January 18, 2012

Marilyn Tavenner, RN, BSN, MHA
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Ms. Tavenner:

The undersigned organizations are pleased to submit these recommendations in anticipation of rulemaking to implement Section 2709 of the Public Health Service Act as enacted under the Patient Protection and Affordable Care Act (ACA). Section 2709 establishes strong new federal safeguards to protect patient access to clinical trials by requiring group health plans and insurance issuers to cover routine patient care costs incurred when individuals enroll in clinical trials for the prevention, detection, or treatment of cancer and other life-threatening diseases.

Through enhancing our understanding of cancer–and of the risks and benefits of promising new agents–we improve treatment, diagnosis, and prevention options for patients. In addition, clinical trials offer individual cancer patients access to novel therapies that may improve outcomes, prolong survival, and enhance quality of life. Congress affirmed the importance of clinical trials in Section 2709, noting that timely access to clinical trials is critically important to individuals with cancer and other life-threatening diseases. It is a longstanding and firmly held belief in oncology that the option to participate in a clinical trial is a key component of high quality cancer care and should be a readily accessible option for any cancer patient.

Our comments focus on people living with or at high risk for cancer who have the potential to benefit from participation in clinical trials. The undersigned organizations are long-time advocates for insurance coverage of clinical trials – through both private and public health plans and insurers. During the 2010 health care reform debate, these organizations played an active role in advancing legislative provisions that established Section 2709, and we hope to have the opportunity to collaborate with you and your colleagues on an ongoing basis to implement appropriate safeguards for access to clinical trials through this statutory provision.

As you develop implementing regulations and policies, we hope you will consider these comments, which convey our perspective on a number of issues that must be addressed in order to realize the intended goals of Section 2709. In particular, we recommend that regulations include the following provisions (which are discussed in greater detail in the attached document):

- **Prevention of Delays and Administrative Barriers –** We encourage the Secretary to establish explicit safeguards protecting individuals with cancer from delays and administrative barriers that undermine access to clinical trials.

- **Prevention, Detection, and Treatment of Complications –** We encourage inclusion of explicit safeguards to ensure that the prevention, detection, and treatment of complications

arising from clinical trials are covered by group health plans and insurance issuers as routine patient costs under Section 2709 of the Public Health Service Act.

- **Geographic Safeguard to Preserve Local Access** – Implementing regulations should prevent group health plans and insurance issuers from requiring patients to travel extensive distances to enroll in a clinical trial with an in-network provider.

- **Clear Coverage Information for Enrollees** – There should be safeguards to ensure patients are informed in an unambiguous manner as to whether or not their group health plan or insurance issuer covers the routine costs associated with participation in clinical trials.

- **Referral to Specialists** – Implementing rules should prevent financial incentives arising from Accountable Care Organizations or other new delivery models from inadvertently creating barriers for patients to participate in clinical trials.

- **Method for Consumer Reporting** – There should be a clear and effective mechanism for reporting concerns relating to the coverage of clinical trials.

We would appreciate your assistance in arranging follow-up with the most appropriate CMS officials to discuss our recommendations for successful implementation of Section 2709. We would be pleased to serve as a resource for CMS' ongoing work involving clinical trials, as well as any other issues involving the prevention, diagnosis, and treatment of cancer. To discuss these issues further, please contact Allison Baer at 571-483-1624 or Allison.Baer@asco.org with any questions.

Sincerely,

American Association for Cancer Research (AACR)-
The AACR, representing 34,000 laboratory, translational, and clinical researchers; other health care professionals; and cancer survivors and patient advocates, is the world's oldest and largest scientific organization focused on every aspect of high-quality, innovative cancer research.

American Cancer Society Cancer Action Network (ACS CAN)-
ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society that supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem.

American Society for Radiation Oncology (ASTRO)-
ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapy. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy.

American Society of Clinical Oncology (ASCO)-
The American Society of Clinical Oncology (ASCO) is the national organization representing more than 30,000 physicians and other health care professionals committed to conquering cancer through research, education, prevention, and delivery of high-quality cancer care.

American Society of Hematology (ASH)-

The American Society of Hematology (ASH) is the world's largest professional society concerned with the causes and treatments of blood disorders. The mission of the Society is to further the understanding, diagnosis, treatment, and prevention of disorders affecting the blood, bone marrow, and the immunologic, hemostatic and vascular systems, by promoting research, clinical care, education, training, and advocacy in hematology.

