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The Honorable Kathleen Sebelius
Secretary,
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

July 12, 2010

Re: OCIIO-9991-IFC; Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act

Dear Secretary Sebelius,

On behalf of American Society of Clinical Oncology (ASCO), I am pleased to submit these comments in response to the interim final rule issued in the *Federal Register* entitled, "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). With more than 28,000 members, ASCO is the leading medical society for specialists involved in cancer treatment and research. We commend the Departments of Health and Human Services, Labor and the Treasury for developing this interim final rule, which provides clarification regarding the status of grandfathered health plans.

Health plans should be encouraged to enhance the scope of covered benefits whenever possible, and ASCO strongly agrees with the Departments that health plans should not lose grandfathered status as a result of adding benefits to an existing grandfathered plan. We support the language in the preamble of the interim final rule that states, "These interim final regulations will generally permit, for example, plans and issuers to make voluntary changes to increase benefits, to conform to required legal changes, and to adopt voluntarily other consumer protections in the Affordable Care Act." We urge the Departments to highlight this important clarification in all notices and guidance documents, emphasizing the desirability of voluntarily adopting consumer protections that will become mandatory for non-grandfathered plans, such as the coverage of the routine costs associated with clinical trials. This will help ensure that plans can continue to meet the changing needs of their participants, which is especially important during this period of rapid innovation in the field of medicine.

ASCO also commends the Departments for affirming that health plans will lose grandfathered status if the plans eliminate all or substantially all benefits to diagnose or treat a particular disease or condition. Because of the potential that health plans might employ undesirable cost-cutting strategies, ASCO recommends that the Departments describe scenarios in which this safeguard would be triggered to protect

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consumers with cancer. Specifically, we urge the Departments to include the following examples:

- If a health plan eliminates coverage for the routine costs associated with clinical trials. (This addition will also benefit consumers with other life-threatening diseases.)
- If a health plan eliminates coverage for evidence-based, off label usage of drugs and biologics for anticancer regimens.
- If drugs or biologics that are part of an evidence-based anticancer regimen are either removed from a health plan formulary or moved to a different payment tier, thus increasing a patient's copayment responsibility.
- If a health plan institutes more restrictive limits to the number of chemotherapy treatments or hospital admissions that a patient with cancer can receive.
- If a patient's physician (who is participating in a preferred provider network) has agreed to use insurer-designated treatment pathways and the patient is denied coverage for an indicated pharmaceutical agent because it is not on the pathway but would otherwise have been covered by the plan.

In the case of individuals with cancer, meaningful access to cancer care requires coverage of the routine medical costs associated with participation in clinical research, which is otherwise required under the new law. As you are aware, clinical trials provide important options for the treatment of individuals with cancer and other life-threatening diseases and promote advancement in scientific discovery and knowledge. In fact, such coverage does not significantly impact the premiums or aggregate costs of providing health insurance.

We encourage the Departments to take steps to urge grandfathered plans to voluntarily provide coverage for clinical trial participation. The Departments can do this by issuing public statements on the topic and by adding "clinical trials coverage" as a point of comparison on the website (www.healthcare.gov) the Department is developing to enable consumers to compare health plans.

ASCO also encourages HHS to issue additional guidance regarding how health plans will be monitored for breeches that would cause a plan's loss of grandfathered status. This guidance should indicate how patients and providers can report coverage concerns. A transparent and efficient reporting and review process will ensure that health plans are held accountable. The reporting should not overly burden patients and providers.

ASCO notes that many health plans do not have a transparent mechanism of articulating specific services that *are* covered by the plan. This may present challenges in determining what coverage was in effect on March 23, 2010. ASCO recommends that language be added to the rule indicating that when coverage documentation is ambiguous, the Department will determine what services must be covered based on past patterns of coverage and a reasonable interpretation of the plan's documents.

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We appreciate the important collaboration and efforts by the Departments of Health and Human Services, Labor and the Treasury to address these important issues. Overall, we commend this interim final rule and encourage you to contact Shelagh Foster, ASCO's Director of Government Relations (shelagh.foster@asco.org or 571-483-1612) if you have any questions or would like to discuss these comments in greater detail.

Thank you for your consideration,

A handwritten signature in black ink, appearing to read "GWS", is centered on the page. The signature is written in a cursive, flowing style.

George W. Sledge, Jr., MD
President
American Society of Clinical Oncology

GWS:ab