
PUBLIC SUBMISSION

As of: August 17, 2010
Received: August 16, 2010
Status: Pending_Post
Tracking No. 80b323e6
Comments Due: August 16, 2010
Submission Type: Web

Docket: HHS-OS-2010-0015

Group Health Plans and Health Insurance Coverage: Interim Final Rules for Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable Care Act

Comment On: HHS-OS-2010-0015-0001

Group Health Plans and Health Insurance Coverage: Interim Final Rules for Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable Care Act

Document: HHS-OS-2010-0015-DRAFT-0094

Comment on FR Doc # 2010-14488

Submitter Information

Name: Christine Simmon

Organization: CVS Caremark Corp.

General Comment

Dear Mr. Angoff:

CVS Caremark appreciates the opportunity to submit comments on the "Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act ("ACA")," (the "IFR") published in the Federal Register on June 17, 2010.

CVS Caremark is the nation's leading provider of comprehensive pharmacy services. CVS Caremark's pharmacy benefit management companies (PBMs) administer prescription drug benefits to over 50 million plan members who have health coverage through their employers, health insurers, labor unions, and Medicare plans. Many of our health plan customers are interested in maintaining their plans' status as grandfathered plans but are unsure how these regulations apply to some of the unique features of their pharmacy benefits. Unlike medical benefits, pharmacy benefits usually provide a much broader array of therapeutic choices to treat a particular condition, and utilize a formulary to allow participants to understand the cost trade-offs in exercising that choice.

CVS Caremark recommends that HHS clarify that plans can continue to have broad latitude to make clinically appropriate formulary changes within their prescription drug benefit portion of their health plan, consistent with practices today, provided that those formulary changes do not result in the elimination of all or substantially all essential benefits to treat a particular condition. We also urge HHS to clarify that it should not matter whether the covered drug is a brand, generic or OTC drug as long as the plan provides coverage for a drug or drugs that can be used to treat the associated condition.

Attachments

HHS-OS-2010-0015-DRAFT-0094.1: Comment on FR Doc # 2010-14488



August 16, 2010

Jay Angoff
Director
Office of Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

**Re: File Code: OCIO-9991-IFC
CVS Caremark Comments on Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act**

Dear Mr. Angoff:

CVS Caremark appreciates the opportunity to submit comments on the “Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act (“ACA”),” (the “IFR”) published in the Federal Register on June 17, 2010.

CVS Caremark is the nation’s leading provider of comprehensive pharmacy services. CVS Caremark’s pharmacy benefit management companies (PBMs) administer prescription drug benefits to over 50 million plan members who have health coverage through their employers, health insurers, labor unions, and Medicare plans. Many of our health plan customers are interested in maintaining their plans’ status as grandfathered plans but are unsure how these regulations apply to some of the unique features of their pharmacy benefits. Unlike medical benefits, pharmacy benefits usually provide a much broader array of therapeutic choices to treat a particular condition, and utilize a formulary to allow participants to understand the cost trade-offs in exercising that choice.

As reflected in the preamble to this IFR, the ACA “balances the objective of preserving the ability of individuals to maintain their existing coverage with the goals of ensuring access to affordable essential coverage and improving the quality of coverage.” The preamble also acknowledges that the “statute does not . . . address at what point changes to a group health plan. . . are significant enough to cause the plan . . . to cease to be a grandfathered health plan, leaving that to be addressed by regulatory guidance.”

CVS Caremark recognizes the challenges that the Departments of Treasury, Labor, and Health and Human Services (“HHS”) face in balancing the competing goals articulated in the preamble to this IFR. We also appreciate the opportunity to comment on the application of this IFR to pharmacy benefits and request that HHS consider the unique role of formularies in the structure and operation of the pharmacy benefit in further clarifying the application of the final regulation to pharmacy benefits so that our

customers can have some certainty as to which changes to their pharmacy benefit may cause them to lose their “grandfathered” status.

Our detailed comments on this IFR appear below.

Section 1251 of the ACA-Preservation of Right to Maintain Existing Coverage

1. Maintenance of Grandfathered Status--45 CFR 147.140

A. Reductions in the Scope of Benefits/Elimination of Benefits (Paragraph (g)(1)(i))

The language of this section of the rule provides that the elimination of all or substantially all benefits to diagnose or treat a particular condition causes a plan or health insurance coverage to cease to be a grandfathered plan. CVS Caremark encourages HHS to allow plans continued flexibility to change their drug formularies to accommodate ongoing innovation that results in equal or greater choice and cost savings without reducing or eliminating benefits.

For example, a plan may decide to eliminate coverage of a particular *prescription brand drug* in a certain therapeutic drug class when an equivalent generic or over-the-counter (“OTC”) product becomes available in the marketplace. As long as the plan provides ongoing and equivalent coverage of the generic or OTC drug to treat the same condition previously treated by the brand prescription drug, the elimination of the brand drug does not result in the elimination of “all or substantially all” benefits to treat a particular condition. On the contrary, it simply substitutes a more cost effective treatment.

