

The Exceptions and Appeals Process: Issues and Concerns in Obtaining Coverage Under the Medicare Part D Prescription Drug Benefit

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INTRODUCTION

This paper describes current information about how Medicare beneficiaries may use the exceptions, appeals, and grievances processes to get access to medically necessary prescriptions under the new Medicare Part D prescription drug benefit. It identifies differing rules for various processes that will be available and describes policy issues that may make it difficult for beneficiaries to utilize the processes.

PRESCRIPTION DRUG COVERAGE UNDER MEDICARE PART D

Beginning January 1, 2006, Medicare will cover prescription drugs through a new voluntary and privately-administered Part D program, including drugs for all Medicare beneficiaries, regardless of how they become eligible for Medicare. This new program was created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). To obtain coverage, Medicare beneficiaries must take the affirmative step of enrolling in a Medicare Part D prescription drug plan that is either a free-standing prescription drug plan (PDP) or a Medicare Advantage prescription drug plan (MA-PD).

While some Medicare beneficiaries may choose not to enroll in a Part D plan, beneficiaries who are also eligible for Medicaid (the “dual-eligibles”) will have virtually no choice about participation as they will be automatically enrolled in a randomly-selected Part D plan in the Fall 2005.¹ Accordingly, Medicaid coverage for prescription drugs for dual-eligible persons will end on January 1, 2006

The MMA and its implementing regulations give PDPs and MA-PDs broad discretion to decide which specific drugs to include in their formularies, the strengths and dosage forms of covered drugs to include, and the types of “utilization management processes” to use. Under utilization management, plans may establish different co-payments for different drugs; “tiered pricing” distinguishes among preferred drugs, non-preferred drugs, and generic drugs. Plans may also require that beneficiaries request prior authorization for covered prescription drugs or that they try particular medications included in the plan’s formulary before those prescribed by the physician (“step therapy”).

The Centers for Medicare & Medicaid Services (CMS), the agency that administers Medicare, states that everyone who enrolls in a prescription drug plan will have access to all medically necessary prescriptions. In order to have such access, however, plan enrollees may have to avail themselves of various processes established by the MMA and the regulations that enable them to challenge a plan’s formulary.

¹ Dual-eligible beneficiaries can opt out of a Part D plan and may want to opt out if they have employer coverage for prescription drugs. If they do so, however, they will not be eligible for the low-income subsidy or “extra help” from Medicare to assist with premiums and other cost sharing, and in some states they may lose Medicaid if they do not take Part D. Unfortunately, some individuals with employer coverage may lose all of their retiree health benefits if they enroll in a Part D plan.

TRANSITION PROCESS

Each organization that sponsors a Part D plan, whether a PDP or an MA-PD, must establish for that plan a “transition process” to account for new enrollees who are prescribed drugs that are otherwise covered by Part D but that are not on the plan’s list of covered drugs. During the transition process, the enrollee may ask that a non-formulary drug be covered or ask the prescribing doctor to change the drug regimen to include a formulary drug.

The transition process affords an enrollee time to adjust to the requirements of the new drug plan. The concept acknowledges that individuals with certain chronic conditions may have specific medication needs and/or may be stabilized on certain non-formulary medications. The concept also protects dual eligible individuals who are auto-enrolled in a plan but who may not understand the plan’s formulary and how it might differ from their Medicaid coverage. The process must be available to all enrollees, regardless of the number of medications they take or their income levels.

As with the plan formularies themselves, each plan has the flexibility to determine its own transition process. The only requirement is that the process be consistent with “written policy guidelines and other CMS instructions.” Because there is no one standard process, beneficiaries who believe that they may need to make use of the transition process will have to evaluate the processes established by each of the Part D plans they are considering.

CMS has issued several policy statements regarding the transition process, more, in fact, than it has issued about any other process an enrollee may use to gain access to a prescribed non-formulary medication. The primary policy guidance is found in a specific Transition Guidance document issued by CMS in March 2005.

