A Comparison of Proposed and Final Regulations Governing Medicare Part D Plan Enrollment and Part D Benefit Appeal and Grievance Procedures

Prepared by
Sara Rosenbaum
The George Washington University School of Public Health and Health Services

For

The Henry J. Kaiser Family Foundation

March 2005

The Henry J. Kaiser Family Foundation: 2400 Sand Hill Road, Menlo Park, CA 94025 (650) 854-9400 Facsimile: (650) 854-4800
Washington, D.C. Office: 1330 G Street, N.W., Washington, DC 20005 (202) 347-5270 Facsimile: (202) 347-5274 **Website:** www.kff.org
The Henry J. Kaiser Family Foundation is an independent national health philanthropy and is not associated with Kaiser Permanente or Kaiser Industries.

A Comparison of Proposed and Final Regulations Governing Medicare Part D Plan Enrollment and Part D Benefit Appeal and Grievance Procedures

Prepared by
Sara Rosenbaum[1]
The George Washington University School of Public Health and Health Services

For

The Henry J. Kaiser Family Foundation

March 2005

[1] This analysis follows up on an earlier analysis of Part D appeals and grievance rights, "Grievance and Appeals Procedures: An Analysis of the MMA and Proposed Regulations" prepared by Sara Rosenbaum for the Kaiser Family Foundation, September 2004. Available at [http://www.kff.org/medicare/7162.cfm].

Introduction

The final Medicare prescription drug benefit regulations issued by the Centers for Medicare and Medicaid Services on January 28, 2005 (70 Fed. Reg. 4193-4742) clarifies and revises proposed regulations governing the Medicare Part D program. The final regulations address, among other matters, procedural protections for Medicare beneficiaries eligible for or covered under the Part D program, as well as beneficiaries eligible for the related low-income subsidy program.[2] Specifically, the regulations address the following matters: procedural safeguards for persons whose application to a part D plan is denied; procedures to be used by Part D plan enrollees for appealing coverage decisions made by the Part D plan sponsor (including requests for coverage of non-formulary drugs or to obtain higher-tier formulary drugs at a lower cost-sharing amount); grievance procedures for disputes involving Part D plans and their enrollees that do not involve a coverage dispute; and eligibility determination and appeals procedures related to the low-income subsidy program.

In several respects the final regulations improve the protections available to Medicare beneficiaries. Of particular note, the final regulations add a clear definition of what constitutes a "coverage determination" for the purpose of triggering redetermination and appeals rights. The final regulations also shorten the permissible time frame for coverage determinations as well as expedited coverage determinations and clarify that beneficiaries who face a reduction or loss of low-income subsidies are entitled to continued assistance if they file a timely appeal of an adverse decision. The final regulations also clarify that full-benefit dual eligibles, SSI recipients, and Medicare Savings Program enrollees are not required to undergo a separate eligibility determination in order to qualify for full subsidies.

In some instances, the final regulations clarify new obligations for beneficiaries and place limits on beneficiary protections. For example, the Preamble to the final rule specifically provides that a pharmacy's failure to fill a prescription when presented cannot be interpreted as a coverage determination, even though the final regulations define the term "coverage determination" as a decision not to provide or pay for a Part D drug. As a result, a beneficiary faced with the refusal of a pharmacy to fill a prescription on a covered basis would have to separately contact his or her plan and formally initiate the process of requesting coverage. In other words, even where the pharmacy submits the prescription to the plan and the plan expressly denies it, the submission and denial on behalf of the patient would not count as a request for coverage.

[2] On March 4, 2005, the Social Security Administration issued separate proposed regulations governing low-income subsidy determination procedures for individuals who apply for assistance at SSA offices. 70 Fed. Reg. 10558.

As was the case with the proposed regulations, the final Part D regulations do not provide for the right to continued Part D benefits pending resolution of a decision to reduce or terminate benefits. Unlike the protections provided under Medicaid, the Medicare program does not provide for benefit continuation pending the appeal of a decision to reduce or terminate benefits. Thus, the shift of dual enrollees from Medicaid to Medicare eliminates the right to continued benefits pending the outcome of an appeal.