Association of American Cancer Institutes (AACI)-

The Association of American Cancer Institutes (AACI) is dedicated to promoting the nation's leading cancer research institutions' efforts to eradicate cancer through a comprehensive and multidisciplinary program of research, treatment, patient care, prevention, education and community outreach.

Coalition of Cancer Cooperative Groups-

The Coalition of Cancer Cooperative Groups is an independent non-profit service organization working to improve physician and patient access to cancer clinical trials through broad-based education and outreach, advocacy at the federal level on behalf of the public cancer clinical trials system, and direct regulatory support services to the National Cancer Institute-sponsored Cooperative Groups and their network of 14,000+ clinical research professionals in over 3,100 medical facilities nationwide, who collectively enroll about 25,000 patients annually in clinical trials and monitor another 150,000 patients in follow-up care.

LIVESTRONG, Lance Armstrong Foundation-

LIVESTRONG serves people and families fighting cancer and empowers communities to take action. It provides free, one-on-one, confidential consultation to cancer survivors for the host of challenges that accompany a diagnosis, including insurance questions, fertility issues, legal and career concerns and emotional support.

National Coalition for Cancer Research (NCCR)-

National Coalition for Cancer Research (NCCR) is a nonprofit organization comprised of 23 national cancer organizations. The mission of NCCR is to advocate on behalf of federal legislation and regulations which will enhance and expand basic, clinical and translational research, and to ensure the infrastructure and reimbursement mechanisms are in place to support the translation of research from the laboratory to the bedside.

National Comprehensive Cancer Network (NCCN)-

The National Comprehensive Cancer Network (NCCN) is a not-for-profit alliance of 21 of the world's leading cancer centers, is dedicated to improving the quality and effectiveness of care provided to patients with cancer. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. Our programs offer access to expert physicians, superior treatment, and quality and safety initiatives that continuously improve the effectiveness and efficiency of cancer care.

National Lung Cancer Partnership-

The National Lung Cancer Partnership is the only lung cancer advocacy organization founded by doctors and researchers working together with survivors and advocates to increase lung cancer awareness and research funding.

Oncology Nursing Society (ONS)-

The Oncology Nursing Society (ONS) is a professional organization of over 35,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing.

Pancreatic Cancer Action Network-

The Pancreatic Cancer Action Network is a nationwide network of people dedicated to working together to advance research, support patients and create hope for those affected by pancreatic cancer.

Prevent Cancer Foundation-

The Prevent Cancer Foundation is a national non-profit that advocates and supports the prevention and early detection of cancer through Research, Education and Community Outreach.

Research Advocacy Network-

The mission of the Research Advocacy Network is to develop a network of advocates and researchers who influence cancer research–from initial concept to patient care delivery—through collaboration, education and mutual support.

Susan G. Komen for the Cure Advocacy Alliance-

The Susan G. Komen for the Cure® Advocacy Alliance is the nonprofit, nonpartisan advocacy arm of Susan G. Komen for Cure®, the largest breast cancer organization in the world. With a network of more than 300,000 advocates, the Alliance is the voice for the 2.6 million breast cancer survivors and those who love them, working to ensure that the fight against breast cancer is a priority among policymakers in Washington, D.C., and every Capitol across the country.

Detailed Recommendations for Clinical Trials Coverage Regulation

January 2012

These recommendations are supported by the following organizations:

- American Association for Cancer Research
- American Cancer Society Cancer Action Network
- American Society for Radiation Oncology
- American Society of Clinical Oncology
- American Society of Hematology
- Association of American Cancer Institutes
- Coalition of Cancer Cooperative Groups
- LIVESTRONG, Lance Armstrong Foundation
- National Coalition for Cancer Research
- National Comprehensive Cancer Network
- National Lung Cancer Partnership
- Oncology Nursing Society
- Pancreatic Cancer Action Network
- Prevent Cancer Foundation
- Research Advocacy Network
- Susan G. Komen for the Cure Advocacy Alliance

I. **Prevention of Delays and Administrative Barriers –** We encourage the Secretary to establish explicit safeguards protecting individuals with cancer from delays and administrative barriers that undermine access to clinical trials.

