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Medicare Part D Policy Document

I. General Description					
Number:	Medicare-TS-04			**Revision:**	
Title:	2016 Medicare Part D – Transition Supply				
Effective Date:	Jan 1, 2016	**Revision Date:**	4/19/2015	**Validation Date:**	
Prepared By:	T. Deubel			**Distribution:**	External/Internal

Regulation/Requirement:	42 CFR §423.120(b)(3) Prescription Drug Manual, Chapter 6, Section 30.4
Purpose:	This document defines Amida Care Policy which ensures compliance with Medicare Part D transition supply requirements
Scope:	This Policy is applicable to the Amida Care Prescription Drug Plan and its enrollees covered under CMS Contract H6745.
Policy:	Where applicable and as required by CMS, Amida Care provides transition supplies to new and current enrollees. Transition processes are designed to ensure that transition eligible members have continued access to needed drugs where the drug meets one or more of the following conditions: not included on the Plan's formulary or is on the Plan's formulary but is subject to utilization management rules including Prior Authorization, Step Therapy or Plan imposed Quantity limits. The process ensures that enrollees are given sufficient time to work with their health care providers to switch to a therapeutically appropriate formulary alternative or to request an exception on the grounds of medical necessity.

II. Definitions	
CMS	Centers for Medicare and Medicaid Services – The United States federal agency responsible for administering the Medicare Health Insurance Program.
Express Scripts, Inc. (ESI)	The pharmacy benefit management organization who is delegated the role of providing services to clients that operated as a Medicare-Medicaid Plan Sponsor.
Amida Care P&T	Amida Care Pharmacy and Therapeutics Committee – A group of independent, actively practicing physicians and pharmacists who are not employed by Amida Care.
HICL	Hierarchical Ingredient Code List- One of First Data Bank's Smart Key that identifies the chemical ingredient of a drug.
GCN	Generic Code Number - One of First Data Bank's Smart Keys that is specific to a particular drug
LTC	Long Term Care – A facility that provides long-term care including

	the dispensing of Part D covered drugs.
MDD	Maximum Daily Dose – The maximum amount of a drug per dosing event as defined by the manufacturer and included on approved drug labeling.
Current Enrollee	A beneficiary who remains enrolled in an Plan across a contract year without any gaps in coverage.
New Enrollee	Beneficiaries who enroll for the first time into a Plan through voluntary or passive enrollment.
Pharmacy and Therapeutics Committee (P&T)	A committee, comprising of members from various clinical specialties, that makes decisions affecting formulary content, including exceptions, tier value, prior authorizations, step therapies, quantity limitations, generic substitutions and other drug utilization activities that affect drug access.
Part D Eligible Drugs	Medications determined by Medicare to count toward the true out of pocket costs for a Medicare Part D beneficiary.
RT	Route of Administration – One of First Data Bank's Smart Key that identifies how a drug is administered (e.g., oral, injectable)
RTS	Refill Too Soon – Ann edit that exists indicating that a drug claim has been presented too early for the pharmacy to dispense to an enrollee.
SCF	Short Cycle Fill – Guidance and related edits pertaining to enrollees receiving certain drugs in a long-term care setting. Drugs subject to short-cycle fill edits were defined by CMS and must be dispensed to patients in limited quantities as per the CMS guidance.

III. Policy		
Task 1:	**<u>Transition Requirements</u>**	
	1.1	The Part D Plan policy and related processes ensures transition supplies are extended to members in the following scenarios that are consistent with 42 CFR §423.120(b)(3): (1) New enrollees into its Prescription Drug Plan at the beginning of the plan year; (2) Newly eligible Medicare beneficiaries from other coverage at the beginning of the contract year; (3) Individuals who switch from one Plan to another after the beginning of a contract year; (4) Enrollees residing in LTC facilities; (5) Current enrollees affected by a formulary change from one contract year to the next and;