Plans may also impose quantity limit restrictions, consistent with manufacturer or FDA labeling. The imposition of quantity limits that do not significantly reduce benefits should not trigger a plan's loss of its “grandfathered” status under the IFR. Quantity limits should only jeopardize a plan's grandfathered status where the quantity limits are so restrictive that they are inconsistent with quantities necessary to effectively treat certain conditions.

In addition, plans' step therapy programs and changes to a particular drug's tier placement on the formulary do not significantly reduce benefits or change cost sharing levels that would otherwise trigger a plan's loss of its “grandfathered” status under the IFR. As indicated above, a formulary is designed to assist enrollees in making clinically appropriate and cost effective choices, and as long as there is a therapeutic option available at the lower cost sharing tier, moving a drug from one tier to another should not be viewed as reducing benefits or increasing cost sharing. Accordingly, we do not believe that a plan's decision to implement a step therapy program or change drug tiers should affect the plan's status as a grandfathered plan unless the effect of the formulary change is that there are no covered drugs available to treat conditions previously covered, or the cost sharing is higher by an amount greater than that permitted by the IFR.

CVS Caremark also requests that HHS consider the definition of “essential benefits” in Section 1302 of the ACA. This is important because the grandfathering rules set forth in the IFR are not limited to “essential benefits.” Therefore, a plan could lose grandfathered status even if it does not eliminate any essential benefits, but instead eliminates benefits which are widely recognized as non-essential benefits today, such as hair loss drugs or cosmetic drugs. We believe Congress intended that plans not be allowed to retain grandfathered status while reducing or eliminating *essential* benefits and that Congress did not intend to regulate the continued coverage of non-essential benefits. Specifically, we do not believe that Congress intended that the elimination of coverage for non-essential benefits would constitute the elimination of all or substantially all benefits to treat a particular condition, thereby triggering a loss of the

plan's grandfathered status. CVS Caremark believes that such a result would be inconsistent with the "Essential Health Benefits" provisions in the ACA.

CVS Caremark Recommendation:

We encourage HHS to clarify that plans can continue to have broad latitude to make clinically appropriate formulary changes within the pharmacy benefit portion of their health plan, consistent with practices today, provided that those formulary changes do not result in the elimination of all or substantially all benefits to treat a particular condition. We understand that where the effect of this type of formulary change is that the plan no longer provides drugs to treat a certain condition, this would cause the plan to lose its grandfathered status. However, we urge HHS to clarify that it should not matter whether the drug is a prescription, OTC or generic drug as long as the plan provides coverage for a drug or drugs that can be used to treat the associated condition.

In addition, we urge HHS to confirm that (i) quantity limits are permissible where they are consistent with FDA labeling; (ii) step therapy and other utilization management programs (such as prior authorization) will not jeopardize the loss of a grandfathered plan's status where the effect of the program is to simply require that clinically appropriate and/or cost effective drugs are tried first when these are available; and (iii) changes to a particular drug's tier placement on the formulary will not jeopardize a plan's grandfathered status unless there are no other drugs available in the lower tier to treat the condition in question.

Finally, we recommend that HHS amend the IFR to make clear that plans will only lose their grandfathered status if they eliminate all or substantially all *essential* benefits, as determined by the Secretary of HHS, to diagnose or treat a particular condition.

B. Elimination of Benefits "For Any Necessary Element" (Paragraph (g)(1)(i))

The language of this section of the rule also states that the elimination of benefits for "any necessary element" to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition, resulting in the loss of grandfathered status. CVS Caremark urges HHS to be more transparent about who will determine what is "necessary" and the medical authority or authorities upon which those determinations will be based.

CVS Caremark Recommendation

We encourage HHS to provide further clarification regarding the medical authority that must be used to make determinations related to "any necessary element" to treat a particular condition or to otherwise clarify the meaning of this term.

C. Increase in Fixed-Amount Copayment (Paragraph (g)(1)(iv))

This requirement states that any increase in a fixed-amount copayment causes a plan to lose grandfathered health plan status if the increase is greater than the maximum percentage increase of medical inflation plus 15 percentage points or five dollars increased by medical inflation.