II. **Prevention, Detection, and Treatment of Complications –** We encourage inclusion of explicit safeguards to ensure that the prevention, detection, and treatment of complications arising from clinical trials are covered by group health plans and insurance issuers as routine patient costs under Section 2709 of the Public Health Service Act.

III. **Geographic Safeguard to Preserve Local Access** – Implementing regulations should prevent group health plans and insurance issuers from requiring patients to travel extensive distances to enroll in a clinical trial with an in-network provider.

IV. **Clear Coverage Information for Enrollees** – There should be safeguards to ensure patients are informed in an unambiguous manner as to whether or not their group health plan or insurance issuer covers the routine costs associated with participation in clinical trials.

V. **Referral to Specialists** – Implementing rules should prevent financial incentives arising from Accountable Care Organizations or other new delivery models from inadvertently creating barriers for patients to participate in clinical trials.

VI. **Method for Consumer Reporting** – There should be a clear and effective mechanism for reporting concerns relating to the coverage of clinical trials.

Discussion:

I. Prevention of Delays and Administrative Barriers

We encourage the Secretary to establish safeguards to ensure that administrative requirements do not create delays or barriers to patient access to clinical trials for cancer and other life-threatening conditions. The statutory language is very clear and comprehensive in specifying the types of trials that qualify for the ACA coverage requirement. Therefore, the determination that a trial meets the statutory requirements should be straightforward.

The spirit and plain meaning of Section 2709 of the Public Health Service Act reflect the need to protect individuals with cancer from unnecessary administrative or procedural burdens that can interfere with patients' timely access to clinical trials. Individuals with cancer are extremely vulnerable to delays in clinical interventions due to the nature of their illnesses and the time sensitivity associated with initiating treatment. In the absence of robust safeguards, the primary protective purpose of Section 2709 could easily be lost.

The cancer community already has widespread experience with both federal and state rules that require the coverage of routine patient costs for participants in cancer clinical trials. In addition to the federal policy for Medicare coverage, thirty-four states and the District of Columbia have laws or coverage agreements for cancer clinical trials. This experience highlights at least two problematic areas that should be addressed in the rulemaking for Section 2709.

From the patient's perspective, the most critical, time-sensitive decision is whether the health plan or insurance issuer will provide coverage for routine costs associated with the trial. Patients often raise questions about insurance coverage during the informed consent process, and potential trial participants may desire resolution of the issue of insurance coverage prior to consenting to participate or even initiate screening studies to determine if they are clinically eligible for the study. Therefore, prolonged waiting periods can lead to significant barriers to care by delaying clinical trial enrollment and initiation of treatment, regardless of whether the treatment takes place as part of the study. Another persistent and unacceptable problem involves requests from health plans for excessive information regarding the clinical trial in question. For example, some insurers attempt to require that investigators provide detailed copies of clinical trial protocols even though trial sponsors routinely require confidentiality of these documents. Implementation of section 2709 does not require the level of detail provided in a clinical trial protocol. In some instances, insurers make similarly unnecessarily burdensome requests for other documentation regarding clinical trial details that are already available on public sources, such as the ClinicalTrials.gov.

Ultimately, the undersigned organizations recommend that ClinicalTrials.gov be modified to include additional information as needed to provide a one-stop, clear-cut determination of whether a trial qualifies for coverage, according to the statutory requirements for an approved clinical trial. In the meantime, we encourage the Department of Health and Human Services to develop a standardized form that could be used by a trial sponsor or investigator attesting that a particular trial meets the criteria in Section 2709 for an approved clinical trial so as to limit any further requests for information from health plans that may prolong the clinical trial enrollment

decision for patients. The undersigned organizations would be happy to assist with development of this form.

Under the requirements of Section 2709 as enacted by Congress, affirmation that a clinical trial meets the ACA criteria should be very straightforward and should be made in a timely fashion. We urge the Secretary to adopt the following language as part of the implementing regulations for Section 2709 of the Public Health Service Act:

- Group health plans and insurance issuers must accept a standardized electronic form submitted by individuals or health care providers as affirmation that the clinical trial in question meets the criteria in Section 2709 for an ACA approved Phase I, II, III, or IV clinical trial. Group health plans and insurance issuers may not require individuals or health care providers to provide information beyond what is included on the standardized electronic form for purposes of affirming that a clinical trial meets the statutory requirement for coverage. Group health plans and insurance issuers are required to accept the completed standardized attestation form as determination of whether the clinical trial in question meets the criteria in Section 2709 for an approved clinical trial.

