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*Albert and Mary  
Lasker Foundation*

*American Association  
for Cancer Research*

*American Cancer Society, Inc.*

*American College  
of Radiology*

*American Society for  
Therapeutic Radiology  
and Oncology*

*American Society of  
Clinical Oncology*

*American Society  
of Hematology*

*Association of American  
Cancer Institutes*

*Cancer Research  
and Prevention Foundation*

*Cancer Treatment  
Research Foundation*

*Candlelighters Childhood  
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*Coalition of Cancer  
Cooperative Groups*

*CureSearch National  
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*International Cancer  
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*International Myeloma Foundation*

*Kidney Cancer Association*

*The Leukemia and  
Lymphoma Society*

*The Lustgarten Foundation for  
Pancreatic Cancer Research*

*Oncology Nursing Society*

*Pancreatic Cancer Action Network  
PanCAN*

*Prostate Cancer Foundation*

*Radiation Research Society*

*Society of Nuclear Medicine*

*The Society of  
Gynecologic Oncologists*

*The V Foundation for  
Cancer Research*

August 16, 2010

U.S. Department of Labor  
Office of Health Plan Standards  
and Compliance Assistance  
Employee Benefits Security Administration  
Room N-5653  
Attn: RIN1210-AB42  
200 Constitution Avenue NW  
Washington, DC 20210

Office of Consumer Information and Insurance Oversight  
Department of Health and Human Services  
Attn: OCIO-9991-IFC  
P.O. Box 8016  
Baltimore, MD 21244-1850

Internal Revenue Service  
CC:PA:LPD:PR (Reg-118412-10)  
Room 5205  
P.O. Box 7604  
Ben Franklin Station  
Washington DC 20004

**Re: OCIO-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**

Ladies and Gentlemen:

The National Coalition for Cancer Research (NCCR) is pleased to submit these comments in response to the interim final rules 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" (PPACA) (OCIO-9991-IFC).

The NCCR is a coalition of cancer research, cancer care and lay groups, and foundations representing cancer survivors, adults and children with cancer and their families, cancer researchers, nurses and physicians, and cancer hospitals, centers, clinics and specialized research institutions. The NCCR directs its efforts at educating public policy makers and legislators about the impact of specific legislation on cancer research. Specifically, the NCCR advocates for Federal legislation and regulations that will enhance and expand basic, translational and clinical research and ensure that the infrastructure and reimbursement mechanisms are in place to support the translation of research from the laboratory to the bedside. The NCCR supports these goals in their broadest terms, emphasizing national priorities essential to progress in cancer research, treatment, early detection and prevention of cancer.

## **National Coalition for Cancer Research Recommendations**

The implementation of Section 2709 of the PPACA, “Coverage for Individuals Participating in Approved Clinical Trials,” is of paramount importance to NCCR. As such, we will limit our recommendations on the Interim Final Rules Relating to Status of a Grandfathered Health Plan under PPACA to clinical trial coverage.

We strongly support the provisions of the Interim Final Rules that permit health plans to add benefits to an existing grandfathered plan, or to voluntarily adopt consumer protections that will become necessary for non-grandfathered plans, without forfeiting its grandfathered status. We encourage the Departments to clarify and emphasize this point with respect to a plan adding coverage of routine patient costs for clinical trial participants. We also encourage the Department of Health and Human Services (HHS) to provide information on this topic in written communications to consumers and by including “Coverage of Clinical Trials” as a point of health plan comparison when consumers utilize the HHS healthcare website ([www.healthcare.gov](http://www.healthcare.gov)). Furthermore, we strongly encourage the Departments to specifically state that elimination of coverage for routine patient costs associated with clinical trial participation would, in fact, result in the immediate loss of grandfathered status of the plan.

As you are aware, for patients with cancer and others struggling with life-threatening illnesses, standard therapy may not be effective, and frequently the best therapies are available only through participation in a clinical trial. Unfortunately, access to cutting-edge treatment through clinical trials is often denied, as many health plans refuse to cover routine patient care costs on the grounds that the care is “experimental.”

We also understand some plans that do not generally provide coverage of routine patient costs for clinical trial participants have provided coverage of such costs on a case-by-case basis. While we strongly encourage all health plans to voluntarily adopt the provisions of Section 2709 of PPACA, we do not believe that a plan should be ceased to be grandfathered if it provides such coverage for individual plan participants on a case-by-case basis when such coverage is not provided for in the plan language.

We acknowledge and appreciate the tremendous manpower and monetary costs associated with implementation of PPACA. However, we are concerned the Interim Final Rules for grandfathered plans do not provide adequate guidance on how such plans will be monitored to determine initial compliance, to determine future compliance and to avoid potential abuse. We believe it is imperative that the final regulations contain additional guidance on how the Departments will monitor health plans and on the mechanism for adopting non-grandfathered plan requirements if the health plans are found to be in violation. This guidance should also include information regarding how consumers and/or providers can report potential breeches that could cause the loss of a plan’s grandfathered status, including changes in clinical trials coverage determinations.

Finally, we encourage the Departments to require all health plans (grandfathered and non-grandfathered) to provide consumers with understandable, unambiguous information regarding coverage or non-coverage of routine patient costs associated with clinical trial participation. In order to increase the transparency of the health care system, this information regarding coverage of clinical trials should be included with additional consumer information regarding grandfathered health plans. Such information should include (i) a comprehensive explanation of grandfathered plan status, (ii) information regarding actions that would trigger the loss of

grandfathered status, (iii) a listing of PPACA provisions that are and are not applicable to grandfathered plans, including clinical trials coverage (iv) affirmatively stating that plans may add additional consumer protection benefits without loss of grandfathered status and (v) a means by which consumers can obtain information regarding the grandfathered status of their own health plan.

## **Conclusion**

While we remain concerned that even the limited grandfathering status provision of PPACA could have the unintended consequence of undermining the overall objective of health care reform, the National Coalition for Cancer Research agrees that the Interim Final Rules reflect the intent of the grandfathering status provision in PPACA. We commend the Departments for their collaborative efforts to develop the Interim Final Rules, which provide clarity to consumers, researchers and providers regarding the status of grandfathered health plans.

At a time when more than 400 anti-cancer therapeutics are in various stages of clinical development, it is essential to preserve and expand our nation's robust clinical trial system. We believe the recommendations contained within this letter will help achieve these objectives and also provide essential information and assistance to clinical trial participants.

We thank you for the opportunity to provide these comments and respectfully request they be given full and fair consideration as the Departments proceed with additional rulemaking regarding group health plans and health insurance coverage relating to status as a grandfathered health plan under the Patient Protection and Affordable Care Act.

Sincerely,

American Association for Cancer Research  
American Cancer Society Cancer Action Network  
American College of Radiology  
American Society of Clinical Oncology  
American Society of Hematology  
American Society for Radiation Oncology  
Association of American Cancer Institutes  
Gateway for Cancer Research  
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CureSearch Childhood Cancer Foundation  
Friends of Cancer Research  
International Cancer Advocacy Network  
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Kidney Cancer Association  
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The Lustgarten Foundation  
Oncology Nursing Society  
Pancreatic Cancer Action Network  
Prevent Cancer Foundation  
Prostate Cancer Foundation  
Society of Gynecologic Oncologists  
V Foundation for Cancer Research