Two years after the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare has begun to cover some outpatient prescription drugs for every beneficiary who chooses to enroll in a drug plan under the new Medicare Part D.\(^1\) Enrollment is voluntary for all but those who are also eligible for Medicaid (the “dual eligibles”); Medicaid prescription drug coverage ended for them on December 31, 2005.\(^2\) The Centers for Medicare and Medicaid Services (CMS), the Medicare administrators, automatically enrolled all dual eligibles in a randomly selected Part D plan in late 2005 to ensure that they had Part D coverage in place when the Part D program went into effect on January 1, 2006.\(^3\)

The extent of meaningful prescription drug coverage to which Part D will provide Medicare beneficiaries remains to be seen. Advocates are concerned that the flexibility accorded to the private suppliers of the benefit will limit the scope of the new drug benefit and access to prescribed medications.\(^4\)

Two examples of plan flexibility are pertinent to this discussion. First, drug plans have broad discretion to decide

---


\(^4\) Prescription drug coverage is provided by private insurance companies either through stand-alone prescription drug insurance plans or through Medicare Advantage Prescription Drug plans such as health maintenance organizations and preferred provider organizations that offer drug coverage. 42 U.S.C.A. §§ 1395w-101(d), 1395w-141(a)(14) (West Supp. 2005).
which specific drugs to include in their formularies (i.e., list of covered drugs), the strengths and dosage forms of covered drugs, and the types of “utilization management processes.”5 Under utilization management, plans may establish “tiered” copayments to distinguish among preferred drugs, nonpreferred drugs, and generic drugs.6 Plans may impose quantity limits on prescriptions, require that beneficiaries request prior authorization for covered prescription drugs, or require that they try particular medications in the plan’s formulary before those prescribed by the doctor (“step therapy”).7

Second, drug plans may remove a drug from or add it to the formulary or change the preferred or tiered cost-sharing status of a drug at almost any time during the year.8 Although plans can in this way change their contract with their enrollees, most of their enrollees may not leave the plan if the formulary changes, with limited exceptions, until the next annual coordinated enrollment period.9

To protect beneficiaries, CMS requires a plan to give sixty days’ advance notice of a formulary change to enrollees who use the drug. The plan must give such notice also to CMS, prescribing doctors, pharmacists, network pharmacies, state pharmacy assistance programs, and other organizations that provide drug coverage, such as retiree health plans. Written notice to affected enrollees must identify the drug; describe the change and the reason for it; list other available drugs and their cost sharing; and explain how to request an exception or appeal.10 Plans also may post information about a formulary change on their websites.11 Instead of a sixty days’ advance notice to enrollees, a plan may give written notice and a sixty-day supply of the drug when the enrollee requests a refill. Retroactive notice is allowed if the Food and Drug Administration removes a drug for safety reasons.12

Despite Part D plans being allowed to design their benefits to suit their business needs, CMS claims that every prescription drug plan enrollee will have access to all medically necessary drugs.13 However, to have access, plan enrollees may have to avail themselves of the Act’s processes for challenging a plan’s formulary, including its utilization management tools. In this article, I describe three processes—exception, appeal, and grievance—that may help beneficiaries get prescribed medicines.

I. Challenging a Plan’s Decision

All Part D plan sponsors must have a process for enrollees to challenge a plan’s decisions.14 Congress based this process

---

5See id. § 1395w-104(b)(3)(C); 42 C.F.R. § 423.120(b) (2005).
842 C.F.R. § 423.120(b)(5), (6) (2005). Changes may not be made during the annual coordinated enrollment period (November 15 to December 31) or for sixty days after the start of a contract year. Id. § 423.120(b)(6). A drug no longer deemed safe by the Food and Drug Administration may be removed at any time. Id. § 423.120(b)(5)(iii).
1042 C.F.R. § 423.120(b)(5)(i), (ii) (2005).
1442 U.S.C.A. § 1395w-104(g), (h) (West Supp. 2005).
on the appeal process under Medicare Part C for claims or services denied by Medicare Advantage Prescription Drug plans.\textsuperscript{15}

