

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.

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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 \_\_\_\_\_

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**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) APPOINTMENT OF MEMBERS OF METHODOLOGY  
 8 COMMITTEE.—

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

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

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

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

23 “(F) CONSIDERATION OF FULL RANGE OF  
 24 OUTCOMES DATA.—Research shall be designed,  
 25 as appropriate, to take into account and cap-

1           ture the full range of clinical and patient-cen-  
2           tered outcomes relevant to, and that meet the  
3           needs of, patients, clinicians, purchasers, and  
4           policy-makers in making informed health deci-  
5           sions. In addition to the relative health out-  
6           comes and clinical effectiveness, clinical and pa-  
7           tient-centered outcomes shall include the poten-  
8           tial burdens and economic impacts of the utili-  
9           zation of medical treatments, items, and serv-  
10          ices on different stakeholders and decision-mak-  
11          ers respectively. These potential burdens and  
12          economic impacts include medical out-of-pocket  
13          costs, non-medical costs to the patient and fam-  
14          ily, effects on future costs of care, workplace  
15          productivity and absenteeism, and healthcare  
16          utilization.”.

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

20                   “(iv) EXPERT ADVISORY PANEL FOR  
21                   HIGH-IMPACT RESEARCH.—The Institute  
22                   shall appoint an expert advisory panel for  
23                   purposes of assisting and advising the In-  
24                   stitute on ways to take into account and  
25                   target diseases, conditions, and care inter-

1                   ventions that have a high-impact on na-  
2                   tional health expenditures and advance the  
3                   incorporation of practical evidence into  
4                   health care delivery in the national prior-  
5                   ities for research and the research project  
6                   agenda under paragraph (1). Such panel  
7                   shall include members representing private  
8                   and public payers while maintaining the  
9                   composition requirements described in sub-  
10                  paragraph (B).”.

11               (f) ENSURING COVERAGE FOR CLINICAL TRIALS  
12 UNDER EXISTING STANDARD OF CARE.—

13               (1) REVISION TO DEFINITION OF APPROVED  
14 CLINICAL TRIAL IN INDIVIDUAL AND GROUP MAR-  
15 KET.—

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

21               “(D) The study or investigation is ap-  
22 proved or funded (which may include funding  
23 through in-kind contributions) by the Patient-  
24 Centered Outcomes Research Institute estab-

1 lished under section 1181 of the Social Security  
2 Act.”.

3 (B) APPLICABILITY DATE.—The amend-  
4 ment made by this paragraph shall apply with  
5 respect to plan years beginning on or after Jan-  
6 uary 1, 2020.

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

9 (A) IN GENERAL.—Section 1862(m)(2) of  
10 the Social Security Act (42 U.S.C.  
11 1395y(m)(2)) is amended, in the matter pre-  
12 ceding subparagraph (A), by inserting “(includ-  
13 ing a trial funded by the Patient-Centered Out-  
14 comes Research Institute established under sec-  
15 tion 1181)” after “means a trial”.

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

20 (g) ADDITIONS TO ANNUAL REPORTS BY THE INSTI-  
21 TUTE.—Subsection (d)(10)(A) of such section 1181 is  
22 amended—

23 (1) by inserting “, including narrative state-  
24 ments of funding announcements of the Institute,”  
25 after “paragraph (1)(A)”; and

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

8           (h) GAO OVERSIGHT.—Subsection (g)(2)(A) of such  
9 section 1181 is amended by adding at the end the fol-  
10 lowing new clause:

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

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

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

1           “(b) IMPLEMENTATION.—The Agency for Healthcare  
2 Research and Quality, in consultation with relevant med-  
3 ical and clinical associations, shall carry out activities to  
4 promote the timely implementation of research findings  
5 disseminated under subsection (a) into clinical practices,  
6 including by assisting users of health information tech-  
7 nology focused on clinical decision support in such imple-  
8 mentation, in order to improve quality of care, health out-  
9 comes, and population health and to promote the ease of  
10 use of such implementation.”.

11           (2) PAPERWORK REDUCTION ACT.—Section 937  
12 of the Public Health Service Act (42 U.S.C. 299b–  
13 37) is amended by adding at the end the following:  
14           “(h) ADMINISTRATION.—Chapter 35 of title 44,  
15 United States Code, shall not apply to any activity carried  
16 out under this section.”.

17           (3) OFFICE OF COMMUNICATION AND KNOWL-  
18 EDGE TRANSFER.—

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

23           (i) in subsection (a)(1), by striking  
24           “The Office of Communication and Knowl-  
25           edge Transfer” and all that follows

1 through “Healthcare Research and Qual-  
2 ity)” and inserting “The Agency for  
3 Healthcare Research and Quality”; and

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

7 (B) PATIENT-CENTERED OUTCOMES RE-  
8 SEARCH TRUST FUND.—Section  
9 9511(d)(2)(C)(i) of the Internal Revenue Code  
10 of 1986 is amended by striking “the Office of  
11 Communication and Knowledge Transfer” and  
12 all that follows through “Healthcare Research  
13 and Quality)” and inserting “the Agency for  
14 Healthcare Research and Quality”.

15 (j) PROMOTION OF TIMELY IMPLEMENTATION OF  
16 RESEARCH FINDINGS.—Subsection (c) of such section  
17 1181 is amended by inserting “and promotion of the time-  
18 ly implementation” after “dissemination”.

19 (k) IDENTIFICATION OF RESEARCH PRIORITIES.—  
20 Subsection (d)(1)(A) of such section 1181 is amended by  
21 adding at the end the following new sentence: “Such prior-  
22 ities should reflect a balance between long-term priorities  
23 and short-term priorities, and be responsive to changing  
24 medical evidence and health care treatments.”.

1           (1) EFFECTIVE DATE.—Except as otherwise provided  
2 in this section, the provisions of, and the amendments  
3 made by, this section shall take effect on the date of the  
4 enactment of this Act.