

111TH CONGRESS
1ST SESSION

S. 1213

To amend title XI of the Social Security Act to provide for the conduct of comparative effectiveness research and to amend the Internal Revenue Code of 1986 to establish a Patient-Centered Outcomes Research Trust Fund, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 9, 2009

Mr. BAUCUS (for himself and Mr. CONRAD) 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 provide for the conduct of comparative effectiveness research and to amend the Internal Revenue Code of 1986 to establish a Patient-Centered Outcomes Research Trust Fund, 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 Act of 2009”.

1 **SEC. 2. COMPARATIVE EFFECTIVENESS RESEARCH.**

2 (a) IN GENERAL.—Title XI of the Social Security Act
3 (42 U.S.C. 1301 et seq.) is amended by adding at the end
4 the following new part:

5 “PART D—COMPARATIVE EFFECTIVENESS RESEARCH

6 “COMPARATIVE EFFECTIVENESS RESEARCH

7 “SEC. 1181. (a) DEFINITIONS.—In this section:

8 “(1) BOARD.—The term ‘Board’ means the
9 Board of Governors established under subsection (f).

10 “(2) COMPARATIVE CLINICAL EFFECTIVENESS
11 RESEARCH.—

12 “(A) IN GENERAL.—The term ‘compara-
13 tive clinical effectiveness research’ means re-
14 search evaluating and comparing the clinical ef-
15 fectiveness, risks, and benefits of 2 or more
16 medical treatments, services, and items de-
17 scribed in subparagraph (B).

18 “(B) MEDICAL TREATMENTS, SERVICES,
19 AND ITEMS DESCRIBED.—The medical treat-
20 ments, services, and items described in this sub-
21 paragraph are health care interventions, proto-
22 cols for treatment, care management, and deliv-
23 ery, procedures, medical devices, diagnostic
24 tools, pharmaceuticals (including drugs and
25 biologicals), and any other strategies or items
26 being used in the treatment, management, and

1 diagnosis of, or prevention of illness or injury
2 in, patients.

3 “(3) COMPARATIVE EFFECTIVENESS RE-
4 SEARCH.—The term ‘comparative effectiveness re-
5 search’ means research evaluating and comparing
6 the implications and outcomes of 2 or more health
7 care strategies to address a particular medical condi-
8 tion for specific patient populations.

9 “(4) CONFLICTS OF INTEREST.—The term
10 ‘conflicts of interest’ means associations, including
11 financial and personal, that may be reasonably as-
12 sumed to have the potential to bias an individual’s
13 decisions in matters related to the Institute or the
14 conduct of activities under this section.

15 “(5) INSTITUTE.—The term ‘Institute’ means
16 the ‘Patient-Centered Outcomes Research Institute’
17 established under subsection (b)(1).

18 “(b) PATIENT-CENTERED OUTCOMES RESEARCH IN-
19 STITUTE.—

20 “(1) ESTABLISHMENT.—There is authorized to
21 be established a nonprofit corporation, to be known
22 as the ‘Patient-Centered Outcomes Research Insti-
23 tute’ which is neither an agency nor establishment
24 of the United States Government.

1 “(2) APPLICATION OF PROVISIONS.—The Insti-
2 tute shall be subject to the provisions of this section,
3 and, to the extent consistent with this section, to the
4 District of Columbia Nonprofit Corporation Act.

5 “(3) FUNDING OF COMPARATIVE EFFECTIVE-
6 NESS RESEARCH.—For fiscal year 2010 and each
7 subsequent fiscal year, amounts in the Patient-Cen-
8 tered Outcomes Research Trust Fund (referred to in
9 this section as the ‘PCORTF’) under section 9511
10 of the Internal Revenue Code of 1986 shall be avail-
11 able, without further appropriation, to the Institute
12 to carry out this section.

13 “(c) PURPOSE.—The purpose of the Institute is to
14 assist patients, clinicians, purchasers, and policy makers
15 in making informed health decisions by advancing the
16 quality and relevance of evidence concerning the manner
17 in which diseases, disorders, and other health conditions
18 can effectively and appropriately be prevented, diagnosed,
19 treated, monitored, and managed through research and
20 evidence synthesis that considers variations in patient sub-
21 populations, and the dissemination of research findings
22 with respect to the relative clinical outcomes, clinical effec-
23 tiveness, and appropriateness of the medical treatments,
24 services, and items described in subsection (a)(2)(B).

25 “(d) DUTIES.—

1 “(1) IDENTIFYING RESEARCH PRIORITIES AND
2 ESTABLISHING RESEARCH PROJECT AGENDA.—

3 “(A) IDENTIFYING RESEARCH PRIOR-
4 ITIES.—The Institute shall identify national
5 priorities for comparative clinical effectiveness
6 research, taking into account factors, includ-
7 ing—

8 “(i) disease incidence, prevalence, and
9 burden in the United States;

10 “(ii) evidence gaps in terms of clinical
11 outcomes;

12 “(iii) practice variations, including
13 variations in delivery and outcomes by ge-
14 ography, treatment site, provider type, and
15 patient subgroup;

16 “(iv) the potential for new evidence
17 concerning certain categories of health care
18 services or treatments to improve patient
19 health and well-being, and the quality of
20 care;

21 “(v) the effect or potential for an ef-
22 fect on health expenditures associated with
23 a health condition or the use of a par-
24 ticular medical treatment, service, or item;

1 “(vi) the effect or potential for an ef-
2 fect on patient needs, outcomes, and pref-
3 erences, including quality of life; and

4 “(vii) the relevance to assisting pa-
5 tients and clinicians in making informed
6 health decisions.

