

Grievance and Appeals Procedures: An Analysis of the MMA and Proposed Regulations

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Introduction

This analysis examines two separate aspects of the Medicare Part D prescription drug regulations which were published by the Centers for Medicare and Medicaid Services (CMS) on August 3, 2004 (69 Fed. Reg. 46632-46863). The first has to do with the protections afforded under the rules when a dispute arises between a Part D eligible or enrolled person and the Medicare Part D program. It is critical to understand the dispute resolution procedures that are available for various types of disputes since these procedures are intended to protect the interests of Medicare beneficiaries.

The second issue has to do with the procedural protections for indigent Medicare beneficiaries who need low-income subsidies in order to qualify for Part D benefits. Of particular importance are the procedures for enrolling “full benefit dual enrollees” (i.e., very poor Medicare beneficiaries who currently receive Medicaid prescription drug coverage, and who as of January, 2006, will see their Medicaid prescription drug coverage replaced with the new Part D benefit).

Understanding how the proposed CMS rules address these two sets of issues in implementing the Part D legislation is very important. The law itself offers relatively detailed provisions. At the same time, as with many large and complex laws, the legislation contains many areas of ambiguity and silence. Under the traditional principles of law which govern rulemaking under Social Security Act programs such as Medicare, the Secretary of HHS the power to “fill in the picture,” even when the legislation does not explicitly order him to do so in order to amplify on the meaning of a particular statutory provision in order to increase protections for program beneficiaries. As a result, understanding where the rules might be strengthened while remaining true to the broader language of the statute represents an essential step in ensuring full realization of beneficiary safeguards.

Why Understanding Beneficiary Protections in Medicare Part D Disputes Is Important

A fundamental question in any insurance program, public or private, is the safeguards that exist when a dispute arises, i.e., when an insurer acts in a way that the enrollee or applicant considers erroneous. In any insurance scheme, endless types of disputes can arise. In a dispute context, Medicare Part D operates as a public/private system, with public funds used to purchase benefits from private risk-bearing entities charged with negotiating the terms of coverage from suppliers, arranging for covered services, and administering claims. Because of this public/ private mix, the range of disputes which can arise may be somewhat broader than that found in the “traditional” Medicare Parts A and B programs.

Any insurance program conditions coverage on meeting various conditions of eligibility related to enrollment or coverage once enrolled. Part D is no exception. With every condition which an applicant or enrollee must satisfy, a possible dispute can arise. The more conditions, the more potential for disputes.

Consider the following examples of possible disputes that could arise under the Part D program. These disputes begin with the Part D enrollment and disenrollment process itself. A beneficiary might erroneously be told that she is ineligible for Part D enrollment at all, or she might be

denied enrollment into a specific prescription drug plan (PDP). She might be told that in order to enroll she must pay an enrollment penalty, because her enrollment is not timely. She might be denied the right to enroll during a “special enrollment period.” She might be disenrolled for “disruptive” behavior in a plan.

Once a beneficiary is enrolled, she might find that she fails to receive a covered benefit. This might happen when her physician makes a formal request to her PDP on her behalf for prior authorization to prescribe a particular drug that does not appear on the PDP formulary. She might also discover that she cannot get a prescription at the point at which she brings her prescription to a pharmacy and is told by a pharmacy clerk that she has to pay herself because the plan has denied the coverage. This could happen because of a contraindication, or because she has exhausted the allowable supply, or because of a change in the formulary, or some other reason. She also may get a prescription drug that is in fact not what the physician prescribed at all but is instead the generic version or a therapeutic equivalent. She also might find that her “in network” pharmacy has such long waits that she cannot get a prescription filled on the same day, or she might encounter what she considers to be a rude and unhelpful clerk.

A Medicare beneficiary seeking low-income subsidy assistance may be denied a subsidy on the basis of excess income or resources in relation to the subsidy eligibility limits, or for failure to either produce verifiable information or supply needed documents. A beneficiary receiving a subsidy could receive a notice that because of a change in income or resources or any other type of altered living arrangement (e.g., moving into or out of a nursing facility), the subsidy is being reduced or terminated.

