



CANCER INNOVATION COALITION

August 18, 2015

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Thomas E. Perez
Secretary
US Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Dear Mr. Slavitt and Secretary Perez,

The undersigned organizations are participants in the Cancer Innovation Coalition (CIC,) a coalition of cancer stakeholder organizations formed in 2014 to accelerate cancer innovation and deliver more promising new treatments to patients.

A white paper published by the CIC in 2014, *Securing the Future of Innovation in Cancer Treatment*, identifies clinical research as central to the success of innovation and delivery of new treatments to patients. And despite passage of the Patient Protection and Affordable Care Act (ACA,) which included strong new 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, gaps still exist in coverage and access for patients.¹

As the paradigm for conducting clinical trials evolves as research and treatment move towards precision or personalized medicine, it is essential that coverage of routine care costs associated with cancer clinical trials adapts, and that insurers do not impose overly burdensome barriers on patients attempting to access novel trials. An example of such a trial includes the recently announced National Cancer Institute (NCI) launch of the MATCH Trial, a nationwide research study that will sort patients into treatment groups based on genetic mutations in their tumors, rather than by cancer type.

The undersigned organizations encourage the Departments to reconsider your decisions not to issue regulations to address implementation of Section 2709 of the Public Health Service Act as added by the ACA. We appreciate your guidance through the April 2013 Question and Answer document issued by

¹ Martin, Paul J. "Responsibility for Costs Associated With Clinical Trials," *Journal of Clinical Oncology*, October 2014.

the Departments, yet the lack of specific regulations leaves unaddressed potential barriers to access and lack of uniformity in the ability of cancer patients to be guaranteed coverage of routine patient care costs associated with participation in a clinical trial. The need for this access to clinical trials was clearly communicated by Congress in passage of the ACA.

Specifically, we encourage you to address several issues through regulation or subregulation, which will ensure that oncology patients across the country can access clinical trials as an option for prevention, detection or treatment of cancer. These issues include:

- Development of safeguards to prevent delays and administrative barriers intended to undermine access to trials.
- 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.
- Implementing regulations to 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.
- Requirement that networks established by insurance plans include out-of-network coverage when in-network providers do not offer an appropriate clinical trial.
- Require transparency and full disclosure to a patient as to whether or not their group health plan or insurance issuer covers the routine costs associated with patient participation in a clinical trial.
- Rules to encourage patients in Accountable Care Organizations or other new delivery models to participate in clinical trials and prevent financial incentives arising from Accountable Care Organizations or other new delivery models that may inadvertently create barriers for patients to participate in a clinical trial as a treatment pathway.
- Requirement for clear and effective mechanisms for consumers to report concerns related to the coverage of clinical trials.

Clinical trials are a driver of innovation in oncology and can offer patients the opportunity to receive the best treatment option available to them. Patients participating in clinical trials often receive a higher level of care due to the care coordination and team approach often inherent in trial design as well as earlier access to potential new, improved therapies. Unfortunately, today, fewer than 5 percent of adult cancer patients enroll in a clinical trial. Our organizations believe that additional guidance as noted above from your Departments is essential in guaranteeing that patients will have access to clinical trials as a treatment option and will remove barriers to patient participation and provider referrals to trials.

Thank you for your attention to this request. We would be happy to discuss this information further with you at your convenience. Please contact Lisa Hughes, Director of Strategic Partnerships and Projects, National Patient Advocate Foundation at 202-281-9872 or at lisa.hughes@npaf.org with any questions or if you would like to schedule time to discuss further.

Sincerely,

American Association for Cancer Research
American Brain Tumor Association
American Cancer Society Cancer Action Network
Association of American Cancer Institutes
Association of Community Cancer Centers
C-Change
Cancer Support Community
Colon Cancer Alliance
Cutaneous Lymphoma Foundation
Fight Colorectal Cancer
FORCE: Facing Our Risk of Cancer Empowered
The George Washington University Cancer Center
International Myeloma Foundation
Men's Health Network
National Coalition for Cancer Research
National Patient Advocate Foundation
Oncology Nursing Society
Pancreatic Cancer Action Network
Prevent Cancer Foundation