		(6) In some cases, enrollees who change treatment settings due to a change in their level of care.
	1.2	For current enrollees whose drugs are no longer on the Plan's formulary, or remain on the formulary but to which new prior utilization, quantity limits, or step therapy restrictions are applied, the Plan will effectuate a meaningful transition by either: (1) Providing a transition process consistent with the transition process required for new enrollees beginning in the new contract year or ; (2) Effectuating a transition prior to the beginning of the new contract year. A current enrollee is provided with a 90 day cross-plan year transition window at the beginning of each contract year. During this time, a current enrollee will be provided with a transition supply of an eligible drug anytime there is evidence of prior utilization of the drug within a 365 day look back window, unless the drug was previously filled as a transition supply. A look-back window begins on the last day of the previous plan year and extends 365 days prior. Prior utilization is confirmed based on the HICL and Route of Administration code associated with the drug on the incoming claim to any claim that paid for the enrollee within the same CMS Contract ID for the same HICL and RT code. If the member is lacking utilization within the look-back window will preclude a transition supply from being extended to a current enrollee during their cross-plan year window as that member is not impacted by transition.
	1.3	The transition process is applicable to non-formulary drugs, meaning both: (1) Part D drugs that are not on a Plan's formulary (2) Part D Drugs that are on a Plan's formulary but require prior authorization or step therapy under a Plan's utilization management rules. The Plan will ensure that its policy addresses procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. This will be addressed through the Plan's coverage review process and care coordination process.
Task 2:	**<u>Transition Submission</u>**	
	The Plan will submit a copy of its transition policy to CMS. The Plan will ensure all submission are per CMS guidelines and ensure the policy conforms to the requirements of the prescription drug manual, Chapter 6, section 30.4	
Task 3:	**<u>New Prescriptions Versus Ongoing Drug Therapy</u>**	
	The Plan ensures that transition processes are applied to both new and ongoing prescriptions for a non formulary drug at the point of sale as we cannot always make the distinction if the	

		prescription is new or continuing therapy. Since new and refilled prescriptions for on-going therapy for a transition eligible drug cannot always be distinguished, the Plan's transition process does not limit a transition supply to one fill. The process will allow for refills of a transition eligible drug at the point of sale to ensure enrollees receive at least a 30 day supply of a transition eligible drug. In some cases, more than a 30 day supply will be extended up to the point the total transition day supply is exhausted. The transition day supply may also be exceeded when the drug is prepackaged and cannot be dispensed at a lower day supply.
Task 4:	**<u>Transition Timeframes and Temporary Fills</u>**	
	4.1	At retail, home-infusion or mail-order pharmacies, The Plan ensures that in the retail setting, the transition policy provides for at least a one-time, temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days in which case the Plan will allow multiple fills to provide up to a total of 30 days of medication) anytime during the first ninety days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage. In some instances, greater than a 30 day supply will be dispensed in order to avoid having an enrollee that encounters a hard reject leave the pharmacy without their prescribed drug.
	4.2	The Plan will ensure that in the long-term care setting: (1) the transition policy provides for a 91 to 98 day fill consistent with the dispensing increment (unless the enrollee presents with a prescription written for less), with refills provided if needed during the first 90 days of a beneficiary's enrollment in a 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 a LTC facility, early refill edits can be overridden at point of sale to ensure the member is able to access their Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge.
	4.3	The Plan will continue to provide necessary Part D drugs to enrollees via an extension of the transition period, on a case-by-case basis, when 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 to either a switch to an appropriate formulary drug or a decision on the exception request.
	4.4	The Plan has system capabilities that allow them to provide 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 Plan 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 reasons.
Task 5:	**Transition Across Contract Years**	
	The Plan will extend its transition policy across contract years should a beneficiary enroll in a plan with an effective enrollment date of November 1 or December 1 and need access to a transition supply. Special handling is in place to ensure appropriate treatment of those members with respect to a transition supply and a window that crosses a contract year. These new enrollees are ensured a minimum 90 day transition window under this across plan year transition process	
Task 6:	**Emergency Supply for LTC Members Outside of their Transition Period**	
	Anytime an enrollee is outside of their transition window and presents a drug claim while in an LTC facility, the claim will hard reject with the message IF LEVEL OF CARE prompting the pharmacy to contact the Pharmacy Services Help Desk. A manual process is used to confirm whether or not the member is eligible for an emergency fill. If the member is eligible and the enrollee receives the emergency supply, transition notifications will be generated for both member and prescriber.	
Task 7:	**Level of Care Changes**	
	Enrollees whose transition window has expired and who present a drug claim that is otherwise transition eligible, the claim will reject with appropriate reject codes returned to the pharmacy. There is additional secondary messaging associated in these cases to inform the pharmacy to contact the help desk if a level of care change has occurred for the enrollee. Anytime a pharmacy takes the action to contact the help desk as per the rejected claim secondary messaging, a manual process is used to confirm whether or not a level of care change has occurred for the enrollee. When the process is invoked and a level of care change is confirmed, the help desk attendant provides a series of override codes to the calling pharmacy to allow a one-time transition supply to be dispensed and the associated notifications generated. This secondary reject messaging to the pharmacy and the associated manual process may also occur for a member still within their transition window who has already received a transition supply of the drug which satisfied the Plan's transition obligation to the enrollee. In addition, the Plan is provided daily rejected claims data for oversight of these members experiencing a change in their care.	
Task 8:	**Edits for Transition Fills**	
	8.1	The Plan's transition process will automatically effectuate a transition supply where appropriate for members except where the following edits apply to the claim: (1) Determine Part B versus Part D overlap drugs; (2) Edits to prevent coverage of non-Part D drugs; (3) Edits to promote safe utilization of a Part D drug; (4) SCF requirements;