In view of all of these possible scenarios, the issue of how the government stays accountable to individual program beneficiaries lies at the heart of Medicare and Medicaid. Accountability to individuals is fundamental to insurance generally. And because Medicare and Medicaid operate as individual legal entitlements guaranteed by the government, the U.S. Constitution compels the government to extend certain basic protections before benefits can be denied, reduced or terminated. Lawmakers traditionally have paid a good deal of attention to the establishment of procedural safeguards in Medicare and Medicaid, and Part D is no exception.

In designing beneficiary safeguards, Congress has attempted to take into account the evolving nature of health insurance itself. The advent of managed care has made procedural safeguards in health insurance arrangements more complex. This is because in the context of a legal analysis means any form of health insurance in which enrollees secure full access to their benefits by obtaining them through a member of their insurer’s participating provider network. As a consequence, disputes which a generation ago were strictly between a patient and a health care provider and which had nothing to do with the insurer now may be part of the insurance arrangement itself. In short, a complaint against an insurer today may have nothing to do with one’s *eligibility* for benefits or *coverage*, and yet it is the insurer (in this case, the Medicare program, along with its participating health plans) that remains accountable.

For several reasons, it is very important to understand which types of disputes qualify for which types of beneficiary protections, as well as how these protections operate. First, basic rights under the plan can be lost to a beneficiary if the wrong dispute system is used. Part D coverage

offers financial protection against the cost of essential and enormously expensive health care. A denial of coverage can be devastating, both health wise and financially. If a beneficiary fails to pursue the correct dispute procedures, the ultimate result may be loss of medical care access itself, given the nexus between coverage and utilization of care.

Second, in the context of Part D, payments for prescriptions that are determined not to be covered, no matter how steep, do *not count* toward the out-of-pocket maximum payment threshold which beneficiaries must reach before they can trigger their Part D catastrophic coverage. Every denial not only means the loss of basic coverage, but an inability to reach the spending threshold that triggers the additional coverage available for individuals with very high out-of-pocket costs. In other words, *only* out-of-pocket payments for *covered* drugs count toward the catastrophic coverage threshold. As a result, every coverage denial or request for an exception under a tight formulary should be actively pursued.

Third, low-income Medicare beneficiaries face a particularly challenging situation under Part D. Not only is the subsidy essential to their ability to access the benefit, but in the case of full benefit dual enrollees, their Medicaid coverage actually could stop prior to their successful enrollment into the new Part D subsidy. This is because as part of the Part D program, Congress eliminated Medicaid prescription drug coverage for Medicare enrollees with dual eligibility. Because Medicaid coverage ends, they must be transitioned from Medicaid to Medicare without a break in their coverage. And because Medicaid coverage ceases, these dual enrollees also will lose what, from a legal viewpoint, may be the most critical Medicaid procedural protection available, namely the right to a *pre-termination hearing* when the right to *ongoing drug treatment* is reduced or terminated. This special protection exists in Medicaid as a result of a landmark United States Supreme Court decision¹ which held that welfare recipients are so poor and thus have such a “brutal need” for government help that their benefits must continue pending resolution of any dispute over their reduction or termination. This right to a pre-termination hearing has been interpreted by courts to apply to Medicaid beneficiaries, even when enrolled in private managed care plans.² Congress has never extended this extraordinary additional protection to Medicare beneficiaries, however, so the protection of pre-termination reviews will no longer be available once dual enrollees transition to Medicare.

Medicare’s Two Basic Dispute “Pathways:” Grievances and Appeals

For beneficiaries who receive Part D benefits, there are two basic pathways for dealing with disputes, each of which has its own purposes and uses. These pathways were first established for private managed care arrangements, and Congress applied them to Part D as well. They are *appeals* and *grievances*.

