Philosophy/Purpose:
Health Alliance Plan (HAP) will maintain an appropriate transition process in accordance with federal regulations CFR § 423.120(b) and CMS requirements for new and existing Medicare Part D beneficiaries to provide a safe accommodation of the Part D enrollee's medical needs with the plan's formulary. The purpose of this document is to describe a consistent Part D Transition Process policy and procedure for HAP Pharmacy Care Management staff to ensure compliance with all applicable federal and state laws and CMS requirements.

Scope:
All Medicare Advantage Products with Part D Benefits – H2312, H2322, S3440

Definitions:

CMS (Centers for Medicare and Medicaid Services) – 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 Fill - After the initial new enrollee transition period, LTC facility residents who are ordered non-formulary drugs must receive their medications as ordered without delay. Therefore, Part D plans must cover an emergency supply of these drugs for LTC facility residents as part of their transition process. These emergency supplies of non-formulary 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 – must be for at least 31 days of medication, unless the prescription is written by a prescriber for less than 31 days.

Formulary Changes Across Contract Years – Part D drugs that become non-formulary (no longer covered on the formulary), or drugs that remain on the formulary but have new PA or ST restrictions added from one contract year to another.
Level of Care Change – Defined as when an enrollee is changing from one
treatment setting to another. Examples include but are not limited to:

1. Beneficiaries who enter LTC facilities from the hospital
2. Beneficiaries who are discharged from the hospital to the home setting
3. Beneficiaries who end their skilled nursing facility Medicare Part A stay
   (payments under Part A include drug costs) and who need to revert to
   their Part D benefit
4. Beneficiaries who rescind hospice status to revert back to standard
   Medicare Part A and B benefits (includes Part C administered by the
   Medicare Advantage Organization)
5. Beneficiaries who end an LTC facility stay and return to the community
6. Beneficiaries discharged from a psychiatric hospital with drug regimens
   that are highly individualized

Non-formulary Drug – non-formulary drug shall mean both Part D drugs that are
not on the Plan’s formulary as well as those Part D drugs that are on the
formulary but are subject to utilization management such as prior authorization
(PA) or step therapy (ST).

Outpatient Pharmacy Setting – includes retail, home infusion, safety net and
I/T/U pharmacies.

PDE (Prescription Drug Event) – a file that reports all claims transactions to CMS
for inclusion in the annual financial reconciliation between CMS and the Plans.

P&T Committee (Pharmacy and Therapeutics Committee) – an independent
group of internal and external health care practitioners that are responsible for
evaluating the efficacy, safety, and cost effectiveness of medications to
determine potential additions, deletions, and other changes to the formulary.

Transition Population -
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. Enrollees residing in LTC facilities (including Level of Care Changes and
   Emergency Fills)
5. Current enrollees affected by formulary changes from one contract year to
   the next whom have utilization history (history look-back is 120 days)
Implementation Statement

**Claims Adjudication System:** All Medicare transition-eligible beneficiaries are identified in the claims processing system by enrollment date so an individual appropriate transition period can be determined. RxClaim, the claims adjudication system, maintains logic to determine if the beneficiary is a new enrollee, if there is a gap in coverage, or if there is a change in Contract and/or PBP. Because the 90 days are calculated from the member’s Part D plan start date, beneficiaries with an effective enrollment date of either November 1 or December 1 maintain access to a transition supply across plan years. If the system detects any of these elements, Health Alliance Plan will provide a temporary supply fill for Part D drugs anytime during the first 90 days of the beneficiary’s enrollment in the Plan. This temporary supply will accommodate the immediate needs of the beneficiary and allow the plan and/or beneficiary sufficient time to work out with the prescriber an appropriate switch to a therapeutically equivalent medication that is on the Plan Formulary or to request an exception for continued coverage of an existing drug based on medical necessity. HAP will make available prior authorization or exception request forms to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on the plan web site. The 90 day transition window applies to the retail, home infusion, LTC, ITU, and mail-order pharmacy settings.

**Policy**

The outpatient pharmacy setting includes retail, home infusion, safety net and I/T/U pharmacies. In this setting, HAP Pharmacy Care Management provides for at least a one-time, temporary 30-day fill for non-formulary Part D drugs (unless the prescription is written for less than 30 days in which case multiple fills will be permitted to provide up to a total of 30 days of medication) anytime during the first 90 days of the beneficiaries entitlement to transition. This includes drugs that are on the plan formulary but subject to utilization management such as prior authorization or step therapy.

