

October 16, 2009

The Honorable Harry Reid
Office of the Senate Majority Leader
Capitol Building, S-221
Washington, DC 20510-7020

Dear Majority Leader Reid:

As you work to merge the Senate Finance Committee “America’s Healthy Futures Act” and the Senate Health, Education, Labor and Pensions (HELP) Committee “Affordable Health Choices Act,” the Coalition for Health Services Research asks that you consider our recommendations for the placement, governance, and scope of comparative effectiveness research (CER). The Coalition’s mission is to support the development of research that leads to accessible, affordable, high-quality health care. As the advocacy arm of AcademyHealth, we represent the interests of 3,800 researchers, scientists, and policy experts, as well as 160 organizations that produce and use health services research (HSR). The field of HSR includes many of the scientists that any new entity overseeing CER will rely upon to conduct this research and ensure the funds are used efficiently for high value studies. Our members have considerable experience with existing mechanisms for funding HSR, which informs our views about placement of the CER activities.

CER—where pharmaceuticals, medical devices and medical procedures used to treat the same conditions are evaluated for their relative safety, effectiveness, and cost—has great potential to improve health care quality and patient outcomes while ensuring that consumers receive the best care at the best value. The Senate Finance and HELP bills each recognize the value of CER and significantly increase investment in this research. However, the bills fundamentally differ in how to best organize the research infrastructure. We respectfully ask that you consider our suggestions as you work to reconcile these differences:

- **Ensure Close Linkage with Agency for Healthcare Research and Quality**

In 2005, the AcademyHealth Board released its report, *Placement, Coordination, and Funding of Health Services Research within the Federal Government*, in which leading experts reviewed options for the placement of the CER function. The experts agreed that CER, as a subset of health services research, should be “established within the Agency for Healthcare Research and Quality, or through the creation of new entity that would, in varying degrees, be linked to AHRQ as the lead agency for HSR.” Such linkage would ensure that the research conducted under this authority is undertaken in a way that is consistent with the best available research, methods, data, and dissemination strategies. Further, these experts agreed that because CER produces information that is in the broad public interest (what economists characterize as a “public good”) it should not be wholly privatized outside the federal government.

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As the debate has evolved, we have become increasingly concerned that the CER structure proposed in the Senate Finance Committee bill does not take advantage of the considerable expertise located in AHRQ and other federal research agencies. We urge you to consider the model proposed by the Senate HELP Committee, which would establish a CER center within AHRQ with governance by an external board of public and private stakeholders. This construct would build upon the existing federal research infrastructure and expertise of federal research agencies, while at the same time provide for appropriate input from key private sector stakeholders and research experts. This structure would also provide needed separation between the federal agencies funding this research and the decision-making apparatus that would set priorities and approve scientifically rigorous research studies.

- **Strengthen Governance and Coordination through Public and Private Stakeholder Participation**

The significant investment in the CER infrastructure proposed by both the Senate HELP and Finance Committees necessitates coordination across the federal government to ensure the resources are used efficiently and effectively for the benefit of the American people. And with taxpayers already vested in CER, stakeholder input is invaluable in prioritizing research investments. AcademyHealth's *Placement Report* emphasized the importance of stakeholder involvement in developing the CER agenda and ensuring the validity of the research produced. AcademyHealth also stressed the importance of coordination between public and private stakeholders to reduce duplication and to focus collective knowledge and expertise to shape the nation's CER agenda according to the most urgent needs.

As amended, the Senate Finance Committee proposal no longer includes federal representation on the governing board established to oversee CER. Excluding from governance the Department of Health and Human Services and its research agencies, as well as the Veterans Health Administration (VHA), would significantly weaken the CER infrastructure. With many federal agencies including AHRQ, the National Institutes of Health (NIH), and the VHA currently funding CER and expected to continue to do so in the future, the participation of federal agencies in the new entity's governance structure will be critical to facilitate shared learning for the benefit of the broader research enterprise. We recommend you consider the governance structure proposed in the Senate HELP legislation—and originally proposed in the Finance Committee—that would allow for a balance of federal and private representation on the CER governing board.

- **Broaden the Scope of Work**

We feel strongly that scientific exploration should not be hindered by putting unnecessary restrictions on what may and may not be studied. We suggest that an expanded CER program allow for comparative research on health care delivery mechanisms as well as their comparative costs, as proposed in the Senate HELP Committee bill and recommended by the Institute of Medicine in its recent report on national CER priorities. As written, the Senate Finance Committee proposal would allow for only the analysis of *clinical* comparative effectiveness research. Limiting studies to the clinical practice of medicine would inadvertently limit our country's need to better understand how the organization and financing of care impacts the effectiveness of the care delivered. We also believe that patients and providers need to understand cost implications even if not bound to accept the lower cost alternative. To achieve the stated goals for "bending the cost curve," it is very important to provide more and better information about the relative value of treatments and the most

efficient and effective care delivery models. This scientific research can make an important contribution to transforming health care, and for this reason we believe it should not be unnecessarily restricted.

- **Elicit the Best Science through Competitive Grants and Contracts**

Many of the sentinel studies that have changed the face of health and health care in the United States are the result of ingenuity on the part of investigators who believed their ideas had the promise to clarify a phenomenon, improve methods and measurement, or make an otherwise unmanageable policy problem manageable. This principle is the basis for most of the funding managed by NIH.

The Senate Finance Committee proposal for CER does not include authority for new and competing grants that would support such investigator innovation and rejuvenate the free marketplace of ideas. The bill provides authority for only contracted research, where the funder has substantial and direct control over the entirety of the research project. We urge you to support a CER model that allows for a balanced research portfolio of competing grants and contracts. Such flexibility will elicit the best science and spur creativity in health system improvements, as well as in the methods and data used for this research.

The Coalition commends you and your colleagues' leadership for striving to develop a robust, adequately-funded CER program that will provide a much needed basis for improvements in our health care system. As you move forward, we hope you will consider our recommendations to ensure a publicly accountable, credible, and innovative research infrastructure. If you have any questions, please contact our Washington, D.C. Representative, Emily Holubowich at 202.484.1100 or eholubowich@dc.crd.com.

Sincerely,



Michael Chernew, Ph.D.
Chair



W. David Helms, Ph.D.
President & CEO

CC: The Honorable Max Baucus, Chair, Senate Finance Committee
The Honorable Chris Dodd, Senate HELP Committee