¹ *Goldberg v Kelly*, 397 U.S. 254 (1970)

² Rand Rosenblatt, Sylvia Law and Sara Rosenbaum, *Law and the American Health Care System* (Foundation Press, NY, NY 1997; 2001-2002 Supplement and 2004-2005 Update)

Appeals

The Medicare program provides for a formal appeals process for Medicare beneficiaries who dispute decisions made regarding their entitlement to Part A or B services or coverage decisions made by the government or its private insurance contractors. Because the entitlement to coverage itself is what is at stake in an appeal, the process is far more formal than is the case with a grievance and contains many more layers of review.

The appeals process under the original Medicare program begins with an initial determination by a carrier or intermediary, followed by an informal redetermination. If the beneficiary is dissatisfied, he or she can file a formal appeal and at this point enters an administrative review process directly overseen by the United States Department of Health and Human Services. From this point, the beneficiary can appeal to federal court.

Federal law also permits beneficiaries to challenge Medicare coverage determinations under certain decisions. A coverage determination is a formal process in which the government makes a decision whether particular treatments or services will be covered *at all* for any beneficiary. Coverage decisions are typically made in the context of emerging medical technologies.

In the case of persons enrolled in Medicare managed care, an adverse initial coverage determination made by a managed care organization is reviewed prior to a beneficiary's government appeal by the Center for Health Dispute Resolution, a private entity under contract to the government to conduct impartial external reviews of disputed coverage decisions. Managed care decisions to terminate coverage for hospital, nursing and rehabilitation facility, and home health services, trigger special federal fast track appeals protections because of the heightened potential for serious and adverse health consequences.³

In fashioning the Part D coverage determination process, Congress used the approach specified for managed care plan appeals. Thus, the Part D process begins with an initial coverage determination by a prescription drug plan (PDP), extends through a reconsideration process, and is followed by a formal external appeals process.⁴ PDP sponsors are expected to "meet the requirements" applicable to Medicare Advantage coverage determinations,⁵ and the Secretary is specifically given the authority to modify the process to make it work in an outpatient prescription drug context.⁶

Grievances

A grievance is an informal process offered by all Medicare managed care contractors to assist program enrollees resolve complaints that do not involve challenges to coverage determinations. Grievance procedures are available when a managed care plan enrollee is unhappy with an aspect

³ <http://www.cms.hhs.gov/healthplans/appeals/grijalva%20guidance%204-28fnl.pdf>. For general information on the appeals process in managed care, see http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_cat_lv12=88

⁴ Maximus CHDR, Medicare Appeals and Your Rights (accessed September 1, 2004) www.medicareappeal.com/page.asp?Script=12.

⁵ Social Security Act §1860D-4(g)(1)

⁶ Social Security Act §1860D-4 (h)(1)

of plan operations. A grievance process involves informal dispute resolution techniques and is designed to ensure that disputes over treatment or quality are considered in a structured manner. The process lies within the health plan itself and the dispute is not appealable to a formal federal administrative process or the courts.

The MMA requires PDP sponsors to offer grievance procedures similar to those available for Medicare Advantage enrollees.

How Do the Medicare Part D Regulations Address Various Types of Disputes?

A. Disputes involving the entitlement to enroll in a Part D plan

What process is available when the entitlement to coverage itself is in dispute? The basic Part D entitlement consists of the right of eligible persons (i.e., Medicare beneficiaries) to enroll in and receive covered benefits through, a qualified Part D PDP, as well as a right to an additional subsidy in the case of eligible low-income beneficiaries. While the Part D statute clearly speaks to grievance and appeals rights of *Part D plan enrollees*, the statute is unclear regarding the availability and extent of appeals rights in the context of the basic entitlement to *any* coverage under *any* plan.