7 “(B) ESTABLISHING RESEARCH PROJECT
8 AGENDA.—

9 “(i) IN GENERAL.—The Institute shall
10 establish and update a research project
11 agenda for comparative clinical effective-
12 ness research to address the priorities
13 identified under subparagraph (A), taking
14 into consideration the types of such re-
15 search that might address each priority
16 and the relative value (determined based
17 on the cost of conducting such research
18 compared to the potential usefulness of the
19 information produced by such research) as-
20 sociated with the different types of re-
21 search, and such other factors as the Insti-
22 tute determines appropriate.

23 “(ii) CONSIDERATION OF NEED TO
24 CONDUCT A SYSTEMATIC REVIEW.—In es-
25 tablishing and updating the research

1 project agenda under clause (i), the Insti-
2 tute shall consider the need to conduct a
3 systematic review of existing research be-
4 fore providing for the conduct of new re-
5 search under paragraph (2)(A).

6 “(2) CARRYING OUT RESEARCH PROJECT AGEN-
7 DA.—

8 “(A) COMPARATIVE CLINICAL EFFECTIVE-
9 NESS RESEARCH.—In carrying out the research
10 project agenda established under paragraph
11 (1)(B), the Institute shall provide for the con-
12 duct of appropriate research and the synthesis
13 of evidence, in accordance with the methodo-
14 logical standards adopted under paragraph
15 (10), using methods, including the following:

16 “(i) Systematic reviews and assess-
17 ments of existing research and evidence.

18 “(ii) Primary research, such as ran-
19 domized clinical trials, molecularly in-
20 formed trials, and observational studies.

21 “(iii) Any other methodologies rec-
22 ommended by the methodology committee
23 established under paragraph (7) that are
24 adopted by the Board under paragraph
25 (10).

1 “(B) CONTRACTS FOR THE MANAGEMENT
2 AND CONDUCT OF RESEARCH.—

3 “(i) IN GENERAL.—The Institute may
4 enter into contracts for the management
5 and conduct of research in accordance with
6 the research project agenda established
7 under paragraph (1)(B) with the following:

8 “(I) Agencies and instrumental-
9 ities of the Federal Government that
10 have experience in conducting com-
11 parative clinical effectiveness research,
12 such as the Agency for Healthcare
13 Research and Quality, to the extent
14 that such contracts are authorized
15 under the governing statutes of such
16 agencies and instrumentalities.

17 “(II) Appropriate private sector
18 research or study-conducting entities
19 that have demonstrated the experience
20 and capacity to achieve the goals of
21 comparative effectiveness research.

22 “(ii) CONDITIONS FOR CONTRACTS.—
23 A contract entered into under this sub-
24 paragraph shall require that the agency,
25 instrumentality, or other entity—

1 “(I) abide by the transparency
2 and conflicts of interest requirements
3 that apply to the Institute with re-
4 spect to the research managed or con-
5 ducted under such contract;

6 “(II) comply with the methodo-
7 logical standards adopted under para-
8 graph (10) with respect to such re-
9 search;

10 “(III) take into consideration
11 public comments on the study design
12 that are transmitted by the Institute
13 to the agency, instrumentality, or
14 other entity under subsection
15 (i)(1)(B) during the finalization of the
16 study design and transmit responses
17 to such comments to the Institute,
18 which will publish such comments, re-
19 sponses, and finalized study design in
20 accordance with subsection
21 (i)(3)(A)(iii) prior to the conduct of
22 such research; and

23 “(IV) in the case where the agen-
24 cy, instrumentality, or other entity is
25 managing or conducting a compara-

1 tive effectiveness research study for a
2 rare disease, consult with the expert
3 advisory panel for rare disease ap-
4 pointed under paragraph (5)(A)(iii)
5 with respect to such research study.

6 “(iii) COVERAGE OF COPAYMENTS OR
7 COINSURANCE.—A contract entered into
8 under this subparagraph may allow for the
9 coverage of copayments or co-insurance, or
10 allow for other appropriate measures, to
11 the extent that such coverage or other
12 measures are necessary to preserve the va-
13 lidity of a research project, such as in the
14 case where the research project must be
15 blinded.

16 “(C) REVIEW AND UPDATE OF EVI-
17 DENCE.—The Institute shall review and update
18 evidence on a periodic basis, in order to take
19 into account new research, evolving evidence,
20 advances in medical technology, and changes in
21 the standard of care as they become available,
22 as appropriate.

23 “(D) TAKING INTO ACCOUNT POTENTIAL
24 DIFFERENCES.—Research shall—

1 “(i) be designed, as appropriate, to
2 take into account the potential for dif-
3 ferences in the effectiveness of health care
4 treatments, services, and items as used
5 with various subpopulations, such as racial
6 and ethnic minorities, women, age, and
7 groups of individuals with different
8 comorbidities, genetic and molecular sub-
9 types, or quality of life preferences; and

10 “(ii) include members of such sub-
11 populations as subjects in the research as
12 feasible and appropriate.

13 “(E) DIFFERENCES IN TREATMENT MO-
14 DALITIES.—Research shall be designed, as ap-
15 propriate, to take into account different charac-
16 teristics of treatment modalities that may affect
17 research outcomes, such as the phase of the
18 treatment modality in the innovation cycle and
19 the impact of the skill of the operator of the
20 treatment modality.

21 “(3) STUDY AND REPORT ON FEASIBILITY OF
22 CONDUCTING RESEARCH IN-HOUSE.—

23 “(A) STUDY.—The Institute shall conduct
24 a study on the feasibility of conducting research
25 in-house.

