

Transition Process Requirements for Part D Sponsors April 2006

Overview

CMS's review of plan formularies will ensure that plans offer a comprehensive array of drugs that reflects best practices in the pharmacy industry, as well as current treatment standards. We expect plan formularies and benefit designs to include the full range of treatment options and, at the same time, reflect drug benefit management tools that are proven and in widespread use in prescription drug plans today. As described in detail in our Formulary Guidance for 2007, our goal is to ensure beneficiaries receive clinically appropriate medications at the lowest possible cost. In reaching this goal, we also need to account for the specific needs of individuals who are already stabilized on certain drug regimens. In addition, it is important to recognize the needs of new full-benefit dual eligibles who may be auto-enrolled in a prescription drug plan and who, despite education and outreach efforts on the changing nature of their drug coverage under the Medicare drug benefit, may be unaware of the impact of the prescription drug plan's formulary or utilization management practices on their existing drug regimens.

An effective transition process for new enrollees must assure timely access to needed drugs while allowing for the flexibility necessary for Part D plans to develop a benefit design that promotes beneficiary choice and affordable access to medically necessary drugs. We will review each plan sponsor's transition process as part of our plan benefit design review.

While each drug plan must cover multiple drugs that have been shown to be similarly safe and effective for the vast majority of beneficiaries, the specific drugs used by an individual beneficiary may initially differ from those covered by the plan's formulary. To address the needs of individuals who are stabilized on certain drug regimens when they join a plan, Part D plans are required to establish an appropriate transition process for new enrollees who are transitioning to a Part D plan from other prescription drug coverage – including other Part D plans – and whose current drug therapies may not be included in their new Part D plan's formulary. Plan transition processes must address situations in which enrollees are stabilized on formulary drugs that require prior authorization or step therapy under a plan's utilization management rules. Transition processes must also address cases in which a beneficiary changes their setting of care, for example from a hospital to a home or institutional setting, to provide uninterrupted access to needed drugs.

Based on our experience with implementing the Part D benefit in 2006 – and in order to ensure the smoothest possible transition for new plan enrollees in 2007 – this document establishes a minimum set of standards for a Part D sponsor transition process. These minimum standards specify the components of a transition process beyond simply the assurance of a temporary supply of non-formulary drugs or a transition period constituting a particular length of time. These standards are based on policy clarifications provided to Part D plans in early 2006, but we emphasize that these standards are

minimums and that plans are encouraged to go beyond these minimum requirements – particularly for enrollees with extenuating circumstances. We also note that since plans have attested to meeting the requirements of this transition guidance, violation of any of these requirements is subject to corrective action by CMS per our established compliance processes.

Plans must submit their transition processes for 2007 to PartDformularies@cms.hhs.gov by Monday, May 1, 2006 at 5 p.m. EST. We will provide further instructions on how plans must submit this information.

I. General Transition Process Requirements

In creating standards for a transition process, we have attempted to balance safeguards for a smooth transition process for plan enrollees with maximum flexibility for plan sponsors in managing their prescription drug benefit offerings. A transition process is necessary with respect to: (1) the transition of new enrollees into prescription drug plans on January 1, 2007 following the 2006 annual coordinated election period; (2) the transition of newly eligible Medicare beneficiaries from other coverage in 2007; (3) the transition of individuals who switch from one plan to another after January 1, 2007; and (4) enrollees residing in long-term care (LTC) facilities. Plans should also consider how to expedite transitions to formulary drugs for enrollees who change treatment settings due to changes in level of care.

In addition, transition process requirements will be applicable to non-formulary drugs, meaning both: (1) Part D drugs that are not on a plan's formulary, and (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, since a formulary drug whose access is restricted via utilization management requirements is essentially equivalent to a non-formulary Part D drug to the extent that the relevant utilization management requirements are not met for a particular enrollee.

P&T Committee Role

At a minimum, a transition process will address 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. We will look to transition process submissions for assurances that a plan's pharmacy and therapeutics (P&T) committee will review and provide recommendations regarding the procedures for medical review of non-formulary drug requests. P&T committee involvement will help ensure that transition decisions appropriately address situations involving enrollees stabilized on drugs that are not on the plan's formulary (or that are on the formulary but require prior authorization or step therapy under a plan's utilization management requirements) and which are known to have risks associated with any changes in the prescribed regimen.

