UPDATED CVS CAREMARK
GUIDANCE DOCUMENT ON THE
INTERIM FINAL RULE ON HEALTH PLANS'
GRANDFATHERED STATUS
September 14, 2010

The Departments of Health and Human Service (HHS), Labor and Treasury released an interim final rule (IFR) on June 14, 2010 regarding health plans that qualify as so-called "grandfathered" health plans under the Patient Protection and Affordable Care Act (ACA). Under the ACA, grandfathered health plans must comply with some, but not all, of the health reform provisions of Subtitles A and C of Title I of the ACA, commonly known as the "group market reform" provisions. The IFR explains how health plans in existence on March 23, 2010 can retain their grandfathered status.

Many CVS Caremark clients have asked us questions about whether formulary changes and step therapy programs will impact a plan's grandfathered status. This Q&A is designed to assist in answering these questions.

Q1: What is a grandfathered health plan?

An existing group health plan in which at least one individual was enrolled on March 23, 2010, is considered a grandfathered health plan. The benefit of being a grandfathered health plan is that such a plan will not be required to comply with the ACA's broader group market reform provisions. An individual who was enrolled in a group health plan on March 23, 2010 can generally add his or her family members to the coverage after this date without impacting the grandfathered status of the plan. New employees, and current employees and their families can also join a grandfathered plan after this date without affecting the grandfathered status of the plan.

Q2: What must a plan do to maintain its grandfathered status?

To maintain its grandfathered status, a plan must retain certain standards related to benefits and cost-sharing. Specifically, to maintain its grandfather status, the IFR reflects that a plan in effect on March 23, 2010 may not:

- Eliminate all or substantially all benefits to diagnose or treat a particular condition, regardless of how many individuals would be affected under the plan.
- Increase the percentage of a cost-sharing requirement that is based on a percentage (i.e., coinsurance).
- Increase a fixed-amount copayment by an amount that is more than the greater of $5 (adjusted annually for medical inflation[1]) or a percentage, compared to the percentage measured from March 23, 2010, that is greater than the sum of medical inflation plus 15 percentage points.
- Increase any deductible (or other fixed amount cost-sharing requirement, other than copayment) by a percentage, compared to the percentage measured from March 23, 2010, that is greater than the sum of medical inflation plus 15 percentage points.
- Lower the employer contribution rate by more than five percentage points below the contribution rate on March 23, 2010.

[1] "Medical inflation" is defined as the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers published by the Department of Labor using the 1982–1984 base of 100.

- Add an annual limit on the dollar value of benefits or lower an existing annual limit. For example:

    - For plans that on March 23, 2010 had no annual or lifetime limit on benefits, adding any annual limit will result in a loss of grandfathered status.
    - For plans that on March 23, 2010 had no annual limit on benefits, but did have a lifetime limit on benefits, adopting an annual limit that is lower than the lifetime limit on March 23, 2010 will result in a loss of grandfathered status.
    - For plans that on March 23 2010 had an annual limit on benefits, any decrease in the annual limit will result in a loss of grandfathered status, regardless of any lifetime limit on benefits.
- Change the insurance company. (Applies to fully insured group health plans that are not collectively bargained.)
    - This does not apply to self-insured plans that change their plan administrators.

In addition to the above requirements for plans maintaining grandfathered status, a plan that seeks to maintain grandfathered status must include a statement in the materials that describe the plan benefits that disclose the plan's grandfathered status and provides a number for questions or complaints.[2]

Q3: What benefit changes may trigger a loss in a plan's grandfathered status?

As a general rule, if a plan significantly reduces its benefits or increases member cost-sharing or premiums above those in effect on March 23, 2010, then the plan could lose its grandfathered status and be subject to additional requirements under the ACA.

Q4: What happens if a plan loses its grandfathered status?

If a plan loses its grandfathered status, the plan will be required to implement additional mandates required by the ACA. Some of the additional mandates include:

- Enhanced appeal procedures, including the establishment of an external review process.
- New HHS reporting requirements on various practices (e.g., claims payment and policies and ratings practices, enrollment/disenrollment and efforts to improve member health, safety and wellness).
- Required coverage of preventive services without cost-sharing.
- A prohibition against preauthorization or increased cost-sharing for emergency services and preauthorization for OB/GYN services.
- A requirement to allow members to select their primary care provider (or a pediatrician in the case of a child) from any available participating primary care provider.
- A requirement to pay for services provided as part of a clinical trial if those services would otherwise be covered.

HHS has specifically asked for comments on whether changes to a plan's formulary should affect the plan's grandfathered status and, if so, what magnitude of changes could cause a plan to lose its

[2] The IFR provides model language that plans may use to satisfy this disclosure requirement.

grandfathered status. Therefore, the answers to Q5, Q6, Q7, Q8 and Q11 could change with the issuance of the final rule.