CVS Caremark Recommendation

Because many formularies are designed to give participants a wide variety of therapeutic alternatives with clear cost trade-offs, CVS Caremark recommends that HHS limit the applicability of this rule to only those formulary tiers that contain drugs for which there is not a therapeutic alternative for an essential

benefit on a lower cost sharing tier. For example, if a formulary includes drugs to diagnose or treat all conditions previously covered on the first two tiers, and then includes more expensive therapeutic alternatives or drugs to treat cosmetic or non-essential benefit drugs on higher tiers, the IFR rules limiting cost sharing changes should apply only to the two lower tiers. This is because most prescription drug benefit plans use behavioral economics to incentivize plan members to use the most cost-effective drugs on the drug formulary. This cap would limit a grandfathered plan's ability to create meaningful economic incentives that encourage plan members to use cost-effective drugs that are purposefully placed on the lowest tiers of the drug formulary and that generally cover drugs in all therapeutic classes necessary to provide comprehensive pharmacy care to individuals.

Finally, CVS Caremark recommends that HHS adopt prescription drug inflation rather than general medical care inflation as the benchmark for allowable increases in drug benefit copayments. Such data on prescription drug inflation are already available and published through the Department of Labor's Bureau of Labor Statistics.

D. Decrease in Contribution Rate by Employers and Employee Organizations/Contribution Rate Based on Cost of Coverage (Paragraph (g)(1)(v))

The IFR indicates that a health plan will lose its grandfathered status when an employer decreases its contribution rate based on the cost of coverage for "any tier of coverage for any class of similarly situated individuals" by more than five percent below the contribution rate as of March 23. However, the IFR does not define the term "tier of coverage." We infer from the examples, where HHS refers to "self and family" as two tiers of coverage, that HHS means individual or family or similar coverage classifications, but recommend that HHS make this clear by defining the term.

CVS Caremark Recommendation

CVS Caremark recommends that HHS clarify what "tier of coverage" means by defining it in the Final Rule.

2. Request for Comments on Additions to List of Changes that Result in Loss of Grandfathered Status

HHS has asked for comments on what other changes, if any, should be added to the list of changes in a health plan or insurance coverage that would cause the plan or coverage to cease to be grandfathered. The following changes are specifically noted:

Changes in Plan Structure – Innovation in providing pharmacy benefit management services to health plans and their participants has allowed many plans to be able to continue offering affordable drug benefits despite the rapid increase in drug costs. It is essential that health plans be allowed ongoing flexibility to structure their plans in innovative ways to promote the most cost-effective use of prescription drugs.

CVS Caremark does not believe that changes to the plan structure of the pharmacy benefit should trigger a loss in a plan's grandfathered status as long as the benefit still covers drugs to treat all conditions previously treated and that are part of an essential benefit that was previously offered. The test should be whether the pharmacy benefits provided as a whole are as good as the benefits previously provided and not one that focuses merely on changes in plan structure. For example, it should not matter if a plan changes its plan structure to require that plan members receive their maintenance medications through the mail order benefit rather than at retail since access to the underlying benefit is left unchanged.

CVS Caremark Recommendation

CVS Caremark recommends that HHS make clear that a plan's structural changes to its pharmacy benefit will not jeopardize the plan's grandfathered status as long as the benefit still covers drugs to treat all conditions previously treated and that are part of an essential benefit that was previously offered.

Changes in Plan's Provider Network – It is important that plans be allowed to continually update their pharmacy networks in order to address participant needs, assure quality of care and keep drug benefits affordable. For example, plans must be able to remove pharmacies that do not meet quality standards or are found to be involved in fraud and abuse. In addition, a preferred pharmacy network option may help a plan to save money without unduly restricting access. Therefore, CVS Caremark believes HHS should allow grandfathered plans and insurers the flexibility to manage their provider networks in a manner that is cost-effective for plans without the plans risking a loss in their grandfathered status.

CVS Caremark Recommendation

CVS Caremark recommends that HHS not add changes in a plan's provider network to the list of changes that would result in loss of grandfathered status.

Changes to a Prescription Drug Formulary – As noted above, CVS Caremark believes that grandfathered plans must be allowed to make clinically appropriate changes to their drug formularies that are consistent with evolving clinical standards and result in the cost-effective utilization of the plan's drug benefit.

CVS Caremark Recommendation

CVS Caremark recommends that HHS clarify that plans can continue to have broad latitude to make clinically appropriate formulary changes within their prescription drug benefit portion of their health plan, consistent with practices today, provided that those formulary changes do not result in the elimination of all or substantially all *essential* benefits to treat a particular condition. We also urge HHS to clarify that it should not matter whether the covered drug is a brand, generic or OTC drug as long as the plan provides coverage for a drug or drugs that can be used to treat the associated condition.

* * * * *

We appreciate your careful consideration of our comments. On behalf of CVS Caremark, we look forward to continuing to work with the Departments of Treasury, Labor, and Health and Human Services.

Sincerely,

Rusty Ring
Senior Vice President
Government Affairs

cc: Phyllis C. Borzi
Assistant Secretary of Labor
Office of Health Plan Standards and Compliance Assistance

Employee Benefits Security Administration
U.S. Department of Labor

Douglas Shulman
Commissioner
Internal Revenue Service
Department of the Treasury