



Member Organizations

*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
Cancer Foundation*

*Coalition of Cancer
Cooperative Groups*

*CureSearch National
Childhood Cancer Foundation*

*International Cancer
Advocacy Network*

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). 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
Candlelighters Childhood Cancer Foundation
Coalition of Cancer Cooperative Groups
CureSearch Childhood Cancer Foundation
Friends of Cancer Research
International Cancer Advocacy Network
International Myeloma Foundation
Kidney Cancer Association
Leukemia and Lymphoma Society
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