Thus the steps in the appeal process, discussed in detail in I.B, include a coverage determination and a redetermination by the drug plan, reconsideration by the independent review entity, a hearing before an administrative law judge, Medicare Appeals Council review, and an appeal to federal court.\textsuperscript{16} Like the Part C appeal process, Part D’s allows for expediting requests at all review levels before the administrative law judge’s.\textsuperscript{17}

**A. Exception Process**

One very important difference between Medicare Part C and Medicare Part D is Part D’s allowance for requesting “exceptions” to the design of a plan’s formulary. An enrollee may use the exception process to ask the drug plan to cover a nonformulary drug, including one already removed from the formulary, or to reduce cost sharing for a formulary drug.\textsuperscript{18} In other words, the enrollee asks the drug plan to make a ruling that formulary requirements apply to all plan enrollees “except for” the requesting enrollee.

An exception request is a subset of the initial determination, or coverage determination, by the plan.\textsuperscript{19} Like other coverage determinations, an unfavorable exception determination gets an enrollee into the appeal process.\textsuperscript{20} However, unlike other coverage determinations, an exception request has its own process and requires the prescribing doctor to participate.

**General Requirements for Exceptions.** A plan enrollee, the enrollee’s appointed representative, or the prescribing doctor may request an exception.\textsuperscript{21} However, even if an enrollee or an appointed representative requests the exception, the enrollee’s doctor must participate by disclosing medical information required by the plan.\textsuperscript{22} In fact, the time under which the Part D plan must make a decision is calculated from when a doctor’s statement is received.\textsuperscript{23} However, the submission of a supporting statement by the prescribing doctor does not automatically result in a favorable decision.\textsuperscript{24}

The regulations having established parameters for the exception process, each plan may develop its own procedures and evidentiary requirements within these parameters.\textsuperscript{25} Hence the amount and type of medical and other evidence to support an exception request and the weight given to the doctor’s statement may differ among plans. Doctors with a large number of Medicare beneficiaries among their clients have to become familiar with the different requirements of exception processes for each Part D plan in their community.\textsuperscript{26}

\textsuperscript{15}Id. § 1395w-22(g). Medicare Advantage Prescription Drug plans include health maintenance organizations, preferred provider organizations, and private fee-for-service plans. Id. § 1395w-21(a)(1).


\textsuperscript{17}Id. §§ 422.570, 422.584, 423.570, 423.584, 423.600 (2005).

\textsuperscript{18}42 U.S.C.A. § 1395w-104(g), (h) (West Supp. 2005).

\textsuperscript{19}42 C.F.R. § 423.566(b)(3) (2005).

\textsuperscript{20}Id. § 423.580.

\textsuperscript{21}Id. § 423.578(a)(3). An appointed representative is someone appointed by an enrollee to act on behalf of the enrollee in the claims and appeals process or someone authorized under state or other law to act on the enrollee’s behalf. Id. § 423.560.

\textsuperscript{22}Id. § 423.578(a)(4), (b)(5).

\textsuperscript{23}Id. §§ 423.568(a), 423.572(a).

\textsuperscript{24}Id. § 423.578(c), (f).

\textsuperscript{25}Id. § 423.578(a)(2)(i), (b)(2).

\textsuperscript{26}Most states have more than forty prescription drug insurance plans. For information about the total number of prescription drug insurance plans and Medicare Advantage Prescription Drug plans in each state, see Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, Landscape of Local Plans: State-by-State Breakdown, www.medicare.gov/medicareform/map.asp (last updated Sept. 16, 2005).
The differences may result in barriers to the effectiveness of doctors’ assistance. A doctor who considers the process too complicated may decide not to file a supporting statement. Or a doctor confused by different requirements may not give the required information.

