MEDICARE PART D GRIEVANCES, APPEALS, AND EXCEPTIONS

This issue brief describes the grievance and appeals processes currently in effect for prescription drug plans (PDPs) and Medicare Advantage plans (MA-PDs) that offer prescription drug coverage under Medicare Part D. These rules are likely to change in the near future. The Centers for Medicare & Medicaid Services (CMS) has indicated that it will be issuing final regulations for Part C and Part D plans that will probably include some modifications to the Part D appeals process.

In addition, Section 3312 of the Patient Protection and Affordability Act of 2010 (health care reform law) requires each drug plan sponsor to use a single, uniform exceptions and appeals process. The law requires plan sponsors to use a single, uniform model form, to the extent that CMS determines such a form is feasible, and to provide plan enrollees with access to the process through a toll-free telephone number and an internet website. The single, uniform process applies to exceptions and appeals filed on or after January 1, 2012.

A. Grievance Procedures

All Part D plans must establish a process for hearing and resolving grievances similar to the process utilized by Medicare Advantage (MA) plans under Medicare Part C.\(^1\) Grievances are separate and distinct from appeals and from quality of service complaints, which are filed with a Quality Improvement Organization (QIO). Grievances may be filed with the drug plan orally or in writing within 60 days after the incident; plans generally must resolve grievances within 30 days. However, plans must resolve within 24 hours a grievance arising from the plan's decision not to expedite a coverage determination or redetermination under the appeals process.\(^2\)

B. Coverage Determinations and Appeals

1. The Coverage and Appeals Process

As directed by Congress, the coverage determination and appeals process for Part D also mirrors closely the process utilized by MA plans.\(^3\) The process begins when the drug plan issue coverage determination.\(^4\) The beneficiary or prescriber\(^5\) may request a Redetermination, performed by the

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\(^1\) 42 U.S.C. §1395w-104(f).
\(^2\) 42 C.F.R. §423.564.
\(^3\) 42 U.S.C. §1395w-104(g)–(h).
\(^4\) See discussion about notice at §11.09[D].
\(^5\) The prescribing physician or other professional may request a Redetermination without having an appointment of representative form filed with the drug plan. An appointment of representative form is still necessary, however, if the prescriber wants to appeal beyond the plan level. 42 C.F.R. §423.582.
drug plans, of an unfavorable coverage determination. Individuals who remain dissatisfied after the Redetermination can request a further review known as Reconsideration; the Reconsideration is 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.\textsuperscript{6}

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 seven days in which to notify enrollees of a Redetermination decision. Plans must act on requests for expedited coverage determination no later than 24 hours after receiving the request, and on expedited redeterminations within 72 hours.\textsuperscript{7} Note that beneficiaries who file an appeal after paying out of pocket for a needed prescription are not eligible for expedited consideration.

Unlike under Medicare Part C, unfavorable Part D Redeterminations are not automatically forwarded to the IRE. The beneficiary must file a request for reconsideration with the drug plan within 60 days of the redetermination decision.\textsuperscript{8} However, the plan must forward the beneficiary's request to the IRE within 24 hours if it does not act in a timely manner on a Redetermination request. The IRE must issue its Reconsideration decision within the same time frames noted above for issuing a Redetermination.

A beneficiary must file a written request for an ALJ hearing with the entity specified in the IRE Reconsideration notice within 60 days of receiving an unfavorable Reconsideration determination. Beneficiaries are entitled to appeal to ALJ provided the amount remaining in controversy meets the threshold requirement.\textsuperscript{9} In determining whether the jurisdictional amount is met in a claim involving the refusal to provide a covered drug, CMS projects the costs of the drug based on the number of refills prescribed for the disputed drug during the calendar year. The ALJ hearing is conducted pursuant to the procedures for hearings of Part A and B appeals.\textsuperscript{10}

A beneficiary may appeal further to the MAC and then to federal court, following procedures for MA plans.\textsuperscript{11}