1 “(B) REPORT.—Not later than 5 years
2 after the date of enactment of this section, the
3 Institute shall submit a report to Congress con-
4 taining the results of the study conducted under
5 subparagraph (A).

6 “(4) DATA COLLECTION.—

7 “(A) IN GENERAL.—The Secretary shall,
8 with appropriate safeguards for privacy, make
9 available to the Institute such data collected by
10 the Centers for Medicare & Medicaid Services
11 under the programs under titles XVIII, XIX,
12 and XXI as the Institute may require to carry
13 out this section. The Institute may also request
14 and, if such request is granted, obtain data
15 from Federal, State, or private entities, includ-
16 ing data from clinical databases and registries.

17 “(B) USE OF DATA.—The Institute shall
18 only use data provided to the Institute under
19 subparagraph (A) in accordance with laws and
20 regulations governing the release and use of
21 such data, including applicable confidentiality
22 and privacy standards.

23 “(5) APPOINTING EXPERT ADVISORY PANELS.—

24 “(A) APPOINTMENT.—

1 “(i) IN GENERAL.—The Institute
2 shall, as appropriate, appoint expert advisory
3 panels to assist in identifying research
4 priorities and establishing the research
5 project agenda under paragraph (1). Panels
6 shall advise the Institute in matters
7 such as identifying gaps in and updating
8 medical evidence in order to ensure that
9 the information produced from such research
10 is clinically relevant to decisions
11 made by clinicians and patients at the
12 point of care.

13 “(ii) EXPERT ADVISORY PANELS FOR
14 PRIMARY RESEARCH.—The Institute shall
15 appoint expert advisory panels in carrying
16 out the research project agenda under
17 paragraph (2)(A)(ii). Such expert advisory
18 panels shall, upon request, advise the Institute
19 and the agency, instrumentality, or
20 entity conducting the research on the research
21 question involved and the research
22 design or protocol, including the appropriate
23 comparator technologies, important
24 patient subgroups, and other parameters of
25 the research, as necessary. Upon the re-

1 quest of such agency, instrumentality, or
2 entity, such panels shall be available as a
3 resource for technical questions that may
4 arise during the conduct of such research.

5 “(iii) EXPERT ADVISORY PANEL FOR
6 RARE DISEASE.—In the case of a compara-
7 tive effectiveness research study for rare
8 disease, the Institute shall appoint an ex-
9 pert advisory panel for purposes of assist-
10 ing in the design of such research study
11 and determining the relative value and fea-
12 sibility of conducting such research study.

13 “(B) COMPOSITION.—

14 “(i) IN GENERAL.—An expert advi-
15 sory panel appointed under subparagraph
16 (A) shall include individuals who have ex-
17 perience in the relevant topic, project, or
18 category for which the panel is established,
19 including—

20 “(I) practicing and research clini-
21 cians (including relevant specialists
22 and subspecialists), patients, and rep-
23 resentatives of patients; and

24 “(II) experts in scientific and
25 health services research, health serv-

1 ices delivery, and evidence-based medi-
2 cine.

3 “(ii) INCLUSION OF REPRESENTA-
4 TIVES OF MANUFACTURERS OF MEDICAL
5 TECHNOLOGY.—An expert advisory panel
6 appointed under subparagraph (A) may in-
7 clude a representative of each manufac-
8 turer of each medical technology that is in-
9 cluded under the relevant topic, project, or
10 category for which the panel is established.

11 “(6) SUPPORTING PATIENT AND CONSUMER
12 REPRESENTATIVES.—The Institute shall provide
13 support and resources to help patient and consumer
14 representatives on the Board and expert advisory
15 panels appointed by the Institute under paragraph
16 (5) to effectively participate in technical discussions
17 regarding complex research topics. Such support
18 shall include initial and continuing education to fa-
19 cilitate effective engagement in activities undertaken
20 by the Institute and may include regular and ongo-
21 ing opportunities for patient and consumer rep-
22 resentatives to interact with each other and to ex-
23 change information and support regarding their in-
24 volvement in the Institute’s activities. The Institute
25 shall provide per diem and other appropriate com-

1 pensation to patient and consumer representatives
2 for their time spent participating in the activities of
3 the Institute under this paragraph.

4 “(7) ESTABLISHING METHODOLOGY COM-
5 MITTEE.—

6 “(A) IN GENERAL.—The Institute shall es-
7 tablish a standing methodology committee to
8 carry out the functions described in subpara-
9 graph (C).

10 “(B) APPOINTMENT AND COMPOSITION.—
11 The methodology committee established under
12 subparagraph (A) shall be composed of not
13 more than 17 members appointed by the Comp-
14 troller General of the United States. Members
15 appointed to the methodology committee shall
16 be experts in their scientific field, such as
17 health services research, clinical research, com-
18 parative effectiveness research, biostatistics,
19 genomics, and research methodologies. Stake-
20 holders with such expertise may be appointed to
21 the methodology committee.

