. Performance is tracked with regard to transition services, and immediate action is taken when problems are identified related to adherence to this CMS Part D Transition Policy.