A plan must inform the enrollee and the prescribing doctor of its decision on an exception request within seventy-two hours after receiving the doctor’s supporting statement or as expeditiously as the enrollee’s health condition requires.\(^\text{27}\) If the enrollee requests expedited consideration, the plan must decide within twenty-four hours of receiving the doctor’s statement or as expeditiously as the enrollee’s health condition requires.\(^\text{28}\) Part D uses the same standard as Part C’s for determining whether a request for expedited consideration will be granted, namely, that application of the standard time frame may seriously jeopardize the enrollee’s life or health or the enrollee’s ability to regain maximum function.\(^\text{29}\) The plan must grant a request for expedited consideration if made by a doctor.\(^\text{30}\) Thus doctors should request expedited consideration of an exception when they submit their supporting documentation.

If the plan fails to make a determination and notify the enrollee within the required time frame, either standard or expedited, the exception request is deemed to be denied. This is the only situation in which the appeal is automatic. The Part D plan must forward the exception request to the independent review entity within twenty-four hours of the end of the statutory time frame to act.\(^\text{31}\)

If the plan denies an exception request, the enrollee may appeal further, as discussed in I.B. If the plan grants the request, the request remains effective as long as the doctor continues to prescribe the drug, the drug remains safe, and the enrollment period has not expired. If an enrollee renews membership in a plan, the plan has the option to continue the exception into the next year.\(^\text{32}\) Whether plans will require their enrollees to seek exception requests on a yearly basis remains to be seen.

**Exceptions Related to Tiered Cost Sharing.** An enrollee who must pay a high copayment or coinsurance for a prescribed drug on the plan’s formulary may request to reduce the cost sharing to a lower tier on the formulary. Enrollees may so request at enrollment, or when the doctor prescribes the drug for them, or if the plan changes its tiered cost-sharing structure during the year.\(^\text{33}\)

The prescribing doctor must assert that the prescribed drug is less effective than the preferred drug or would have adverse effects on the enrollee, or both. The doctor may give an oral statement, although the plan may request that the statement be written or that the doctor give additional supporting documentation.\(^\text{34}\) The plan may establish its own criteria for reviewing the exception request. At a minimum, the criteria must describe the criteria for evaluating the doctor’s statement and consider whether the drug in question is the therapeutic equivalent of any other formulary drug and how many drugs on the formulary are in the same class and category.\(^\text{35}\)

The implementing regulations limit the drugs for which an enrollee may request an exception to the plan’s tiered cost sharing, although no such limits are in

\(^{27}\) 42 C.F.R. § 423.568(a) (2005).

\(^{28}\) id. § 423.578(c).

\(^{29}\) id. § 423.578(c)(2).


\(^{31}\) id. § 423.578(c)(2).

\(^{32}\) id. § 423.578(c)(3).

\(^{33}\) id. § 423.578(a).

\(^{34}\) id. § 423.578(a)(4), (5).

\(^{35}\) id. § 423.578(a)(2).
the Act itself. If the plan has a separate tier for generic drugs, an enrollee may not get an exception to cover the nonpreferred drug at the generic drug cost-sharing tier. Also, if the plan has a separate tier for high-cost or unique drugs, such as genomic and biotech products, those drugs are not eligible for a tiering exception.36 These limits have significant consequences for individuals who have slightly too much income or too many assets or both to be eligible for the low-income subsidy and who must pay full cost-sharing amounts.37 They effectively penalize beneficiaries based on medical conditions or illnesses that require costly treatments and seem to contradict the regulatory prohibition against approval of benefit and plan designs likely to discourage enrollment of certain beneficiaries.38

Exceptions Related to Nonformulary Drugs. An enrollee may file an exception to ask the drug plan to cover a drug that is allowed to be covered under Part D but that is not on the plan’s formulary. As with a tiered cost-sharing exception, enrollees may file a formulary exception when they enroll in the Part D plan, when they are prescribed a nonformulary drug or a drug subject to utilization management tools, or when the plan notifies them of a midyear formulary change.39

