August 13, 2010

By Mail

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To whom it may concern:

The American Cancer Society Cancer Action Network ("ACS CAN") is the advocacy affiliate of the American Cancer Society (the "Society"). The Society is a nationwide, community-based, voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives, and diminishing suffering from cancer, through research, education, advocacy, and service. The American Cancer Society, operating through its national office and 13 chartered, geographic division affiliates throughout the United States is the largest voluntary health organization in the United States.

ACS CAN appreciates the opportunity to provide comments to the U.S. Department of Labor, the Department of Health and Human Services and the Internal Revenue

Service (the "Departments") 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 ("the "Interim Rules") as published in the Federal Register on June 17, 2010. For convenience, references to "plan" herein are intended to include both employer-sponsored group health plans and individual and group coverage obtained in the insurance market and references to "participant" include both employees covered by a group health plan and other individuals who obtain individual or group coverage in the insurance market.

The regulation, on the whole, is well constructed, and ACS CAN applauds the careful and thoughtful balancing of interests that is represented in this interim regulation. Although we are very supportive of the "immediate" insurance reforms in the law, we recognize and respect the commitment that Congress made in allowing people to keep their existing plans. We also recognize that there is great variation among existing plans, and for some of them, complying almost immediately with the new reforms would result in dramatic premium increases or plan termination, neither of which is desirable. Overall, the interim regulation is a constructive compromise that advances reform without creating unacceptable disruption of the markets.

Summary of ACS CAN Recommendations

By grandfathering certain group health plans and health coverage, Congress created a significant exemption from the insurance market reforms and consumer protections mandated by the Patient Protection and Affordable Care Act ("PPACA"). ACS CAN supports reasonable, well-defined limits to the scope of the grandfathering protection to ensure that consumers are not denied the benefits of the PPACA reforms and to avoid the potential for confusion among consumers in the health insurance marketplace. ACS CAN believes the Interim Rules take a meaningful stride toward this objective. However, as set forth in greater detail below, ACS CAN also believes that, in a number of areas, the Interim Rules do not adequately address several key areas of concern.

Enhanced Disclosure. A key concern for ACS CAN is that participants will fail understand the significance of a plan's grandfathered status and will be unable to adequately evaluate the effect of post-March 23, 2010 plan changes on such status. Accordingly, ACS CAN recommends that the model disclosure be enhanced to provide participants with (I) a more comprehensive explanation of grandfathered plan status, (ii) information on the triggers that can result in a cessation of such status, (ii) a complete listing of the specific PPACA reforms that are inapplicable to the plan by virtue of its status, and (iv) access to a formal process for obtaining a determination on a plan's status from the appropriate government agency.

Oversight. The Interim Rules establish a largely self-regulating regime for compliance with the grandfathering exemption. However, this approach may encourage misuse and abuse of the exemption to the serious detriment of

participants. To correct this deficiency, ACS CAN recommends that the Interim Rules incorporate (i) a requirement for initial reporting to the appropriate agency of grandfathered status followed by annual reporting to confirm such status, (ii) annual disclosure updates to participants and (iii) a process for participants to request a determination regarding the status of their plan.

Elimination of Benefits. The Interim Rules properly treat the elimination of certain benefits under a plan as an event resulting in the cessation of grandfathered status. However, ACS CAN recommends that this trigger be revised to create greater certainty for plans and participants regarding the circumstances when the elimination of a specific diagnostic technique or treatment will be treated as the elimination of a benefit.

Change in Plan Design, Physician Network or Formulary. In response to the specific request for comment in the Interim Rules release, ACS CAN recommends that, in certain clearly defined circumstances, changes in plan design, physician networks or plan formulary result in the cessation of the grandfathering exemption. ACS CAN's specific recommendations follow below.

Discussion

Comprehensive Disclosure Requirements for Grandfathered Plans. A claim of grandfathered plan status has significant consequences for the participants who receive coverage under the plan. Not only are participants in a grandfathered plan unable to take advantage of significant PPACA protections, they may have only a limited opportunity to obtain alternative coverage, particularly if their current coverage derives from their employment. In the absence of comprehensive disclosure requirements, the potential for consumer confusion about the status of their coverage under the grandfather rule is enhanced, and the opportunities are increased for unscrupulous parties to take advantage of an exemption to which they are not entitled. For these reasons, ACS CAN believes that, in several key respects, the disclosure requirements under the Interim Rules for plans or policies claiming grandfathered status are inadequate. Specifically, we are concerned that the model disclosure fails to provide consumers with (i) an adequate explanation of the requirements for, and the significance of, grandfathered status, (ii) information regarding the actions that could lead to a cessation of grandfathered status and (iii) a clear picture of which PPACA protections apply and which do not apply to the plan or policy.

