

June 18, 2013

The Honorable Kathleen Sebelius  
Secretary of Health and Human Services  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

The Honorable Seth D. Harris  
Acting Secretary of Labor  
U.S. Department of Labor  
200 Constitution Avenue NW  
Washington, DC 20210

Dear Secretary Sebelius and Acting Secretary Harris:

On behalf of the undersigned organizations, we write to share our disappointment with the Departments' announcement, through a Frequently Asked Questions document released on April 29, that the Departments do not expect to issue regulations in the near future to address implementation of section 2709 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act (ACA). We appreciate the initial direction in the FAQ to group health plans and health insurance issuers to implement the requirement for plan years beginning on or after January 1, 2014. However, we urge the Departments to issue regulations or guidance before January 2014.

As you know, this important insurance protection requires health plans to cover the routine medical costs for individuals participating in approved clinical trials. In enacting this provision, Congress was seeking to remove an obstacle to participation in research for patients—a goal that we very strongly support. It is important that meaningful access to clinical trials is an integral component of any health insurance product. Individuals with challenging forms of cancer or other life-threatening illnesses typically choose to participate in clinical trials when they conclude (in consultation with their physicians) that the trial provides the best odds of a successful clinical outcome when compared to other existing therapies. Further, this new protection recognizes that there is a greater public good to encouraging increased patient participation in clinical research. Through enhancing our understanding of serious and life-threatening conditions—and of the risks and benefits of promising new therapies—we improve treatment, diagnosis, and prevention options not just for participating patients but for all of us through the advancement of medical knowledge.

Participation in such research should therefore be encouraged through the removal of insurance barriers. Unfortunately, participation in clinical trials is very low: Fewer than 5 percent of cancer patients enroll in clinical trials, and only 6 percent of patients with severe chronic illnesses participate. These low participation rates mean that research takes longer, costs more, and ultimately results in delays in the development of new therapies or a lag in evidence about the safety and effectiveness of existing therapies.

In previous communications with the Centers for Medicare and Medicaid Services (CMS) officials, our groups have identified a number of issues that we strongly believe need to be addressed through rulemaking in order to ensure that section 2709 lives up to the promise of the law. Unfortunately, we have learned through our work over the years to improve coverage of clinical trials in Medicare and at the state level that even when health plans purport to cover routine costs associated with clinical trials, patients often continue to have difficulty getting coverage for some of these expenses. In fact, a study published in 2010 found that of 628 eligible cancer patients denied coverage for their routine clinical

trial costs between 2003 and 2008, ***nearly 80 percent of those denied had insurance coverage that generally purported to allow coverage for clinical trial participation.***<sup>1</sup>

Specifically, some of the issues that we have previously identified that we would like to see addressed through rulemaking or guidance include:

- **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 under the definition of “routine costs.”
- **Meaningful Access to Clinical Trials:** Implementing regulations should prevent group health plans and insurance issuers from requiring patients to travel unreasonable distances to enroll in a clinical trial with an in-network provider. According to the Center for Information & Study on Clinical Research Participation, fewer than 4 percent of all U.S. physicians participate in clinical trials. The likelihood is therefore high that patients will not have meaningful access to approved clinical trials unless safeguards are in place to ensure that patients can use their out-of-network coverage to participate.
- **Prevention of Delays and Administrative Barriers:** We encourage you to establish explicit safeguards protecting patients from delays and administrative barriers that undermine access to clinical trials, including preventing financial incentives arising from new delivery models from inadvertently creating barriers for patients to participate in clinical trials.
- **Determining a Life-Threatening Condition:** Because the definition of a life-threatening condition can be subject to various interpretations, we believe that it is very important that determination about whether an individual is an appropriate candidate for participation in a trial that qualifies for coverage should be made by the patient’s health care professional.

