DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTERS for MEDICARE & MEDICAID SERVICES

CENTER FOR DRUG and HEALTH PLAN CHOICE

Date: March 25, 2010

To: All Part D Sponsors

Subject: Reminder of the Part D Transition Policy

From: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C&D Data Group

As we prepare for the submission of CY 2011 formularies and transition requirements CMS is taking this opportunity to remind Part D sponsors of our transition policy. The Part D transition policy is explained in Chapter 6 of the Medicare Prescription Drug Benefit Manual at the following address: http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage The attached summary chart, derived from guidance contained in Chapter 6, outlines CMS' transition policy as it applies to specific subgroups of beneficiaries, as well as CMS' expectations of Part D sponsors. The transition policy represents an important beneficiary protection to prevent serious adverse health consequences from occurring as a result of enrolled beneficiaries – who may be unfamiliar with the plan's formulary requirements – being unable to obtain their needed prescription medications at the point-of-sale.

As we have stated in previous communications and guidance on this topic, the purpose of the transition process under the Medicare prescription drug benefit is not simply to provide a temporary supply of non-formulary drugs to enrollees for a specified period of time, but rather to provide plan 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 a temporary fill is provided so that an appropriate and meaningful transition can be effectuated. We remind Part D sponsors that CMS has developed a Model Transition Letter that sponsors may use in this effort, which may be found on the CMS website at the following address: http://www.cms.hhs.gov/PrescriptionDrugCovContra/PartDMMM/list.asp

We also note that is it is very important that sponsors have a transition process in place for current enrollees who may have experienced negative changes as a result of revisions to their plan's formulary across contract years. In effectuating such a transition, Part D sponsors should have worked aggressively to prospectively transition current enrollees to a therapeutically equivalent formulary drug or worked to complete requests for formulary and tiering exceptions to the new formulary prior to the start of the contract year.

Sending the Annual Notice of Change (ANOC) is not sufficient to effectuate this transition. Thus, to the extent that the Part D sponsor did not engage in these efforts prior to 2010, current enrollees experiencing negative formulary changes across the 2009-2010 contract year should be provided with a transition supply and receive transition notices to ensure that they understand how to proceed after receiving the temporary fill.

Additionally, consistent with Section 30.4.1 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, we also remind sponsors that they must make available plan transition process information on their website. The plan's formulary page should include a specific link to transition guidance or a specific page outlining the plan's transition process.

Finally, we remind Part D sponsors that they have attested to compliance with the Part D transition policy during the annual formulary submission window. In 2011, CMS will be conducting a more rigorous review of transition policies and processes to ensure all plan sponsors are implementing their transition policies consistent with CMS guidance. Therefore, as part of the CY 2011 formulary submission, each plan sponsor must 1) complete the transition attestations through the formulary submission module in the Health Plan Management System; 2) submit its 2011 transition policy and 3) provide a description of how the transition policy will be implemented within the sponsor's claims adjudication system, including pharmacy notification. The transition policy and process must contain the plan sponsor's contract number(s) and be submitted to the CMS Part D transition mailbox at PartDtransition@cms.hhs.gov. Please note that all requirements related to the CY 2011 transition process will be due to CMS by **April 19, 2010**.

We expect plans to carefully track their performance and to take immediate action when they identify problems related to their adherence to the Part D transition policy. Please note that we intend to closely monitor plan performance in this regard. Where plan performance is interfering with enrollees' rights to obtain the drugs they need on a timely basis, we will take prompt action. That action could include imposing corrective action plans to achieve immediate improvements but also, when necessary, employing stronger sanctions, including marketing and enrollment sanctions, and civil monetary penalties.

Thank you in advance for your cooperation to ensure a smooth transition for Part D enrollees. Please feel free to contact your account manager if you have additional questions.

Attachment I

Summary of CMS 2010 Transition Process Requirements and Expectations

Transition process	CMS Requirements and Expectations
New enrollees into prescription drug plans on January 1, 2010 following the 2009 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 2010 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, 2010; (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, the temporary supply must be 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 93 days supply within the first 90 days of their coverage under the new plan
Enrollees who remain in same plan they were enrolled in for 2009 but experience negative formulary changes in 2010	Plan sponsors may select one of the following two options for effectuating an appropriate and meaningful transition for enrollees who experience negative formulary changes:

Transition process	CMS Requirements and Expectations
(e.g., is taking a drug that was on-formulary in 2009 but is not on formulary in 2010, or taking a drug on formulary in 2009 that was not subject to prior authorization or step therapy in 2009 but is subject to these utilization management edits in 2010).	1. Provide a transition process for current enrollees consistent with the transition process required for new enrollees beginning January 1, 2010. In order to prevent coverage gaps, plans choosing this option must provide a temporary supply of the requested prescription drug, 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, 2010. In effectuating this transition, plans should have aggressively worked to (1) prospectively transitioned current enrollees to a therapeutically appropriate formulary alternative; and (2) completed requests for formulary and tiering exceptions to the new formulary prior to January 1, 2010.
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 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 2009 and are on a drug as a result of an exception that was granted in 2009.	Plans have the option of "honoring" exceptions that were granted in 2009 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 2009 plan year and either (1) offer to process a prospective exception requests for the 2010 plan year or (2) provide the enrollee with a temporary supply of the requested prescription drug at the beginning of 2010 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.
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.

Transition process	CMS Requirements and Expectations
	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.