		(5) The drug on the claim is being refilled too soon. Secondary messaging is sent to the pharmacy to further inform the pharmacy on the reason for the edit and additional required action on the part of the pharmacy to ensure eligible member's transition fills of needed medications are appropriately dispensed. In the case of Part B versus D overlap drugs or excluded drugs, a coverage determination is required prior to payment. Step Therapy and Prior Authorization edits will be resolved at POS through system logic.
	8.2	The Plan will ensure that the transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits that are based on approved product labeling.
Task 9:	**<u>Cost-Sharing Considerations</u>**	
	The Plan will ensure that when a transition supply is dispensed to a low-income subsidy eligible enrollee under the transition process, the enrollee cost sharing will never exceed the statutory maximum copy amounts for low-income subsidy members. For non-LIS enrollees, the Plan will charge the same cost sharing for non-formulary drugs provided during transition that would apply for non-formulary drugs if an approved coverage exception is applied in accordance with 42 CFR § 423.578	
Task 10:	**<u>Transition Notices</u>**	
	10.1	The Plan will send a written notice via USPS First Class Mail to enrollee within three business days of adjudication of a temporary 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 Plan and the enrollee's prescriber to identify appropriate therapeutic alternatives that are on the Plan's formulary; (3) An explanation of the enrollee's right to request a formulary exception; 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 fourteen days-or-less. The Plan will submit the transition notice to CMS for marketing review via the file-and-use process or as a non-model transition notice subject to a 45-day review. The Plan's system interrogates the daily claims data to identify enrollees who received a transition supply of a drug for the first time on the prior business day. That information is used to generate a notification to the enrollee about their transition supply. The notification includes information to enable them to switch to a formulary product and, as an alternative, provides information to assist the enrollee in requesting an exception allowing them to continue receiving the existing drug.

	10.2	The Plan will also ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice. Prescriber notifications are targeted for mailing within five business days of the adjudication date of a transition supply dispensed to their patient. Prescriber notification utilizes a separate letter for the prescribing physician notifying them of the type of transition supply obtained by the member.
	10.3	There are circumstances in which notifications cannot be mailed to either a member or a prescriber. Those circumstances include members for whom the Plan does not have an approved USPS mailing address on file, prescribers for whom may have a transient address, and situations where the transition claim has been reversed prior to the notification being generated.
Task 11:	**Exception Request Forms**	
	Enrollees and prescribers may call Customer Service lines and request a prior authorization or exceptions request forms upon request via a variety of mechanisms including mail, fax, email or they may download it from the Plan's website.	
Task 12:	**Public Notice of Transition Process**	
	The Plan will make their transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to the Plan's web site and include in pre-and post-enrollment marketing materials as directed by CMS.	
Task 13:	**Transition Process Oversight and Monitoring**	
	The Plan oversees and monitors the Transition Supply process to ensure that enrollees have access to necessary drugs as required by CMS guidance. Reporting is made available to show paid and rejected transition supply claims and member and prescriber communication mailings. Rejected claims where a transition supply may be in order because the enrollee is within a transition window are monitored three times a day. When action is not taken by a pharmacy to clear a reject and successfully adjudicate the claim, outreach is made by automated outbound messaging to assist the pharmacy attendant through the steps necessary to have the claim pay.	
Task 14:	**Role of the Pharmacy and Therapeutics Committee**	
	The P&T Committee performs the following functions relative to the Transition Supply process:	
	14.1	Reviews and approves the Medicare Part D Transition Policy as outlined in this document on an annual basis.
	14.2	Per CMS guidance, P&T involvement will help ensure that transition decisions

		appropriately address situations involving enrollees stabilized on drugs that are not on The Plan's formulary. This is accomplished via annual P&T review and approval of the appropriate Policies and Procedures.
	14. 3	Per CMS guidance, P&T involvement will help ensure that transition decisions appropriately address situations involving enrollees stabilized on drugs that are on the formulary but are subject to Prior Authorization, Step Therapy, and Quantity Limits as part of a Plan's utilization management requirements. This is accomplished via P&T review and approval of the appropriate Policies and Procedures.