It might appear that this entitlement is not subject to dispute and that any Medicare beneficiary is automatically enrolled in a plan. This is not the case however. Certain criteria need to be satisfied, and certain enrollment obligations must be fulfilled. For example, the only individuals who are eligible for Part D are persons who are entitled to benefits under Part A or enrolled under Part B.⁷ An entitled beneficiary may face restrictions on enrollment, such as being limited to enrollment during a special enrollment period (where other coverage is lost) or having to pay an enrollment penalty or being charged with a late enrollment fee. An individual may lose enrollment if a plan goes under or if she is disenrolled by a plan for disruptive behavior.⁸

The statute requires the Secretary to establish a process under Part D for enrollment, disenrollment, and termination and change of enrollment. Although the proposed regulations track the statute in terms of defining who is eligible for enrollment and the enrollment process, they do not address the question of what dispute resolution procedures are available to individuals whose disputes relate to an enrollment denial or termination or the imposition of a penalty in connection with enrollment. There are well-established and formal appeals procedures for resolving disputes related to the underlying Part A or Part B Medicare entitlement itself.⁹ But rules fail to address the means by which disputes arising from plan enrollment denials, penalties, or terminations. Grievances are not available since individuals are not plan members in many of these cases. Furthermore, because the benefit entitlement itself is on the line, a simple grievance procedure, even if available, would not be sufficient protection under concepts of Constitutional due process.

⁷ Social Security Act §1860D-1(a)(3)(A).

⁸ Proposed 42 C.F.R. §423.44(b)(i) [sic] [appears that this should be identified as “(ii)”]

⁹ Social Security Act §1869.

Issue for comment: Clarification within the rules of the appeals rights is needed for individuals whose disputes arise in connection with the denial of enrollment into a Part D plan, the imposition of an enrollment penalty, or the termination of Part D plan enrollment. Eligibility and enrollment itself would appear to be essential. As written, the proposed rules appear not to resolve this statutory “gap” or “silence” regarding how Part D enrollment disputes will be handled. Presumably, since these disputes involve access to the coverage entitlement, the dispute resolution process would involve a formal determination, followed by a redetermination and full access to the appeals process. Resolution of this matter in the final regulations would appear to be fundamental to protection of the Part D legal entitlement.

B. Part D enrollee disputes that carry appeals rights

1. *What is a coverage determination?* In the case of Part D, beneficiaries have formal appeals *only* when a dispute involves conduct known as a “coverage determination.” Under the law, a “coverage determination” is defined as a “failure to provide or pay for a covered Part D drug.”¹⁰ A coverage determination in turn follows a “request for coverage.”

The definition of a “coverage determination” appears to be very broad and could be read as encompassing virtually any situation in which a prescription goes unfilled. At the same time, the regulations are not sufficiently clear regarding whether the presentation of a prescription constitutes a request for coverage or whether the failure to fill a prescription will be considered a “coverage determination” for purposes of triggering appeals rights as opposed to the lesser grievance process. This ambiguity is critical, since the most common way in which a beneficiary will experience a coverage denial may be the simple refusal on the part of a pharmacy to fill a prescription, either as written or at all. Although the rules follow the statute in identifying requests for exceptions to “tiered cost sharing” and formulary restrictions as appealable, the rules are silent with respect to what may turn out to be the most common type of denial, namely the series of events which unfold between the time a beneficiary hands the claim for benefits (i.e., the prescription) to a pharmacist and the time that the pharmacist indicates that the plan has denied the claim. No written denial might issue, and yet the action clearly falls within the terms of the definition of a “coverage determination.

Issue for comment: Identifying what constitutes a request for coverage, thereby triggering a PDP sponsor’s coverage determination obligations and appeals rights is needed. The proposed rules should be clarified to indicate that the presentation of a prescription constitutes a request for coverage and also, whether a pharmacy’s failure to dispense the prescription as written constitutes a coverage determination. Without this clarification, many disputes regarding the filling of prescriptions may not be considered appealable. If the presentation of a prescription is not considered a request, then the protections stand to lose much of their meaning, unless and until a separate and formal request is filed by the beneficiary. Because of the urgent nature of many prescription

¹⁰ Proposed 42 C.F.R. §423.566(b)(1)

drugs, a system that requires the beneficiary to leave the pharmacy without a prescription and to then begin a formal request process poses a real health danger.