The concept of a nonformulary drug exception is defined broadly. It covers circumstances in which the drug is on the formulary but may not be covered in the dosage amount (e.g., 50 milligrams instead of 100 milligrams) or form (e.g., liquid instead of pill) that the enrollee requires. The concept restricts the amount of medicine dispensed, for example, when the prescription requires the enrollee to take a particular medicine twice a day but the plan authorizes only thirty pills. An enrollee may request an exception to a step-therapy requirement under which the enrollee must show that other less costly medications may not work before the prescribed medication is covered or to a therapeutic substitution requirement, whereby a therapeutically equivalent drug is substituted for the prescribed drug.40 Although the regulations are not clear, advocates assume that plans will use the formulary drug exception process for reviewing prior authorization requests. However, advocates should note that the regulations preclude the use of the exception process to get coverage for a drug that does not meet the definition of a Part D drug.41

Each Part D plan will establish its own standard of proof and its own process for evaluating the evidence in support of the exception request. The procedures must describe the criteria for evaluating the doctor’s supporting statement and must compare any applicable medical and scientific evidence on the safety and effectiveness of the drug in question versus any formulary drug.42 The Part D plan process must determine the cost-sharing tier to which a drug will be assigned if an exception is granted.43

The doctor’s statement will be crucial to the nonformulary drug exception request. The rules allow for oral statements.44 However, given the complexity of the issues, the statement should be

36Id. § 423.578(a)(6), (7).
39Id. § 423.578(b).
40Id. § 423.578(b)(1).
41See id. § 423.578(e). Some excluded Part D drugs may be covered when used to treat other conditions not specifically excluded. 70 Fed. Reg. 4193, 4230 (Jan. 28, 2005). The exception process limitation may cause problems for beneficiaries who seek coverage for excluded drugs prescribed for other uses.
43Id. § 423.578(c)(4).
44Id. § 423.578(b)(6).
written even if the plan does not require a written certification. At a minimum, the doctor must state that the requested drug is medically necessary because no formulary drug is as effective as the requested drug. The doctor’s statement should include the enrollee’s identifying information, patient history and diagnosis, and the reasons, as discussed in the following paragraph, why the formulary drug is not acceptable for the enrollee.45 The doctor may add other information to help evaluate the medical necessity of the requested drug and may need to refer to relevant clinical, medical, and scientific evidence for the request to be granted.46

For issues involving nonformulary drugs or a step-therapy requirement, the medical necessity determination may be based on the fact that all formulary drugs have not been effective in treating the enrollee. If the enrollee has not already tried the formulary drug, medical necessity may be established where both sound clinical evidence and medical and scientific evidence indicate that the formulary drug would not be as effective as the nonformulary drug or is likely to cause an adverse reaction or other harm given the known relevant physical or mental characteristics of the enrollee and the known characteristics of the drug regimen.47 Where the exception involves the number of doses of a prescribed drug that the plan will cover, the issue is whether the limited number of doses already has proven to be ineffective in treating the enrollee’s disease or condition or whether clinical, scientific, and medical evidence indicates that the limited number of doses would be an ineffectual treatment or would be likely to cause harm given the enrollee’s physical and mental characteristics and the drug regimen’s characteristics.48 These criteria may prove onerous especially if no clinical studies support treatments that doctors have found to be effective through years of practical experience.

If coverage is granted for a nonformulary drug based on the exception request, the enrollee may not request a tiering exception to reduce the cost sharing.49 Again, to avoid the arbitrary or even discriminatory assignment of drugs to a cost-sharing tier, each plan is supposed to include in its exception process information on how nonformulary drugs will be assigned to such a tier. A nonformulary drug covered under the exception process is treated as a formulary drug for the enrollee involved. Enrollee cost sharing for the drug will count toward the plan’s deductible and the enrollee’s out-of-pocket expenses needed to reach catastrophic coverage.50