Temporary One-Time Fills

A plan's transition process must address situations in which an individual first presents at a participating pharmacy with a prescription for a drug that is not on the formulary, unaware of what is covered by the plan or of the plan's exception process to provide access to Part D drugs that are not covered. This may be particularly true for full-benefit dual eligible beneficiaries who are auto-enrolled in a plan and who do not make an affirmative choice based on review of a plan's benefit relative to their existing medication needs. Plans must have systems capabilities that allow them to provide a one-time, 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) 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 out with the prescriber 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.

A plan may charge cost-sharing for a temporary supply of drugs provided under its transition process. Cost-sharing for transition supplies for low-income subsidy (LIS) eligibles can never exceed the statutory maximum copayment amounts (\$3 or \$5 copays, or 15% coinsurance, depending on the level of LIS for which a particular enrollee qualifies). For non-LIS enrollees, a plan must charge cost-sharing based on one of its approved drug cost-sharing tiers (if the plan has a tiered benefit design), and this cost-sharing must be consistent with cost-sharing that the plan would charge for non-formulary drugs approved under a coverage exception.

Transition Timeframes

In order to balance the need for a smooth transition with plans' ability to effectively manage their benefits, we believe it makes sense to both limit and define the amount of time during which a transition process is applicable to new enrollees. To that end, plans will be required to provide a temporary supply fill anytime during the first 90 days of a beneficiary's enrollment in a plan. Because it is possible that beneficiaries transitioning from other prescription drug coverage will have obtained extended (e.g., 90-day) supplies of maintenance drugs prior to the last effective date of their previous coverage, 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 (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. Since certain enrollees may join a plan at any time during the year, this requirement will apply beginning on an enrollee's first effective date of coverage, and not only to the first 90 days of the contract year.

Edits for Transition Supplies

One of our most important goals for a transition process is to ensure that a new enrollee is

able to leave a pharmacy with a temporary supply of non-formulary Part D drugs without unnecessary delays. To this end, plans should use sound business and clinical decision-making with regard to the establishment of certain edits associated with temporary supplies of non-formulary Part D drugs at the point of sale. While Part D plans may implement additional step therapy or prior authorization edits during transition, they may do so only if such edits are resolved at the point of sale. For example, if a prescriber writes a prescription for 5mg tablets at 2 tablets daily, Part D plans might have dose optimization edits in place to require the prescription to be changed to 10mg tablets, one tablet daily. However, during transition, Part D plans would need to allow pharmacies to override this edit if the prescriber will not authorize the change at point of sale. In other words, the beneficiary should leave the pharmacy with sufficient quantity of medication (either 5mg or 10mg tablets) to last the plan allowable days supply, unless the prescriber originally wrote for a lesser days supply. If the dose optimization edit (or any other step therapy/prior authorization edit) is overridden at point of sale for transition purposes only, but not permanently, the beneficiary must be so notified so that he or she can begin the exception process if necessary. As part of their transition process submissions to CMS, plans should describe any edits on transition drugs and their process for resolving those edits at the point of sale.

We note that although Part D plans may implement quantity limits for safety purposes or drug utilization edits that are based upon approved product labeling during a beneficiary's transition period, to the extent that the prescription is dispensed for less than the written amount due to a plan edit, plans must provide refills for that transition supply (up to a 30-day supply in a retail setting and a 90-day supply in a long-term care setting). For example, if a beneficiary presents at a retail pharmacy with a prescription for one tablet per day for 30 days and a plan has a quantity limit edit in place that limits the days supply to 14 per prescription for safety purposes, the beneficiary would receive a 14-day supply (consistent with the safety edit). At the conclusion of the 14-day supply, the beneficiary should be entitled to another 14-day supply while he/she continues to pursue an exception with the Part D plan, or a switch to a therapeutic alternative that is on the plan's formulary.

Irrespective of transition, all of these edits are subject to exceptions and appeals. For example, if a quantity limit edit (based upon maximum recommended daily dose) results in the dispensing of a quantity that is less than indicated on the prescription and is less than the plan allowable days supply (as determined by the prescribed daily dose), Part D sponsors must ensure that beneficiaries are made aware of this quantity limit and that an exception is required to obtain a greater quantity. Part D plans must expeditiously process such exception requests so that beneficiaries will not experience unintended interruptions in medically necessary Part D drug therapies and/or will not inappropriately pay additional cost-sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.