IV. Approval History

Rev	Approver Name	Department Name	Date
1	 Kathryn Mihalevich - Chair VP Government Programs Compliance	Policy Committee	05/28/2014
	Kathryn Mihalevich - Chair	Policy Committee	05/23/2014

V. Revision History

Rev	Step(s)	Summary of Revision(s)		Date	Approved By
New		Orig:	New F-14 Policy for 2016 Transition Supply – Health Plan Template	4/19/2015	Policy Committee

VI. Attachments

A) Related Policies/Procedures/Work Instructions:
Implementation Statement

B) Retired Polices:
None

Attachment A

Amida Care, Inc.
Transition Supply – Implementation Statement

This document provides the following information:

- A detailed explanation of the Amida Care processes in support of transition supply requests within our adjudication system;
- How a pharmacy is notified when a transition supply of medication is processed at the point of sale; and
- A description of the edits and an explanation of the process pharmacies must follow to resolve those edits at the point of sale during the adjudication of a transition supply.

The Plans adjudication process that supports transition supply requirements operates as follows:

1. A mail-order, retail or Long Term Care (LTC) pharmacy receives a prescription request from:
   - A enrollee who is new to a CMS Plan and within their first 90 days of enrollment or
   - An existing enrollee at the beginning of a plan year who is established on a drug that has become transition eligible or
   - An enrollee who has experienced a Level of Care change or
   - A LTC resident enrollee in need of an emergency supply
2. The pharmacy submits the prescription request and the drug is either non-formulary or, on the formulary but with utilization management edits applied.
3. The process verifies that the enrollee is a member in a Part D plan.
4. Verification that the enrollee is within a transition window occurs by interrogating their available Part D eligibility history.
5. The process verifies that the drug submitted qualifies for a transition supply based on the reject messaging about to occur. The rejects indicate one of the four transition eligible categories: Non-Formulary, Prior Authorization Required, Step Therapy rules and Quantity rules.
6. The process determines the allowable days supply for a transition fill.
7. The process verifies that the enrollee is eligible for a transition supply of the drug based on the date of service on the claim falling within their transition window.
8. If an LTC enrollee is outside of a transition window and presents a transition eligible prescription drug request, the process will hard reject the claim and return an IF LEVEL OF CARE CHANGE message to the pharmacy with instruction to contact the pharmacy help desk to determine if the enrollee is eligible for an emergency supply.
9. An existing enrollee is eligible when a paid claim is found within the last 365 days of the previous plan year for the same drug (defined by HICL/RT) within the same CMS Contract ID and the history claim did not pay under transition logic.
10. Using the submitted days supply from the claim, the process will verify that the claim is within the transition days supply limit or has remaining transition day supply to be dispensed.

- Option 1 – Hard reject on transition day supply Transition claims will be limited to the transition day supply limit established unless it is a prepackaged drug and cannot be dispense lower than the transition day supply. Refills may be allowed on transition claims up to the point where the transition day supply obligation has been met or exceeded by the last fill.
- Option 2 – Hard reject on overarching plan day supply Transition claims may provide greater than the transition day supply limit established but not more than the overarching plan limits. Refills may be allowed on transition claims up to the point where the transition day supply obligation has been met or exceeded by the last fill.
- When greater than the overarching plan limits, the claim will hard reject and a message will be returned to the pharmacy noting the allowable day supply/quantity for a transition fill. The pharmacy is then notified to resubmit the claim within the limits presented in the message.

