

116TH CONGRESS
1ST SESSION

S. 2897

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

NOVEMBER 19, 2019

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 Finance

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

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) 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 capture 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, 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)”; and

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.

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