The Guidance includes two suggestions for how a plan might choose to handle transition issues. First, the Guidance suggests that a plan *could* authorize a temporary one-time 30-day transition refill of the existing prescription. Again, the enrollee would use the 30-day time period to either ask the plan to pay for the non-formulary drug or to change to a formulary medication. Alternatively, the Guidance suggests that the plan could contact all new enrollees before coverage begins to review the medicines they take, to suggest changes or to advise them how to request an exception to get the drug included on the formulary.

CMS also recognized that residents of long-term care facilities may be particularly vulnerable to medication changes. In Guidance concerning residents, CMS suggested that plans provide a 90-180 transition period for residents with multiple medications. Again, the additional time is in recognition of that fact that residents may need longer time periods to transition from non-formulary drugs to formulary drugs, given the potential for adverse consequences from interactions among drugs and from withdrawal from certain medications.

Finally, CMS suggested that states may want to consider authorizing a 90-day refill in December 2005 of prescriptions covered by the state Medicaid program for people who are dually eligible for Medicare and Medicaid. The extra supply would protect dual eligibles who are confused about the transition to Medicare prescription drug coverage, or who are not assigned to a Part D plan, and would assure that they have needed drugs while the transition from Medicaid drug coverage to Medicare drug coverage takes place. It is unclear whether any states will act on this suggestion. Many Medicaid state plans only allow Medicaid to pay for a 30-day supply of Medicaid-covered drugs. Laws in some states also preclude dispensing of a 90-day supply of certain medications.

TRANSITIONS WITHIN A PLAN'S FORMULARY

Not only do the MMA and regulations give plans authority to decide which drugs they will include on their formulary, they also allow plans to change their formulary during the course of a given year. A plan may remove a drug from its formulary; add a drug to its formulary; or change the preferred or tiered cost-sharing status of a drug, subject to certain limitations.

No changes can be made during the annual coordinated enrollment period, which will generally extend from November 15th to December 31st of each year, or for 60 day after the start of the contract year associated with that time period. In other words, plans generally will not be able to change their formularies until March of each year. An exception is made for a drug no longer deemed safe by the Food and Drug Administration (FDA). Such a drug may be removed from the formulary at any time.

A plan that decides to remove a drug from its formulary or change a drug's cost-sharing status must provide 60-days advance notice of the formulary change to:

- enrollees who use the drug,
- CMS,
- prescribing physicians,
- 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 include the name of the drug, describe the change, explain why the change is being made, identify other available drugs and their cost-sharing, and describe how to request an exception or appeal. Plans may also provide information about an up-coming formulary change by posting the information on its web site. In lieu of providing 60-days' advance notice to enrollees, the plan may provide written notice and a 60-day supply of the drug when the enrollee requests a refill. If a drug is removed because the FDA deems it unsafe, notice may be provided retroactively. A plan enrollee who receives notice that a drug he or she is taking will be removed from the formulary or changed to a higher, and therefore more costly, cost-sharing tier has only two choices. The enrollee may request an exception to have the plan continue to pay for

the drug or for the enrollee to continuing paying the lower cost-sharing amount. Alternatively, the enrollee may change to a different formulary drug. The enrollee cannot change to a different drug plan if needed drugs are no longer included on the plan's formulary. Once someone chooses a drug plan he or she cannot change that drug plan, with limited exceptions, until the next annual coordinated enrollment period.

THE APPEALS PROCESSES

All plan sponsors must include in their drug plans a process through which a plan enrollee may challenge decisions made by the Part D plan. Congress determined that the appeals process for Part D should be based on the appeals process utilized by Medicare Advantage plans (which include a variety of coordinated care delivery systems such as health care maintenance organizations (HMOs) and preferred provider organizations (PPOs), to provide benefits under Medicare Part C. Thus, the Part D appeals process contains elements similar to the process used to challenge decisions made by Medicare HMOs, PPOs, and private fee-for-service plans. Medicare appeals processes are generally founded on Constitutional due process principles.

