To amend title XI of the Social Security Act to reauthorize the Patient-Centered Outcomes Research Institute, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. WARNER (for himself, Mr. CASSIDY, Mr. VAN HOLLEN, and Mrs. CAPITO) introduced the following bill; which was read twice and referred to the Committee on __________

A BILL

To amend title XI of the Social Security Act to reauthorize the Patient-Centered Outcomes Research Institute, and for other purposes.

Be it enacted by the Senate and House of Representa-
tives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Patient-Centered Out-
comes Research Institute Reauthorization Act”.

SEC. 2. REAUTHORIZATION OF PATIENT-CENTERED OUT-
COMES RESEARCH INSTITUTE.

(a) EXTENSION OF FUNDING.—
(1) **Mandatory Appropriations.**—Section 9511 of the Internal Revenue Code of 1986 is amended—

(A) in subsection (b)(1)(E), by striking “2014” and all that follows through “2019” and inserting “2014 through 2029”;

(B) in subsection (d)(2)(A), by striking “2019” and inserting “2029”; and

(C) in subsection (f), by striking “2019” and inserting “2029”.

(2) **Extension of Medicare Transfers.**—Section 1183(a)(2) of the Social Security Act (42 U.S.C. 1320e–2(a)(2)) is amended by striking “2014” and all that follows through “2019” and inserting “2014 through 2029”.

(3) **Extension of Certain Health Insurance Fees.**—

(A) **Health Insurance Policies.**—Section 4375(e) of the Internal Revenue Code of 1986 is amended by striking “2019” and inserting “2029”.

(B) **Self-Insured Health Plans.**—Section 4376(e) of the Internal Revenue Code of 1986 is amended by striking “2019” and inserting “2029”.
(b) BOARD COMPOSITION.—Subsection (f) of section 1181 of the Social Security Act (42 U.S.C. 1320e) is amended—

(1) in paragraph (1)—

(A) in subparagraph (C)—

(i) in the matter preceding clause (i)—

(I) by striking “Seventeen” and inserting “Twenty-three”; and

(II) by striking “, not later than 6 months after the date of enactment of this section,”; and

(ii) in clause (iii), by striking “3” and inserting “7”; and

(2) in paragraph (3)—

(A) in the first sentence—

(i) by striking the “the members” and inserting “members”; and

(ii) by inserting the following before the period at the end: “to the extent necessary to preserve the evenly staggered terms of the Board.”; and

(B) by inserting the following after the first sentence: “Any member appointed to fill a vacancy occurring before the expiration of the
term for which the member’s predecessor was appointed shall be appointed for the remainder of that term and thereafter may be eligible for reappointment to a full term. A member may serve after the expiration of that member’s term until a successor has been appointed.”.

(c) APPOINTMENT OF MEMBERS OF METHODOLOGY COMMITTEE.—

(1) IN GENERAL.—Subsection (d)(6)(B) of such section 1181 is amended, in the first sentence, by striking “the Comptroller General of the United States” and inserting “the Board”.

(2) CONFORMING AMENDMENT.—Subsection (h)(4)(A)(ii) of such section 1181 is amended by striking “the Comptroller General” and inserting “the Board”.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to appointments made on or after the date of the enactment of this Act.

(d) CONSIDERATION OF FULL RANGE OF OUTCOMES DATA.—Subsection (d)(2) of such section 1181 is amended by adding at the end the following subparagraph:

“(F) CONSIDERATION OF FULL RANGE OF OUTCOMES DATA.—Research shall be designed, as appropriate, to take into account and cap-
ture the full range of clinical and patient-centered outcomes relevant to, and that meet the needs of, patients, clinicians, purchasers, and policy-makers in making informed health decisions. In addition to the relative health outcomes and clinical effectiveness, clinical and patient-centered outcomes shall include the potential burdens and economic impacts of the utilization of medical treatments, items, and services on different stakeholders and decision-makers respectively. These potential burdens and economic impacts include medical out-of-pocket costs, non-medical costs to the patient and family, effects on future costs of care, workplace productivity and absenteeism, and healthcare utilization.”.

(c) Establishment of Expert Advisory Panel.—Subsection (d)(4)(A) of such section 1181 is amended by adding at the end the following new clause:

“(iv) Expert Advisory Panel for High-Impact Research.—The Institute shall appoint an expert advisory panel for purposes of assisting and advising the Institute on ways to take into account and target diseases, conditions, and care inter-
ventions that have a high-impact on national health expenditures and advance the incorporation of practical evidence into health care delivery in the national priorities for research and the research project agenda under paragraph (1). Such panel shall include members representing private and public payers while maintaining the composition requirements described in sub-paragraph (B).”.

