

116TH CONGRESS
1ST SESSION

S. _____

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.

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

3 **SECTION 1. SHORT TITLE.**

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

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

8 (a) EXTENSION OF FUNDING.—

1 (1) MANDATORY APPROPRIATIONS.—Section
2 9511 of the Internal Revenue Code of 1986 is
3 amended—

4 (A) in subsection (b)(1)(E), by striking
5 “2014” and all that follows through “2019”
6 and inserting “2014 through 2029”;

7 (B) in subsection (d)(2)(A), by striking
8 “2019” and inserting “2029”; and

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

11 (2) EXTENSION OF MEDICARE TRANSFERS.—
12 Section 1183(a)(2) of the Social Security Act (42
13 U.S.C. 1320e–2(a)(2)) is amended by striking
14 “2014” and all that follows through “2019” and in-
15 serting “2014 through 2029”.

16 (3) EXTENSION OF CERTAIN HEALTH INSUR-
17 ANCE FEES.—

18 (A) HEALTH INSURANCE POLICIES.—Sec-
19 tion 4375(e) of the Internal Revenue Code of
20 1986 is amended by striking “2019” and in-
21 serting “2029”.

22 (B) SELF-INSURED HEALTH PLANS.—Sec-
23 tion 4376(e) of the Internal Revenue Code of
24 1986 is amended by striking “2019” and in-
25 serting “2029”.

1 (b) BOARD COMPOSITION.—Subsection (f) of section
2 1181 of the Social Security Act (42 U.S.C. 1320e) is
3 amended—

4 (1) in paragraph (1)—

5 (A) in subparagraph (C)—

6 (i) in the matter preceding clause

7 (i)—

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

10 (II) by striking “, not later than
11 6 months after the date of enactment
12 of this section,”; and

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

15 (2) in paragraph (3)—

16 (A) in the first sentence—

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

19 (ii) by inserting the following before
20 the period at the end: “to the extent nec-
21 essary to preserve the evenly staggered
22 terms of the Board.”; and

23 (B) by inserting the following after the
24 first sentence: “Any member appointed to fill a
25 vacancy occurring before the expiration of the

1 term for which the member's predecessor was
2 appointed shall be appointed for the remainder
3 of that term and thereafter may be eligible for
4 reappointment to a full term. A member may
5 serve after the expiration of that member's
6 term until a successor has been appointed.”.

7 (c) CONSIDERATION OF FULL RANGE OF OUTCOMES
8 DATA.—Subsection (d)(2) of such section 1181 is amend-
9 ed by adding at the end the following subparagraph:

10 “(F) CONSIDERATION OF FULL RANGE OF
11 OUTCOMES DATA.—Research shall be designed,
12 as appropriate, to take into account and cap-
13 ture the full range of clinical and patient-cen-
14 tered outcomes relevant to, and that meet the
15 needs of, patients, clinicians, purchasers, and
16 policy-makers in making informed health deci-
17 sions. In addition to the relative health out-
18 comes and clinical effectiveness, clinical and pa-
19 tient-centered outcomes shall include the poten-
20 tial burdens and economic impacts of the utili-
21 zation of medical treatments, items, and serv-
22 ices on different stakeholders and decision-mak-
23 ers respectively. These potential burdens and
24 economic impacts include medical out-of-pocket
25 costs, including health plan benefit and for-

1 mulary design, non-medical costs to the patient
2 and family, including caregiving, effects on fu-
3 ture costs of care, workplace productivity and
4 absenteeism, and healthcare utilization.”.

5 (d) ESTABLISHMENT OF EXPERT ADVISORY
6 PANEL.—Subsection (d)(4)(A) of such section 1181 is
7 amended by adding at the end the following new clause:

8 “(iv) EXPERT ADVISORY PANEL FOR
9 HIGH-IMPACT RESEARCH.—The Institute
10 shall appoint an expert advisory panel for
11 purposes of assisting and advising the In-
12 stitute on ways to take into account and
13 target diseases, conditions, and care inter-
14 ventions that have a high-impact on na-
15 tional health expenditures and advance the
16 incorporation of practical evidence into
17 health care delivery in the national prior-
18 ities for research and the research project
19 agenda under paragraph (1). Such panel
20 shall include members representing private
21 and public payers in addition to the com-
22 position requirements described in sub-
23 paragraph (B).”.