Implications for Dual Eligibles. Current Medicaid law entitles Medicaid recipients to a temporary supply of their medication pending a request for prior authorization and to drugs pending a termination of services.51 No such protection is available under Medicare Part D for dual eligibles. Individuals who reside in a long-term care facility, regardless of income, are entitled to an emergency supply of their medication pending an exception request.52 Thus, despite statements by Congress and CMS that low-income individuals

45 Id. § 423.578(b)(5).
46 See id. § 423.578(b)(5)(i)(A), (B) (requiring the doctor’s statement to be based on sound clinical evidence and medical and scientific evidence).
47 Id. § 423.578(b)(5)(i), (ii).
48 See id. § 423.578(b)(5)(iii).
49 Id. § 423.578(c)(4)(iii).
50 Id. § 423.578(b)(3).
will benefit from Part D, dual eligibles who are denied coverage for medications that they require actually may have fewer rights than they currently do under Medicaid.

B. Appeal Process

Because of the complexity of both the Part D program and its appeal process, some coverage denials likely will arise outside the context of the exception process. Ensuing appeal rights are the same whether the unfavorable decision is expressed as a denied exception request or more generally as a denied coverage determination.

Coverage Determination. The regulations define a coverage determination to include a drug plan’s decision not to pay for or provide a drug because the drug is not covered by Part D, the drug is not on the plan’s formulary drug, the drug is not considered medically necessary, or an out-of-network pharmacy furnished the drug. As noted in I.A, decisions on an exception request, including a decision on the amount of cost sharing and an untimely decision that would adversely affect the enrollee’s health, are also coverage determinations. A statement by the pharmacy that the plan will not cover a requested drug is not a coverage determination.

A coverage determination may be requested by a beneficiary, a beneficiary’s appointed representative, or the prescribing doctor. The coverage determination may be made only by the Part D plan or by an entity acting on behalf of the Part D plan. As discussed in II, this provision, based on the process in private employer-sponsored plans, may create an almost insurmountable barrier for some individuals denied drug coverage.

The drug plan must issue a written coverage determination as expeditiously as the enrollee’s health requires but no later than

- seventy-two hours after receiving a standard request for a coverage determination,
- seventy-two hours when the beneficiary has already paid for the drug, or
- twenty-four hours if the plan has granted a request for expedited review.

The beneficiary or a doctor may request expedited review when the standard time frame could jeopardize the life or health of the beneficiary or the beneficiary’s ability to regain maximum function. Plans must grant a doctor’s request for expedited review. If the plan denies an enrollee’s request for expedited review, the plan may advise the enrollee to refile the request with a doctor’s statement or to file a grievance.

Redetermination. If a coverage determination is unfavorable, a plan enrollee may appeal by filing a written request for a redetermination with the drug plan within sixty days of the date of the coverage determination. A plan has the option to accept oral requests. The enrollee or an appointed representative, ...

---

53 C.F.R. § 423.566(b) (2005).
54 Id. § 423.566(a), (b).
56 C.F.R. § 423.566(c) (2005).
57 Id. § 423.562(a)(2), (3).
58 Id. § 423.568(a).
59 Id. § 423.568(b).
60 Id. § 423.570(c).
61 Id. § 423.570(b).
62 Id. § 423.570(c).
63 Id. § 423.570(d).
64 Id. §§ 423.580, 423.582(a), (b).
65 Id. § 423.582(a).
but not the prescribing doctor, must request a redetermination.\textsuperscript{66} The redetermination is the first level of the appeal process, and the Act requires that an appeal be filed by the enrollee.\textsuperscript{67} The prescribing doctor may still be needed to submit evidence or support a request for an expedited redetermination or both.\textsuperscript{68}

The enrollee and the prescribing doctor, where appropriate, must be given the opportunity to submit supporting evidence either in writing or in person. Such opportunity may be more limited if the plan grants a request for expedited redetermination.\textsuperscript{69} The plan personnel who review the redetermination must be different from those involved in making the initial coverage determination.\textsuperscript{70} If the plan originally determined that the drug was not medically necessary, the reviewer on redetermination must be a doctor with expertise in the field of medicine appropriate to the drug in question.\textsuperscript{71} The doctor does not have to be of the same specialty or subspecialty as the prescribing doctor.\textsuperscript{72}