New Prescriptions versus Ongoing Medication Therapy

We are aware that it may be difficult for plans to distinguish between new prescriptions for non-formulary Part D drugs and refills for ongoing medication therapy involving non-formulary Part D drugs. For example, some new enrollees may need to switch pharmacies when they enroll in a new Part D plan (or when they enroll in Part D for the first time) and, depending on state law, their prescriptions may not transfer from pharmacy to pharmacy. In other words, some enrollees may need to present at their new network pharmacy with a new prescription for use at that pharmacy, even if that prescription is for ongoing medication therapy. We recognize that it may be difficult for plans to distinguish between ongoing medication therapy and a brand-new prescription for a non-formulary Part D drug. Although plans may attempt to follow up with prescribing physicians and pharmacies to ascertain the status of a prescription presented during the transition period, we clarify that if a plan is unable to make this distinction at the point of sale, it will be required to apply all transition process standards specified by CMS in this document to a new prescription for a non-formulary Part D drug. In other words, a brand-new prescription for a non-formulary drug will not be treated any differently than an ongoing prescription for a non-formulary drug when a distinction cannot be made at the point of sale.

Transition Notices

A successful transition process is contingent upon informing enrollees and their caretakers about their options for ensuring that enrollees' medical needs are safely accommodated within a Part D plan's formulary. An enrollee who receives a temporary supply of a non-formulary Part D drug at a network pharmacy might simply assume that, by virtue of filling his or her prescription, that the plan will cover that drug for the remainder of a the plan year. For this reason, plans must provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing 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).

Plans will be required to send a written notice, via U.S. mail, to each enrollee who receives a transition fill. This standard is consistent with our requirement that other beneficiary communications, including formulary change notices and explanations of benefits, be sent via U.S. mail. In addition, this notice must be sent to each affected enrollee within three business days of the temporary fill. We believe this turnaround is necessary in order to provide an affected enrollee with sufficient time -- especially in light of our 30-day transition fill policy in the retail setting -- to work with his or her prescriber to switch to a therapeutically equivalent drug that is on the plan's formulary or to process an exceptions request.

The notice must include the following elements: (1) an explanation of the temporary nature of the transition supply an enrollee has received; (2) instructions for working with the plan sponsor 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. As we did in 2006, we will provide plans with a model letter that they may submit to CMS under the file and use certification process. Given that a notice that conforms with our model letter will be generic, we expect that plans will make prior authorization or exception request forms available upon request to both enrollees and prescribing physicians and via a variety of mechanisms -- including by mail, fax, email, and on plan websites. While plans must, at a minimum, send affected enrollees a generic notice, we encourage plans to provide more detailed transition notices -- including the reason for a transition fill, alternative formulary drugs, and any prior authorization or exception request forms a beneficiary will need to effectuate a transition -- to the extent they have that capacity.

In addition, we strongly encourage point-of-sale notification of enrollees about transition supplies by pharmacists. We are working with the pharmacy and drug benefit industry, including the National Council for Prescription Drug Programs (NCPDP), to incorporate a work-around process for using structured payment coding in the message field of billing transaction responses indicating that a particular fill is a transition supply. This process will be consistent with the current NCPDP 5.1 standard. We will require plans to adopt this coding, as well as require their trading partners (including pharmacies) to use and implement it for 2007 and until such time as such messaging is superseded by a new HIPAA-approved standard with appropriate coding.

Public Notice of Transition Process

As a general matter, we believe plan sponsors must make general information about their transition processes available to beneficiaries in a manner similar to information provided on formularies and benefit design. It is likely that individuals will base their decision on which prescription drug best meets their needs on a variety of factors. Matching their current medication list with a Part D plan's formulary may be only one factor in the decision making process. Other factors, such as cost issues and inclusion of the retail pharmacy that they are most familiar with in the plan's network, may bear more weight in the final decision-making process. Having information about a plan's transition process in plan enrollment materials and websites, as well as on the Medicare Prescription Drug Plan Finder, may reassure beneficiaries that there will be procedures in place to assist them in switching to therapeutic alternatives or in obtaining a formulary exception where appropriate. It will also serve to educate advocates and other interested third parties -- for example, state Medicaid agencies -- about plan transition processes.

To this end, we will make available plan transition process information via a required link from the Medicare Prescription Drug Plan Finder to individual plan websites. This is consistent with the manner in which current enrollees, prospective enrollees, and other stakeholders will be able to access information about plan exception and appeals processes in 2007. We will provide plans with model submission forms so that plan transition process information is presented consistently from plan to plan. We will provide these model submission forms to plans very shortly. Via our marketing guidelines, we will also require that plans include transition process information in their pre- and post-enrollment materials as appropriate.