One very important difference between the Medicare Part C and the Medicare Part D process is the inclusion of a process to request exceptions to the design of a plan's formulary. An exception request is a subset of the coverage determination, the initial determination issued by the plan that gets the enrollee into the appeals process. Unlike other coverage determinations, however, an exceptions request has its own process and procedure and requires participation by the prescribing physician.

Exceptions Process

Each drug plan must develop its own exceptions process under which a plan enrollee may ask the drug plan to cover a non-formulary drug or to reduce cost sharing for a formulary drug. 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 unfavorable exception determination gets an enrollee into the appeals process.

a. General requirements: A plan enrollee, the enrollee's appointed representative or the prescribing physician may request an exception. An appointed representative includes someone who is appointed by an enrollee to act on behalf of the enrollee in the claims and appeals process or someone who is authorized under state or other law to act on behalf of the enrollee.

i. Physician participation. Even if the exception is requested by an enrollee or an appointed representative, the enrollee's doctor must participate in the process by providing the medical information required by the plan. In fact, the time under which the Part D plan must provide a decision is calculated from receipt of a statement by the doctor. The submission of a supporting statement by the prescribing physician will not automatically result in a favorable decision, however.

ii. Review of evidence in support on an exception. The regulations establish parameters for the exceptions process. Each plan may then develop its own procedures and evidentiary requirements within these parameters. The amount and type of medical and other evidence needed to support an exceptions request and the weight given to the doctor's statement may therefore differ among plans. Thus, doctors whose practices include a large number of Medicare beneficiaries will have to become familiar with the different requirements of exceptions processes for each Part D plan that serves their community.

A plan must inform the enrollee and the prescribing physician of its decision on an exceptions request with in 72 hours after receipt of the doctor's supporting statement, or as expeditiously as the enrollee's health condition requires. If the enrollee requests expedited consideration, the decision must be made within 24 hours of receipt of the physician's statement or as expeditiously as the enrollee's health condition requires. Part D uses the same standard as used under Part C for determining whether a request for expedited consideration will be granted, namely, that application of the standard timeframe may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. The plan must grant a request for expedited consideration if made by a doctor. Thus, as a matter of routine, doctors should request expedited consideration of an exception request at the time they submit their supporting documentation.

iii. Notification of exceptions decision. 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. In this situation only the appeal will be automatic. The Part D plan must forward the exception request to the independent review entity (IRE) within 24 hours of the end of the statutory time frame to act.

If an exception request is denied, then the enrollee may appeal further, as discussed below. If the request is granted, the request remains effective as long as the physician 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.

b. Exceptions related to tiered cost-sharing structure (formulary drugs): An enrollee who must pay a high co-payment or co-insurance for a prescribed drug on the plan's formulary may file a request to have the cost-sharing reduced to that of a lower tier on the formulary. Such a request may be filed when the individual first enrolls in the plan, when the individual is prescribed the drug, or if the plan changes its tiered cost-sharing structure during the year.

The prescribing physician must assert that the preferred drug is less effective than the preferred drug or would have adverse effects on the enrollee, or both. The physician may provide an oral statement, although the plan could request that the statement be written or that the physician provide additional supporting documentation. The plan may establish its own criteria for reviewing the exception request. At a minimum, the criteria must

include a description of the criteria used to evaluate the physician's statement; consideration of whether the drug in question is the therapeutic equivalent of any other formulary drug; and consideration of the number of drugs on the formulary that are in the same class and category as the drug in question.