The drug plan must act as expeditiously as the enrollee’s condition requires but not more than seven days from the request for a standard review or more than seventy-two hours for an expedited review.\textsuperscript{73} If the appropriate time frame is not met, then the plan must send the redetermination to the independent review entity within twenty-four hours of the expiration of the required time.\textsuperscript{74} If the decision is unfavorable, the notice must explain the reasons for the denial, the right to request a reconsideration, and the process for doing so. The notice also must describe the expedited process if the redetermination does not involve a claim in which the enrollee seeks reimbursement for payment already made.\textsuperscript{75}

Reconsideration. The Part D appeal process differs from Part C’s on which it is based in how an unfavorable redetermination by the plan reaches the reconsideration level of review. Under Part C, the Medicare Advantage plan automatically sends an unfavorable redetermination to the independent review entity, which must review all unfavorable decisions.\textsuperscript{76} Under Part D, the enrollee must act affirmatively and request a reconsideration within sixty days of the date of the redetermination decision. The only exception, as noted above, occurs if the plan fails to meet the time frame for deciding either a coverage determination or a redetermination; then the appeal to the independent review entity is automatic. The enrollee’s request for a reconsideration must be in writing.\textsuperscript{77} At this level of review, the plan does not have the option of accepting an oral appeal.\textsuperscript{78}

After the appeal is filed, the independent review entity must solicit the prescribing doctor’s views. The doctor’s opinion must be recorded if given orally, and all such statements, written or oral, must be included in the independent review enti-
ty’s records.\footnote{\textit{id} \ § 422.600(b).} If the reconsideration involves a determination not to cover a nonformulary drug, the prescribing doctor must determine that all covered Part D drugs on any tier of the plan’s formulary for treatment of the enrollee’s disease or condition would not be as effective for the enrollee or would cause adverse effects or both.\footnote{\textit{id} \ § 423.600(c).} As with a redetermination of an unfavorable coverage determination, a reconsideration of a redetermination denied due to lack of medical necessity must be conducted by a doctor with expertise in the field of medicine appropriate to the drug at issue.\footnote{\textit{id} \ § 423.600(e).}

The independent review entity must issue a decision within seven days for a standard review or within seventy-two hours for expedited review.\footnote{\textit{id} \ § 423.600(d).} A copy of the decision must be sent to CMS. The notice must explain the reasons for the independent review entity’s decision, inform the enrollee of the right to an administrative law judge’s hearing if the amount in controversy is met, and describe how to obtain such a hearing.\footnote{\textit{id} \ § 423.602.} \footnote{\textit{See id.} \ § 423.612.} \footnote{\textit{id} \ § 423.612(b).}

\textbf{Administrative Law Judge’s Hearing and Beyond:} After the independent review entity reconsiders an unfavorable redetermination, the Part D appeal process converges with those for claims denied under Medicare Parts A, B, and C.\footnote{\textit{id} \ §§ 405.1102(a), 422.608, 423.612.} From the date of the reconsideration notice, the enrollee has


Part D claims are subject to regulations governing the administrative law judge and Medicare Appeals Council levels of review that went into effect for some claims in 2005 and for all claims in 2006.\footnote{\textit{Id} \ §§ 405.1102(a), 422.608, 423.612.} Many of the problems that a Medicare beneficiary may encounter in pursuing an appeal at these levels of review will be the same whether the appeal involves denial of coverage for a prescription drug, a nursing home stay, or a doctor’s visit. The one issue specific to Part D concerns calculation of the amount in controversy. To appeal a denial of any Medicare claim to an administrative law judge and then to federal court, the beneficiary must show that the value of the claim equals or exceeds an amount set by the secretary of the U.S. Department of Health and Human Services.\footnote{\textit{Id.} Fed. Reg. 11472 (March 8, 2005) (adding 42 C.F.R. pt. 405, subpt. I).} In 2005 the amount in controversy was $100 for an administrative law judge’s hearing and $1,050 for a federal court appeal.\footnote{\textit{Id.} C.F.R. §§ 423.610(a), 423.630(a)(2) (2005).} That amount may change each year based on an inflation factor.\footnote{\textit{Id.} fed. Reg. 11419, 11423 (March 8, 2005).}