11. Daily outreach via telephone Update for AOM is made to any retail network pharmacy that does not resolve hard rejects for a transition eligible claim on their own. The outreach is intended to achieve a paid transition supply claim for an enrollee.
12. If a previous transition supply of the same drug was already dispensed within the same transition window, the process will verify whether a refill is allowable based on the previous days supply already dispensed.
13. If a required full transition supply was found to have already been provided to the enrollee while in their transition window, the process will hard reject the claim and return an IF LEVEL OF CARE CHANGE message to the pharmacy with instruction to contact the pharmacy help desk to determine if the enrollee is eligible for a Level of care fill.
14. The process will calculate cost-sharing for the transition supply. Formulary drugs that require Prior Authorization or that have Step Therapy and Quantity rules applied will be priced within the Co-Payment Tier on which the drug resides. When a non-formulary drug is provided, the co-payment is calculated based on one tier lower than the non-formulary tier, thereby providing the drug at the formulary cost-sharing amount.
15. The process will successfully adjudicate the claim and message the pharmacy with a paid response of either "TRANSITION FILL" or "EMERGENCY SUPPLY" depending on the type of adjudication which was completed.
16. The required member notifications are mailed within 3 business days of the first fill of a transition supply (mail notifications for refills of a transition supply are not generated).
17. The required prescriber notifications are mailed within 5 business days after the first fill of a transition supply (mail notifications for refills of a transition supply are not generated).
18. The Plans' adjudication process described above which supports transition supply requirements from CMS will automatically pay a claim barring certain instances where a hard reject is returned that require the pharmacy to take action before resubmitting the claim and achieving a paid transaction.

Whenever an edit is in place that triggers the hard reject of a transition eligible claim for a transition eligible member, the pharmacy is required to take steps in order to achieve a paid

transaction. The steps required by the pharmacy are included in the associated messaging returned at point of sale. The hard reject messaging conditions that may be triggered during adjudication of a transition supply eligible claim are:

1. Plan Limitations Exceeded
   When this message is returned, the pharmacy is required to modify the submitted quantity to be equal to or less than the amount included in the point of sale message. Upon resubmission with corrected information, the transition supply claim will pay and be marked as a transition supply. One message text example is: "ALLOW QT nnnn."
2. If Level of Care Change Call Help Desk
   When this message is returned, the pharmacy is required to contact the Pharmacy Help Desk. A process is in place with the Help Desk and includes a series of questions that are posed to the pharmacy. If any of the questions are answered with YES, then a level of care change is confirmed. The Help Desk provides override codes to the pharmacy to place on the claim and the pharmacy is asked to resubmit. Upon resubmission with the override codes the claim will pay and be marked as a transition supply
3. Maximum Daily Dose Exceeded
   For patient safety reasons, the recommended maximum daily dose (MDD) will not be exceeded when dispensing a transition supply of a drug. When this message is returned, the pharmacy is required to modify the submitted quantity or apply the appropriate override. Upon resubmission, these transition supply claims will then automatically pay and be marked as a transition supply. One message text example is: "MX DOSE/DAY= nnn OVR/DR APV."
4. Refill Too Soon (RTS)
   To limit inappropriate or unnecessary access to Part D drugs, an early refill edit will trigger a hard reject for a Transition eligible drug during an enrollee's transition period. The Plan's RTS logic considers paid claims, both mail and retail, for the same drug, dispensed in the previous 180 days to calculate an on-hand days' supply. The pharmacy may resubmit a claim with overrides for RTS at point-of-sale but limits the override use to 2 for each of the following reasons within 180 days:
   - Therapy change,
   - Lost or spilled medication,
   - Vacation supply.

   The Plan's RTS allowance requires that an enrollee has consumed at least 70% of their drug on-hand of an ophthalmic agent and at least 75% of any other medication. The consumption requirement for enrollees in an LTC facility is 50%.
5. Med B/D Determination Required
   B/D overlap drugs are excluded from Transition Supply processing. Messaging returned to the pharmacy indicate "B/D Determination Required."
6. Med D/non D Determination Required
   D/non-D drugs are excluded from Transition Supply processing. Messaging returned to the pharmacy indicate "Med D/Non-D Determination Req."
7. Short Cycle Fill (SCF)
   To comply with CMS guidance related to the LTC pharmacy requirement to dispense certain Part D drugs in small increments, various edits exist that may trigger a hard reject for an enrollee during a transition period. All SCF related hard rejects occur prior to transition

supply processing and are required to be cleared by the LTC pharmacy before the claim will automatically pay as a transition supply. Once the rejects are cleared and a paid transition supply claim is adjudicated, the pharmacy receives one of the two paid claim messages of "TRANSITION FILL" or "EMERGENCY SUPPLY".