\section*{2. What Constitutes a Coverage Determination?}

Coverage determinations that trigger appeal rights include a drug 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 and delay would adversely affect the health of the beneficiary; a request for an exception is rejected; or the individual is dissatisfied with a decision regarding the copayment

\begin{itemize}
  \item \textsuperscript{6} 42 C.F.R. §§423.560–423.638.
  \item \textsuperscript{7} 42 C.F.R. §§423.568, 423.572, 423.582, 423.590.
  \item \textsuperscript{8} 42 C.F.R. §423.600.
  \item \textsuperscript{9} The amount in controversy, $130 in 2010, may increase yearly based on increases in health costs.
  \item \textsuperscript{10} 42 C.F.R. §§423.610, 423.612.
  \item \textsuperscript{11} 42 C.F.R. §§423.620, 423.630.
\end{itemize}
required for a drug. A coverage determination may be requested by the beneficiary, the beneficiary's appointed representative, the prescribing physician, or another health care professional authorized under state law to write prescriptions.\textsuperscript{12}

C. The Exceptions Process

Part D plans that use formularies to manage drug utilization must also have an Exceptions process whereby plan enrollees can seek coverage for a non-formulary drug or request that a formulary drug be provided at a lower cost-sharing tier (thereby reducing the copayment or coinsurance).\textsuperscript{13} As noted above, denial of an exception request constitutes an unfavorable coverage determination from which appeal rights flow. The importance of the exceptions process cannot be overstated; CMS guidance indicates that the exceptions process will provide all beneficiaries with access to the medically necessary drugs prescribed for them.\textsuperscript{14}

In order to get an exception to require the plan to cover a non-formulary drug, the prescribing doctor or other prescribing professional must show that all of the drugs on any tier of the plan's formulary for treatment of the same condition would not be as effective or would have adverse consequences, or both, for the individual requesting the exception. For this purpose the term formulary includes the application of cost-savings tools, such as dose restrictions, quantity limits, prior authorization, step therapy, and therapeutic substitution requirements, all of which would result in non-coverage for an otherwise coverable Part D drug.

If the plan approves the Exceptions request, the drug will be treated as other drugs on the formulary for the remainder of the year, so that the beneficiary's cost-sharing counts toward the deductible and the annual out-of-pocket limit. A beneficiary will not have to file a new exception request each time the prescription is refilled. If the beneficiary renews her membership in the plan after the plan year, the plan has the option of continuing coverage of the medicine.\textsuperscript{15} If the plan does not adopt this option, the beneficiary would have to reapply for an exception the next year.

Many plans require their enrollees or prescribing providers to request prior authorization (PA) before the plan will pay for or cover a particular drug. The denial of a PA request is considered a coverage determination. Because the process for requesting PA is burdensome and requires the same information as requesting an exception, advocates and providers tend to request an exception to the PA requirement rather than simply asking for PA. Being granted an exception to PA rather than PA brings an additional saving to the beneficiary. Plans often grant PA for a limited time period, requiring beneficiaries to go through the process multiple times in a plan year. If an exception to the PA requirement is granted, however, the exception continues throughout the plan year, and possibly into the next one if the beneficiary remains enrolled in the plans.

\textsuperscript{12} 42 C.F.R. §§423.450, 423.566.
\textsuperscript{13} 42 U.S.C. §1395w-104(g), (h); 42 C.F.R. §423.578.
\textsuperscript{15} 42 C.F.R. §423.578(c)(4).
Plan enrollees may also use the exceptions process to ask that a drug they require be assigned to a lower tier to reduce their cost-sharing for the drug when the preferred drug would not be as effective or would have adverse consequences. The exceptions process must also address situations where a formulary's tiered copayment 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.\(^\text{16}\)

Because exceptions requests are coverage determinations and are governed by the rules for coverage determinations, the plan must act within the time frames for standard coverage determinations (72 hours) or expedited coverage determinations (24 hours), depending on which standards are met. A beneficiary may appeal the denial of an exception request through the appeals process.

Despite its importance, the exceptions process has proven to be both burdensome and time-consuming. Drug plans may require a doctor's or other prescriber's certificate explaining why the plan enrollee needs the non-formulary drug. Each plan has its own criteria for what must be included in the certificate; many plans have different forms a doctor must use depending on the drug in question. CMS has approved a standard exceptions request form but has not required that plans honor the standard form. Each plan determines how it will evaluate the doctor's determination that the enrollee requires a non-formulary drug, including establishing a process to compare the medical and scientific evidence about the safety and effectiveness of the non-formulary and formulary drugs. Most plans require extensive documentation, sometimes asking for both the beneficiary's own medical records and medical journals. Because the Part D appeals process follows the appeals process for MA plans, it involves the exhaustion of multiple layers in order to get a face-to-face hearing.

