September 17, 2010

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
Department of Labor
200 Constitution Avenue, NW
Washington, D.C. 20210

Attention: RIN 1210-AB44

The undersigned organizations, representing cancer patients, researchers, physicians, and other health professionals, are pleased to have the opportunity to comment on the interim final rules for group health plans and health insurance issuers relating to coverage of preventive services under the Patient Protection and Affordable Care Act (ACA). These ACA provisions, which require coverage of and prohibit the imposition of cost-sharing for certain preventive services, hold the promise of improving access to a wide range of health care services that contribute to the prevention, early detection, and treatment of cancer as well as the prevention and early detection of second cancers and the management and treatment of many other late and long-term effects of cancer.

The services for which cost-sharing would be prohibited are those services that enjoy an A or B recommendation of the U.S. Preventive Services Task Force; immunizations for children, adolescents, and adults that are recommended by the Advisory Committee on Immunization Practices and adopted by the Director of the Centers for Disease Control and Prevention (CDC); and preventive care and screenings for infants, children, and adolescents that are recommended by the Health Resources and Services Administration (HRSA). Among the services currently recommended and therefore covered by this provision are many that are vital for cancer prevention, diagnosis, and treatment, including but not limited to screening for breast cancer, chemoprevention of breast cancer, screening for cervical cancer, counseling related to BRCA screening, screening for colorectal cancer, screening for hepatitis B, screening for HIV, screening and counseling for obesity (for children and adults), screening for osteoporosis, counseling for sexually transmitted infections (STIs), counseling for tobacco cessation, and immunization for hepatitis B and human papillomavirus.
The potential impact of this provision on cancer care is significant. Our comments below recommend some changes in the implementation of the ACA provision.

**Cost Sharing For Office Visits at Which Preventive Services are Provided**

The interim rules include standards for imposition of cost-sharing requirements when services are provided as part of an office visit. According to the rules: 1) if the preventive services are billed separately from the office visit, cost-sharing may be imposed with respect to the office visit; 2) if the preventive service is not billed separately and the delivery of the preventive service or item is the primary purpose of the office visit, no cost-sharing requirements may be imposed; and 3) if the preventive service is not billed separately and the primary purpose of the office visit is not the delivery of the preventive good or service, cost-sharing requirements may be imposed with respect to the office visit.

We have serious concerns about the implementation of the standards above, as we think there will be confusion on the part of beneficiaries about their cost-sharing responsibilities. If beneficiaries have no confidence that they will enjoy protection from cost-sharing requirements, the incentive to utilize preventive services will be diminished.

We recognize that it may not be possible to prohibit the imposition of cost-sharing requirements for any office visit at which preventive services are provided. In lieu of that step, which would ensure the greatest beneficiary protection and the strongest incentives for preventive care utilization, we strongly urge that plans and issuers be instructed to develop clear and precise plan materials that will outline the circumstances when cost-sharing requirements related to office visits will be imposed and when they will not.

**Coverage and Cost-Sharing for Preventive Services Provided Out-of-Network**

The interim rules establish that plans and issuers are not required to cover preventive services provided by out-of-network providers and may impose cost-sharing requirements for preventive services provided by out-of-network providers. The departments indicate that they made these decisions regarding out-of-network care to restrain the cost of the preventive care cost-sharing protections and to retain incentives for providers to agree to network participation.

We appreciate the need to weigh cost and provider participation in networks, but we believe that the out-of-network provisions may undermine the benefits of the cost-sharing protections for cancer survivors, as some of the important cancer prevention benefits may be available only from providers who are out-of-network or may be provided in a comprehensive and coordinated fashion only by out-of-network providers. For example, counseling related to BRCA screening may not be available from in-network providers in all insurance plans. In addition, for some cancer survivors, many of the preventive services covered by the ACA provision—obesity counseling, tobacco cessation counseling, cancer screening, and chemoprevention for breast cancer -- will be provided
as part of a comprehensive survivorship follow-up care program that is coordinated in survivorship clinics or community oncology practices that may not be network providers. The benefits associated with eliminating cost-sharing requirements will not be realized if cancer survivors are not able to access without cost-sharing requirements certain high-quality preventive services, whether in special survivorship clinics or in breast cancer centers with expertise and experience in BRCA test counseling.

The ACA authorizes the Secretary to develop guidelines to permit plans and issuers to utilize value-based insurance designs. We are not persuaded that current models for value-based insurance will address the special issues that may confront cancer survivors seeking certain preventive services. We encourage the departments to use the authority granted under the ACA to encourage the development of insurance models that would permit the delivery of preventive services to cancer survivors through a coordinated system of care, whether provided by a survivorship clinic team, an academic health center, or a community-based cancer care team.

One-Year Period Between New Recommendation and Requirement for Coverage

The ACA requires that there be an interval of at least one year between the issuance of any new preventive care guideline by the Preventive Services Task Force, CDC, or HRSA and the effective date of coverage (without cost-sharing) of any new service. We understand that the departments do not have the flexibility to require a more rigorous schedule for coverage of a newly recommended preventive service or item. However, we urge the departments to encourage more rapid coverage by plans and issuers in those circumstances where the new service or item holds significant promise for disease prevention or early detection of disease.

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We appreciate the opportunity to comment on the interim final rules implementing special cost-sharing protections related to preventive services and goods.

Sincerely,

Cancer Leadership Council

American Society for Radiation Oncology
American Society of Clinical Oncology
Bladder Cancer Advocacy Network
C3: Colorectal Cancer Coalition
Cancer Support Community
The Children's Cause for Cancer Advocacy
Education Network to Advance Cancer Clinical Trials (ENACCT)
International Myeloma Foundation
Lance Armstrong Foundation
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
Ovarian Cancer National Alliance
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen for the Cure Advocacy Alliance
Us TOO International Prostate Cancer Education and Support Network