



July 1, 2009

The Honorable Max Baucus, Chairman
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Kent Conrad, Chairman
Committee on Budget
624 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Baucus and Chairman Conrad:

The Partnership to Improve Patient Care (PIPC) is writing in support of the "Patient-Centered Outcomes Research Act of 2009" (S. 1213) as a sound framework for comparative clinical effectiveness research that helps center CER on patients and providers and incorporates the science of personalized medicine into the research program.

PIPC supports comparative effectiveness research as an important element of health care reform that, if appropriately structured, can have a significant benefit for patients. We believe the goal of CER is to provide doctors and patients with the information they need to make good health care decisions.

The bill includes a number of important patient safeguards, including the requirement that dissemination of research results by the Institute "shall not include practice guidelines or recommendations," and protections against use of research in ways that could prevent Medicare beneficiaries from gaining access to the tests and treatment options that best meet their needs. We believe these are critically important provisions, and look forward to working with you to further strengthen the bill's patient protections.

The legislation also includes clear recognition of patient differences in study design and results communication. S. 1213 stipulates that communication protocols must address differences in patient subpopulations, and that study designs must "take into account potential differences in outcomes among different subpopulations, such as racial and ethnic minorities, women, different age groups, and individuals with different comorbidities." The importance of this was recognized in a letter from the Congressional Black Caucus in April 2008, which called for CER research to "recognize and account for the variation in outcomes of medical treatments" due to differences in racial and ethnic populations and other patient differences. We look forward to working with you to further strengthen this element of the legislation, including requirements for disaggregation of data and results, in support of tailored patient care.



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S. 1213 further encourages a focus on patient and provider needs by focusing on comparative clinical effectiveness research rather than cost-effectiveness research. Many patient and provider organizations have expressed concern with inclusion of cost-effectiveness in any new government research program, because cost-effectiveness research is more vulnerable to being misused in ways that restrict patient access to medically beneficial care based on subjective “value” thresholds and broad population averages.

PIPC also supports provisions of the bill that ensure the research program will examine all evidence gaps that impact the quality of patient care. This includes pharmaceuticals, medical technology and procedures, treatment protocols, and delivery system interventions. It is consistent with the recent work of the HHS Federal Coordinating Committee on CER, and is essential to ensuring the research achieves its potential to improve the quality of patient care.

Finally, the bill includes carefully developed, well-defined provisions to ensure openness, transparency and accountability in the operation of the CER program. This includes assurance of public comment periods at appropriate points throughout the process. It also defines a strong peer-review process, and ensures transparency via a public website identifying the entity conducting the research, draft study designs, research protocols, public comments and responses, and progress reports. To help achieve the goals of openness, transparency, and accountability, the Patient-Centered Outcomes Research Act creates an independent, public-private Institute to help ensure the research is objective and credible, and centered on the needs of patients and providers. This approach is recommended in the Institute of Medicine report on “Knowing What Works in Health Care,” and by the Medicare Payment Advisory Commission and many other organizations.

PIPC appreciates the considerable work that you have done to advance legislation on comparative effectiveness research that is truly patient-centered. We look forward to working with you to advance patient-centered outcomes research and secure enactment of S. 1213 as part of comprehensive health care reform.

Sincerely yours,

Tony Coelho
Chairman
Partnership to Improve Patient Care