During the beneficiary’s transition period, no hard edits are utilized to manage transition supplies; therefore all eligible transition drugs will pay without additional input from the submitting pharmacist and the enrollee will never leave the pharmacy without a transition supply. Step therapy and prior authorization edits will be lifted at the point of service. The only edits that are enforced by the Claims Adjudication System are:

- Edits to determine proper coverage bucket (B vs. D)
Edits to prevent coverage of non-Part D drugs (i.e. excluded categories)

Edits to promote safe utilization of Part D drugs (i.e. quantity limits based on FDA maximum recommended daily dose, DUR)

Refills will be provided 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, to allow the multiple fills up to the overall transition day supply limit.

As Plan Sponsor, HAP ensures that the cost-sharing for a temporary supply of drugs provided under our transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS enrollees, we will charge 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 § 423.578(b) and the same cost-sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

HAP Pharmacy Care Management applies the transition process to a brand-new prescription for a non-formulary drug without discrimination as to whether the prescription is new or an on-going prescription therapy at the point-of-sale.

Until such time as alternative transactional coding is implemented in a new version of the HIPPA standard, HAP will promptly implement either: (1) appropriate systems changes to achieve the goals of any additional new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim (see the 5.1Editorial Document), or (2) alternative approaches that achieve the goals intended in the messaging guidance. When a transition supply claim is paid through RxClaim, pharmacies will be notified via an electronic message informing them that the fill was part of a transition supply. If the claim encounters a valid transitional reject, an additional message is returned to the pharmacy indicating the reason for the rejection.

HAP Pharmacy Care Management will make 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). Continued coverage of the transition...
drug is accomplished by placement of a point-of-sale override.

Also in accordance with CMS requirements, drugs that are excluded from Part D coverage due to Medicare statute are not eligible to be filled through the transition process. However, to the extent that HAP covers certain Part D excluded drugs under an Enhanced benefit, those drugs will be treated the same as Part D drug for the purposes of the transition process.

HAP will allow appropriate transition fills for drugs manufactured in “unbreakable packages”, when greater than the customary transition supply may be necessary.

**LTC Setting**

CMS requires a minimum of a 31-day transition supply in the LTC setting unless the prescription is written for less than 31 days. HAP honors multiple fills of non-formulary Part D drugs as necessary during the entire length of the transition period (90 days) for a 91 – 98 day fill consistent with the dispensing increment, with refills provided if needed during the first 90 days of a beneficiary’s enrollment with HAP. Additionally after the transition period has expired, an emergency fill as defined above will be provided while an exception or prior authorization is requested. HAP administers the LTC transition process in accordance with CMS requirements.

Enrollees admitted to or discharged from an LTC setting experience a level of care change and are not subject to “refill too soon” edits. This is to enable these enrollees to fill prescriptions for medications that cannot be taken with them from or into such settings.

**LTC Member and Level of Care Changes**

RxClaim has automated programming to identify Level of Care changes based on the Patient Residence Code when compared to the most recent claim submission with a different fill date. The following edits will automatically override to allow the claim to pay:

- Refill too soon
- Duplicate Prescription
- Duplicate Therapy
- Non-formulary
- Prior authorization (does not exclude BvD administrative authorization)
- Step Therapy
In the event that the enrollee has not experienced a change in Patient Residence Code but has moved to a different LTC facility, the Pharmacy Care Management team will place a manual authorization to effectuate a transition period in RxClaim. These authorizations will be entered as one-time authorizations and may require subsequent one-time authorizations to ensure there are no gaps in therapy.

**Transitions across Contract Years**

CMS transition guidance requires that current members affected by a negative formulary change across contract years are provided with a transition process that is consistent with the transition process required for new enrollees. Logic is in place at the point of sale to accommodate this by allowing current members to access transition supplies when their claims history from the previous calendar year contains an approved claim for the same drug during the past 120 days that the member is attempting to fill through transition.

**Six Classes of Clinical Concern**

Per CMS guidance, members transitioning to a Plan while taking a drug within the six classes of clinical concern must be granted continued coverage of therapy for the duration of treatment, up to the full duration of active enrollment in the Plan. Utilization management restrictions and/or non-formulary status, which may apply to new members naïve to therapy, are not applied to those members transitioning to the Medicare Part D plan on agents within these key categories. The six classes include:

1. Antidepressant;
2. Antipsychotic;
3. Anticonvulsant;
4. Antineoplastic;
5. Antiretroviral; and
6. Immunosuppressant (for prophylaxis of organ transplant rejection).