Q5: If a formulary change is made by a health plan, would the plan's "grandfathered status" be affected?

Formulary changes generally do not significantly cut or reduce benefits or change cost-sharing levels that would otherwise trigger a plan's loss of its grandfathered status under the recently released IFR. Accordingly, we do not believe that typical formulary changes will affect a plan's status as a grandfathered plan under the IFR.

Q6: Would a plan's grandfathered status be affected by a formulary change that involves elimination of an entire drug class, such as proton pump inhibitors (PPIs) or non-sedating antihistamines (NSAs)?

If this type of formulary change would result in the plan no longer providing drugs to treat a certain condition, the change would cause the plan to lose its grandfathered status. The IFR states that the elimination of a necessary element of a treatment is equivalent to eliminating all benefits for a treatment. The IFR gives the example of a plan that provides benefits for treatment of a particular mental health condition. The treatment involves prescription drugs and counseling, and the plan subsequently eliminates the counseling benefit. The IFR states that this would cause the plan to lose its grandfathered status, since counseling is a necessary element of treatment. By eliminating the counseling element, the plan is considered to have eliminated "substantially all" benefits for treatment of the condition. We believe the same principle would apply if the drugs to treat the condition, rather than the counseling, had been eliminated.

It is possible that if the plan continues to provide equivalent coverage of other drugs that are sufficient to treat a particular condition, the elimination of a drug class would not be viewed as elimination of "substantially all" benefits for treatment of the condition. For example, if OTC drugs are viewed as sufficient to treat a particular benefit, the elimination of prescription drugs to treat the condition would likely not result in a loss of grandfathered status. The answer to this question could change on the issuance of the final rule since HHS has specifically asked for comments on whether changes to a plan's formulary should affect the plan's grandfathered status.

Q7: What about a formulary change that involves implementing quantity limits?

As a general rule, the imposition of quantity limits that do not significantly cut or reduce benefits would not trigger a plan's loss of its grandfathered status under the IFR. Accordingly, we do not believe that a plan's decision to implement quantity limits will affect the plan's status as a grandfathered plan under the IFR, particularly quantity limits based on FDA labeling, which would be a clinical safety edit. However, if the quantity limits are so restrictive that they result in limitations that are inconsistent with quantities necessary to effectively treat certain conditions, the imposition of a limit could cause a plan to lose its grandfathered status.

Q8: If the plan implements a step therapy program and moves all non-preferred drugs to another tier, thereby resulting in a higher member copay, would these plan design changes impact a plan's grandfathered status?

As a general rule, step therapy programs and changes to a particular drug's tier placement on the formulary do not significantly cut or reduce benefits or change cost-sharing levels that would otherwise trigger a plan's loss of its grandfathered status under the IFR. Accordingly, we do not believe that a plan's decision to implement a step therapy program or change its drug tiers will affect the plan's status as a grandfathered plan under the IFR. However, if the effect of the formulary change is that drugs to treat certain conditions are no longer covered, or the cost-sharing for all drugs is increased by a margin greater than permitted by the IFR, these changes would cause a plan to lose its grandfathered status.

Q9: Will a plan lose its grandfathered status if it changes copay amounts by more than $5?

Not necessarily; the IFR states that the plan may not increase copays by more than the greater of (i) $5 (adjusted annually for medical inflation) or (ii) a percentage equal to medical inflation plus 15 percentage points. HHS gives the following example:

- A plan has a copay of $30 on March 23, 2010 and increases the copay from $30 to $40 within 12 months. The rate of medical inflation over that same 12-month period is approximately 23%.
- In this instance, the maximum permitted copay increase is the greater of (i) $6.15 ($5 increased by 23%, the rate of medical inflation) or (ii) 38% (23% +15%).
- In this example, an increase from $30 to $40 is an increase of 33%, which is less than the maximum permitted increase of 38%, and so the plan is able to retain its grandfathered status despite a copay increase from $30 to $40.

Q10: What if a client wants to change from flat dollar copays to coinsurance?

Because the IFR appears to prohibit any increase in coinsurance, this could be viewed as a change from zero coinsurance to some coinsurance. This change would likely be prohibited by a plan that wants to maintain its grandfathered status.

Q11: What if a client wants to lower copays for some products and increase copays for others, or institute coinsurance for others? For example, could a client lower copays on generics but increase copays for brands?

