DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR BENEFICIARY CHOICES

Date: November 1, 2006

Memorandum to: All Part D Sponsors

Subject: Reminder of Part D Transition Policy and Expectations for the Upcoming Contract Year

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

As the time approaches for the annual open enrollment period, and as Part D sponsors are communicating with their beneficiaries, we wanted to remind plan sponsors again of our transition policy for the upcoming contract year. As a reminder, we have prepared the attached summary chart that outlines our policy as it applies to specific subgroups of beneficiaries and our requirements and expectations for Part D sponsors.

As we have stated in previous communications and guidance, the purpose of the transition process under the Medicare prescription drug benefit is not simply to provide a temporary supply of non-formulary drugs for a specified period of time but, rather, to provide your enrollees with sufficient time to work with their health care providers to switch to a therapeutically appropriate formulary alternative or to request a formulary exception on the grounds of medical necessity. It is vital that enrollees be given clear guidance regarding how to proceed after any temporary fill is provided so that an appropriate and meaningful transition can be effectuated.

It is also very important that plans have a transition process in place for current enrollees who may experience negative changes as a result of the plan's 2007 formulary. If an enrollee does not realize that a medication he or she is receiving will not be on the plan's new formulary in 2007 or that the cost-sharing status for the drug will change, coverage gaps may occur, causing the enrollee to pay higher out-of-pocket costs for the medication or not being able to receive the medication at all. To minimize the impact of these formulary changes on enrollees, it is critical that your enrollees receive their ANOC by October 31st of this year. The ANOC is intended to outline benefit changes for the upcoming year, including changes in cost-sharing and drug tier structures, and to provide notice of changes for the upcoming year's formulary. Enrollees must also receive a comprehensive or abridged formulary with the ANOC, which will provide enrollees with at least 60 days to review the new formulary to determine if their medications are covered and whether the cost-sharing for their covered medications will change for the 2007 contract year.

After enrollees receive their ANOC, CMS expects plan sponsors, consistent with our May 12, 2006 Q&A guidance, to select one of the following two options for effectuating an appropriate and meaningful transition for enrollees whose drugs are no longer on the formulary:

- Provide a transition process for current enrollees consistent with the transition process required for new enrollees beginning January 1, 2007. In order to prevent coverage gaps, plans choosing this option are expected to provide a temporary supply of the requested prescription drug (where not medically contraindicated), consistent with the 2007 Formulary Transition Guidance, and provide enrollees with notice that they must either switch to a therapeutically appropriate drug on the plan's formulary or get an exception to continue taking the requested drug; or

- Effectuate a transition for current enrollees prior to January 1, 2007. In effectuating this transition, plans must aggressively work to: (1) prospectively transition current enrollees to a therapeutically equivalent formulary alternative; and (2) complete requests for formulary and tiering exceptions to the new formulary prior to January 1, 2007. Note: If a plan sponsor approves such an exception request pursuant to the Part D regulations, the plan sponsor shall authorize payment prior to January 1, 2007 and provide coverage beginning January 1, 2007. If, however, plans have not successfully transitioned affected enrollees to a therapeutically appropriate formulary alternative or processed an exception request by January 1, 2007, they will be expected to provide a transition supply beginning January 1, 2007 and until such time as they have effected a meaningful transition, consistent with the 2007 transition guidance.

We also want to remind plans of the requirement in our 2007 transition guidance that we will make available plan transition process information via a required link from the Medicare Prescription Drug Plan Finder. The plan's formulary page should include a specific link to transition guidance or a specific page outlining the plan's transition process. We noted in our guidance that we would provide plans with model submission forms so that plan transition process information is presented consistently from plan to plan. Please find attached the model transition form that plans may use in this regard.

We appreciate your cooperation to ensure a smooth transition for your enrollees. Please feel free to contact your account manager if you have additional questions.

Attachment I

Summary of CMS 2007 Transition Process Requirements and Expectations

Transition process	CMS Requirements and Expectations
New enrollees into prescription drug plans on January 1, 2007 following the 2006 annual coordinated election period (non long term care beneficiaries)	Plans must provide a temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days) when a beneficiary presents at a pharmacy to request a refill of a non-formulary drug he or she was taking prior to enrollment (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) within the first 90 days of their coverage under the new plan.
Newly eligible Medicare beneficiaries from other coverage in 2007 into a Part D plan (non long term care beneficiaries)	Plans must provide a temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days) when a beneficiary presents at a pharmacy to request a refill of a non-formulary drug he or she was taking prior to enrollment (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) within the first 90 days of their coverage under the new plan.
Individuals who switch from one Part D plan to another after January 1, 2007; (non long term care beneficiaries, including re-assignees, and any individual moving to a new plan)	Plans must provide a temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days) when a beneficiary presents at a pharmacy to request a refill of a non-formulary drug he or she was taking prior to switching plans (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) within the first 90 days of their coverage under the new plan.
New Enrollees - LTC residents	Plans must provide a temporary supply of non-formulary Part D drugs – including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules – for a new enrollee in a LTC facility for up to 31 days (unless the prescription is written for less than 31 days). In addition, plans must honor multiple fills of non-formulary Part D drugs for up to 90 days of their coverage under the new plan
Enrollees who remain in same plan they were enrolled in for 2006 but experience negative formulary changes in 2007	After enrollees receive their ANOC on October 31st of a given year, CMS expects plan sponsors to select one of the following two options for effectuating an appropriate and meaningful transition for enrollees who experience