**Notice Requirement for Temporary Transition Fills**

Notification occurs in two ways:

1. Point-of-sale notification is sent to the pharmacy at time of adjudication with messaging that may be passed to the member regarding the status of the particular non-formulary drug or drug with UM. The transition messaging is sent to pharmacies in a retail setting (including home infusion, safety-net and Indian Tribal Union) as well as pharmacies in an LTC setting. The transition messaging is passed in the proper messaging fields as specified by CMS and NCPDP standards.
Dispensing pharmacists are notified when a claim paid or rejected due to a transition supply by custom messaging that defines the reason such as NF, PA, ST etc. Additionally the phone number to call for questions, concerns, and overrides is also included in the messaging. If the claim encounters a valid transitional reject, a message is returned to the pharmacy to indicate the reason for the rejection.

2. HAP is supplied with a daily file of any members with a transition claim and will send written notice via U.S. first class mail to enrollee within three business days of adjudication of a temporary fill as outlined in Appendix A. HAP will use the CMS model transition letter via the file and use process. The notice will include:

   a. an explanation of the temporary nature of the transition supply an enrollee has received;
   b. instructions for working with the plan sponsor and the enrollee's prescriber to identify appropriate therapeutic alternatives that are on the plan's formulary;
   c. an explanation of the enrollee's right to request a formulary exception; and
   d. 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 43.154, the written notice will be provided within 3 business days after adjudication of the first temporary fill.

Prescribing physicians will also receive notification within 3 business days via first class mail. Prescriber notifications include a cover sheet with key demographic information of the prescriber and member, along with formulary alternative recommendations. Additionally, a cc of the member transition letter is included in the notice to the prescriber.

**PDE Reporting**

Since this is a CMS required process, any drugs dispensed that qualify under the transition period are reported as covered Part D drugs with appropriate Plan and member cost sharing amounts on the Prescription Drug Event (PDE).

**Summary**
Health Alliance Plan (HAP) administers a transition process that is compliant with the established CMS transition requirements and will make the transition policy available to enrollees via link from the Medicare Prescription Drug Plan Finder to the sponsor web site. The transition policy is also included in pre-and post-enrollment marketing materials as directed by CMS.

Procedures for addressing a medical necessity review of non-formulary drug requests, and when appropriate, the process for switching new Part D Plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination is addressed in the Departmental Coverage Determinations and Exceptions Policy and Procedure.

The HAP P&T Committee reviews this transition policy at least annually to ensure transition decisions appropriately address situations involving enrollees stabilized on non-formulary drugs, including formulary drugs that require prior authorization or step therapy and which may have risks associated with a change in the prescribed regimen.

References:

42 CFR §423.120(b)(3)
Chapter 6 Medicare Part D Manual
Medicare Marketing Guidelines
400-PD-011 Medicare Part D Coverage Determinations

Compliance:

A. Enforcement:
Kelly E. Barta is responsible for enforcing this policy. Failure to abide by the conditions of this policy may result in corrective action, up to and including termination. Employees are responsible for reporting any observed violations of this policy to the Office of Compliance.

B. Responsibility:
Kelly E. Barta

C. Review Cycle:
Annual

D. Recommended Compliance Monitors and Audits:
Pharmacy Care Management monitors compliance with this policy and department procedures through audits, observing department activities, reviewing departmental procedures and otherwise as deemed appropriate
by the department. All violations of this policy and departmental procedures are reported promptly to the Vice-President of Pharmacy Care Management.

E. **Documentation:**
Procedures for implementing the requirements of this policy, if necessary, are incorporated in written department procedures. Such procedures shall be reviewed and updated as necessary but not less than annually.

F. **Departmental Application:**
This is a departmental policy that applies to the development, maintenance and provision of transition regarding Part D benefits. Pharmacy Care Services has obligations under this policy.
Appendix A
Exception Process

Transition Exception Process: - New enrollees are granted a one-time 30-day temporary fill for a non-formulary drug (up to 98 days for LTC), during the first 90-days of a beneficiary’s enrollment in a plan. This will allow time for a switch to formulary drug or an exception process (prior authorization) to be implemented.

Notes:
PBM = Pharmacy Benefit Manager, MRF= Medication Request Form
Signature:

Adopted By: Antonio Petitta, VP Pharmacy Care Management
Reviewed By: Kelly Barta, Pharm D Pharmacy Care Management
Original Effective Date: 1/2015
Report Issues to: Compliance & Privacy Officer
Policy Owner: Manager, Medicare Benefits, PCM

†The “Policy Owner” is the person responsible for ensuring that this policy is reviewed and updated on according to the Review Cycle.

Review and Revision History:

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