



May 16, 2019

The Honorable Richard Neal,
Chairman
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington D.C. 20515

The Honorable Kevin Brady
Ranking Member
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington D.C. 20515

Dear Chairman Neal and Ranking Member Brady,

AcademyHealth, the professional society for health services research and health policy, urges Congress to reauthorize the Patient Centered Outcomes Research Institute (PCORI) before it expires at the end of the current fiscal year. Since its establishment in 2010, PCORI has supported research that puts patients' concerns first and has generated and disseminated evidence that patients and their health care providers may use to make treatment decisions that are best for them.

AcademyHealth's 4,000 members produce and use health services research and are highly engaged with PCORI and its work. Our members informed the creation of PCORI, have served in PCORI's leadership, and have received funding support. Our members also have extensive experience in the federal health research ecosystem and recognize PCORI's unique contributions to the evidence base. As you consider reauthorization of PCORI, we ask that you consider the following principles:

Principle 1: Preserve Stable, Predictable Funding

PCORI and its Trust Fund were established to provide stable, predictable, funding for patient-centered outcomes research (PCOR) and comparative effectiveness research, as well as the dissemination of that research. Supported by annual direct appropriations and fees from Medicare and private insurers who benefit from better evidence, 80 percent of the Trust Fund supports PCORI, while 20 percent supports essential and complimentary activities such as data development, analysis and coordination; dissemination research; and training at the Agency for Healthcare Research and Quality (AHRQ) and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Specifically, in the current fiscal year, the Trust Fund transfer supports about one quarter of AHRQ's program level budget, including a significant portion of the agency's budget for training and dissemination research. Thus, the Trust Fund is critical to both PCORI and AHRQ and their missions to improve patient care and efficiency in the health care system.

Preserving the Trust Fund—the level of funding, the diverse funding streams, and the duration of funding—is essential to PCORI and the broader research enterprise, including AHRQ. As with all scientific research, PCOR is a long-term endeavor requiring sustained, reliable funding to ensure that studies are rigorous and yield reliable results, and that those awarding funding can invest strategically. AcademyHealth strongly recommends that the Trust Fund, as currently constituted, be maintained in any new legislation.

Principle 2: Maintain and Strengthen Engagement with Patient Community

Patient organizations have a long history of working to help individuals understand their care and access to services. These organizations' collective position of trust with patients and understanding of the broader health landscape puts them in a unique position to contribute to meaningful PCOR. In its short history, PCORI has become a leader in both requiring meaningful engagement in research



and in identifying how to achieve it. In an effort to improve the lives of their constituents, patient organizations regularly seek opportunities to engage with PCORI, leveraging their own limited resources to encourage patient participation in research. PCORI's relationship with patients is key to building a PCOR portfolio that is meaningful to the patients themselves. AcademyHealth supports a reauthorization that maintains or strengthens PCORI's commitment to patient engagement in all phases of the research lifecycle. This includes supporting the organizations and individuals who train, support, and represent patient groups in research.

Principle 3: Connectivity to and Coordination with Existing Research Infrastructure

PCORI, AHRQ, ASPE, the National Institutes of Health (NIH), the Department of Defense (DOD) and the Veterans Health Administration (VHA) all play important roles in the federal health research continuum to support PCOR and comparative effectiveness research. ASPE supports agency activities and coordination to enhance overall federal data capacity that provides the foundation for PCOR. AHRQ supports the training of the next generation of researchers and various activities to enhance the dissemination and use of PCOR findings to and by patients and health care providers. PCORI generates information to help patients and their providers make the best decisions for each patient with input from a variety of stakeholders including patients, providers, insurers, and more, and supports methods development that supports health services research more broadly. NIH, VHA, and DOD, while not direct recipients of Trust Fund dollars, both conduct comparative effectiveness research on treatments for specific diseases and conditions for specific populations. Each of these institutions leverages their existing expertise and infrastructure to advance PCOR and improve care. Reauthorization should continue to promote a well-coordinated, complementary effort that enhances communication between research funders throughout and outside of government to enhance synergy and value and prevent duplication of effort.

Principle 4: Strong Governance and Enhanced Accountability

As designed by the law, PCORI is a nongovernmental organization charged with carrying out research that aims to improve health care decision-making for everyone. Thus, the current governance structure appropriately emphasizes inclusion of individuals representing the full breadth of stakeholders in PCORI's work.

Looking to the future, a governance structure that emphasizes appropriate oversight, transparency and accountability is desirable. Strong governance and enhanced accountability will help ensure that federal funds are spent efficiently and in the best interest of American taxpayers.

Principle 5: Funding Research on Cost and Value

AcademyHealth feels strongly that scientific exploration should not be hindered by putting any restrictions on the topics pursued or how findings are used. Limiting studies to the clinical practice of medicine would inadvertently limit our country's need to better understand how many other factors affect patients' and clinicians' ability to deliver the best possible care. We believe that patients and providers need to understand the cost implications of treatment choices for their patients. There is no value to patients in recommending a treatment they cannot access due to cost or because of undue financial, time, or other constraints in adhering to care. Doing so could also reduce efficiency and increase overall system costs by driving non-compliance with an otherwise effective treatment protocol. Indeed, American voters consistently cite health care costs among their top policy concerns. 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 recommend that current restrictions on the considerations of cost and cost-effectiveness in PCORI-funded research be removed from reauthorizing legislation.

Principle 6: Commitment to the Best Science

Research funders use various mechanisms to support research, which affects the types of research conducted and the degree of scientific independence researchers are afforded in conducting their studies. For example, when a grant is awarded, no substantial funder involvement with recipients is anticipated during the performance of a research activity. Conversely, contracts are awarded when a funder's purpose is to acquire goods or services for the direct benefit or use of the funder. In these circumstances, the funder has substantial and direct involvement with the contractor throughout the life of the project and must pre-specify many of the details of the research study.

Many of the sentinel studies that have changed the face of health and health care in the United States have been funded through grants—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 intractable health care problem manageable. This principle of scientific freedom is the basis for most of the funding managed by NIH and why a majority of its research is funded through a competitive, peer review, grant-making process.

Under the current statute, PCORI does not have the direct authority to award grants; its funding authority is restricted to contracts. AcademyHealth believes a balanced research portfolio of competing grants and contracts strengthens the free marketplace of ideas by allowing new ideas and thinkers to participate in generating research topics. Expanding PCORI's authority to explicitly award grants will elicit the best science and spur creativity in health system improvements, as well as in the methods and data used for this research.

AcademyHealth looks forward to working with Congress on efforts to reauthorize PCORI and its Trust Fund. 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 Representative, Emily Holubowich at 202.484.1100 or eholubowich@dc.crd.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa Simpson". The signature is fluid and cursive, with a large initial "L" and "S".

Lisa Simpson, MB, BCh, MPH, FAAP
President and Chief Executive Officer