Information for Part D Sponsors on Requirements for a Transition Process
March 16, 2005

Overview

CMS 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 plan 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. Our goal is to ensure beneficiaries receive clinically appropriate medications at the lowest possible cost. In reaching this goal, we also need to acknowledge the specific needs of individuals with certain medical conditions who are already stabilized on certain drug regimens (for example, enrollees with HIV/AIDS, mental illness, and those with other cognitive disorders). In addition, it is important to recognize the needs of 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 new Medicare drug benefit, may be unaware of the impact of the prescription drug plan's formulary or utilization management practices on their existing drug coverage.

To address the needs of individuals who are stabilized on certain drug regimens, Part D plans are required to establish an appropriate transition process for new enrollees who are transitioning to Part D from other prescription drug coverage, and whose current drug therapies may not be included in their Part D plan's formulary. This transition process will need to address the plan sponsor's method of educating both beneficiaries and providers to ensure a safe accommodation of an individual's medical needs with the plan's formulary. We believe some period of adjustment may be necessary to introduce the new formulary requirements, and set forth our expectations of what constitutes a reasonable transition timeframe. As we indicate later in this paper, we also recommend the transition process address unplanned transitions as individuals change treatment settings due to changes in level of care.

We will review the plan's transition process as part of the formulary and plan benefit design review. As we indicate in the preamble to our final rule for the Medicare prescription drug benefit, we believe that a requirement for an appropriate transition process for new enrollees balances the protection of certain vulnerable populations with flexibility necessary for Part D plans to develop a benefit design that promotes beneficiary choice and affordable access to medically necessary drugs.

I. General Transition Process for New Enrollees

The issue of transition is important with respect to (1) the initial transition of beneficiaries to the Medicare prescription drug benefit on January 1, 2006, (2) the transition of new enrollees after the initial implementation of the program, and (3) the transition of individuals who switch from one plan to another after implementation of the benefit. Our intent when evaluating a transition process is to ensure that beneficiaries will transition smoothly to drugs on the formulary while providing potential plan sponsors with maximum flexibility in order to manage their prescription drug benefit offerings. To that end, we encourage plan sponsors to consider a variety of

strategies and communication methods to address the needs of vulnerable groups such as individuals with chronic conditions and Medicare/Medicaid full-benefit dual eligibles.

P& T Role

At a minimum, we expect that a transition process would 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 would expect 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 and we will look to the transition process for assurances and clarification of the P&T committee role. 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 and which are known to have risks associated with any changes in the prescribed regimen. If the prescribed drugs are on the plan's formulary but require step-therapy or prior authorization to access the drug, P&T committee involvement should ensure that procedures limiting access are appropriate in situations in which a new enrollee is already stabilized on a drug or has already tried the lower step agents.

Temporary One-time Supply Fills Recommended

The transition process should also address situations where 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 what is included in 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 did not make an affirmative choice based on review of a plan's benefit relative to their existing medication needs. We expect that plan sponsors would consider processes such as the filling of a temporary one-time transition supply in order to accommodate the immediate need of the beneficiary and to allow the plan and/or the enrollee time to work out with the prescriber an appropriate switch to another medication or the completion of an exception request to maintain coverage of an existing drug based on reasons of medical necessity. Such practices exist in the industry today and may represent the most efficient method of triaging requests for filling initial prescriptions of non-formulary drugs for large numbers of new enrollees who, despite education efforts to make beneficiaries aware of the plan's benefit, may not be aware of all the drugs listed on the plan's formulary.

Transition Timeframes

Plan sponsors have discretion in deciding the appropriate time frame for a one-time transition supply. Such time frames need not necessarily be uniform and may vary based on the drug in question, the unique needs of an individual, and an individual's setting (e.g., a long term care setting). However, the transition process should sufficiently document the range and circumstances which impact decisions regarding the temporary supply time period. As a general indicator, we believe that a temporary "first fill" supply of 30 days may be reasonable for new enrollees who first present at a pharmacy with a prescription for a drug not on the formulary so that the plan and/or enrollees may contact the provider to work out appropriate therapeutic

substitutions or to allow the enrollee and the provider time to request exceptions for continued access to Part D drugs not on the plan's formulary. We expect that the use of this method will reflect more than simply a one-time delay, but rather will involve action on the part of the plan and the enrollee to contact the provider to identify appropriate drug substitutions. We further expect sponsors to have systems capability to effectuate temporary supply policies.

