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

August 5, 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 the Association of American Cancer Institutes (AACI), an organization composed of 95 leading cancer research centers in the United States, I am writing to comment on 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).

Representing the nation's premier National Cancer Institute-designated centers and academic-based cancer research programs receiving NCI support, AACI applauds the Administration and Congress for their commitment to ensuring quality care for cancer patients, as well as for providing researchers with the tools that they need to develop better cancer treatments and, ultimately, create a cancer-free world. We thank the Administration for writing an interim final rule that will answer many questions about the status of grandfathered health plans.

AACI supports the Administration's position that health plans expanding their coverage should not lose grandfathered status. We believe that allowing voluntary "changes to increase benefits, to conform to required legal changes, and to adopt ... other consumer protections" is vital and should be highlighted in all notices and guidance documents. By emphasizing this provision, the Administration would affirm the value of adopting provisions of the Patient Protection and Affordable Care Act and ensure that health plans can continue to meet their beneficiaries' needs. In the field of cancer care, standard treatments can change rapidly due to research conducted by AACI members, and it is critical that plans have the flexibility to meet participants' varying needs.

While AACI commends the Administration for stating that health plans will lose grandfathered status if they eliminate all or substantially all benefits to treat or diagnose a disease, we believe that including examples of such benefit reductions would increase transparency and prevent cost-cutting strategies that would harm our patients. Many of our cancer researchers are also physicians whose patients would be significantly affected by seemingly innocuous changes a health plan might make in order to protect profits. For example, health plans might try to save money by eliminating coverage or increasing beneficiaries' copayments, which would effectively end physicians' ability to practice evidence-based medicine – a tremendous blow to cancer care. In another effort to cut costs, health plans might drop coverage for routine costs associated with clinical trials,

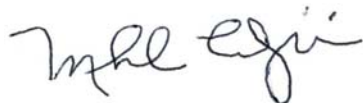
causing many patients to lose their last, best hope of survival. Coincidentally, several studies have shown that participating in a clinical trial is no more expensive than receiving standard therapy. Clinical trials are the cornerstone of cancer research and are of great importance to AACI. They lead to better treatments, improve patient survival and have a positive effect on the nation's economy.

Without clinical trials we cannot discover new cancer drugs and better treatments, and without volunteers, we cannot conduct trials. This is why clinical trial coverage was mandated for new health plans and why we ask that the Administration 1) encourage grandfathered plans to voluntarily provide coverage for clinical trial participation; 2) clarify that dropping coverage of routine care costs of clinical trials would result in the loss of grandfathered status; and, 3) add "clinical trials coverage" as a point of comparison between health plans on its new website (www.healthcare.gov).

In conclusion, AACI notes that the interim final rule does not provide enough guidance on how grandfathered health plans' compliance will be monitored and how potential abuse will be avoided. We recommend that additional guidance be issued, particularly focusing on how patients and providers can report potential abuses. AACI also asks that the Administration create a transparent reporting and review process that will keep health plans accountable but not burden patients or providers. The reporting and review process may be hindered by health plans not clearly articulating specific services covered on March 23, 2010. To address this problem, AACI recommends that the Administration add language to the interim final rule indicating that if coverage documentation is ambiguous, then the determination of services that must be covered will be based on past coverage patterns and a reasonable interpretation of the available documents.

Thank you for your willingness to consider our views. If you have questions or require additional information, please contact Barbara Duffy Stewart, Executive Director, AACI at 412.647.2076 or Barbara@aaci-cancer.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Caligiuri". The signature is fluid and cursive, with the first name "Michael" written in a larger, more prominent script than the last name "Caligiuri".

Michael A. Caligiuri, MD
President, Association of American Cancer Institutes
Director, Ohio State University Comprehensive Cancer Center
CEO, James Cancer Hospital and Solove Research Institute