The implementing regulations place limitations on the drugs for which an enrollee may request an exception to the plan's tiered cost-sharing, although no such limitations were included in the MMA itself. If the plan has a separate tier for generic drugs, an enrollee cannot get an exception to cover the non-preferred 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 tiering exception.

c. Exceptions related to non-formulary drug: A plan enrollee may also file an exception request to ask the drug plan to cover a drug that could be covered under Part D but that is not on the plan's formulary. The concept of a non-formulary drug is broader than the above statement indicates. It includes circumstances in which the drug is on the formulary but may not be covered in the dosage amount (ex., 50 milligrams instead of 100 milligrams) or form (ex., liquid instead of pill) required by the enrollee.

The concept also includes restrictions on the amount of medicine dispensed, for example, when the prescription requires the enrollee to take a particular medicine twice a day but the plan will only authorize 30 pills. An enrollee may also request an exception to the application of other cost utilization tools. These include a step therapy requirement under which the enrollee must show that other less costly medications may not work before the prescribed medication will be covered, or therapeutic substitution. As with an exception request to tiered cost-sharing, a formulary exception may be filed when an individual first enrolls in the Part D plan, when the individual is prescribed a non-formulary drug or a drug subject to utilization management tools, or when the plan notifies the enrollee of a mid-year formulary change.

i. Standard of proof. Each Part D plan will establish its own standard of proof and its own process for evaluating the evidence in support of the exceptions request. The procedures must include a description of the criteria that will be used to evaluate the doctor's supporting statement. The Part D plan must also have a process for comparing any applicable medical and scientific evidence on the safety and effectiveness of drug in question versus any formulary drug. Finally, the Part D plan must have a set process for determining the cost-sharing tier to which a drug will be assigned if an exception is granted.

ii. Physician's statement. The physician's statement will be crucial to the non-formulary drug exception request. The rules allow the statement to be made orally, however, given the complexity of the issues, the statement should be written even if the plan does not require a written certification. At a minimum, the doctor has to state that the requested drug is medically necessary because no formulary drug is as effective as the requested drug. The doctors' statement should include the enrollee's identifying information, patient history and diagnosis, and then the reasons why the formulary drug

is not acceptable for the enrollee, as discussed below. The doctor may add other information to help evaluate the medical necessity of the requested drug, and in fact may need to add references to relevant clinical, medical, and scientific evidence in order for the request to be granted.

iii. Step-therapy and non-formulary drugs. 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 can be established where both sound clinical evidence and medical and scientific evidence indicate that the non-formulary drug would not be effective 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.

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 has already proven to be ineffective in treating the enrollee's disease or condition, or whether clinical, scientific, and medical evidence indicate that the limited number of doses would be an ineffectual treatment or is likely to cause harm given the physical and mental characteristics of the enrollee and the characteristics of the drug regimen.

iv. Other considerations. If coverage is granted for a non-formulary drug based on the exception request, the enrollee cannot request a tiering exception to reduce the cost-sharing. 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 non-formulary drugs will be assigned to such a tier. A non-formulary drug covered under the exceptions process is treated as a formulary drug for the enrollee involved. Enrollee cost-sharing for the drug will count towards the plan's deductible and the enrollee's out-of-pocket expenses needed to reach catastrophic coverage.

Under current Medicaid law, Medicaid recipients are entitled to a temporary supply of their medication pending a request for prior authorization by the plan and to drugs pending a termination of services. No such protection is available under Medicare Part D for dual eligibles. Individuals who reside in a long-term care facility, however, are entitled to an emergency supply of their medication pending an exception request.