A Part D plan enrollee claim may satisfy the amount in controversy in several ways. The enrollee may aggregate appeals from more than one claim that the inde-
pended review entity has denied at the reconsideration level, provided that all of the claims are identified separately, involve prescriptions for the same person, and were denied not more than sixty days before the enrollee filed the appeal. Several enrollees may aggregate claims that the independent review entity denied if all of the claims involve the same drug, the appeals are listed separately, and the request for an administrative law judge’s hearing is filed within the appropriate time frame.92

If the appeal is from a denial by the Part D plan to provide benefits, the amount in controversy is based on the projected value of the benefits. The projected value is determined by calculating the costs that the enrollee could incur based on the number of refills prescribed for the disputed drug during the calendar year.93 For example, if the plan denies coverage in August for a drug that costs $25, and the prescription allows refills until the following August, then the amount in controversy would be $125 (the five months from August through December multiplied by $25 per month), and the enrollee could request an administrative law judge’s hearing. If the refill is good only for three months, the amount in controversy would be $75 and insufficient to request a hearing. However, if the enrollee had an unfavorable reconsideration decision for another drug with a projected value of $50, and the time frame for appealing both claims to the administrative law judge had not run, the enrollee could combine both appeals to satisfy the amount in controversy.

C. Grievance Process

Each drug plan must have a grievance process, separate from its appeal process, to address issues that do not amount to coverage determinations and appeals.94 An enrollee may file a grievance either orally or in writing within sixty days of its occurrence.95 The plan determines whether a complaint filed by an enrollee constitutes an appeal and is therefore processed through its appeal system or a grievance to be processed as such.96 A grievance may include concerns about delays in processing mail order requests, concerns about the inability to access the plan’s customer service center, or rudeness by a customer service representative.

In general, a plan must resolve a grievance within thirty days of receiving the grievance.97 The plan may respond to an oral grievance orally or in writing unless the enrollee requests a written response.98 The plan must respond to a written grievance in writing.99 The plan must respond to a grievance involving a quality-of-care complaint—for example, a mail order pharmacy sending the wrong prescription—in writing and must explain the enrollee’s right to file a complaint with the Quality Improvement Organization.100

If the plan denies an enrollee’s request to expedite a coverage determination or a redetermination, the enrollee may file a grievance.101 In this situation the plan must act on the grievance request within twenty-four hours, provided that the enrollee has not already paid for and received the drug in question.102

92 42 C.F.R. § 423.610(c) (2005).
93 Id. § 423.610(b).
96 Id. § 423.564(b), (c).
97 Id. § 423.564(e)(2).
98 Id. § 423.564(e)(3)(i).
99 Id. § 423.564(e)(3)(ii).
100 Id. § 423.564(e).
101 Id. §§ 423.570(d)(2)(i), 423.584(d)(2)(i).
102 Id. § 423.564(f).
II. Beneficiary Access to Exception, Appeal, and Grievance

The Part D exception, appeal, and grievance processes are effective only if those who enroll in a drug plan know how to use them. Part D plans are supposed to include information about them in materials sent to beneficiaries upon enrollment and every year thereafter. However, most people do not pay attention to information about appeals unless and until the plan denies a claim for a requested item or service. Thus Medicare practice has been to give beneficiaries information about appeal rights when they are told that an item or service will not be paid for so that they have the information that they need to take action. However, as noted previously, an enrollee will not automatically receive an unfavorable coverage determination at the pharmacy level, where the enrollee probably will first learn that the plan will not pay for or otherwise provide the requested prescription or refill. Instead the regulations require each drug plan to arrange with pharmacies within their network either to post a generic notice telling enrollees to contact the plan if they disagree with the information from the pharmacist or to distribute such a generic notice.

