



MEDICARE PART D APPEALS: A MIXED BAG FOR BENEFICIARIES

On January 28, 2005, the Centers for Medicare & Medicaid Services (CMS) published final regulations implementing the Prescription Drug Benefit provisions, Part D, of the Medicare Modernization Act of 2003 (MMA), Public Law 108-173 (December 3, 2003). The final regulations are in the Federal Register at 70 Fed. Reg. 4194.

In the coming weeks, the Center for Medicare Advocacy's *Weekly Alerts* will highlight various aspects of these voluminous regulations. We focus here on the coverage determinations and exceptions process of the appeals provisions included in Subpart M – Grievances, Coverage Determinations, and Appeals, 42 C.F.R §§423.560 – 423.636.

Coverage Determinations and Appeals

As directed by Congress, the coverage determination and appeals process for Part D mirrors closely the process utilized for Medicare Part C, the Medicare Advantage (MA) program. The process begins when the prescription drug plan (PDP) or Medicare Advantage plan with prescription drug coverage (MA-PD) issues a **Coverage Determination**. The plan enrollee may request a **Redetermination** of an unfavorable coverage determination; the Redetermination will be performed by the drug plan. Individuals who remain dissatisfied after the Redetermination can request a further review known as Reconsideration; the Reconsideration will be performed by the "Independent Review Entity" (IRE). Following an IRE review, the enrollee may appeal to an administrative law judge (ALJ), then to the Medicare Appeals Council (MAC), and finally to federal court. An **Expedited Review** is available if the standards set out in Medicare Part C are met.

At the request of consumer advocates, including the Center for Medicare Advocacy, CMS shortened the amount of time for the PDP or MA-PD to notify the enrollee (and the prescribing physician involved, if appropriate) of its Coverage Determination. *Plans must notify enrollees of Initial Coverage Determinations as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. They have 7 days in which to notify enrollees of a Redetermination decision. Plans must act on requests for expedited Coverage Determinations no later than 24 hours after receiving the request, and on expedited Redeterminations within 72 hours.*

Unlike Medicare Part C, unfavorable Redeterminations are not automatically forwarded to the IRE; the enrollee must file a request for a Reconsideration with the drug plan. However, the plan must forward the enrollee's request to the IRE within 24 hours if it

does not act in a timely manner on the Redetermination request. The Part D regulations require the IRE to issue its Reconsideration decision within the same time frames noted above for issuing a Redetermination.

What Triggers a Right To Appeal?

Coverage Determinations that trigger appeal rights include a plan's decision not to pay for or provide a medication because the drug is not on the plan's formulary, is not considered medically necessary, is furnished by an out-of-network pharmacy, or is not a drug for which Medicare will pay under Part D. An individual may also appeal when:

- A Coverage Determination is not provided in a timely manner, when that delay would adversely affect the health of the enrollee;
- A request for an Exception is rejected and;
- The individual is dissatisfied with a decision regarding the co-payment required for a drug.

Exceptions Process

PDPs and MA-PDs must have an Exceptions process for enrollees to request that a formulary drug be provided at a lower tier for cost sharing (thereby reducing the co-payment), and that a non-formulary drug be covered by the plan. Because Exception requests are Coverage Determinations and are governed by the rules for Coverage Determinations, the plan must act within the time frame for *standard* Coverage Determinations (72 hours) or *expedited* Coverage Determinations (24 hours), depending on which standards are met.

The plan may grant an Exception request to change the cost-sharing tier if it determines that the non-preferred drug is medically necessary or that the preferred drug would not be as effective, or would have adverse consequences. In addition, the Exceptions process must address situations where a formulary's tiered co-pay structure changes during the year and an enrollee is using a drug affected by the change. However, a plan does *not* have to cover non-preferred drugs at the lower, generic drug co-pay level if the plan maintains a separate tier dedicated to generic drugs. Further, if the plan maintains a formulary co-pay tier in which it places very high cost and unique items, such as genomic and biotech products, it may exclude these very high costs or unique drugs from its Exceptions process.

The plan may also grant an Exception if it determines that the drug would be covered for the individual *but for* the fact that it is an off-formulary drug. For this purpose "formulary" includes the application of cost saving tools, such as dose restrictions, and "step therapy" and therapeutic substitution requirements – all of which would result in non-coverage for an otherwise coverable Part D drug.

Although the regulations include some criteria for plans to consider when evaluating an Exception request to change the tiered co-pay level or to pay for a non-formulary drug, each plan has the flexibility to establish its own criteria and to develop its own exception

process. In addition, the regulations leave to a plan's discretion whether it will continue coverage after an Exception has been granted into subsequent plan years.

Notice and Other Due Process Issues

Plans must send a written notice of a formulary change, including a change in the cost-sharing, to only those enrollees who use an affected drug; the notice must be sent at least 60 days in advance of the change. Notice must also be provided to CMS, state pharmacy assistance programs, pharmacies and prescribing providers. The notice must include the name of the affected drug, whether the drug is being removed from the formulary or moved to another cost-sharing tier, the reason for the change, alternative drugs in the class, and the right to request an Exception. Alternatively, the plan may give the enrollee a 60-day supply of the drug and the 60-day notice at the time the enrollee presents a prescription for an affected drug.

The regulations place the burden on the plan to provide notice of appeal rights for other Coverage Determinations. The Preamble to the regulations states clearly that CMS does not consider the transaction at the pharmacy to be a Coverage Determination; thus, pharmacies have no obligation to provide individualized notice at the point of sale when coverage for a prescription is denied. *Plans are required to arrange with their network pharmacies – but not with non-network pharmacies at which an individual may fill a prescription – to post or distribute general notices instructing enrollees to contact their plan to obtain a Coverage Determination or to request an Exception. This system places the burden on the enrollee to contact the plan for information about why a prescription was denied and about appeal rights.*

The regulations also do not contain the current Medicaid protection for continued coverage of a prescription pending an appeal. Thus, enrollees who are dually eligible for Medicare and Medicaid will lose an important protection currently available to them. Although some plans may choose to give their enrollees a 60-day supply of a prescription when there is a formulary change, instead of sending notice 60 days in advance, it is unclear how this right will work. Since the pharmacy will only be required to post notice or give a general notice to call the plan for further information, it seems that individuals who want the 60-day supply in this situation will have to first contact the plan and then return to the pharmacy to get their medicine.

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