As long as the cost-sharing structure is not changed, or only changed within the limits permitted (e.g., increasing any fixed copayment by no more than that permitted by the formula described in Q2), the IFR currently does not prohibit a plan from moving drugs from one tier to another on the formulary. So, for example, a plan would be permitted to raise the cost-sharing for a certain tier from $30 to $40 (assuming the facts are as in Q9), and there is currently no limit on moving drugs to or from that tier. Similarly, if the formulary currently has flat copayments for certain tiers and coinsurance for others, this structure could be retained and drugs could be moved from one tier to the other.

Q12: How long does grandfathering status apply – forever?

There is theoretically no time limit on grandfathered status. However, under the ACA, grandfathered plans are subject to certain mandates, several of which become effective beginning 2014 (e.g. prohibition on pre-existing condition exclusions). Therefore, grandfathered plans will be required to comply with these, even if they retain their grandfathered status. In addition, several of the formulae listed in the prohibitions described in Q2 above are measured on a cumulative basis from March 23, 2010, so that the plans will have greater flexibility in the early years and less flexibility over time. HHS anticipates that this loss in flexibility will cause most plans to give up their grandfathered status over time.

Q13: Are grandfathered plans allowed to impose annual or lifetime limits on benefits?

Lifetime Limits.

All health plans, including grandfathered plans, are subject to the ACA prohibition on imposing lifetime limits for plan years beginning on or after September 23, 2010. Therefore, any existing lifetime limits will have to be lifted for plans years starting on or after that date, regardless of whether the plan qualifies as a grandfathered plan.

Annual Limits.

With respect to annual limits, a grandfathered plan must adhere to the following guidelines to avoid losing grandfathered status:

1. Plans that on March 23, 2010 did not impose an annual or lifetime limit on benefits may not impose any annual limit after March 23, 2010.

2. Plans that on March 23, 2010 imposed a lifetime limit, but no annual limit may not impose an annual limit that is lower than the lifetime limit that was in place on March 23, 2010. For example, if the plan had a lifetime limit of $10,000 on March 23, 2010, it could not impose an annual limit lower than $10,000 after March 23, 2010.

3. Plans that on March 23, 2010 imposed an annual limit may not decrease the annual limit below the amount of the limit that was in place on March 23, 2010, regardless of whether the plan has a lifetime limit or the amount of the lifetime limit on March 23, 2010. For example, if a plan had an annual limit of $5,000 on March 23, 2010 and a lifetime limit of $10,000, it may not lower the annual limit after March 23, 2010 below $5,000. This is the case even though the lifetime limit is lifted after September 23, 2010.

Q14: Does a plan that moves its pharmacy benefits from a "carved in" to a "carved out" status impact the plan's grandfathered status under the IFR?

As a general rule, if a plan does not significantly reduce its benefits or increase member cost-sharing or premiums above those in effect on March 23, 2010, then the plan would not lose its grandfathered status nor would it be subject to additional requirements under the ACA.

However, for fully insured group health plans only, *a change of the insurance issuer will also cause the plan to lose its grandfathered status*. This rule does not apply to self-insured plans, which may change third party administrators without affecting their grandfathered status. As HHS states "for self-insured plans, a change in third party administrator in and of itself does not cause a group health plan to cease to

be a grandfathered health plan." (See 75 Fed. Reg. 34551, footnote 24). Therefore, if the change from a "carved in" to a "carved out" status means that a self-insured plan is merely changing its PBM or third party administrator, this will not cause the plan to lose its grandfathered status.

Q15: What are preventive services? Do prescriptions count as preventive services?

Generally effective for plan years starting after September 23, 2010, group health plans (but excluding grandfathered plans) must provide coverage of preventive services without any cost-sharing. Preventive services generally include (i) certain items or services that are recommended or strongly recommended by the U.S. Preventive Services Task Force; (ii) certain immunizations; (iii) preventive care for infants, children and adolescents as supported in guidelines issued by the Health Resources and Services Administration; (iv) certain preventive care and screenings for women as supported in guidelines issued by the Health Resources and Services Administration; and (v) breast cancer screening, mammography and prevention.

Prescriptions are not specifically listed under preventive services in the ACA, although certain prescriptions may be considered "preventive" if listed in the recommendations or guidelines described above. HHS is expected to issue implementing regulations on the coverage requirements for preventive services shortly. Note that the preventive services requirements do not apply to grandfathered plans.

Q16: Do clinical trials need to be covered?

Beginning in 2014, group health plans (but excluding grandfathered plans) may not deny qualifying individuals participation in certain clinical trials or deny the coverage of routine patient costs for items and services furnished in connection with the clinical trial if those costs would otherwise be covered. This applies to all clinical trials that treat cancer or other life threatening diseases. HHS is likely to issue further guidance on this requirement in the future. Note that the clinical trials requirements do not apply to grandfathered plans.

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