2. *Who bears the burden of proof in an appeal of a coverage denial involving cost sharing or formulary requests for exceptions?* The legislation appears to place the burden of proof on beneficiaries in connection with a request for an exception to tiered cost sharing or a formulary exclusion. In the case of tiered cost-sharing, an enrollee must submit evidence that the

prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects * * * or both.¹¹

Even where a beneficiary makes a requisite showing, the legislation is ambiguous regarding the extent to which PDPs have discretion to deny an exception to tiered cost sharing rules. This is because the statute provides that a non-preferred drug “*could*” be covered as a preferred drug “*if*” the physician determines that the preferred drug would not be as effective or would have adverse effects.¹² In other words, even if the beneficiary meets the statutory burden of proof, the regulations are silent on the resulting PDP coverage determination obligations.

The same is true for formulary exception requests. Where the issue is an exception to a formulary exclusion, a PDP denial is appealable only if the treating physician supplies evidence that *any* tier of available formulary coverage would not be as effective or would have adverse effects or both.¹³ Yet this ambiguity does not address the obligations of a PDP in cases in which the physician has in fact supplied this information in the first instance.

Issues for comment: The legislation appears to give PDP sponsors discretion over how to determine requests for cost sharing and formulary exceptions, even where requested evidence is supplied. Since these determinations must be based on medical evidence to be submitted by the enrollee, the regulations should be clarified to require PDPs to grant exceptions requests where the weight of the evidence submitted supports the exception request. (Comments should also note that external quality reviews of PDP performance should include sampling exceptions cases to determine whether the PDP in fact acted upon the weight of the evidence). It certainly is important that a coverage denial of a tiered cost sharing or formulary exception request can be appealed. At the same time, the role of an initial coverage determination is to rapidly resolve matters to the maximum extent possible. If a beneficiary submits the proper evidence, and the weight of the evidence justifies an approval of the exception, the rules should be clarified to require the PDP to grant the exception without further appeal.

3. *Reversing previously granted exceptions approvals:* The proposed rules specify that once a formulary or tiered cost sharing exceptions request has been granted, the PDP sponsor is precluded from requiring beneficiaries to file a new exceptions request in order to be permitted to continue the exception. At the same time, however, this safeguard against the imposition of

¹¹ Social Security Act §1860D-4(g)(2)

¹² Social Security Act §1860D-4(g)(2)

¹³ Social Security Act §1860D-4(h)(2)

incessant appeals loops is limited by one aspect of the proposed rule, which provides that the approval stands

as long as * * * the drug continues to be considered safe for treating the enrollee's disease or medical condition.”¹⁴

This ambiguously worded clause could be read as permitting such a determination by the PDP sponsor itself, as opposed to an authoritative government body (i.e., the FDA). As worded the provision allows a plan to determine that the drug is no longer safe or effective and to then require more exception requests.

Issue for comment: The proposed rule could be revised to permit reversal of a previously granted coverage exception for safety reasons *only* in cases in which the new safety information is generated by an authoritative government agency (i.e., the FDA).

4. Expedited requests and timeframes: The proposed rule permits PDP sponsors to toll an expedited coverage request for up to 14 days if the sponsor believes that additional information is necessary to resolve a coverage dispute.¹⁵ Arguably, this extension of time appears to be too long in the context of an expedited request, particularly where the request involves the continuation of a prescription drug. (Dual enrollees with Medicaid drug coverage previously would have had the right to have a prescription drug continued pending a final determination in the case of a timely appeal of a Medicaid agency's decision to terminate or adversely alter the coverage). Whereas an extension of time may be justified in the case of reviewing an initial coverage request – even one which is being expedited – when the adverse determination involves the reduction or termination of a currently used prescription drug, a 14-day time lapse could pose real harm if not at least accompanied by a temporary extension of the current prescription pending completion of the expedited review.

Issue for comment: The regulations could be modified to reduce the 14-day extended time period where the expedited request involves the renewal of an ongoing prescription and to require the continuation of the prescription during the period in which the extension of time takes place. In this way, the timeframe for extended review would both be briefer and coextensive with the current prescription so that the review can be completed and a suitable alternative identified by the PDP sponsor.