The final regulations preserve considerable discretion on the part of PDP sponsors to deny requests for exceptions to tiered cost sharing and formulary limits, even where the beneficiary submits written evidence from the prescribing physician satisfying the medical necessity standard applicable to such requests under the law. Thus, even where a physician provides evidence that a particular prescription is medically necessary, the plan is not bound by the physician's assessment but can substitute its own judgment. Finally, the final regulations permit PDP sponsors to refuse to provide any exceptions process to tiered cost sharing structures for "very high cost and unique items, such as genomic and biotech products," but does not define these terms.

The following table provides a comparison of the proposed and final regulations on key aspects of appeals and grievance protections under the MMA, from Subpart M (Grievances, Coverage Determinations, and Appeals) and Subpart P (Premiums and Cost-Sharing Subsidies for Low-Income Individuals) in the final rule.

Issue	Proposed Regulations	Final Regulations
Prescription Drug Plan Enrollment and Part D Benefit Appeals Procedures		
Legal protections applicable to disputes involving the denial of the right to enroll in a plan	Proposed regulations did not specify the process for resolving disputes involving initial denials of the right to enroll in any plan or the termination of enrollment rights.	The final regulations do not establish a formal procedure to resolve disputes involving enrollment denials by PDPs. CMS instead will monitor the procedures used by PDPs to handle disputes involving the denial of enrollment into the plan. [70 Fed. Reg. 4204]
Definition of a "coverage determination" for purposes of triggering Part D appeals rights	Proposed regulations were silent regarding what constituted a coverage determination and whether the presentation of a prescription constitutes a request for coverage.	The final regulations define the term "coverage determination" as (1) a decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, the drug is determined not to be medically unnecessary, the drug is furnished by an out-of-network pharmacy, or the Part D plan sponsor determines that the drug is otherwise excludable under §1862(a) of the Act; (2) failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee; (3) decisions concerning an exceptions requests; and (4) decisions on cost sharing amounts. The final regulations also clarify that presentation of a prescription (i.e., a "point of sale transaction") is *not* a coverage

Issue	Proposed Regulations	Final Regulations
		determination triggering appeals rights. According to the final regulations, the transaction simply is a point at which the "pharmacist is conveying information regarding the plan's benefit design as it pertains to all enrollees, and is exercising no discretion on behalf of a plan." [70 Fed. Reg. 4348] Upon not receiving the prescription, the enrollee would need to separately contact the plan in order to initiate the "coverage determination" process.
Continuation of Part D benefits during appeals involving PDP sponsor decisions to reduce or terminate coverage	Proposed regulations did not provide for continuation of part D benefits pending the resolution of disputes involving termination or reduction of coverage. Unlike Medicaid, Medicare does not provide for pre-termination hearings.	No change.
Tiered cost sharing and formulary exceptions	Proposed regulations appeared to permit PDP sponsors to deny requests for exceptions to cost sharing tiers or formulary limits, even when the beneficiary provided satisfactory medical evidence from a treating physician (i.e., that the preferred drug was not as effective as an alternative, higher-tier drug, or that *any* covered drug on the formulary's tiers was not as effective, or would have adverse effects, or both).	The final regulations continue to provide PDP sponsors with broad discretion over requests for exceptions to formulary limits and cost sharing tiers. "The Part D sponsor grants an exception whenever *it determines* that the non-preferred drug for treatment of the enrollee's condition is medically necessary, *consistent with the physician's statement*." [42 C.F.R. §423.578 (a) and (b)] [emphasis added]. Thus, while the PDP is expected to act consistent with the statement, the