22 “(C) FUNCTIONS.—Subject to subpara-
23 graph (D), the methodology committee shall
24 work to develop and improve the science and
25 methods of comparative effectiveness research

1 by undertaking, directly or through subcontract,
2 the following activities:

3 “(i) Not later than 2 years after the
4 date on which the members of the method-
5 ology committee are appointed under sub-
6 paragraph (B), developing and periodically
7 updating the following:

8 “(I) Establish and maintain
9 methodological standards for com-
10 parative clinical effectiveness research
11 on major categories of interventions to
12 prevent, diagnose, or treat a clinical
13 condition or improve the delivery of
14 care. Such methodological standards
15 shall provide specific criteria for inter-
16 nal validity, generalizability, feasi-
17 bility, and timeliness of such research
18 and for clinical outcomes measures,
19 risk adjustment, and other relevant
20 aspects of research and assessment
21 with respect to the design of such re-
22 search. Any methodological standards
23 developed and updated under this sub-
24 clause shall be scientifically based and
25 include methods by which new infor-

1 mation, data, or advances in tech-
2 nology are considered and incor-
3 porated into ongoing research projects
4 by the Institute, as appropriate. The
5 process for developing and updating
6 such standards shall include input
7 from relevant experts, stakeholders,
8 and decision makers, and shall pro-
9 vide opportunities for public comment.
10 Such standards shall also include
11 methods by which patient subpopula-
12 tions can be accounted for and evalu-
13 ated in different types of research. As
14 appropriate, such standards shall
15 build on existing work on methodo-
16 logical standards for defined cat-
17 egories of health interventions and for
18 each of the major categories of com-
19 parative effectiveness research meth-
20 ods (determined as of the date of en-
21 actment of the Patient-Centered Out-
22 comes Research Act of 2009).

23 “(II) A translation table that is
24 designed to provide guidance and act
25 as a reference for the Board to deter-

1 mine research methods that are most
2 likely to address each specific com-
3 parative clinical effectiveness research
4 question.

5 “(ii) Not later than 3 years after such
6 date, examining the following:

7 “(I) Methods by which various
8 aspects of the health care delivery sys-
9 tem (such as benefit design and per-
10 formance, and health services organi-
11 zation, management, information com-
12 munication, and delivery) could be as-
13 sessed and compared for their relative
14 effectiveness, benefits, risks, advan-
15 tages, and disadvantages in a scientif-
16 ically valid and standardized way.

17 “(II) Methods by which efficiency
18 and value (including the full range of
19 harms and benefits, such as quality of
20 life) could be assessed in a scientif-
21 ically valid and standardized way.

22 “(D) CONSULTATION AND CONDUCT OF
23 EXAMINATIONS.—

24 “(i) IN GENERAL.—Subject to clause
25 (iii), in undertaking the activities described

1 in subparagraph (C), the methodology
2 committee shall—

3 “(I) consult or contract with 1 or
4 more of the entities described in
5 clause (ii); and

6 “(II) consult with stakeholders
7 and other entities knowledgeable in
8 relevant fields, as appropriate.

9 “(ii) ENTITIES DESCRIBED.—The fol-
10 lowing entities are described in this clause:

11 “(I) The Institute of Medicine of
12 the National Academies.

13 “(II) The Agency for Healthcare
14 Research and Quality.

15 “(III) The National Institutes of
16 Health.

17 “(IV) Academic, non-profit, or
18 other private entities with relevant ex-
19 pertise.

20 “(iii) CONDUCT OF EXAMINATIONS.—
21 The methodology committee shall contract
22 with the Institute of Medicine of the Na-
23 tional Academies for the conduct of the ex-
24 aminations described in subclauses (I) and
25 (II) of subparagraph (C)(ii).

1 “(E) REPORTS.—The methodology com-
2 mittee shall submit reports to the Board on the
3 committee’s performance of the functions de-
4 scribed in subparagraph (C). Reports submitted
5 under the preceding sentence with respect to
6 the functions described in clause (i) of such
7 subparagraph shall contain recommendations—

8 “(i) for the Institute to adopt meth-
9 odological standards developed and up-
10 dated by the methodology committee under
11 such subparagraph; and

12 “(ii) for such other action as the
13 methodology committee determines is nec-
14 essary to comply with such methodological
15 standards.

16 “(8) PROVIDING FOR A PEER-REVIEW PROCESS
17 FOR PRIMARY RESEARCH.—

18 “(A) IN GENERAL.—The Institute shall en-
19 sure that there is a process for peer review of
20 the research conducted under paragraph
21 (2)(A)(ii). Under such process—

22 “(i) evidence from research conducted
23 under such paragraph shall be reviewed to
24 assess scientific integrity and adherence to

1 methodological standards adopted under
2 paragraph (10); and

3 “(ii) a list of the names of individuals
4 contributing to any peer-review process
5 during the preceding year or years shall be
6 made public and included in annual reports
7 in accordance with paragraph (12)(D).

8 “(B) COMPOSITION.—Such peer-review
9 process shall be designed in a manner so as to
10 avoid bias and conflicts of interest on the part
11 of the reviewers and shall be composed of ex-
12 perts in the scientific field relevant to the re-
13 search under review.

14 “(C) USE OF EXISTING PROCESSES.—

15 “(i) PROCESSES OF ANOTHER ENTI-
16 TY.—In the case where the Institute enters
17 into a contract or other agreement with
18 another entity for the conduct or manage-
19 ment of research under this section, the
20 Institute may utilize the peer-review proc-
21 ess of such entity if such process meets the
22 requirements under subparagraphs (A) and
23 (B).

24 “(ii) PROCESSES OF APPROPRIATE
25 MEDICAL JOURNALS.—The Institute may

1 utilize the peer-review process of appro-
2 priate medical journals if such process
3 meets the requirements under subpara-
4 graphs (A) and (B).