Appeals Process

As indicated, each drug plan must have an appeals process, including a process for expedited requests at all levels of review before the administrative law judge level. The first step in the process is a coverage determination issued by the drug plan. The next steps are a redetermination by the drug plan; reconsideration by the independent review entity (IRE), a hearing before an administrative law judge (ALJ); Medicare Appeals Council (MAC) review; and finally an appeal to federal court.

a. Coverage Determinations Timeline: A coverage determination may be requested by a beneficiary, a beneficiary's appointed representative, or the prescribing physician. The drug plan must issue a coverage determination as expeditiously as the enrollee's health requires, but no later than 72 hours for a standard request for a coverage determination; 72 hours when the beneficiary has already paid for the drug; or 24 hours if a request for expedited review has been granted. Expedited review may be requested by the beneficiary or a doctor 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 request for expedited review made by a physician. If an enrollee's request for expedited review is denied, the plan may advise the enrollee to re-file the request with a doctor's statement, or to file a grievance.

b. Coverage Determinations Defined: A coverage determination is defined under the regulations to include:

- A decision by the drug plan not to pay for or provide a drug because
 - The drug not covered by Part D;
 - The drug is not on the plan's formulary drug;
 - The drug is not considered medically necessary; or
 - The drug was furnished by an out-of-network pharmacy.
- A decision on an exceptions request.
- An untimely decision that would adversely affect the enrollee's health
- A decision on the amount of cost sharing

A statement by the pharmacy that the plan will not cover a requested drug is not a coverage determination. The coverage determination can only be made by the Part D plan or an entity acting on behalf of the Part D plan. The plan will give the enrollee a written notice of the coverage determination. If it is unfavorable, the notice must explain the reasons for the decision and the right to request a redetermination, which is really the first level of appeal. The plan may provide oral notice, followed by a written notice in expedited cases.

c. 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 60 days of the date of the coverage determination. A plan has the option to accept oral requests. The enrollee or an appointed representative acting on behalf of the enrollee, and not the prescribing physician, must request a redetermination. The redetermination is the first level of the appeal process, and the MMA requires that an appeal be filed by the enrollee. Nevertheless, the prescribing physician may still be needed to submit evidence and/or to support a request for an expedited redetermination.

The enrollee and the prescribing physician, where appropriate, must be given the opportunity to submit supporting evidence either in writing or in person. This opportunity may be more limited if a request for expedited reconsideration is granted. The plan personnel who review the redetermination must be different from the personnel involved in making the initial coverage determination. The reviewer on redetermination must be a

physician with expertise in the field of medicine appropriate to the drug in question if the plan originally determined that the drug was not medically necessary. The physician does not have to be of the same specialty or subspecialty as the prescribing physician.

The drug plan must act as expeditiously as the enrollee's condition requires, but not more than seven days for a standard review, including where payment has already been made, or more than 72 hours for an expedited review. If the appropriate time frame is not met, then the plan must send the redetermination to the IRE within 24 hours of the expiration of the required time. 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 must also describe the expedited process if the redetermination did not involve a claim in which the enrollee seeks reimbursement for payment already made.

d. Reconsideration: The Part D appeals process differs from the Part C appeals process 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. Under Part D, the enrollee must act affirmatively and request a reconsideration within 60 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 IRE is automatic. The enrollee's request for a reconsideration must be in writing. There is no option at this level of review for accepting an oral appeal.

After the appeal is filed, the IRE must solicit the view of the prescribing doctor. The physician's opinion must be recorded if provided orally, and all such statements, whether written or oral, must be included in the IRE's records. If the reconsideration involves a determination not to cover a non-formulary drug, the prescribing physician 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, would cause adverse effects, or both. 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 physician with expertise in the field of medicine appropriate to the drug at issue.

The IRE must issue a decision within seven days for a standard review, or where payment has been made, or within 72 hours for expedited review. A copy of the decision must be sent to CMS. The notice must explain the reasons for the IRE's decision, inform the enrollee of the right to an ALJ hearing if the amount in controversy is met, and describe the process for obtaining an ALJ hearing.

e. ALJ hearing and beyond: After the IRE reconsideration, the Part D appeals process converges with the appeals processes for claims denied under Medicare Parts A, B, and C.

i. Notice of decision. The enrollee has 60 days from the date of the reconsideration notice to request an ALJ hearing on an unfavorable reconsideration decision, 60 days to request Medicare Advisory Council (MAC) review of an unfavorable ALJ decision, and then 60 days to request review in federal court.

