



PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

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

Attention: OCIIO-9991-IFC

Dear Mr. Angoff:

The Pharmaceutical Care Management Association (PCMA) 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,” published in the Federal Register on June 17, 2010. PCMA is the national association representing America’s pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage through Fortune 500 employers, health insurers, labor unions, and Medicare.

PCMA appreciates all the tasks that the Departments of Treasury, Labor, and Health and Human Services must complete to implement the recently enacted health care reform statute and we value opportunities to comment on the many aspects of regulations to implement the law. PCMA is generally supportive of the Grandfathered Health Plan IFR, but we do have concerns with several aspects of the rules. Our detailed comments appear below.

Section II: Section 1251 of PPACA, Preservation of Right to Maintain Existing Coverage

- 1. Maintenance of Grandfathered Status of Paragraph (g) of 45 CFR 147.140**
 - Elimination of benefits (Paragraph (g)(1)(i)) -- The language of this section of the rule 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. PCMA is concerned about the interpretation of “any necessary element” as it might be applied to the coverage or formulary status of a particular medication. We are also concerned about who will determine what is “necessary” and whether that determination will be based on medical compendia or other published medical authority.

The specific drugs on a health plan formulary change as new products come to market, older products lose their patents and become available as less costly generic versions, or products are removed from the market for safety reasons. Formularies and cost-sharing arrangements for covered drugs currently change from one plan year to the next, and often change within a plan year as new products are approved for use. PCMA believes that grandfathered health plans must be allowed to continue to make formulary changes that maintain a commensurate level of coverage without risking loss of their grandfathered plan status.

If grandfathered health plans were not allowed the flexibility to modify their formularies, plan members would not be able to access new drugs that come to market under their plan benefits. In addition, such restrictions on grandfathered plans would disadvantage them in their negotiations with pharmaceutical manufacturers, which could lead to higher drug prices.

***PCMA Recommendation:** PCMA recommends that the Departments clarify that grandfathered health plans retain the ability to make routine formulary changes consistent with those made prior to March 23, 2010, as long as a commensurate level of coverage is maintained. We also recommend that the Departments clarify that grandfathered health plans may continue to encourage the use of generic drugs and utilize incentives to encourage clinically appropriate drug utilization. Finally, PCMA recommends that the Departments modify this section of the rule to add further clarification regarding the basis for determining what constitutes “any necessary element” to treat a condition. PCMA recommends that such determinations be made by independent medical experts (e.g., Institute of Medicine).*

- Increase in Percentage Cost-sharing (Paragraph (g)(1)(ii)) -- This requirement states that any increase measured from March 23, 2010, in a percentage cost-sharing requirement (such as an individual’s coinsurance) causes a group health plan or health insurance coverage to cease to be a grandfathered health plan. Next, in sections (iii) and (iv), the Grandfathered Health Plan IFR discusses allowable increases in deductibles or out-of-pocket limits, and fixed-amount copayments. PCMA is concerned that many prescription drug benefit plans utilize a combination of coinsurance and fixed-amount copayments, and that these arrangements do not fit neatly into the three categories listed in subparts (ii), (iii), and (iv) of Paragraph (g)(1). For example, a drug benefit plan may require the subscriber to pay coinsurance, with a maximum dollar amount (e.g., 20% coinsurance, with a maximum of \$35).

***PCMA Recommendation:** PCMA recommends that the Departments clarify that grandfathered health plans with hybrid drug benefit designs utilizing both coinsurance and fixed-amount copayments, or coinsurance and fixed-amount cost-sharing other than a copayment, may increase the fixed-amount portions of such arrangements as long as the increase is otherwise in compliance with the terms of Paragraph (g)(1)(iii) and (iv).*

- 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. While this requirement may be appropriate with regard to hospital services or physician payments, PCMA believes that application of this requirement on a per prescription basis would be unduly restrictive given the tiers of coverage used by most group health plans and the large number of prescription drug transactions completed in any given plan year. For example, a grandfathered health plan should be allowed to move a brand name drug into a higher formulary tier once a generic version becomes available without losing grandfathered health plan status. Under the IFR, however, a move to a higher tier could subject the brand to a higher copayment, exceeding the cap imposed by the formula in the IFR.

Instead of the requirements proposed in the IFR, PCMA believes this section of the rule should apply only to increases in the first and second tiers of a prescription drug benefit formulary. Co-pay increases to third or higher tiers of a prescription drug benefit for non-specialty drugs should be excluded from this cap on increases to fixed-amount co-payments. Most prescription drug benefit plans incentivize plan members to use the most cost-effective drugs on the drug formulary, which are purposely placed on the first and second tiers. Alternatively, PCMA recommends that an actuarially equivalent standard be utilized to allow plans to adjust their co-payments with some flexibility provided they are actuarially equivalent to the plan benefits that were in effect on March 23, 2010. Further, PCMA suggests the Departments consider adopting prescription drug inflation rather than general medical care inflation as the benchmark for allowable increases in drug benefits copayments. Data on prescription drug inflation are collected and published by The Bureau of Labor Statistics (BLS).

