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”.

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(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.”.

(e) Consideration of Full Range of Outcomes
Data.—Subsection (d)(2) of such section 1181 is amend-
ed 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-cen-
tered outcomes relevant to, and that meet the
needs of, patients, clinicians, purchasers, and
policy-makers in making informed health deci-
sions. In addition to the relative health out-
comes and clinical effectiveness, clinical and pa-
tient-centered outcomes shall include the poten-
tial burdens and economic impacts of the utili-
ization of medical treatments, items, and serv-
ices on different stakeholders and decision-mak-
ers respectively. These potential burdens and
economic impacts include medical out-of-pocket
costs, including health plan benefit and for-
mulary design, non-medical costs to the patient
and family, including caregiving, effects on fu-
ture costs of care, workplace productivity and
absenteeism, and healthcare utilization.”.

(d) 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 In-
stitute on ways to take into account and
target diseases, conditions, and care inter-
ventions that have a high-impact on na-
tional health expenditures and advance the
incorporation of practical evidence into
health care delivery in the national prior-
ities for research and the research project
agenda under paragraph (1). Such panel
shall include members representing private
and public payers in addition to the com-
position requirements described in sub-
paragraph (B).”.

(e) 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 established 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 Out-
comes 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.

(f) 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)”;

(2) by inserting the following before the semicolon: “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”.

(g) 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 con-
ducting 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) 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”.

(i) 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”.

(j) 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.”.

(k) 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.