D. Notice and Other Due Process Issues

The PDP or MA-PD has the responsibility for giving its plan enrollees notice of a change in the formulary or notice that coverage for a requested drug has been denied. The plan must provide written notice of a formulary change, including a change in tiered cost-sharing, 60 days in advance of the change to those enrollees who use the prescription, as well as to CMS, prescribing physicians, and pharmacies. The notice must include the change, other available drugs, and a description of the exceptions process. Alternatively, a plan can choose to give an enrollee the 60 days notice and a 60-day supply of the drug when a refill request is presented to the plan.\(^\text{17}\) Note that if plans make a non-maintenance mid-year formulary change, they must continue to provide the original coverage to members who are taking the affected drug.\(^\text{18}\)

\(^{16}\) 42 C.F.R. §§423.578(a)(6), (7).
\(^{17}\) 42 C.F.R. §423.120(b)(5).
\(^{18}\) Prescription Drug Benefit Manual, Ch.6 at 30.3.3.1.
It is unclear, however, how enrollees will learn of their rights when coverage of or payment for a prescription is denied at the pharmacy. The regulations place the burden on the plan to provide notice of appeal rights for coverage determinations. CMS states that the pharmacy is not required to provide notice of the reasons for the denial or of the appeals process. Instead, each drug plan must arrange with its network pharmacies to either post at the pharmacy or distribute a generic notice that tells enrollees to contact the plan if they disagree with the information provided by the pharmacist. This approach does not consider the extra burden placed on the enrollee, who must make a special effort to get and then act on the notice, or the practicalities of providing notice when an enrollee uses a non-network pharmacy.

The appeals process also does not provide adequate protection to someone who must appeal to continue receiving coverage of a drug he or she has been using. Unlike under Medicaid, Part D does not provide for continued access to the medication if an appeal is filed on a timely basis. Thus, most dually eligible individuals whose prescription drug coverage will be paid for under Medicare instead of Medicaid lose an important protection. CMS has indicated in sub-regulatory guidance that Part D plans must provide a continued supply of a medicine to nursing home residents through the exceptions process.

**CONCLUSION**

The Medicare Part D prescription drug program continues to evolve. Advocates should monitor whether plans decide to remain in the program in future years, and whether those that do change their formularies and/or cost-sharing structures. Each year a substantial number of individuals eligible for the low-income subsidy need to enroll in a different plan because their plan no longer qualifies for a subsidy to pay the entire premium; those who are in the drug plans to which they were assigned by CMS are automatically reassigned to a new plan by CMS. Enrollees may need to change plans or pursue exceptions if the plan they chose eliminates drugs from its formulary or adds utilization management tools. In any event, beneficiaries and their advocates need to learn about the plan’s grievance, appeal, and exceptions systems.

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20 42 C.F.R. §423.562(a)(3).
MEDICARE PART D APPEALS PROCESS

Requested Coverage Determination

- Standard Process
  72 hour time limit

  Medicare Advantage Prescription Drug Plan Redetermination**
  7 day time limit

  Part D Independent Review Entity
  7 day time limit

  OMHA Administrative Law Judge
  Amount in controversy => $130 (2010)
  90 days after request

  Medicare Appeals Council
  60 days to file

- Expedited Process
  24 hour time limit

  Medicare Advantage Prescription Drug Plan Redetermination**
  72 hour time limit

  Part D Independent Review Entity
  72 hour time limit

  Federal District Court
  Amount in Controversy => $1,260 (2010)
  60 days to file

Coverage Determination

Appeals Level 1

60 days to file

Appeals Level 2

60 days to file

Appeals Level 3

60 days to file

Appeals Level 4

60 days to file

Appeals Level 5

60 days to file

** The adjudication timeframes generally begin when the request is received by the plan sponsor. However, if the request involves an exception request, the adjudication timeframe begins when the plan sponsor receives the physician’s supporting statement.

** A request for a coverage determination includes a request for a listing exception or a formulary exception. A request for a coverage determination may be filed by the enrollee, the enrollee’s appointed representative, or the enrollee’s physician.

*** Starting in 2005, the AIC requirements for an ALJ hearing and Federal District Court are adjusted in accordance with the medical care component of the consumer price index.