We appreciate the acknowledgment in the April 29 FAQ that health plans and issuers are still expected to implement section 2709 using a good faith, reasonable interpretation of the law in the absence of regulations. However, we remain very concerned that implementation of this provision will be very uneven across the country and many consumers may be denied a new protection they should be guaranteed under the law. Guidance from the Departments would be most helpful in the 14 states that do not currently have clinical trials coverage laws or cooperative agreements. At least seven of these states have plans to operate state-run or state-partnership exchanges, and it is very important to ensure that plans offered on the exchanges are following the clinical trials coverage requirement. If the Departments plan to issue coverage manuals, as CMS does for the Medicare program, clinical trials coverage should be highlighted.

We urge the Departments to issue regulations or guidance prior to the effective date of section 2709 on January 1, 2014. If the Departments do not move forward with regulations or guidance before January 2014, HHS, in conjunction with the Department of Labor, should conduct immediate outreach to states operating exchanges to ensure that clinical trials coverage is included and establish a clear and effective mechanism for consumers to report concerns relating to the coverage of clinical trials.

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<sup>1</sup> Klamerus JF, Bruinooge SS, Ye X, et al. The Impact of Insurance on Access to Cancer Clinical Trials at a Comprehensive Cancer Center. *Clin Cancer Res*; 16(24):5997-6003. 2010.

Our organizations would be happy to further discuss our recommendations for successful implementation of section 2709 and to serve as a resource for the Departments' ongoing work involving clinical trials. To discuss these issues further, please contact Stephanie Mohl at the American Heart Association ([Stephanie.Mohl@heart.org](mailto:Stephanie.Mohl@heart.org) or 202-785-7909), Keysha Brooks-Coley at the American Cancer Society Cancer Action Network ([Keysha.Brooks-Coley@cancer.org](mailto:Keysha.Brooks-Coley@cancer.org) or 202-661-5720), or Suanna Bruinooge at the American Society of Clinical Oncology ([suanna.bruinooge@asco.org](mailto:suanna.bruinooge@asco.org) or 571-483-1613).

Sincerely,

American Academy of Neurology  
American Association for Cancer Research  
American Cancer Society Cancer Action Network  
American Childhood Cancer Foundation  
American Diabetes Association  
American Epilepsy Society  
American Heart Association/American Stroke Association  
American Lung Association  
American Society for Gastrointestinal Endoscopy  
American Society of Clinical Oncology  
American Society of Hematology  
Association of American Cancer Institutes  
Association of Community Cancer Centers  
Autism Speaks  
Bladder Cancer Advocacy Network (BCAN)  
Children's Cause for Cancer Advocacy  
Coalition of Cancer Cooperative Groups  
Debbie's Dream Foundation: Curing Stomach Cancer  
Dravet Syndrome Foundation  
Epilepsy Foundation  
Families USA  
Fight Colorectal Cancer  
Friends of Cancer Research  
Hematology/Oncology Pharmacy Association  
Hydrocephalus Association  
International Cancer Advocacy Network (ICAN)  
International Myeloma Foundation  
Kidney Cancer Association  
Leukemia & Lymphoma Society  
**LIVESTRONG** Foundation  
Lupus Foundation of America  
Melanoma Research Alliance (MRA)  
NAMI (National Alliance on Mental Illness)  
National Coalition for Cancer Research (NCCR)  
National Comprehensive Cancer Network  
National Health Council  
National Hemophilia Foundation  
National Lung Cancer Partnership  
National Multiple Sclerosis Society  
National Stroke Association

North American Commission of the International League Against Epilepsy  
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition  
Oncology Nursing Society  
Ovarian Cancer National Alliance  
Pancreatic Cancer Action Network  
Parkinson's Action Network  
Phelan-McDermid Syndrome Foundation  
Prevent Cancer Foundation  
Research Advocacy Network  
Sarcoma Foundation of America  
Society for Women's Health Research (SWHR)  
Society of Gynecologic Oncology  
Susan G. Komen Advocacy Alliance  
Tuberous Sclerosis Alliance  
V Foundation for Cancer Research  
WomenHeart: The National Coalition for Women with Heart Disease