5 “(9) DISSEMINATION OF RESEARCH FIND-
6 INGS.—

7 “(A) IN GENERAL.—The Institute shall
8 disseminate research findings to clinicians, pa-
9 tients, and the general public in accordance
10 with the dissemination protocols and strategies
11 adopted under paragraph (10). Research find-
12 ings disseminated—

13 “(i) shall convey findings of research
14 so that they are comprehensible and useful
15 to patients and providers in making health
16 care decisions;

17 “(ii) shall discuss findings and other
18 considerations specific to certain sub-
19 populations, risk factors, and
20 comorbidities, as appropriate;

21 “(iii) shall include considerations such
22 as limitations of research and what further
23 research may be needed, as appropriate;

1 “(iv) shall not include practice guide-
2 lines, coverage recommendations, or policy
3 recommendations; and

4 “(v) shall not include any data the
5 dissemination of which would violate the
6 privacy of research participants or violate
7 any confidentiality agreements made with
8 respect to the use of data under this sec-
9 tion.

10 “(B) DISSEMINATION PROTOCOLS AND
11 STRATEGIES.—The Institute shall develop pro-
12 tocols and strategies for the appropriate dis-
13 semination of research findings in order to en-
14 sure effective communication of such findings
15 and the use and incorporation of such findings
16 into relevant activities for the purpose of in-
17 forming higher quality and more effective and
18 timely decisions regarding medical treatments,
19 services, and items. In developing and adopting
20 such protocols and strategies, the Institute shall
21 consult with stakeholders, including practicing
22 clinicians and patients, concerning the types of
23 dissemination that will be most useful to the
24 end users of the information and may provide

1 for the utilization of multiple formats for con-
2 veying findings to different audiences.

3 “(C) DEFINITION OF RESEARCH FIND-
4 INGS.—In this paragraph, the term ‘research
5 findings’ means the results of a study or assess-
6 ment.

7 “(10) ADOPTION.—Subject to subsection
8 (i)(1)(A)(i), the Institute shall adopt the national
9 priorities identified under paragraph (1)(A), the re-
10 search project agenda established under paragraph
11 (1)(B), the methodological standards developed and
12 updated by the methodology committee under para-
13 graph (7)(C)(i), any peer-review process provided
14 under paragraph (8), and dissemination protocols
15 and strategies developed under paragraph (9)(B) by
16 majority vote. In the case where the Institute does
17 not adopt such national priorities, research project
18 agenda, methodological standards, peer-review proc-
19 ess, or dissemination protocols and strategies in ac-
20 cordance with the preceding sentence, the national
21 priorities, research project agenda, methodological
22 standards, peer-review process, or dissemination pro-
23 tocols and strategies shall be referred to the appro-
24 priate staff or entity within the Institute (or, in the

1 case of the methodological standards, the method-
2 ology committee) for further review.

3 “(11) COORDINATION OF RESEARCH AND RE-
4 SOURCES AND BUILDING CAPACITY FOR RE-
5 SEARCH.—

6 “(A) COORDINATION OF RESEARCH AND
7 RESOURCES.—The Institute shall coordinate re-
8 search conducted, commissioned, or otherwise
9 funded under this section with comparative clin-
10 ical effectiveness and other relevant research
11 and related efforts conducted by public and pri-
12 vate agencies and organizations in order to en-
13 sure the most efficient use of the Institute’s re-
14 sources and that research is not duplicated un-
15 necessarily.

16 “(B) BUILDING CAPACITY FOR RE-
17 SEARCH.—The Institute may build capacity for
18 comparative clinical effectiveness research and
19 methodologies, including research training and
20 development of data resources (such as clinical
21 registries), through appropriate activities, in-
22 cluding using up to 20 percent of the amounts
23 appropriated or credited to the PCORTF under
24 section 9511(b) of the Internal Revenue Code
25 of 1986 with respect to a fiscal year to fund ex-

1 tramural efforts of organizations such as the
2 Cochrane Collaboration (or a successor organi-
3 zation) and other organizations that develop
4 and maintain a data network to collect, link,
5 and analyze data on outcomes and effectiveness
6 from multiple sources, including electronic
7 health records.

8 “(C) INCLUSION IN ANNUAL REPORTS.—

9 The Institute shall report on any coordination
10 and capacity building conducted under this
11 paragraph in annual reports in accordance with
12 paragraph (12)(E).

13 “(12) ANNUAL REPORTS.—The Institute shall
14 submit an annual report to Congress and the Presi-
15 dent, and shall make the annual report available to
16 the public. Such report shall contain—

17 “(A) a description of the activities con-
18 ducted under this section during the preceding
19 year, including the use of amounts appropriated
20 or credited to the PCORTF under section
21 9511(b) of the Internal Revenue Code of 1986
22 to carry out this section, research projects com-
23 pleted and underway, and a summary of the
24 findings of such projects;

1 “(B) the research project agenda and
2 budget of the Institute for the following year;

3 “(C) a description of research priorities
4 identified under paragraph (1)(A), dissemina-
5 tion protocols and strategies developed by the
6 Institute under paragraph (9)(B), and meth-
7 odological standards developed and updated by
8 the methodology committee under paragraph
9 (7)(C)(i) that are adopted under paragraph
10 (10) during the preceding year;

11 “(D) the names of individuals contributing
12 to any peer-review process provided under para-
13 graph (8) during the preceding year or years, in
14 a manner such that those individuals cannot be
15 identified with a particular research project;
16 and

17 “(E) a description of efforts by the Insti-
18 tute under paragraph (11) to—

19 “(i) coordinate the research con-
20 ducted, commissioned, or otherwise funded
21 under this section and the resources of the
22 Institute with research and related efforts
23 conducted by other private and public enti-
24 ties; and

1 “(ii) build capacity for comparative
2 clinical effectiveness research and other
3 relevant research and related efforts
4 through appropriate activities.

