

August 14, 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 Thomas E. Perez
Secretary of Labor
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Dear Secretary Sebelius and Secretary Perez:

Clinical trial participants receive potentially life-saving treatments that are otherwise unavailable. For patients whose insurance will not cover routine medical costs associated with approved clinical trials, these life-saving treatments may be inaccessible. By enacting section 2709, Congress sought to remove this particular obstacle to clinical trial participation, thereby making cutting-edge treatments available to the people who need them most; trial participants and non-participants alike.

The fields of Endocrinology, Diabetes, and Metabolism and related disciplines are actively engaged in the advancement of scientific and medical knowledge, including improving clinical practice and outcomes through clinical trials. Robust participation in clinical trials is required to generate the necessary data for accurate interpretation and translation into practice. Limitations on subject participation slow the process of moving cutting-edge treatments into the clinic to improve patient care for endocrine, diabetic, and metabolic conditions. Such limitations are particularly onerous for trials that seek to improve treatments for diseases that affect relatively small percentages of the population, such as pituitary and adrenal gland tumors.

We, the undersigned organizations, write to express our disappointment with your Departments' decision not to issue specific regulations or to provide guidance on the implementation of Section 2709 of the Public Health Service Act, "coverage for individuals participating in approved clinical trials", as added by the Patient Protection and Affordable Care Act (ACA). We are encouraged by the direction in the April 29 "Frequently Asked Questions" document instructing group health plans and health insurance issuers to implement the requirement for the plan beginning on or after January 1, 2014. However, without additional, more explicit instruction or guidance, implementation of this provision will likely vary significantly across insurance plans, as interpretation of the law will vary.

We are concerned by the results of a 2010 study that showed a high percentage of denial by insurance companies purporting to cover clinical trial participation.¹ Without explicit regulations or guidance, such practices are likely to continue.

We support the recommendations of the broader clinical research community:

¹Klamerus 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.

Prevention, Detection, and Treatment of Complications: “Research costs” such as additional diagnostic tests for research purposes, or services inconsistent with the standard of care, are not covered by third-party payers under the ACA. We therefore 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. This provision is especially important to ensure adequate representation by underrepresented patient populations and to prevent unintentional discrimination based on socio-economic status.

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 safeguards against the inadvertent creation of barriers that might arise as a result of new care delivery models.

Determining a Life-Threatening Condition: The definition of a life-threatening condition can be subject to various interpretations; therefore, we believe that the determination of an individual’s appropriateness for participation in a trial that qualifies for coverage should be made by his/her health care professional.

We urge your Departments to issue regulations or guidance before January 1, 2014, to ensure accurate and uniform implementation by health insurers across the nation. In the absence of regulations or guidance, the Departments should minimally conduct immediate outreach to states operating exchanges to ensure that clinical trials coverage is included. These measures will be especially critical in states with no current clinical trials coverage laws or cooperative agreements.

We would be happy to serve as a resource to your Departments as you continue your work to improve patient access to clinical trials. To further discuss our recommendations or any other related issues, please contact Mila Becker at The Endocrine Society (mbecker@endocrine.org).

Sincerely,

The Endocrine Society
The American Association of Clinical Endocrinologists
The American Association of Endocrine Surgeons
The American Society for Bone and Mineral Research
The American Society of Endocrine Physician Assistants
The American Society for Reproductive Medicine

The American Thyroid Association
 The Androgen Excess & PCOS Society
 The Endocrine Nurses Society
 The Lawson-Wilkins Pediatric Endocrine Society
 The Obesity Society
 The Pediatric Endocrinology Nursing Society
 The Pituitary Society
 The Society for Gynecological Investigation
 The Society for the Study of Reproduction

