

The Honorable Mark Warner
United States Senate
703 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Bill Cassidy
United States Senate
520 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Chris Van Hollen
United States Senate
110 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Shelley Moore Capito
United States Senate
172 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Warner, Senator Cassidy, Senator Van Hollen and Senator Capito,

On behalf of America's Health Insurance Plans (AHIP), the American Benefits Council, the Blue Cross Blue Shield Association (BCBSA), the ERISA Industry Committee (ERIC), the National Retail Federation (NRF) and the U.S. Chamber of Commerce, we are writing to communicate our support for, and feedback on, the *Patient-Centered Outcomes Research Institute Reauthorization Act* discussion draft.

We believe comparative effectiveness research (CER) is important, and the Patient-Centered Outcomes Research Institute (PCORI) serves as a trustworthy source of CER. PCORI fills gaps in existing healthcare research by including the patient perspective every step of the way. With this in mind, we appreciate the Senators' thoughtful approach to continuing the work of PCORI and thank you for addressing a number of our key concerns regarding current limitations on PCORI's ability to fulfill this mission, including:

- Incorporating consideration of relative cost and value in evaluating and comparing health outcomes and the clinical effectiveness, risks and benefits of two or more medical treatments or services. We believe this is critical for PCORI's findings to be truly patient-centered research, consistent with the health industry's movement to value-based care.
- Ensuring that payers have a meaningful voice in PCORI's governance by increasing the proportion of payer representation on the board to seven members.
- Including PCORI as a "deemed entity" for clinical trials to secure the Medicare rate, decreasing the financial burdens on PCORI and enabling it to conduct necessary studies of treatments and services.
- Increasing the transparency into challenges PCORI may encounter in conducting studies or clinical trials by requiring inclusion in PCORI's annual reports and requiring the Government Accountability Office (GAO) to examine this issue a minimum of every five years.
- Establishing an Expert Advisory Panel, which includes payers, on "high-impact research" that can help PCORI be responsive to changing medical evidence and healthcare treatments, along with requirements for PCORI to balance between long-term and short-term priorities.

As such, we strongly support the Senators' proposed reauthorization legislation. Without these modifications, we would have significant concerns with a 10-year reauthorization as we do not

believe PCORI has sufficiently demonstrated its value under the limitations with which it has operated. We appreciate the Senators' efforts to improve the effectiveness of PCORI.

To address a few technical challenges with the funding for PCORI, particularly given the timing of reauthorization, we request the following changes to the authorizing language:

- **Prevent Double Counting for Assessment Purposes:** We ask Congress to ensure the Department of Treasury's regulations implementing PCORI do not unintentionally double count enrollees for the purpose of collecting the assessment fee. The PCORI user fee was designed to be assessed on a per enrollee basis. The nuances of how one enrollee covers his or her health costs should not factor into PCORI's fee revenues. The agency should not allow double counting of enrollees who have both a medical plan that is insured and/or a health reimbursement arrangement or flexible savings account that is self-insured, regardless of whether they are provided by the same plan sponsor within the same plan year.
- **PCOR Fee Waiver for Plan Year 2020.** Health insurance issuers and self-insured employers have not been able to incorporate the PCOR fee into their planning for coverage beginning Oct. 1, 2019, and, therefore, we ask Congress not to impose the fee for plan year 2020 (i.e., a one-year waiver). PCORI has acknowledged that waiving the 2020 plan year fee will not disrupt the progress of its studies or operations.
- **Changes to Stakeholder Representatives.** When an individual is selected to PCORI's Board as a representative of a stakeholder group, and that individual becomes unaffiliated with that stakeholder group during his term, GAO is currently responsible for replacing the individual. This can be burdensome, takes a very long time and is inconsistent with the intent of maintaining continuity with the congressionally mandated board representation. We recommend establishing an alternative mechanism where the PCORI board is responsible for expeditiously replacing individuals to ensure appropriate stakeholder representation.

Thank you for considering our views on how to improve the utility of PCORI. We stand ready to provide any assistance or information that would be helpful. We urge you to finalize this reauthorization as quickly as possible so PCORI can continue its important work and so issuers and employers can avoid the same financial planning challenges for future plan years as they have for plan year 2020.

Sincerely,

America's Health Insurance Plans

American Benefits Council

Blue Cross Blue Shield Association

ERISA Industry Committee

National Retail Federation

U.S. Chamber of Commerce

CC:

Senator Chuck Grassley, Chairman, Senate Committee on Finance

Senator Ron Wyden, Ranking Member, Senate Committee on Finance