To correct these deficiencies, the model disclosure notice for grandfathered plans should be revised to incorporate the following:

- State that grandfathered status is limited to coverage under a plan or policy that was in effect on March 23, 2010.

- State that grandfathered status may continue indefinitely unless the issuer decides to forego such status or changes to the plan result in a cessation of grandfathered status under applicable regulations.

- State that grandfathered status is not affected by a renewal of coverage, the enrollment of new employees or the addition of new dependents.

- Enumerate the specific PPACA requirements that the plan is electing not to comply with because it is a grandfathered plan.

- State that a covered individual is entitled upon reasonable notice to inspect and copy the documents upon which the issuer relies to establish grandfathered status.

- Provide notice of the opportunity to obtain a determination from the appropriate government agency regarding the grandfathered status of the plan *(see below)* and/or file a complaint relating to the plan's claim of grandfathered status.

Enhanced Compliance Oversight for Grandfathered Plans. While ACS CAN appreciates the policy rationale underlying the decision to grandfather certain health insurance plans and coverage, it is essential that grandfathered plan exemption not be misused or misapplied in a way that undermines the integrity of the PPACA reforms. As currently structured, the initial and ongoing process of determining grandfathered status is largely self-regulating and, ACS CAN believes, highly susceptible to abuse. ACS CAN recommends that the following additional measures be considered to ensure compliance and to provide a sound basis for adequate oversight through the agency audit and enforcement process:

- Plans claiming grandfathered status should be required to make an initial certification of such status with an appropriate government agency. The initial certification should be followed by an annual reporting requirement that would itemize plan changes during the year and require recertification that the plan remains grandfathered or has given up grandfathered status. The reporting requirements could easily be incorporated as an item on existing reporting obligations such as the Form 5500. Absent this kind of detailed periodic reporting, it will be very difficult for the agencies charged with oversight of grandfathered plans to detect possible misuse or abuse of the exemption.

- Plans should be required to provide participants with an annual update to the initial disclosure notice that (i) if applicable, renews the plan's claim to exempt status, (ii) provides an itemization of changes to the

plan since the prior notice and (iii) provides participants with an explanation as to why those changes do not cause the plan to cease its grandfathered status.

- The model disclosure notice should reference a process whereby participants who question the grandfathered status of their plan can obtain a formal determination from the appropriate regulatory agency regarding whether the plan is grandfathered or otherwise contest the plan's claim to grandfathered status. This process would include an opportunity for the plan to respond to the participant's claims and detail the reasons why it is grandfathered. This process could be structured along the lines of the similar process already in place at the Internal Revenue Service that allow workers to obtain a classification of their status as common law employees or the process that provides an opportunity for participant comment when a tax-qualified retirement plan seeks a determination letter from the Internal Revenue Service.

Elimination of Benefits Triggering a Cessation of Grandfathering. Under the Interim Rules, the "elimination of all or substantially all benefits to diagnose or treat a particular condition causes a group health plan or health insurance coverage to cease to be a grandfathered health plan." The Interim Rules go on to clarify 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." While ACS CAN believes this approach is consistent with the limited scope of the grandfathering exemption, it creates substantial uncertainty for both plans and participants by failing to establish a bright line test for circumstances where a reduction in benefits triggers a cessation of grandfathering. This standard is likely to create substantial questions for plans and participants alike regarding whether a particular element of a diagnostic technique or treatment is a ***necessary*** element of the technique or treatment. This standard also appears to inappropriately shift the burden to the participant to demonstrate that a particular element of a diagnostic technique or treatment is a "necessary" element of the technique or treatment. Accordingly, ACS CAN recommends that the regulations establish a rebuttable presumption that the elimination of benefits for ***any*** diagnostic technique or ***any*** treatment for which benefits was available under the plan on March 23, 2010 causes the plan to cease to be a grandfathered health plan, unless the change is consistent with existing (including recently revised) practice guidelines. Under this approach, the presumption could be rebutted by specific, credible evidence that the prior technique or treatment for which benefits are no longer available has been superseded by a new or different technique or treatment that (i) is generally regarded as an advance in diagnosis or treatment, (ii) is substantially as effective as the prior or treatment or (iii) provides a similar clinical result at a reduced cost.