In addition, PCMA is concerned that the hypothetical CPI-U for medical care used in Example 3 of the IFR gives an inaccurate perception of acceptable changes. The CPI-U used in the example is 87 points higher than the current CPI-U for medical care and, because it is skewed so high, the example conveys an incorrect result. If actual 2009 data were used in the example, the result would be that the subject plan would cease to be a grandfathered plan: exactly the opposite of what is depicted in the IFR. We believe the parameters for permissible increases in copayments under the IFR formula are considerably tighter than what Example 3 would lead the reader to believe.

PCMA Recommendation: *PCMA recommends that the Departments clarify that any change in the maximum per prescription price should not cause the cessation of grandfathered status as long as the maximum change in copayment for aggregate prescription drug benefit transactions is otherwise consistent with the IFR. Further, the cap on any increase in a fixed-amount copayment should only apply to the first two tiers of a drug formulary. In the alternative, the*

Departments could allow an actuarially equivalent standard for prescription drug benefits. Further, PCMA recommends that the benchmark for allowable changes in drug benefit copayments be prescription drug inflation and not general medical care inflation.

- Decrease in Contribution Rate by Employers and Employee Organizations/ Contribution Rate Based on Cost of Coverage (Paragraph (g)(1)(v)) -- Under the IFR, if 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, the health plan loses grandfathered health plan status. The IFR does not define “tier of coverage”, but implies in Example 7 that it may refer to “self-only or family”. PCMA believes the “tier of coverage” term should be defined and clarified in the Final Rule.

PCMA is concerned that the five percent formula may be too rigid and fails to take into consideration changes in care that may reduce costs while maintaining, or improving, the quality of outcomes. Nor does the formula take into account safety considerations. For example, shifting coverage from inpatient care to ambulatory or home-based settings for many therapies reduces costs while maintaining quality and safety. Similarly, increased use of outpatient surgery lowers costs, reduces hospital infection rates, and generally improves patient outcomes. However, the rule as written seems to disallow such changes in coverage by a grandfathered health plan if they result in reducing the employer’s contribution rate by more than 5 percentage points below that which was contributed on March 23, 2010.

***PCMA Recommendation:** PCMA recommends that the Departments define and clarify “tier of coverage”. PCMA also recommends that the Departments modify this section of the rule to recognize the value of changes in the site or method of care that enhance quality and safety, or improve patient outcomes, and allow such changes in coverage even if they result in lowering the contribution rate by more than 5 percentage points from the March 23, 2010 benchmark.*

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

The Departments ask 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 -- PCMA believes that the structure or design of a health benefit plan should not, in and of itself, be cause for cessation of grandfathered status. The tests should be the scope of coverage, access to providers, employer contribution, and general level of subscriber cost-sharing, and not the structural elements of how those benefits are delivered to the

subscribers or their beneficiaries. In the drug benefit context, PCMA believes that a change in the channel through which drug benefits are delivered should not imperil retention of grandfathered status. For example, a plan should be able to utilize preferred pharmacy locations, such as mail service pharmacies, which have been shown to increase patient adherence to drug therapy, improve safety of drug dispensing, and lower costs.

PCMA Recommendation: *PCMA recommends that the Departments not add changes in plan structure to the list of causes for loss of grandfathered status. If the Departments do include some changes in plan structure in the list of changes that would cause a plan to lose grandfathering status, the Departments should clarify that changing the channel through which drug benefits are delivered does not implicate grandfathered health plan status.*

- **Changes in Plan’s Provider Network** -- PCMA believes that health plans and insurers must be able to make changes in their networks of participating providers in order to assure subscriber access, maintain quality, and control provider fraud, waste and abuse. Currently, group health plans routinely make changes in their provider networks at the beginning of each new plan year, and even during the plan year (e.g., to prevent or eliminate provider fraud, waste, or abuse or to add a new provider). As long as subscribers are assured of reasonable access to providers and pharmacies for exercising their covered benefits, the Departments should allow grandfathered plans and insurers the discretion to manage their provider networks. In the context of pharmacy benefit access, the Departments should look to the Tri-Care or Medicare Part D pharmacy access standards, or similar access requirements imposed by private sector plan sponsors, for examples of maintaining appropriate network access. For example, the Departments should allow changes in particular pharmacies as long as the total number of network pharmacies remains within an adequate range.