Part D claims will be subject to regulations governing the ALJ and MAC levels of review that went into effect for some claims in 2005 and for all claims in 2006. Many of the problems a Medicare beneficiary may encounter in pursuing an appeal at these levels of review will be the same regardless of whether the appeal involves denial of coverage for a prescription drug, for a nursing home stay, or for a doctor's visit.

ii. Calculating the amount in controversy. The one issue specific to Part D concerns calculation of the amount in controversy. In order to appeal a denial of any Medicare claim to an ALJ 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 Department of Health and Human Services. In 2005 the amount in controversy is \$100 for an ALJ hearing and \$1050 for a federal court appeal. That amount may change each year based on an inflation factor.

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 have been denied at the reconsideration level, provided that all of the claims are identified separately, all of the claims involve prescriptions for the same person, and all of the claims were denied not more than 60 days before the appeal was filed. Several enrollees may aggregate claims denied by the IRE if they all involve the same drug, the appeals are listed separately, and the ALJ request is filed within the appropriate time frame.

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. This is determined by calculating the costs the enrollee could incur based on the number of refills prescribed for the disputed drug during the calendar year. 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 x \$25/month) and the enrollee could request an ALJ hearing. If the refill is only good for three months, the amount in controversy would be \$75 and insufficient to request a hearing. If the enrollee had an unfavorable reconsideration decision from another drug with a projected value of \$50, however, and the time frame for appealing both claims to the ALJ had not run, the enrollee could combine both appeals to satisfy the amount in controversy.

GRIEVANCE PROCESS

Each drug plan must have a grievance process, separate and apart from its appeals process, to address issues that do not amount to coverage determinations and appeals. An enrollee may file a grievance either orally or in writing within 60 days of its

occurrence. It is up to the plan to determine whether a complaint filed by an enrollee constitutes an appeal, and is therefore processed through its appeals system, or a grievance to be processed as such. A grievance might 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 30 days of its receipt. The plan may respond to an oral grievance orally or in writing, unless the enrollee requests a written response. A written grievance must be responded to in writing. The plan must respond to a grievance involving a quality of care complaint, such as, 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 (QIO).

If the plan denies an enrollee's request to expedite a coverage determination or a redetermination, the enrollee may file a grievance. In this situation the plan must act on the grievance request within 24 hours, provided the enrollee has not already paid for and received the drug in question.

POLICY ISSUES

The exceptions, appeals, and other processes described above, are designed to protect Part D plan enrollees and to ensure they get all medically necessary drugs prescribed for them. Questions arise, nonetheless, concerning the effectiveness of the processes and the ability of older people and people with disabilities to use them.

1. Notice of a denial of coverage and appeal rights is [are] should be provided automatically at the pharmacy level.

a. Beneficiary access to good notice. Each Part D drug plan has the obligation to provide notice to an enrollee of an unfavorable coverage determination. This notice starts the appeals process and describes how the enrollee may request a redetermination by the plan. The notice is not provided automatically at the pharmacy level, however, where the enrollee will probably 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 to either post a generic notice telling enrollees to contact the plan if they disagree with the information provided by the pharmacist or to distribute such a generic notice.

b. What notice is required. An enrollee who wants further information or wants to appeal must first contact the plan to get a coverage determination that will inform him or her of any appeals right that might ensue from the denial. Placing the burden on beneficiaries in this way appears contrary to general Constitutional due process rights, which require that notice be provided if services will not be covered. CMS, relying on a similar ruling from the Department of Labor regarding employer-sponsored plans, decided that beneficiaries should contact their plans for formal notice to start the appeals

process on the theory that drug plans, not pharmacies, must issue coverage determinations.