Thus enrollees who want further information or want to appeal after learning from the pharmacy that the plan will not pay for a drug must first contact the plan to get a coverage determination that will inform them of all appeal rights. Placing the burden on beneficiaries in this way appears contrary to general Constitutional due process rights, which require that notice be given if services will not be covered. Indeed, the right to a written notice that explains the reasons for adverse action and how to seek review of that action “lies at the heart of due process” in Medicare as in other benefit programs.

CMS gave several reasons for its decision that beneficiaries should contact their plans for formal notice to start the appeal process after learning from the pharmacy that the drug will not be covered. First, CMS claimed that the information given by the pharmacy regarding plan design, not information specific to the enrollee, and was the same information given to enrollees at the beginning of the plan year. Second, CMS said that drug plans, not pharmacies, must issue coverage determinations. Third, CMS claimed that pharmacies would not be able to issue coverage determination notices, given the number of their customers, and that not all pharmacies had information technology systems capable of receiving patient-specific information.

CMS relied on a similar ruling from the U.S. Department of Labor that employer-sponsored group health plans do not have to treat denials by the pharmacy as claims for benefits triggering notice by the pharmacy. However, due process rights are different for workers and for Medicare beneficiaries, particularly those beneficiaries who are also eligible for Medicaid. Because of their low

103 Id. § 423.128(a), (b).
104 Id. § 423.562(a)(3).
105 See id. § 423.568(a). Notice of an unfavorable coverage determination must include the reasons for the denial and an explanation of appeal rights. Id. § 423.568(c), (d).
106 See Goldberg, 397 U.S. at 267–68.
income, Medicaid recipients are generally due more notice protection when services are denied than might be due to workers.\textsuperscript{111} While requiring people with employment connections to ask their plan for a formal denial and explanation of appeal rights may be sufficient, Medicare beneficiaries, and particularly dual eligibles, may be entitled to receive such information automatically.

If an enrollee goes to a nonnetwork pharmacy, the pharmacy has no obligation to tell the enrollee to contact the drug plan for a formal coverage determination.\textsuperscript{112} This is particularly problematic because the enrollee generally will be required to pay for the drug at the nonnetwork pharmacy. Those who do not understand the concept of network pharmacies or who do not know or understand that the pharmacy that they use is not part of the network will not get a formal statement from the plan explaining why the plan is not paying for the drug and the process for seeking reimbursement.

How the process will work with mail order pharmacies is unclear. When the enrollee files a new prescription or a refill request, and the prescription will not be covered, will the mail order pharmacy send a generic notice that the enrollee must then contact the plan to get a coverage determination? The delay caused by this additional step could be substantial, whereas the mail-order pharmacy could simply send the coverage decision.

Commentators already have identified the failure to treat the decision by the pharmacy as an unfavorable coverage determination as a barrier to the use of the appeal process. One commentator noted that the beneficiary protection provisions of the appeal process will not be invoked if plan enrollees must contact the plan first to find out officially that the plan has denied their claim and to appeal that denial.\textsuperscript{113}

---

The exception, appeal, and grievance processes may offer crucial protection to enrollees who need medically necessary drugs that are not provided by the enrollee’s Part D plan, but the ability to obtain such protection assumes that plan enrollees know about and understand their appeal rights. Exception, appeal, and grievance may take on increased significance in future years if plans narrow their formularies and assign more drugs to higher cost-sharing tiers.

\textsuperscript{111} Goldberg, 397 U.S. at 261, 269.

\textsuperscript{112} The regulations only require Part D plan sponsors to arrange with network pharmacies to post or distribute the notice telling beneficiaries to call their plan. See 42 C.F.R. § 423.562(a)(3) (2005). They are silent about the obligation of plans to make such arrangements with nonnetwork pharmacies.