PCMA Recommendation: *PCMA recommends that the Departments not add changes in a network plan’s provider network to the list of changes that would result in loss of grandfathered status. If the Departments do include some changes in a plan’s provider network in the list of changes that would cause a plan to lose grandfathering status, the Departments should clarify that changes will be allowed as long as the total number of network providers in a category remains within an adequate range.*

- **Changes to a Prescription Drug Formulary** – Prescription drug formularies are “living” arrangements that adapt to changes in available therapy and contemporary standards of medical practice. PCMA believes that grandfathered plans should be able to make changes in their formularies that are consistent with best practices, enhance the quality of care, ensure safety, and improve the cost-effectiveness of the subscriber’s drug benefit. Locking grandfathered plans in to the formularies they had in place on March 23, 2010 would reduce plan members’ access to new and innovative drugs, disadvantage the plans in their negotiations

with pharmaceutical manufacturers, and could result in unnecessarily increasing the cost of providing drug benefits. PCMA believes that as long as formulary changes are subject to objective standards, such changes should not result in jeopardizing the grandfathered status of a health plan or health insurance. Such objective standards would include review and approval by an independent pharmacy and therapeutics (P&T) committee, manufacturer labeling, clinical best practices, and patient safety.

***PCMA Recommendation:** PCMA recommends that the Departments not add changes to a prescription drug formulary to the list of changes that would result in the loss of grandfathered status, as long as formulary changes are made based on objective standards such as those described above.*

- Changes Other than Those Described in the Rule -- The preamble to the IFR states that changes other than those specifically described in the rule will not cause a plan or coverage to cease to be a grandfathered health plan. Examples cited include changes to comply with Federal or state legal requirements, changes in premium, or changing third-party administrators. PCMA supports this clarification, particularly compliance with Federal or state legal requirements. However, there are other requirements that may be imposed by accreditation or certification organizations or professional societies that assure or enhance quality and promote best practices. These requirements or recommendations should be recognized and supported by the Departments as legitimate drivers for making changes in benefits that should not jeopardize grandfathered status.

***PCMA Recommendation:** PCMA recommends that the Departments expand the list of changes that will not cause a plan or insurance coverage to lose grandfathered status to include changes required by accreditation or certification bodies or recommended by professional organizations as “best practices”.*

3. Definition of Grandfathered Health Plan Coverage

- Requirement for plan to include statement in any plan materials that it believes it is a grandfathered plan and to provide a contact for questions or complaints – The requirement for a plan to include a statement in “any plan materials provided to a participant or beneficiary describing the benefits provided” that the plan believes it is a grandfathered health plan needs to be clarified and narrowed. As written, the requirement is overly broad and potentially burdensome. PCMA could support such a requirement if it were narrowed to the summary plan document and documents provided to subscribers during the annual open enrollment period. PCMA supports the proposed model language to meet the disclosure requirement but we do not agree with those who suggested to the Departments that each grandfathered plan be required to list and describe consumer protections that do not apply to the plan (including their effective dates) because it is grandfathered.

***PCMA Recommendation:** PCMA recommends that the Departments narrow the statement requirement to the summary plan document and documents provided to*

subscribers during open enrollment. PCMA supports the model language, but we believe it is not necessary for each grandfathered plan to list and describe every consumer protection in PPACA that does not apply to it: those who are interested in obtaining such information can so inquire with the required point of contact.

- Maintenance of records -- PCMA supports the requirement for maintenance of records documenting the terms of the plan in effect on March 23, 2010.

PCMA Recommendation: PCMA supports the requirement for maintenance of records documenting the terms of the plan in effect on March 23, 2010.

- Inspection of records – While PCMA supports the right of inspection by governmental officials and subscribers, PCMA recommends that the language be modified to require written requests from non-governmental officials and to allow adequate time for plans to respond.

PCMA Recommendation: PCMA recommends that the Departments modify the inspection language to indicate that subscribers, participants or beneficiaries must submit their request in writing and indicate the specific plan by name and/or identifying number. Plans should be allowed a reasonable time to respond to such requests, such as 14 business days.

4. Section IV: Economic Impact and Paperwork Burden

- Subsection B. 2. Regulatory Alternatives -- PCMA agrees with the decision of the Departments to opt against rules that would require a plan sponsor or insurance issuer to relinquish grandfather status if only relatively small changes are made to a plan. We applaud the Departments' conclusion that plan sponsors and issuers should be able to take steps to control costs, including limited changes in cost sharing. Health plans are "living" contractual arrangements that must adapt to changes in the practice of medicine and the delivery of health care goods and services in order to maintain quality and manage costs. With regard to drug benefits, formularies and provider networks are periodically reviewed and modified to reflect changes in medication therapy, patient needs, and to maintain convenient access to pharmacy providers. Allowing plans and issuers the flexibility to make such modifications and retain their grandfather status will go a long way toward preserving the right of individuals to maintain their existing health care coverage.

PCMA Recommendation: PCMA supports the decision by the Departments to not adopt rules that would require a plan sponsor or insurance issuer to relinquish grandfather status if only relatively small changes are made to a plan. We agree that plan sponsors and issuers should be able to take steps to control costs, including limited changes in cost sharing.

As always, we appreciate your consideration of our comments and look forward to continuing to work with the Departments of Treasury, Labor, and Health and Human

Services to ensure successful implementation of the Patient Protection and Affordable
Care Act.

Sincerely,

A handwritten signature in black ink, appearing to read "Michelle Galvanek". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Michelle Galvanek

Vice President, Regulatory Affairs