- The Secretary will develop the standardized electronic affirmation form with input from relevant stakeholders. The form should be made available 60 days prior to January 1, 2014.

- Group health plans and insurance issuers must affirm that the clinical trial meets the criteria in Section 2709 for an approved Phase I, II, III, or IV clinical trial within 48 clock hours. If a plan fails to respond within 48 clock hours it is presumed to be an affirmation that the clinical trial meets the criteria. Plans and issuers must provide a toll-free telephone line, fax line, and an email address that operate without interruption at all hours and on all days to facilitate delivery and confirmation of receipt of the electronic form. The requirement to pay for routine costs under Section 2709 remains contingent on whether the individual ultimately qualifies for and consents to participate in the clinical trial.

II. Prevention, Detection, and Treatment of Complications

An integral component of routine care provided in cancer therapy involves the prevention, detection, and treatment of complications that arise from anticancer treatment regimens. Even within cancer treatment regimens recommended under longstanding, evidence-based guidelines, complications occur routinely.

In the context of clinical trials to prevent, detect, or treat cancer, the need to provide individual patients with full access to the items and clinical services used to prevent, detect, and treat complications is equally important. Coverage of such costs as "routine patient costs" is commonly provided by both public and private insurance programs. For example, the Centers for Medicare & Medicaid Services has promulgated guidance for Medicare stating that the covered routine costs for clinical trials must include items and services related to "complications arising from participation in all clinical trials" (see *Routine Costs in Clinical Trials*, Medicare National Coverage Determinations Manual, Chapter 1, Part 4, Section 310.1).

To address this issue, we urge the Secretary to adopt the following language as part of the implementing regulations for Section 2709 of the Public Health Service Act:

- Coverage of routine patient costs by group health plans and insurance issuers under a clinical trial must include all items and services provided for the prevention, detection, or treatment of complications related to participation in the clinical trial.

III. Geographic Safeguard to Preserve Local Access

Although Section 2709 permits group health plans and insurance issuers to require individuals who are interested in participating in a clinical trial to be seen by an in-network provider, common sense dictates that the Secretary should impose some safeguards to limit the distances that vulnerable cancer patients are required to travel to comply with such a policy. In addition, plans and issuers should be prohibited from delaying coverage while attempting to identify in-network providers who will enroll individuals in the particular clinical trial under consideration. As mentioned above, delays in coverage can have significant implications for patients with cancer or other life-threatening diseases or conditions.

Individuals with cancer are ill-equipped to travel long distances to secure cancer care in large part due to the nature of their illnesses and anticancer treatment regimens. This burden is accentuated for low-income individuals, who have even greater difficulty due to the costs associated with transportation, hotels, food, and other expenses incurred when traveling. As a result, requirements to travel long distances are likely to exacerbate disparities in access to clinical trials.

In particular, for group health plans and insurance issuers that provide both in-network and out-of-network benefits, it is problematic for an insurer to require an individual to travel more than 25 miles to participate in a clinical trial with an in-network provider if an out-of-network provider is available locally. This is consistent with prior determinations in which the Secretary has set 25 miles as the outside limit for a reasonable travel distance to impose on Medicare beneficiaries (69 Federal Register 16083, March 26, 2004; 75 Federal Register 40141, July 13, 2010).

To address this issue, we urge the Secretary to adopt the following language as part of the implementing regulations for Section 2709 of the Public Health Service Act:

- If an in-network provider participating on the trial is not located within 25 miles of the individuals residence but an out-of-network provider participating on the trial is, a group health plan or insurance issuer that provides out-of-network benefits may not require the individual to travel more than 25 miles from his or her residence in order to participate in the clinical trial through an in-network provider.

- If neither an in-network nor an out-of-network provider within 25 miles of an individual's residence will accept an individual as a participant in a specific clinical trial, a group health plan or insurance issuer that provides out-of-network benefits may not require an individual who wishes to participate in that clinical trial to travel any farther from his or her residence

than the closest provider who will accept the individual as a participant in the specific clinical trial.

IV. Clear Coverage Information for Enrollees

A common concern voiced by individuals with cancer and health care providers is that unnecessary complexity exists in understanding whether an individual's health plan provides coverage for the routine patient costs associated with clinical trials. Often this information is not published on the website or print materials of the group health plan or insurance issuer and can only be determined through submission of a formal request. Not only is this burdensome for individuals diagnosed with life-threatening illnesses, but it also prevents healthy individuals from making informed choices when selecting a health plan.