C. Enrollee disputes which are treated as grievances

Like Medicare Advantage plans, PDP sponsors must provide “meaningful procedures” for the resolution of grievances “in accordance with” Medicare Advantage (MA).¹⁶ The proposed rules define a grievance as

¹⁴ Proposed 42 C.F.R. §423.678(c)

¹⁵ Proposed 42 C.F.R. §423.572

¹⁶ Social Security Act §1860D-4 (g)

any complaint or dispute other than one that involves a coverage determination, expressing dissatisfaction with any aspect of a PDP sponsor's operations, activities or behavior, regardless of whether remedial action is requested.

This definition is so broad that it potentially sweeps in all disputes that are not coverage determinations, including disputes regarding entitlement to enrollment or low-income subsidies.

Issue for comment: CMS could revise the proposed definition to clarify that disputes involving coverage determinations, the entitlement to enroll or the entitlement to a low-income subsidy are not "grievances."

D. Disputes involving premium and cost-sharing assistance for low-income individuals:

1. Procedures to protect subsidies for low-income beneficiaries. The law entitles low income persons who are determined to be "subsidy eligible individuals" to subsidies for premiums and cost sharing if they are "determined to" meet the eligibility requirements for subsidies.¹⁷ A subsidy eligible person is an individual who "is enrolled in"¹⁸ a PDP, has family income below 150% of the federal poverty level, and who meets the law's resources requirements (defined as three times the SSI standard or a permissible alternative under the law.)¹⁹ Persons automatically "determined to be" eligible for full subsidies consist of the following individuals: "full benefit" dual enrollees; low income Medicare beneficiaries who receive partial Medicaid coverage for premiums and cost sharing; and SSI recipients.

With respect to subsidy eligible persons, the law states that

the determination of whether a part D eligible individual * * * is a subsidy eligible individual, and whether the individual [qualifies for a full premium subsidy] shall be determined *under the* [Medicaid] state plan * * * under §1935 or by the Commissioner of Social Security.²⁰

The law further provides for annual eligibility periods,²¹ as well as for redeterminations and appeals related to an individual's subsidy eligible status, and it specifies that such decisions

shall be made in accordance with the frequency of, and manner in which, redeterminations and appeals of eligibility are made under [Medicaid].²²

Thus, the entitlement to a Part D low-income subsidy is effectively classified as a mandatory Medicaid eligibility category, even though the benefit received with the subsidy is a Medicare benefit. The initial eligibility determination and annual redetermination process both are treated

¹⁷ Social Security Act §1860D-14

¹⁸ The inclusion of an "enrolled in" test in the definition of a subsidy eligible person is particularly confusing, since presumably the subsidy is necessary in order to effectuate any enrollment.

¹⁹ Social Security Act §1860D-14(a)(3)(A)(i)-(iii)

²⁰ Social Security Act §1860D-14(a)(3)(B)(i)

²¹ Social Security Act §1860D-14(a)(3)(B)(ii)

²² Social Security Act §1860D-14(a)(3)(B)(iii)

under the law as an aspect of Medicaid state plan administration related to eligibility determination.

Numerous issues arising from an eligibility determination or redetermination could trigger the need for an appeal (e.g., whether a beneficiary is eligible for a premium subsidy at all; whether the individual qualifies for a subsidy to offset the late enrollment penalties which might otherwise apply in a specific case; the level of subsidy to which a subsidy-eligible individual is entitled; or whether the individual is “institutionalized” or the “lowest income” dual enrollee for the purpose completely eliminating otherwise applicable cost sharing requirements).

The Preamble to the proposed rule indicates that the

redeterminations and appeals of eligibility determinations are to be made in the same manner as those for medical assistance for those individuals who are determined eligible by the state Medicaid agency.²³

At the same time the proposed rule is silent regarding how fair hearing requirements will be applied in the context of annual redeterminations. This is critical, since if a timely request is made for a hearing to appeal the reduction or elimination of a subsidy, the subsidy must be continued at pre-reduction levels pending a final determination.