5 “(F) any other relevant information (in-
6 cluding information on the membership of the
7 Board, expert advisory panels appointed under
8 paragraph (5), the methodology committee es-
9 tablished under paragraph (7), and the execu-
10 tive staff of the Institute, any conflicts of inter-
11 est with respect to the members of such Board,
12 expert advisory panels, and methodology com-
13 mittee, or with respect to any individuals se-
14 lected for employment as executive staff of the
15 Institute, and any bylaws adopted by the Board
16 during the preceding year).

17 “(e) ADMINISTRATION.—

18 “(1) IN GENERAL.—Subject to paragraph (2),
19 the Board shall carry out the duties of the Institute.

20 “(2) NONDELEGABLE DUTIES.—The activities
21 described in subsections (b)(3)(D), (d)(1), and
22 (d)(10) are nondelegable.

23 “(f) BOARD OF GOVERNORS.—

1 “(1) IN GENERAL.—The Institute shall have a
2 Board of Governors, which shall consist of the fol-
3 lowing members:

4 “(A) The Secretary of Health and Human
5 Services (or the Secretary’s designee).

6 “(B) The Director of the Agency for
7 Healthcare Research and Quality (or the Direc-
8 tor’s designee).

9 “(C) The Director of the National Insti-
10 tutes of Health (or the Director’s designee).

11 “(D) 18 members appointed by the Comp-
12 troller General of the United States not later
13 than 6 months after the date of enactment of
14 this section, as follows:

15 “(i) 3 members representing patients
16 and health care consumers.

17 “(ii) 3 members representing prac-
18 ticing physicians, including surgeons.

19 “(iii) 3 members representing agen-
20 cies that administer public programs, as
21 follows:

22 “(I) 1 member representing the
23 Centers for Medicare & Medicaid
24 Services who has experience in admin-

1 istering the program under title
2 XVIII.

3 “(II) 1 member representing
4 agencies that administer State health
5 programs (who may represent the
6 Centers for Medicare & Medicaid
7 Services and have experience in ad-
8 ministering the program under title
9 XIX or the program under title XXI
10 or be a governor of a State).

11 “(III) 1 member representing
12 agencies that administer other Fed-
13 eral health programs (such as a
14 health program of the Department of
15 Defense under chapter 55 of title 10,
16 United States Code, the Federal em-
17 ployees health benefits program under
18 chapter 89 of title 5 of such Code, a
19 health program of the Department of
20 Veterans Affairs under chapter 17 of
21 title 38 of such Code, or a medical
22 care program of the Indian Health
23 Service or of a tribal organization).

24 “(iv) 3 members representing private
25 payers, of whom at least 1 member shall

1 represent health insurance issuers and at
2 least 1 member shall represent employers
3 who self-insure employee benefits.

4 “(v) 3 members representing pharma-
5 ceutical, device, and diagnostic manufac-
6 turers or developers.

7 “(vi) 1 member representing nonprofit
8 organizations involved in health services re-
9 search.

10 “(vii) 1 member representing organi-
11 zations that focus on quality measurement
12 and improvement or decision support.

13 “(viii) 1 member representing inde-
14 pendent health services researchers.

15 “(2) QUALIFICATIONS.—

16 “(A) DIVERSE REPRESENTATION OF PER-
17 SPECTIVES.—The Board shall represent a broad
18 range of perspectives and collectively have sci-
19 entific expertise in clinical health sciences re-
20 search, including epidemiology, decisions
21 sciences, health economics, and statistics.

22 “(B) CONFLICTS OF INTEREST.—

23 “(i) IN GENERAL.—In appointing
24 members of the Board under paragraph
25 (1)(D), the Comptroller General of the

1 United States shall take into consideration
2 any conflicts of interest of potential ap-
3 pointees. Any conflicts of interest of mem-
4 bers appointed to the Board under para-
5 graph (1) shall be disclosed in accordance
6 with subsection (i)(4)(B).

7 “(ii) RECUSAL.—A member of the
8 Board shall be recused from participating
9 with respect to a particular research
10 project or other matter considered by the
11 Board in carrying out its research project
12 agenda under subsection (d)(2) in the case
13 where the member (or an immediate family
14 member of such member) has a financial
15 or personal interest directly related to the
16 research project or the matter that could
17 affect or be affected by such participation.

18 “(3) TERMS.—

19 “(A) IN GENERAL.—A member of the
20 Board appointed under paragraph (1)(D) shall
21 be appointed for a term of 6 years, except with
22 respect to the members first appointed under
23 such paragraph—

24 “(i) 6 shall be appointed for a term of
25 6 years;

1 “(ii) 6 shall be appointed for a term
2 of 4 years; and

3 “(iii) 6 shall be appointed for a term
4 of 2 years.

5 “(B) LIMITATION.—No individual shall be
6 appointed to the Board under paragraph (1)(D)
7 for more than 2 terms.

8 “(C) EXPIRATION OF TERM.—Any member
9 of the Board whose term has expired may serve
10 until such member’s successor has taken office,
11 or until the end of the calendar year in which
12 such member’s term has expired, whichever is
13 earlier.

14 “(D) VACANCIES.—

15 “(i) IN GENERAL.—Any member ap-
16 pointed to fill a vacancy prior to the expi-
17 ration of the term for which such mem-
18 ber’s predecessor was appointed shall be
19 appointed for the remainder of such term.

20 “(ii) VACANCIES NOT TO AFFECT
21 POWER OF BOARD.—A vacancy on the
22 Board shall not affect its powers, but shall
23 be filled in the same manner as the origi-
24 nal appointment was made.

25 “(4) CHAIRPERSON AND VICE-CHAIRPERSON.—

1 “(A) IN GENERAL.—The Comptroller Gen-
2 eral of the United States shall designate a
3 Chairperson and Vice-Chairperson of the Board
4 from among the members of the Board ap-
5 pointed under paragraph (1)(D).