Transparency will remain of utmost importance following implementation of Section 2709 of the Public Health Service Act. Under any scenario, individuals should be able to refer to unambiguous explanations to understand whether a health plan covers the routine costs associated with clinical trials, similar to the information included in the "Medicare and You" booklet sent yearly to Medicare beneficiaries: http://www.medicare.gov/publications/pubs/pdf/10050.pdf. Transparent information is especially important given that some group health plans and insurance issuers, including some plans with grandfathered status, may be exempt from this coverage requirement. Meanwhile, many plans with grandfathered status voluntarily provide clinical trial coverage or are required to maintain this coverage because it was a benefit provided to beneficiaries prior to March 23, 2010. Due to the obvious complexities that will remain even after implementation of Section 2709, it is important that beneficiaries have access to transparent information that will enable them to make fully informed choices.

To address this issue, we urge the Secretary to adopt the following language as part of the implementing regulations for Section 2709 of the Public Health Service Act:

- Group health plans and insurance issuers shall develop electronic and printed materials to inform beneficiaries in "clear" layman language as to whether or not their health plan provides coverage for the routine patient costs associated with clinical trials. These materials should be written at no greater than a 6th grade reading level. Additionally, this information shall be made available to the public through the websites and marketing materials of group health plans and insurance issuers.

- The Secretary will include "clinical trials coverage of routine costs" as a point of comparison on the website www.healthcare.gov, which the Department has already developed to enable consumers to compare health plans.

V. Referral to Specialists

The undersigned organizations recognize the potential that new public and private payment and delivery reform models hold to improve the quality and value of health care delivered to patients with complex conditions such as cancer. However, we are concerned that as more and more

health plans experiment with some of these new reforms, which may include a variety of different financial incentives, that access to clinical trials could be compromised. Therefore we urge the Secretary to adopt the following language as part of the implementing regulations for Section 2709 of the Public Health Service Act:

- Group health plans and insurance issuers shall establish informational materials and programs to ensure that in-network providers are encouraged to make referrals to oncologists and other cancer specialists who can provide individuals with access to clinical trials. Group health plans and insurance issuers shall send such material to individuals upon their request and shall post such material on the plan website so that it is easily accessible to interested individuals.

VI. Method for Consumer Reporting

It is important that health care providers and patients have clear avenues to report on problems encountered when attempting to secure coverage for routine patient costs associated with clinical trials. The ACA provides at least one such avenue through the new Section 2793 of the Public Health Service Act, which appropriates funding for grants to states to create offices of health insurance consumer assistance and health insurance ombudsman programs. These offices and programs are "required to collect and report data to the Secretary on the types of problems and inquiries encountered by consumers" so that the Secretary can "identify areas where more enforcement action is necessary."

To ensure that federally funded offices of health insurance consumer assistance and health insurance ombudsman programs pay sufficient attention to the important issue of coverage for routine patient costs associated with clinical trials, we urge the Secretary to include the following language as part of any efforts to implement Section 2793 of the Public Health Service Act:

- Applications from prospective offices of health insurance consumer assistance and health insurance ombudsman programs should include a specific proposal for encouraging patients, health care providers, and members of the public to report concerns regarding the practices of group health plans and insurance issuers that may undermine the purposes of Section 2709 of the Public Health Service Act, which requires certain plans and issuers to cover routine patient costs for items and services furnished in connection with participation in clinical trials. Such proposals should include, at a minimum, an email address and a toll-free telephone line that members of the public can use for this purpose. Proposals should also include specific discussions of how information related to problems involving access to clinical trials will be reported to the Secretary to facilitate timely investigation and enforcement.

- If such safeguards are not implemented under Section 2793, we urge the Secretary to establish and to publicize a mechanism for reporting and enforcing problems associated with coverage of clinical trials under the regulatory requirements proposed by the undersigned organizations based on Section 2709. This mechanism should include an email address and toll-free telephone line for patients, health care providers, and members of the public to report concerns regarding the practices of group health plans and insurance issuers that may

undermine the purposes of Section 2709 of the Public Health Service Act. We urge the Secretary to devote sufficient resources to investigate reported problems.