Issue	Proposed Regulations	Final Regulations
		physician's medical opinion is not binding on the plan. In addition, the final regulations allow the PDP sponsor to deny access to any exceptions process for tiered cost sharing where the plan maintains special formulary tiers for "very high cost and unique items, such as genomic and biotech products." These terms are not defined.
Reversing previously granted exceptions to formularies	The proposed regulations appeared to permit PDP sponsors to revoke previously granted exceptions for drug safety reasons, without specifying the evidence that the PDP would be required to use as the basis for the reversal (e.g., FDA rulings, as opposed to the PDP's opinionown judgment).	The final regulations retains the proposed regulations' ambiguity regarding the evidence on which a PDP sponsor may rely in evaluating safety (i.e., "the drug continues to be considered safe for treating the enrollee's disease or medical condition"). [42 C.F.R. §423.587 (c)] The final regulations contain no change in whether the evidence relied on by the PDP regarding safety can be from sources other than the FDA.
Timeframes and extension of time in standard and expedited coverage determinations, redeterminations, and appeals	The proposed regulations permitted PDPs up to 14 days for both new requests and renewal requests if the sponsor believed that the time was necessary.	The final rule establishes 72 hours for standard coverage determinations and 24 hours for expedited coverage determinations if the plan determines (or the patient's prescribing physician indicates) that the standard 72-hour timeframe may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum

Issue	Proposed Regulations	Final Regulations
		function. [42 C.F.R. §§423.568 (a) and 423.570 (c)] The final regulation eliminated the authority of PDP sponsors to extend the time period for expedited redeterminations. PDP sponsors must make redeterminations not later than 7 calendar days from the date of receipt of a request for a standard redetermination, and within 24 hours of the request for an expedited redetermination. [42 C.F.R. §423.590 (a) and (d)]
Appeals Involving Low-Income Subsidies		
Continuation of aid pending decision to terminate or reduce low-income subsidy	The proposed regulations were silent regarding the obligation of state Medicaid agencies to continue subsidies at prior levels in cases where a beneficiary entered a timely appeal of a decision to reduce or terminate the subsidy.	The final regulations clarify that "decisions made by the State or SSA to reduce or terminate a subsidy would trigger a right to continued coverage at the pre-reduction levels pending the appeal" because "the subsidy program, unlike the Medicare drug benefit itself, is a needs-based program. This is also consistent with how states process appeals under Medicaid." [70 Fed. Reg. 4383-4384]
Enrollment of the poorest Medicare beneficiaries in the full subsidy program	The proposed regulations appeared to require full-benefit dual enrollees and SSI recipients to reapply for assistance even though they were automatically entitled to full subsidies.	The final regulations indicate that CMS will work with states and SSA on an outreach strategy "to try to encourage individuals to apply and "pre qualify" for the low income subsidy before enrolling in a Part D plan so that they will know ahead

Issue	Proposed Regulations	Final Regulations
		of time whether they are eligible for extra assistance with the payment of premiums." In addition, the final regulations provide that "individuals who currently receive benefits as a full-benefit dual eligible, SSI recipient, or under the Medicare Savings Program are not required to undergo a separate eligibility determination in order to qualify as a full subsidy eligible. They are "deemed" or treated as full subsidy eligible individuals without having to complete a separate application. [70 Fed. Reg. 4379; 42 C.F.R. §773(c)]
Grievances		
Definition of a "grievance"	The proposed regulations defined grievances to encompass any dispute other than a coverage dispute, expressing dissatisfaction with a PDP's activities or behavior, but did not clarify that the denial of initial enrollment or low income subsidy requests did not constitute a grievance.	The final regulations retain this definition. [42 C.F.R. §423.564]

The Henry J. Kaiser Family Foundation
2400 Sand Hill Road
Menlo Park, CA 94025
Phone: (650) 854-9400 Fax: (650) 854-4800

Washington Office:
1330 G Street, NW
Washington, DC 20005
Phone: (202) 347-5270 Fax: (202) 347-5274

www.kff.org

Additional copies of this publication (#7300) are available on
the Kaiser Family Foundation's website at www.kff.org.