6 “(B) TERM.—The members so designated
7 shall serve as Chairperson and Vice-Chair-
8 person of the Board for a period of 3 years.

9 “(5) COMPENSATION.—

10 “(A) IN GENERAL.—A member of the
11 Board shall be entitled to compensation at the
12 per diem equivalent of the rate provided for
13 level IV of the Executive Schedule under section
14 5315 of title 5, United States Code.

15 “(B) TRAVEL EXPENSES.—While away
16 from home or regular place of business in the
17 performance of duties for the Board, each mem-
18 ber of the Board may receive reasonable travel,
19 subsistence, and other necessary expenses.

20 “(6) DIRECTOR AND STAFF; EXPERTS AND
21 CONSULTANTS.—The Board may—

22 “(A) employ and fix the compensation of
23 an executive director and such other personnel
24 as may be necessary to carry out the duties of
25 the Institute;

1 “(B) seek such assistance and support as
2 may be required in the performance of the du-
3 ties of the Institute from appropriate depart-
4 ments and agencies of the Federal Government;

5 “(C) enter into contracts or make other ar-
6 rangements and make such payments as may
7 be necessary for performance of the duties of
8 the Institute;

9 “(D) provide travel, subsistence, and per
10 diem compensation for individuals performing
11 the duties of the Institute, including members
12 of any expert advisory panel appointed under
13 subsection (d)(5), members of the methodology
14 committee established under subsection (d)(7),
15 and individuals selected to contribute to any
16 peer-review process under subsection (d)(8);
17 and

18 “(E) prescribe such rules, regulations, and
19 bylaws as the Board determines necessary with
20 respect to the internal organization and oper-
21 ation of the Institute.

22 “(7) MEETINGS AND HEARINGS.—The Board
23 shall meet and hold hearings at the call of the
24 Chairperson or a majority of its members. In the
25 case where the Board is meeting on matters not re-

1 lated to personnel, Board meetings shall be open to
2 the public and advertised through public notice at
3 least 7 days prior to the meeting.

4 “(8) QUORUM.—A majority of the members of
5 the Board shall constitute a quorum for purposes of
6 conducting the duties of the Institute, but a lesser
7 number of members may meet and hold hearings.

8 “(g) FINANCIAL OVERSIGHT.—

9 “(1) CONTRACT FOR AUDIT.—The Institute
10 shall provide for the conduct of financial audits of
11 the Institute on an annual basis by a private entity
12 with expertise in conducting financial audits.

13 “(2) REVIEW OF AUDIT AND REPORT TO CON-
14 GRESS.—The Comptroller General of the United
15 States shall—

16 “(A) review the results of the audits con-
17 ducted under paragraph (1); and

18 “(B) submit a report to Congress con-
19 taining the results of such audits and review.

20 “(h) GOVERNMENTAL OVERSIGHT.—

21 “(1) REVIEW AND REPORTS.—

22 “(A) IN GENERAL.—The Comptroller Gen-
23 eral of the United States shall review the fol-
24 lowing:

1 “(i) Processes established by the In-
2 stitute, including those with respect to the
3 identification of research priorities under
4 subsection (d)(1)(A) and the conduct of re-
5 search projects under this section. Such re-
6 view shall determine whether information
7 produced by such research projects—

8 “(I) is objective and credible;

9 “(II) is produced in a manner
10 consistent with the requirements
11 under this section; and

12 “(III) is developed through a
13 transparent process.

14 “(ii) The overall effect of the Institute
15 and the effectiveness of activities con-
16 ducted under this section, including an as-
17 sessment of—

18 “(I) the utilization of the find-
19 ings of research conducted under this
20 section by health care decision mak-
21 ers; and

22 “(II) the effect of the Institute
23 and such activities on innovation and
24 on the health economy of the United
25 States.

1 “(B) REPORTS.—Not later than 5 years
2 after the date of enactment of this section, and
3 not less frequently than every 5 years there-
4 after, the Comptroller General of the United
5 States shall submit a report to Congress con-
6 taining the results of the review conducted
7 under subparagraph (A), together with rec-
8 ommendations for such legislation and adminis-
9 trative action as the Comptroller General deter-
10 mines appropriate.

11 “(2) FUNDING ASSESSMENT.—

12 “(A) IN GENERAL.—The Comptroller Gen-
13 eral of the United States shall assess the ade-
14 quacy and use of funding for the Institute and
15 activities conducted under this section under
16 the PCORTF under section 9511 of the Inter-
17 nal Revenue Code of 1986. Such assessment
18 shall include a determination as to whether,
19 based on the utilization of findings by public
20 and private payers, each of the following are
21 appropriate sources of funding for the Institute,
22 including a determination of whether such
23 sources of funding should be continued or ad-
24 justed, or whether other sources of funding not

1 described in clauses (i) through (iii) would be
2 appropriate:

3 “(i) The transfer of funds from the
4 Federal Hospital Insurance Trust Fund
5 under section 1817 and the Federal Sup-
6 plementary Medical Insurance Trust Fund
7 under section 1841 to the PCORTF under
8 section 1183.

9 “(ii) The amounts appropriated under
10 subparagraphs (A), (B), (C), (D)(ii), and
11 (E)(ii) of subsection (b)(1) of such section
12 9511.

13 “(iii) Private sector contributions
14 under subparagraphs (D)(i) and (E)(i) of
15 such subsection (b)(1).