Request for Comments

The Departments have requested comment on whether changes to (i) plan structure, (iii) a network plan's provider network or (iii) a prescription drug formulary or any other substantial changes to plan design should cause a cessation of grandfathered health plan status. Our recommendations in these areas follow below.

Change in Plan Structure. Under the current structure of the Interim Rules, it is likely that a material change in plan structure will result in the cessation of the grandfathering exemption through the application of an otherwise applicable trigger such as the one applicable to changes in copayments and deductibles. However, some changes are so fundamental, such as when a PPO model plan becomes an HMO plan, that cessation of grandfathered status should be automatic. In addition, it may be appropriate to apply a higher level of scrutiny to plans that undergo a material structural change, such as a change from insured to self-insured, in a manner similar to the kind of heightened scrutiny applicable under the Interim Rules to a grandfathered plan involved in a corporate transaction, i.e., a general anti-abuse rule should apply that results in a cessation of grandfathered status where the principal purpose of the change in plan structure is to avoid the cessation of grandfathered status or otherwise manipulate grandfathered status to the detriment of the participants. Finally, any change in eligibility for a plan--for example, increasing the hours of work required to be eligible for coverage--should trigger the cessation of grandfathered status.

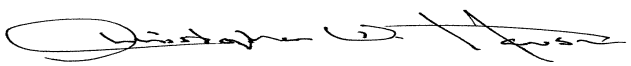
Change in Plan Provider Network. The demographics of plan's provider network are often integral to the participant's ability to effectively utilize the plan's benefits. Accordingly, there are clearly circumstances where a material change in a network plan's plan provider network should trigger a cessation of the grandfathering exemptions. While recognizing the inherent difficulty of drawing workable lines in this area, ACS CAN believes that it is possible for the regulations to highlight by way of example certain events that constitute a material change to the plan and, therefore, should trigger a cessation of grandfathering. These events could include the following: (i) a greater than 25 percent change in the number of network providers in a particular specialty; (ii) a greater than 25 percent change in the overall number of network providers; (iii) the elimination from the network of any hospital utilized by greater than 25 percent of plan participants; (iv) a greater than 25 percent change in the number of providers included in a geographic area previously identified by the plan to participants as an area served by the plan; (v) elimination of all previously covered providers of a certain class or specialty unless there such providers are no longer practicing in the service area. HHS may also want to consider an exception for those plans operating in rural areas and other areas with small provider networks.

Change in Prescription Drug Formulary. As with a provider network, a plan's prescription drug formulary, and the rules relating to a participant's use of the formulary, is an essential feature of plan benefits. A material change in either the structure or content of a plan's formulary represents a material change in the plan and, therefore, should result in a cessation of grandfathering. In developing an appropriate trigger relating to a plan's formulary, ACS CAN recommends that, as an initial matter, the Departments focus on changes in the overall structure of the formulary rather than changes in the specific content of the formulary. These changes should include the following: (i) any change in the tier structure, such as changing from a co-pay to coinsurance or increases in cost-sharing for any tier; (ii) moving a class of drugs to a more expensive tier; (iii) increases in co-pays that exceed medical inflation plus 15 percentage points; (iv) moving a drug from prescription coverage to a medical benefit or vice versa such that a patient is left with significantly greater out of pocket costs; (v) imposing pre-authorization for any tier where there previously was no requirement; (vi) restrictions on or the elimination of a patients appeals process regarding a plan's formulary; (vii) elimination of a drug or class of drugs for which there are no appropriate alternatives on the formulary; (ix) movement of a drug or class of drugs to a higher copayment tier when there is no appropriate alternative drug (i.e., generic) and (vi) a reduction in the total number of drugs covered beyond a certain threshold with exceptions for generic drugs. We believe this approach parallels other requirements in this regulation and is consistent with the intent of the grandfathering exemption.

Conclusion

ACS CAN believes that it is critical to the success of the PPACA that the benefit of its consumer protections and insurance market reforms be available to the American public as rapidly and as widely as possible. While recognizing both the practical and policy rationales for providing limited grandfathering protection to certain plans, the exemption should not be expanded in a way that undermines the national imperative of health care reform. ACS CAN applauds the Departments for crafting regulations that, as a general matter, are consistent with this objective. We hope the Departments will consider our recommended changes and additions, which are intended to provide participants with greater clarity and certainty as they seek to understand both the complexities of the grandfather rule and its context in the larger picture of the PPACA reforms.

Sincerely,



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