Issue for comment: The final rules could clarify that an adverse initial determination or re-determination triggers fair hearing rights and that where the issue is the denial of continued eligibility for a subsidy, a timely request for a fair hearing will preserve the subsidy from reduction or termination until the process is complete.

2. *Automatic enrollment of the poorest beneficiaries without a separate application.* Perhaps even more fundamentally, the proposed rule contains an important ambiguity regarding the three classes of beneficiaries who are classified under the law as automatically eligible for a full subsidy (i.e., full benefit dual enrollees, SSI recipients, and low income Medicaid beneficiaries). It is unclear whether these individuals must go through a new eligibility determination process in order to qualify for a low-income subsidy.²⁴ Were the law to be interpreted in this manner, some 6 million persons could be left in limbo for the months which would elapse between the time that the Medicaid drug benefit ends and they apply for and are found eligible for the new Part D benefit. The statute itself does not expressly specify that no separate determination is required for this population; neither does it provide that a new determination is in fact required.

Issue for comment: The proposed rules thus could clarify that these specified groups are expected to be moved directly into participating PDPs through an auto-enrollment process and with a right to change plans subsequent to enrollment. This will ensure that no break in coverage occurs. Most states have sufficient experience with auto-enrollment of Medicaid beneficiaries into compulsory managed care coverage arrangements so that with guidance from CMS, a parallel process could be developed for full benefit duals.

²³ 69 Fed. Reg. 46727

²⁴ Proposed 42 C.F.R. §423.774(d)

Summary and Conclusion

In sum, the proposed rules raise a number of issues with respect to appeals and grievances involving prescription drug coverage and plans. Of central importance are the following issues:

- the need for clarification regarding the availability of appeals procedures for eligibility and enrollment determinations, and the appeals safeguards and procedures which will apply;
- the need to clarify that the presentation of a prescription to a pharmacy constitutes a request for coverage, thereby preserving all appeals rights;
- the need for clarification regarding the obligation of PDPs to reverse initial denials of tiered cost sharing or formulary exception requests without further appeals, whenever the weight of the evidence supports a reversal;
- the obligation of PDPs to continue to honor previously approved formulary exceptions unless and until the FDA indicates that the particular prescription is no longer safe and effective as used by a particular individual for a particular diagnosis;
- the need to shorten the allowable time frame under which PDPs are allowed in the case of expedited coverage determinations involving the termination of previously approved drug coverage denial of coverage, with continuation of the current prescription pending completion of the expedited review;
- the need for clarification of the availability of Medicaid fair hearing procedures in low-income subsidy cases, including the continuation of benefits pending a final determination when a decision is made to reduce or terminate a low-income subsidy;
- the need to permit the immediate enrollment into the low-income subsidy program, without separate application, in the case of dual enrollees designated as automatically entitled to a full premium subsidy; and finally,
- the need to clarify that grievance procedures cover situations that involve neither a coverage determination nor a dispute involving enrollment or eligibility for Part D.

This analysis points to a number of ways in which beneficiary and enrollee safeguards in grievances and appeals can be strengthened as part of the regulatory revision process. The issues explored here all involve matters in which the legislative language is ambiguous, and the Secretary's administrative authority sufficient, to support an alternative regulatory approach. Thus, for example, the Secretary could, based on current law, adopt an interpretation of the low-income premium subsidy provisions that would provide for the automatic enrollment of those groups of current duals who are automatically entitled to receive the full subsidy without a reapplication. He could further establish a "passive redetermination" process so that automatic redeterminations result continued subsidization in the absence of material new information.

Other reforms would require new legislation. For example, where a dispute involves a request for the renewal of a current prescription, it may be possible by regulation to ensure that the current prescription extends through the initial consideration phase, particularly if the PDP must extend the time period to secure additional information. However, if an enrollee were to be protected throughout the appeal process in the event that the renewal is denied, such a change would require Congressional intervention in the form of a statutory amendment. For this reason, this option was not included in this analysis, since it involves a change in legislation that lies beyond the power of the Administration to achieve through the regulatory process.



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