PhRMA

August 16, 2010

By Electronic Mail

The Honorable Timothy Geithner
Secretary, U.S. Department of Treasury

The Honorable Kathleen Sebelius
Secretary, U.S. Department of Health and Human Services

The Honorable Hilda Solis
Secretary, U.S. Department of Labor

Re: 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 (OCIIO-9991-IFC)

Dear Mr. and Mmes. Secretary:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the interim final rules (OCIIO-9991-IFC) implementing the grandfathered health plan provisions included in the Patient Protection and Affordable Care Act (P.L. 111-148) and the Health Care and Education Reconciliation Act (P.L. 111-152), jointly referred to as the Affordable Care Act (ACA). PhRMA is a voluntary, non-profit organization representing the nation's leading research-based pharmaceutical and biotechnology companies who are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

As stated in the rules, some consumer protection standards in ACA apply broadly to all health insurance plans (including "grandfathered" plans), but other insurance reforms and benefit requirements do not apply to "grandfathered" plans. In establishing the standards defining when health insurance plans retain or lose their "grandfathered" status, PhRMA believes that the new regulations generally strike an appropriate balance allowing flexibility to make reasonable changes to existing plans without triggering application of certain ACA standards and applying ACA's standards to new plans.

Comment on Prescription Drug Formularies; Importance of Consistent Rules Across Types of Care

The agencies have invited comment on whether changes to a health insurance plan's prescription drug formulary should result in a cessation of grandfathered plan's status and, if so, what magnitude of change would result in a loss of grandfathered status. Given that the stated intent of the rules is to allow "reasonable changes routinely made by plan sponsors or insurers," but not allow "unfettered changes" that would be "inconsistent with Congress's intent to preserve coverage that was in effect on March 23, 2010," PhRMA believes that the final regulations affecting a plan's grandfathered status should broadly aim to achieve a "level playing field" with respect to prescription drug coverage and

other aspects of health coverage provided by plans. That is, generally, changes in benefits or cost-sharing that would cause a plan to lose its grandfathered status with respect to coverage for medical services (such as hospital and physician services) should similarly apply to changes a plan makes to its prescription drug coverage.

PhRMA recognizes that establishing appropriate rules for changes to prescription drug coverage is challenging because the design of pharmacy benefits differs in important ways from that of other health care services (such as hospital and physician care). For example, tiered formularies for prescription drug coverage – with differential cost-sharing levels for generic drugs, preferred brand drugs, and non-preferred brand drugs – are the predominant benefit design for employer-sponsored health insurance plans. Eight-nine percent (89%) of workers and their families are covered under some form of tiered cost-sharing arrangement for prescription drugs. Generally, other types of services are not subject to tiered benefits as extensively and at as granular a level.

However, in the absence of a level playing field, plans could make "unfettered" reductions to their prescription drug coverage and maintain their grandfathered status. In fact, if plans must meet certain rules in some areas in order to retain their grandfathered status but are not subject to similar rules in other areas (such as prescription drug coverage), there is a significant risk that the areas left ungoverned will be targeted for particularly extensive changes, to the detriment of patients.

Allowing Routine Changes

Currently, there is substantial variation and dynamism in the structure and content of prescription drug formularies. Health plans make changes to formularies to reflect the availability of new treatments and changing market conditions. For example, when an FDA-approved generic version of an innovator drug that is substitutable (i.e., an AB-rated generic copy of an innovator drug) becomes available in the marketplace, health insurance plans may switch the innovator drug's status on the formulary in order to encourage greater use of the generic substitute. Likewise, over time, plans may change which medicines in a particular therapeutic class they cover on the preferred tier. Such routine changes in formulary design and prescription drug coverage should *not* result in a loss of grandfathered status, and the final rule should allow for the dynamism that currently exists in formulary design to continue. However, significant or "unfettered" changes that reduce patient choice of medicines and the comprehensiveness of *overall* prescription drug coverage should result in a cessation of grandfathered status.

Proposed Grandfathering Standards for Prescription Drug Coverage and Formularies

To achieve the law's intent, PhRMA recommends that the rule establish meaningful standards for the magnitude of changes to (1) prescription drug cost sharing and (2) the number and types of drugs included in plan formularies that may be made by plans seeking to retain grandfathered status, with the standards in these areas consistent with the standards established for other services in the interim final rule. The final rule should include standards such as:

- **Increasing a coverage tier's cost sharing by more than the amounts allowed for other medical services.** The interim final rule limits the amount by which a plan may increase cost-sharing while retaining its grandfathered status. The same requirements should apply to prescription drug coverage. If a health insurance plan increases co-payments for covered prescription drugs on the second tier of a multi-tier formulary by more than the amounts permitted for other services included in the rule (i.e., more than medical inflation plus 15% or medical inflation plus $5, whichever is greater), the plan should lose its grandfathered status. Increases in copayments by less than this amount should not affect a plan's grandfathered

status. Likewise, as for other services encompassed by the interim final rule, if a plan that charges beneficiaries coinsurance for any or all tiers of coverage increases the coinsurance percentage, the plan should lose its grandfathered status.

This rule should apply to increases in co-payments and co-insurance levels for each tier within a plan's drug formulary, as well as to aggregate cost sharing across all tiers[1], while allowing plans to maintain their flexibility to move specific drugs from one tier to another based on market negotiations. Applying the limits at the tier level effectuates the rule, since the utility and value of prescription drug coverage to beneficiaries is defined by the tiered benefits structure. In practice, the tier structure plays a central role in defining the prescription drug coverage available to beneficiaries. Moreover, any rule that does not rely on the tiering structure would be exceptionally challenging to enforce.