24 (e) ENSURING COVERAGE FOR CLINICAL TRIALS
25 UNDER EXISTING STANDARD OF CARE.—

1 (1) REVISION TO DEFINITION OF APPROVED
2 CLINICAL TRIAL IN INDIVIDUAL AND GROUP MAR-
3 KET.—

4 (A) IN GENERAL.—Subsection (d)(1) of
5 the first section 2709 of the Public Health
6 Service Act (42 U.S.C. 300gg–8) is amended by
7 adding at the end the following new subpara-
8 graph:

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

15 (B) APPLICABILITY DATE.—The amend-
16 ment made by this paragraph shall apply with
17 respect to plan years beginning on or after Jan-
18 uary 1, 2020.

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

21 (A) IN GENERAL.—Section 1862(m)(2) of
22 the Social Security Act (42 U.S.C.
23 1395y(m)(2)) is amended, in the matter pre-
24 ceding subparagraph (A), by inserting “(includ-
25 ing a trial funded by the Patient-Centered Out-

1 comes Research Institute established under sec-
2 tion 1181)” after “means a trial”.

3 (B) EFFECTIVE DATE.—The amendment
4 made by this subparagraph shall apply with re-
5 spect to items and services furnished on or
6 after the date of the enactment of this Act.

7 (f) ADDITIONS TO ANNUAL REPORTS BY THE INSTI-
8 TUTE.—Subsection (d)(10)(A) of such section 1181 is
9 amended—

10 (1) by inserting “, including narrative state-
11 ments of funding announcements of the Institute,”
12 after “paragraph (1)(A)”;

13 (2) by inserting the following before the semi-
14 colon: “as well as any barriers that researchers
15 funded by the Institute have encountered in con-
16 ducting studies or clinical trials, including challenges
17 covering the cost of any medical treatments, serv-
18 ices, and items described in subsection (a)(2)(B) for
19 purposes of the research study”.

20 (g) GAO OVERSIGHT.—Subsection (g)(2)(A) of such
21 section 1181 is amended by adding at the end the fol-
22 lowing new clause:

23 “(vi) Not less frequently than every 5
24 years, any barriers that researchers funded
25 by the Institute have encountered in con-

1 ducting studies or clinical trials, including
2 challenges covering the cost of any medical
3 treatments, services, and items described
4 in subsection (a)(2)(B) for purposes of the
5 research study.”.

6 (h) AGENCY FOR HEALTHCARE RESEARCH AND
7 QUALITY ACTIVITIES.—

8 (1) IMPLEMENTATION OF RESEARCH FIND-
9 INGS.—Section 937(b) of the Public Health Service
10 Act (42 U.S.C. 299b–37(b)) is amended to read as
11 follows:

12 “(b) IMPLEMENTATION.—The Agency for Healthcare
13 Research and Quality, in consultation with relevant med-
14 ical and clinical associations, shall carry out activities to
15 promote the timely implementation of research findings
16 disseminated under subsection (a) into clinical practices,
17 including by assisting users of health information tech-
18 nology focused on clinical decision support in such imple-
19 mentation, in order to improve quality of care, health out-
20 comes, and population health and to promote the ease of
21 use of such implementation.”.

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

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

4 (3) OFFICE OF COMMUNICATION AND KNOWL-
5 EDGE TRANSFER.—

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

10 (i) in subsection (a)(1), by striking
11 “The Office of Communication and Knowl-
12 edge Transfer” and all that follows
13 through “Healthcare Research and Qual-
14 ity)” and inserting “The Agency for
15 Healthcare Research and Quality”; and

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

19 (B) PATIENT-CENTERED OUTCOMES RE-
20 SEARCH TRUST FUND.—Section
21 9511(d)(2)(C)(i) of the Internal Revenue Code
22 of 1986 is amended by striking “the Office of
23 Communication and Knowledge Transfer” and
24 all that follows through “Healthcare Research

1 and Quality)” and inserting “the Agency for
2 Healthcare Research and Quality”.

3 (i) PROMOTION OF TIMELY IMPLEMENTATION OF
4 RESEARCH FINDINGS.—Subsection (c) of such section
5 1181 is amended by inserting “and promotion of the time-
6 ly implementation” after “dissemination”.

7 (j) IDENTIFICATION OF RESEARCH PRIORITIES.—
8 Subsection (d)(1)(A) of such section 1181 is amended by
9 adding at the end the following new sentence: “Such prior-
10 ities should reflect a balance between long-term priorities
11 and short-term priorities, and be responsive to changing
12 medical evidence and health care treatments.”.

13 (k) EFFECTIVE DATE.—Except as otherwise pro-
14 vided in this section, the provisions of, and the amend-
15 ments made by, this section shall take effect on the date
16 of the enactment of this Act.