II. Transition Process in the Retail Setting

The minimum transition process standards described in Section I will apply to beneficiaries obtaining their drugs in a retail setting (or via home infusion, safety-net, or I/T/U pharmacies). However, we clarify that, in the retail setting, the one-time, 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 – must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days. Plans should note that, outside the long-term care setting, such a temporary fill may be a one-time fill only.

III. Transition Process in the LTC Setting

It is important that the transition process take into account the unique needs of residents of LTC facilities who enroll in a new Part D plan. Residents of LTC facilities are more likely to be receiving multiple medications for which simultaneous changes could significantly impact the condition of the enrollee. In addition, given that a large proportion of LTC facility residents may be dually eligible for both Medicare and full Medicaid benefits, and could be auto-enrolled into the plan without making an affirmative selection based on the individual’s existing treatment needs, it is critical that the transition process address access to medications at the filling of the first prescription. When possible, we encourage plan sponsors to ensure that LTC pharmacies in the plan’s network that have relationships with LTC facilities work with those facilities prior to the effective date of enrollment to ensure a seamless transition of the facility’s residents.

Transition Period Immediately After Enrollment for LTC Facility Residents

The minimum transition process standards described in Section I will apply to beneficiaries obtaining their drugs in a long-term care setting. The 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 must be for at least 31 days (unless the prescription is written for less than 31 days). We are requiring a 31-day transition supply given that many LTC pharmacies and facilities dispense medications in 31-day increments. However, unlike in the retail setting, plans must honor multiple fills 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, as necessary during the entire length of the 90-day transition period.

Emergency Supply for Current Enrollees

Since, as a matter of general practice, LTC facility residents must receive their medications as ordered without delay, Part D plans must cover an emergency supply of

non-formulary Part D drugs for LTC facility residents as part of their transition process. During the first 90 days after a beneficiary's enrollment, he or she will receive a transition supply via the process described above. However, 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. We are requiring a 31-day emergency supply given that many LTC pharmacies and facilities dispense medications in 31-day increments.

III. Current Enrollee Transitions

In addition to circumstances impacting new enrollees 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 enrollees could arise and in which prescribed drug regimens may not be on plan formularies. These circumstances usually involve level of care changes in which a beneficiary is changing from one treatment setting to another. For example, beneficiaries who enter LTC facilities from hospitals are sometimes accompanied by a discharge list of medications from the hospital formulary, with very short term planning taken into account (often under 8 hours). Similar situations may exist, for example, for beneficiaries who are discharged from a hospital to a home; for beneficiaries who end their skilled nursing facility Medicare Part A stay (where payments include all pharmacy charges) and who need to revert to their Part D plan formulary; for beneficiaries who give up hospice status to revert to standard Medicare Part A and B benefits; for beneficiaries who end a long-term care facility stay and return to the community; and for beneficiaries who are discharged from psychiatric hospitals with medication regimens that are highly individualized.

For these unplanned transitions, beneficiaries and providers must clearly avail themselves of plan exceptions and appeals processes. We have streamlined the grievance, coverage determination, and appeals process requirements in order to ensure that beneficiaries receive quick determinations regarding the medications they need. In all cases, we make it clear that a Part D plan sponsor is required to make coverage determinations and redeterminations as expeditiously as the enrollee's health condition requires. In addition, and as described above, current enrollees entering LTC settings from other care settings 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.

However, even with these protections, there may exist some period of time in which beneficiaries with level of care changes have a temporary gap in coverage while an exception is processed. For this reason, we strongly encourage plans to incorporate

processes in their transition plans that allow for transition supplies to be provided to current enrollees with level of care changes.

In addition, we learned in 2006 that many plans were rejecting claims based on early refill edits in cases in which an enrollee was admitted to or discharged from a LTC facility. An early refill edit is a utilization management tool used to promote compliance and to prevent waste. An early refill edit cannot be used to limit appropriate and necessary access to an enrollee's Part D benefit. For example, if a patient gets a prescription for 30 tablets for a 30 days supply (i.e. 1 tablet daily), but the prescriber changes the dose to 2 tablets daily after only 10 days, it would be inappropriate for a plan to deny as "too soon" a claim for a new prescription with the new dosage because the enrollee will not have enough medication to last until the originally scheduled refill date. Similarly, when an enrollee is admitted to or discharged from a LTC facility, he or she will not have access to the remainder of the previously dispensed prescription (through no fault of his or her own) and, therefore, plans must allow the enrollee to access a refill upon admission or discharge.