Transition process	CMS Requirements and Expectations
(e.g., is taking a drug that was on-formulary in 2006 but is not on formulary in 2007 or had an exception granted in 2006 that will not be honored in 2007).	negative formulary changes: 1.Provide a transition process for current enrollees consistent with the transition process required for new enrollees beginning January 1, 2007. In order to prevent coverage gaps, plans choosing this option are expected to provide a temporary supply of the requested prescription drug (where not medically contraindicated), consistent with the 2007 Formulary Transition Guidance, and provide enrollees with notice that they must either switch to a therapeutically appropriate drug on the plan's formulary or get an exception to continue taking the requested drug; or 2. Effectuate a transition for current enrollees prior to January 1, 2007. In effectuating this transition, plans must aggressively work to (1) prospectively transition current enrollees to a therapeutically appropriate formulary alternative; and (2) complete requests for formulary and tiering exceptions to the new formulary prior to January 1, 2007.
Enrollees who request an exception, but the plan fails to issue a timely decision on the request by the end of the transition period	CMS expects (per the March 30, 2006 memo "Critical Steps as Transition Period Ends") plans to make arrangements to continue providing requested drugs via a case-by-case extension of the transition period to the extent that the individual's exception request or appeal has not been processed by the end of the minimum transition period.
Enrollees who remain in same plan they were enrolled in for 2006 and are on a drug as a result of an exception that was granted in 2006.	Plans have the option of "honoring" exceptions that were granted in 2006 beyond the end of the plan year (i.e. a plan may choose to honor an exception for as long as the beneficiary remains in the plan). If a plan is NOT going to honor an exception beyond the end of the plan year, it must notify the enrollee in writing at least 60 days before the end of the 2006 plan year and either (1) offer to process a prospective exception requests for the 2007 plan year or (2) provide the enrollee with a temporary supply of the requested prescription drug (where not medically contraindicated) at the beginning of 2007 and provide the enrollee with notice that they must either switch to a therapeutically appropriate drug on the plan's formulary or get an exception to continue taking the requested drug.
Enrollees who remain in same	Prior to the beginning of the new plan year, enrollees

Transition process	CMS Requirements and Expectations
plan they were enrolled in for 2006 and are on a drug that has a PA requirement that is expiring.	may either attempt to satisfy the PA requirement by requesting a coverage determination, or requesting a formulary exception if he/she cannot satisfy the PA requirement.
Current enrollee experiencing a level of care change	Enrollees who are outside their transition period may experience circumstances that involve level of care changes in which a beneficiary is changing from one treatment setting to another. CMS encourages, but does not require, plans to incorporate processes in their transition plans that allow for transition supplies to be provided to current enrollees with level of care changes. Thus, beneficiaries and providers must avail themselves of plan exceptions and appeals processes.
Current enrollees entering LTC settings from other care settings	These enrollees will be provided emergency supplies of non-formulary drugs – including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules. This transition supply is not limited only to initial enrollment.
Current enrollee in a LTC setting requiring an emergency supply of non-formulary drug	To the extent that an enrollee in a LTC setting is outside his or her 90-day transition period, the plan must still provide an emergency supply of non-formulary Part D drugs – including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules – while an exception is being processed. These emergency supplies of non-formulary Part D drugs – including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan'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.

Attachment II

General Transition Notice

What if my current prescription drugs are not on the formulary or are limited on the formulary?

New Members

As a new member in our plan, you may currently be taking drugs that are not on our formulary or are on our formulary but your ability to get them is limited. In instances like these, you need to talk with your doctor about appropriate alternative therapies available on our formulary. If there are no appropriate alternative therapies on our formulary, you or your doctor can request a formulary exception. If the exception is approved, you will be able to obtain the drug you are taking for a specified period of time. While you are talking with your doctor to determine your course of action, you may be eligible to receive an initial <*must be at least 30 days*> transition supply of the drug anytime during the first <*must be at least 90*> days you are a member of our plan.

For each of your drugs that is not on our formulary or for situations where your ability to get your drugs is limited, we will cover a temporary <*must be at least 30*>-day supply (unless you have a prescription written for fewer days) when you go to a network pharmacy. [After your first <*must be a least 30*>-day transition supply, we may not continue to pay for these drugs under the transition policy.] *OR* [If you require refills after your first <*must be at least 30*>-day transition supply, we will cover <x> more refills, as necessary. After you have used your <x> refills, we may not continue to pay for those drugs under the transition policy.> You are reminded to discuss with your doctor appropriate alternative therapies on our formulary and if there are none, you or your doctor can request a formulary exception.]>

If you are a resident of a long-term care facility, we will cover a temporary <*must be at least 31*>-day transition supply (unless you have a prescription written for fewer days). We will cover more than one refill of these drugs for the first <*must be at least 90*> days you are a member of our plan. If you need a drug that is not on our formulary or your ability to get your drugs is limited, but you are past the first <*must be at least 90*> days of membership in our plan, we will cover a <*must be at least 31*>-day emergency supply of that drug (unless you have a prescription for fewer days) while you pursue a formulary exception.

Continuing Members

As a continuing member in the plan, you will receive your Annual Notice Of Change (ANOC) by October 31st. You may notice that a formulary medication which you are currently taking is either not on the upcoming year's formulary or its cost sharing or coverage is limited in the upcoming year.

[P*lans should use one of the following options to describe their transition process for continuing members who are impacted by formulary changes in the new contracting year:*

In this case, we will provide for a transition period consistent with the above transition process for new enrollees.

Or

In this case, you must work with your doctor to either find an appropriate alternative therapy on our new formulary or request a formulary exception prior to the beginning of the new year. If the exception request is approved, we will authorize payment prior to January 1st and provide coverage beginning January 1st.]

<Plans must insert their transition policy for current enrollees with level of care changes, if applicable.>

If you have any questions about our transition policy or need help asking for a formulary exception, call <customer/member> services at < phone number, TTY/TDD number>.