- **Applying a new deductible for prescription drug coverage; increasing a deductible for prescription drug coverage by more than the amounts allowed for other services.** The interim final rule provides that a plan loses its grandfathered status if it increases deductibles above specified levels (15% plus medical inflation). While the vast majority of employer-sponsored plans do not feature separate deductibles for prescription drug coverage, about 12% of workers currently have a separate drug deductible (with an average deductible level of $108 annually). Changes in benefit design that establish separate deductibles for prescription drugs (where such a deductible was not previously in effect) or subject prescription drugs to a plan's overall deductible (for health insurance plans that previously exempted prescription drugs from the overall policy's medical deductible) would have the same effect as establishing a deductible for other services where none exists, and should lead to a plan losing its grandfathered status.

  In the case of plans already applying a deductible to prescription drug coverage, we again recommend the same rule that applies to other services. That is, if a plan increases the deductible by an amount greater than medical inflation plus 15%, the plan should lose its grandfathered status.

- **Shifting from co-payments to co-insurance for some or all covered prescription drugs that results in a cost-sharing increase greater than allowed for other services.** While the vast majority of employer-sponsored health insurance plans charge co-payments for prescription drugs, the use of co-insurance is becoming more common – especially for drugs covered under a "specialty tier." Switching from co-payments to co-insurance represents a major change in benefit design – and may result in higher cost-sharing and out-of-pocket expenses for patients that rely on these medicines – and should therefore result in a loss of grandfathered status if doing so results in an increase in beneficiary cost-sharing that exceeds limits established for other health services established in the rule (i.e., medical inflation plus 15%).

---

[1] This would avoid a situation in which cost sharing increases for each tier remain within the 15% + inflation threshold that retains grandfathered status but aggregate patient cost sharing increases by more than 15% + inflation due to the movement of drugs from lower to higher tiers.

- **Establishing new or additional tiers to a prescription drug benefit with cost sharing that exceeds the current highest level by more than would be allowed for other services (e.g. co-payments may not increase by more than $5 or 15 percent plus medical inflation, whichever is greater).** As an example, a health insurance plan that changed from a three-tier drug formulary with a tier-3 copay of $50 to a four-tier formulary with a "specialty tier" with a copay of $75 should lose its grandfathered status as the increase in cost sharing is higher than would be permissible for other types of medical services.

- **Shifting coverage of medicines from the medical/surgical benefit to the prescription drug benefit (or vice versa) that results in cost sharing increases greater than allowed for other services.** Such changes in benefit design represent a major change in benefit coverage, often for those beneficiaries with serious medical conditions. For example, moving coverage for medicines from the medical/surgical benefit to the prescription drug benefit may increase out-of-pocket expenses for consumers. Alternatively, moving coverage for medicines from the prescription drug benefit to the medical/surgical benefit may also increase cost-sharing for consumers. Therefore, such benefit changes should not be permissible for plans seeking to retain their grandfathered status, if they result in an increase in a covered drug's beneficiary cost sharing that exceeds the inflation plus 15% standard applied to other services. This is also consistent with the rule that prevents insurers from eliminating all or substantially all benefits for a particular medical condition for the purposes of retaining their grandfathered status. The rule states that a plan ceases to be a grandfathered plan if it eliminates benefits for a particular medical condition, including any necessary element to diagnose or treat a condition.

- **Changes that reduce the overall number of covered drugs on a formulary, or the number of covered drugs on specific tiers (other than changes to accommodate the introduction of an FDA-approved generic substitute of a previously covered innovator drug).** Plans wishing to retain grandfathered status should sustain their coverage of the choice of medicines available to patients. For purposes of the grandfather rule, plans should be able to continue to make routine changes for coverage of specific medicines (including switching them to different tiers or dropping coverage due to the availability of an FDA-approved generic substitute for a previously covered innovator drug) while retaining grandfathered status. Likewise, for purposes of the grandfather rule, plans should maintain an ability to change which particular drugs they cover within a therapeutic class (subject to applicable transition rules). But other changes which reduce the number of covered drugs are likely to reduce treatment options for patients and have the potential to negatively affect patient care. Accordingly, the final rule should specify that (with the exceptions noted above), in plans wishing to maintain grandfathered status the total number of covered drugs (including distinct molecules) across all tiers, and on each specific tier, may not be reduced by more than a nominal amount. This standard would enable plans considerable flexibility and maneuvering room in the market, as it would allow routine changes for coverage of specific drugs and accommodate the situation that occurs when an a generic substitute of an innovator drug is introduced, while at the same time protecting the overall scope and generosity of prescription drug benefits.

- **Changes to an insurance plan's historical practices regarding review and coverage of new treatments and technologies.** Consistent with "Congress's intent to preserve coverage that was in effect on March 23, 2010," PhRMA recommends that the final regulations require that plans wishing to maintain grandfathered status not narrow their current practices for

review and coverage of new medical treatments and therapies – including new prescription medicines. Without a standard to assure that current processes for routinely updating coverage continue, enrolled members can not be assured that coverage in their grandfathered plan will provide a similar level of insurance protection on an ongoing basis. This recommendation applies to maintaining processes for considering review and coverage of new treatments rather than specifying the particular results that must emerge from such processes.

PhRMA believes the interim final rules for implementing the "grandfathered" health plan provisions included in ACA achieve an appropriate balance between allowing individuals and families to keep their current coverage while providing health plans and sponsors with some flexibility to make reasonable changes. This same balance should apply to prescription drug coverage so that such coverage is on a level playing field with the rules that apply to other covered medical benefits.

We appreciate your consideration of our comments. Please feel free to contact us with any questions.

Sincerely,

Richard I. Smith
Senior Vice President, Policy and Research

Diane E. Bieri
Executive Vice President and General Counsel