(f) Ensuring Coverage for Clinical Trials Under Existing Standard of Care.—

(1) Revision to Definition of Approved Clinical Trial in Individual and Group Market.—

(A) In General.—Subsection (d)(1) of the first section 2709 of the Public Health Service Act (42 U.S.C. 300gg–8) is amended by adding at the end the following new subparagraph:

“(D) The study or investigation is approved or funded (which may include funding through in-kind contributions) by the Patient-Centered Outcomes Research Institute estab-
lished under section 1181 of the Social Security Act.”.

(B) APPLICABILITY DATE.—The amendment made by this paragraph shall apply with respect to plan years beginning on or after January 1, 2020.

(2) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS.—

(A) IN GENERAL.—Section 1862(m)(2) of the Social Security Act (42 U.S.C. 1395y(m)(2)) is amended, in the matter preceding subparagraph (A), by inserting “(including a trial funded by the Patient-Centered Outcomes Research Institute established under section 1181)” after “means a trial”.

(B) EFFECTIVE DATE.—The amendment made by this subparagraph shall apply with respect to items and services furnished on or after the date of the enactment of this Act.

(g) ADDITIONS TO ANNUAL REPORTS BY THE INSTITUTE.—Subsection (d)(10)(A) of such section 1181 is amended—

(1) by inserting “, including narrative statements of funding announcements of the Institute,” after “paragraph (1)(A)”; and
(2) by inserting the following before the semi-colon: “as well as any barriers that researchers funded by the Institute have encountered in conducting studies or clinical trials, including challenges covering the cost of any medical treatments, services, and items described in subsection (a)(2)(B) for purposes of the research study”.

(h) GAO OVERSIGHT.—Subsection (g)(2)(A) of such section 1181 is amended by adding at the end the following new clause:

“(vi) Not less frequently than every 5 years, any barriers that researchers funded by the Institute have encountered in conducting studies or clinical trials, including challenges covering the cost of any medical treatments, services, and items described in subsection (a)(2)(B) for purposes of the research study.”.

(i) AGENCY FOR HEALTHCARE RESEARCH AND QUALITY ACTIVITIES.—

(1) IMPLEMENTATION OF RESEARCH FINDINGS.—Section 937(b) of the Public Health Service Act (42 U.S.C. 299b–37(b)) is amended to read as follows:
“(b) IMPLEMENTATION.—The Agency for Healthcare Research and Quality, in consultation with relevant medical and clinical associations, shall carry out activities to promote the timely implementation of research findings disseminated under subsection (a) into clinical practices, including by assisting users of health information technology focused on clinical decision support in such implementation, in order to improve quality of care, health outcomes, and population health and to promote the ease of use of such implementation.”.

(2) PAPERWORK REDUCTION ACT.—Section 937 of the Public Health Service Act (42 U.S.C. 299b–37) is amended by adding at the end the following:

“(h) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to any activity carried out under this section.”.

(3) OFFICE OF COMMUNICATION AND KNOWLEDGE TRANSFER.—

(A) IN GENERAL.—Section 937 of the Public Health Service Act (42 U.S.C. 299b–37), as amended by paragraph (1), is further amended—

(i) in subsection (a)(1), by striking “The Office of Communication and Knowledge Transfer” and all that follows
through “Healthcare Research and Quality)” and inserting “The Agency for Healthcare Research and Quality”; and

(ii) by striking “Office” each place it appears and inserting “Agency for Healthcare Research and Quality”.

(B) PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND.—Section 9511(d)(2)(C)(i) of the Internal Revenue Code of 1986 is amended by striking “the Office of Communication and Knowledge Transfer” and all that follows through “Healthcare Research and Quality)” and inserting “the Agency for Healthcare Research and Quality”.

(j) PROMOTION OF TIMELY IMPLEMENTATION OF RESEARCH FINDINGS.—Subsection (e) of such section 1181 is amended by inserting “and promotion of the timely implementation” after “dissemination”.

(k) IDENTIFICATION OF RESEARCH PRIORITIES.—Subsection (d)(1)(A) of such section 1181 is amended by adding at the end the following new sentence: “Such priorities should reflect a balance between long-term priorities and short-term priorities, and be responsive to changing medical evidence and health care treatments.”.
(1) **Effective Date.**—Except as otherwise provided in this section, the provisions of, and the amendments made by, this section shall take effect on the date of the enactment of this Act.