Due process rights are different, however, for workers and for Medicare beneficiaries, particularly those beneficiaries who are also eligible for Medicaid. Because of their low income, Medicaid recipients are generally due more notice protection when services are denied than might be due to workers. While it may be sufficient to require people with employment-connections to ask their plan for a formal denial and explanation of appeal rights, Medicare beneficiaries, and particularly dual eligibles, may be entitled to receive such information automatically.

c. Network and non-network pharmacy obligations. In addition, if an enrollee goes to a non-network pharmacy, the pharmacy has no obligation to tell the enrollee to contact the drug plan for a formal coverage determination. This is particularly problematic since the enrollee will generally be required to pay for the drug at the non-network pharmacy. Those who do not understand the concept of network pharmacies or who do not know or understand that the pharmacy 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.

Finally, it is unclear how the process will work with mail order pharmacies. 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 stating that the enrollee must then contact the plan to get a coverage determination?

2. Policy makers must ensure that access to a supply of a required drug pending an appeal is readily available.

Under current Medicaid law, but not under Medicare, individuals are entitled to a 72-hour supply of prescriptions pending a request for prior approval of an on-going medication. They also may be entitled to a continued supply of the drug pending an appeal that is timely filed. These protections are based on long-standing Supreme Court cases that say that Constitutional due process requires a continuation of necessary public benefits pending an appeal by individuals in dire financial need.

CMS guidance indicates that nursing home residents, regardless of income, may be entitled to a continued supply of medication pending an exception request. Thus, when the Medicare prescription drug benefit goes into effect in January 2006, people who are dually eligible for Medicare and Medicaid and who live in other settings will lose a protection they currently have under case law.

3. As the Medicare Prescription Drug benefit is currently crafted, beneficiaries do not have the assurance of a uniform exceptions process, sufficiently broad in scope and standards of review.

a. **Lack of uniformity:** Although the regulations set out minimal requirements for all exceptions processes to meet, each plan may establish the standards by which it will

evaluate doctors' statements in support of an exception request and the medical, scientific, and clinical evidence it will rely upon in evaluating the request. Thus, physicians with patients enrolled in the broad array of drug plans available in their community may have to familiarize themselves with over 40 different exceptions processes. The differences may result in barriers to effective assistance by physicians. A physician may decide the process is too complicated and decide not to file a supporting statement. Or, the physician may be confused by the different requirements and not provide the appropriate information that is specific to the requirements of the plan from which the exception is requested.

b. **Limitation on use of the exceptions process:** The regulations include two limitations on the request for a tiering exception that narrow the scope of this type of exceptions request from the statute. An enrollee cannot request an exception to a lower tier that applies only to generic drugs. An enrollee also cannot request an exception if the plan includes a separate tier for the most costly and unique drugs. Thus, individuals who need these drugs will be penalized based on their medical condition or illness in contradiction of the anti-discrimination requirements in the statute.

c. **Duration of the exception:** If an exception request is granted for a drug to treat a chronic condition, the plan is only obligated to abide by its decision through the end of the year. That means that the individual who continues to require the drug may need to file another exception request at the beginning of the next year.

While CMS has indicated that private sector plans generally continue exceptions as long as the physician continues to prescribe the drug and that it expects Part D drug plans to do the same, there is no legal obligation for them to do so. Having to request a new exception each year will be a burden both on the enrollee and the prescribing physician. Such a policy may dissuade an individual from remaining in a plan and could potentially be used to encourage enrollees with more costly drug requirements to choose a different plan.

CONCLUSION

The exceptions and appeals processes will provide crucial protection to enrollees who need medically necessary drugs that are not provided by the enrollee's Part D plan .. The role of these processes may increase in future years if plans narrow their formularies and assign more drugs to higher cost-sharing tiers.

AUTHORITIES

Medicare Modernization Act, 42 U.S.C. ' ' 1395w-101 et seq.

MMA regulations, 70 Fed. Reg. 4193 (Jan. 28, 2005), adding 42 C.F.R. Part 423



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