Other Transition Methods

Where the use of a temporary "first fill" supply method is not utilized, we expect the sponsor's transition process to describe in sufficient detail how it will ensure new enrollees stabilized on drugs that are not on the plan's formulary and which are known to have risks associated with any changes in the prescribed regimen will continue to have access to medically necessary drugs without adverse health consequences. For example, the plan may have procedures in place to contact enrollees in advance of the initial effective date of their coverage in order to identify needs and to work out substitutions or exception requests with the enrollee and the enrollee's provider who is responsible for prescribing his or her current medications. Since we anticipate that there is a potential for a high volume of beneficiaries, and providers on their behalf, needing to file exceptions or needing alternative prescriptions on a short-turnaround basis after inception of the new Medicare drug benefit on January 1, 2006, this method may not be realistic for some plans during the initial transition to Part D. This is particularly true for large plans with a high number of full-benefit dual eligible individuals auto-enrolled into their plan who may be hard to reach and unaware of the plan's formulary restrictions. Plan sponsors who rely on this method for transition will need to provide an adequate plan for contacting enrollees and their providers, particularly with respect to the period prior to January 1, 2006.

II. Residents of Long Term Care Facilities

It is important that the transition process take into account the unique needs of residents of long term care (LTC) facilities who enroll in a new Part D plan. Given that a large proportion of 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. Plan sponsors will need 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.

Again, plan sponsors may need to provide a temporary "first fill" supply order for a limited quantity of medication prescribed by the attending physician until an appropriate liaison between the facility, the attending physician, and the plan's LTC pharmacy on behalf of the resident can be achieved. Residents of LTC facilities are more likely to be receiving multiple medications for which simultaneous changes could significantly impact the condition of the enrollee. Therefore, plan sponsors may need to identify instances such as polypharmacy circumstances that necessitate a longer transition period in order to appropriately effectuate substitutions to therapeutic alternatives. For example, a transition period of 90 to 180 days might be appropriate for residents of nursing facilities on multiple medications who require some changes to their medication regimen in order to accommodate plan formularies. We expect the plan's transition

process will highlight procedures and time frames to ensure a seamless transition for enrollees who are LTC facility residents.

III. Current Enrollee Transitions and Exceptions and Appeals

In addition to circumstances impacting new enrollees who may enter a plan with a medication list that contains non-formulary drugs, other circumstances exists where unplanned transitions for current enrollees could arise and where prescribed drug regimens may not reflect 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 hrs). Similar situations may exist 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 back to their Part D plan formulary; for beneficiaries who give up Hospice Status to revert back to standard Medicare Part A and B benefits; and for beneficiaries who are discharged from Chronic Psychiatric Hospitals with medication regimens that are highly individualized.

For these unplanned transitions, beneficiaries and providers need to utilize the plan's exceptions and appeals processes. In the final rule, we streamline 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. Even with these protections, there may exist some period of time in which beneficiaries have a temporary gap in coverage while an exception or appeal is undertaken.

We recommend that plan sponsors consider as part of their exceptions processes a transition method for current enrollees with immediate needs for non-formulary Part D drugs. For example, we encourage plans to adopt a one-time temporary or emergency supply process as a method for ensuring that enrollees do not have a coverage gap while proceeding through the plan's exceptions process. This is a particularly important consideration for current enrollees who change treatment settings due to the level of care situations described above. We recommend that plan sponsors consider such procedures and include them in the transition plan for new enrollees.

IV. Public Notice of Transition Process

As a general matter, we believe plan sponsors must make 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 only be 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 may reassure beneficiaries that there will be plan procedures in place to assist them switching to therapeutic alternative medications where appropriate. It will also serve a dual purpose in educating advocates and other interested third parties about plan transition process; for example, state Medicaid agencies with regard to full-benefit dual eligibles auto-enrolled into prescription drug plans.