16 “(B) REPORT.—Not later than 8 years
17 after the date of enactment of this section, the
18 Comptroller General of the United States shall
19 submit a report to Congress containing the re-
20 sults of the assessment conducted under sub-
21 paragraph (A), together with recommendations
22 for such legislation and administrative action as
23 the Comptroller General determines appro-
24 priate.

1 “(i) ENSURING TRANSPARENCY, CREDIBILITY, AND
2 ACCESS.—The Institute shall establish procedures to en-
3 sure that the following requirements for ensuring trans-
4 parency, credibility, and access are met:

5 “(1) PUBLIC COMMENT PERIODS.—

6 “(A) IN GENERAL.—The Institute shall
7 provide for a public comment period of not less
8 than 45 and not more than 60 days at the fol-
9 lowing times:

10 “(i) Prior to the adoption of the na-
11 tional priorities identified under subsection
12 (d)(1)(A), the research project agenda es-
13 tablished under subsection (d)(1)(B), the
14 methodological standards developed and
15 updated by the methodology committee
16 under subsection (d)(7)(C)(i), the peer-re-
17 view process generally provided under sub-
18 section (d)(8), and dissemination protocols
19 and strategies developed by the Institute
20 under subsection (d)(9)(B) in accordance
21 with subsection (d)(10).

22 “(ii) Prior to the finalization of indi-
23 vidual study designs.

24 “(iii) After the release of draft find-
25 ings with respect to a systematic review

1 and assessment of existing research and
2 evidence under subsection (d)(2)(A)(i).

3 “(B) TRANSMISSION OF PUBLIC COM-
4 MENTS ON STUDY DESIGN.—The Institute shall
5 transmit public comments submitted during the
6 public comment period described in subpara-
7 graph (A)(ii) to the entity conducting research
8 with respect to which the individual study de-
9 sign is being finalized.

10 “(2) ADDITIONAL FORUMS.—The Institute
11 shall, in addition to the public comment periods de-
12 scribed in paragraph (1)(A), support forums to in-
13 crease public awareness and obtain and incorporate
14 public input and feedback through media (such as
15 an Internet website) on the following:

16 “(A) The identification of research prior-
17 ities, including research topics, and the estab-
18 lishment of the research project agenda under
19 subparagraphs (A) and (B), respectively, of
20 subsection (d)(1).

21 “(B) Research findings.

22 “(C) Any other duties, activities, or proc-
23 esses the Institute determines appropriate.

24 “(3) PUBLIC AVAILABILITY.—The Institute
25 shall make available to the public and disclose

1 through the official public Internet website of the In-
2 stitute, and through other forums and media the In-
3 stitute determines appropriate, the following:

4 “(A) The process and methods for the con-
5 duct of research under this section, including—

6 “(i) the identity of the entity con-
7 ducting such research;

8 “(ii) any links the entity has to indus-
9 try (including such links that are not di-
10 rectly tied to the particular research being
11 conducted under this section);

12 “(iii) draft study designs (including
13 research questions and the finalized study
14 design, together with public comments on
15 such study design and responses to such
16 comments);

17 “(iv) research protocols (including
18 measures taken, methods of research,
19 methods of analysis, research results, and
20 such other information as the Institute de-
21 termines appropriate) with respect to each
22 medical treatment, service, and item de-
23 scribed in subsection (a)(2)(B);

1 “(v) any key decisions made by the
2 Institute and any appropriate committees
3 of the Institute;

4 “(vi) the identity of investigators con-
5 ducting such research and any conflicts of
6 interest of such investigators; and

7 “(vii) any progress reports the Insti-
8 tute determines appropriate.

9 “(B) Notice of each of the public comment
10 periods under paragraph (1)(A), including
11 deadlines for public comments for such periods.

12 “(C) Public comments submitted during
13 each of the public comment periods under para-
14 graph (1)(A), including such public comments
15 submitted on draft findings under clause (iii) of
16 such paragraph.

17 “(D) Bylaws, processes, and proceedings of
18 the Institute, to the extent practicable and as
19 the Institute determines appropriate.

20 “(E) Not later than 90 days after receipt
21 by the Institute of a relevant report or research
22 findings, appropriate information contained in
23 such report or findings.

24 “(4) CONFLICTS OF INTEREST.—The Institute
25 shall—

1 “(A) in appointing members to an expert
2 advisory panel under subsection (d)(5) and the
3 methodology committee under subsection (d)(7),
4 and in selecting individuals to contribute to any
5 peer-review process under subsection (d)(8) and
6 for employment as executive staff of the Insti-
7 tute, take into consideration any conflicts of in-
8 terest of potential appointees, participants, and
9 staff; and

10 “(B) include a description of any such con-
11 flicts of interest and conflicts of interest of
12 Board members in the annual report under sub-
13 section (d)(12), except that, in the case of indi-
14 viduals contributing to any such peer review
15 process, such description shall be in a manner
16 such that those individuals cannot be identified
17 with a particular research project.

18 “(j) RULES.—

19 “(1) GIFTS.—The Institute, or the Board and
20 staff of the Institute acting on behalf of the Insti-
21 tute, may not accept gifts, bequeaths, or donations
22 of services or property.

23 “(2) ESTABLISHMENT AND PROHIBITION ON
24 ACCEPTING OUTSIDE FUNDING OR CONTRIBU-
25 TIONS.—The Institute may not—

1 “(A) establish a corporation other than as
2 provided under this section; or

3 “(B) accept any funds or contributions
4 other than as provided under this part.

5 “(k) RULES OF CONSTRUCTION.—

6 “(1) COVERAGE.—Nothing in this section shall
7 be construed—

8 “(A) to permit the Institute to mandate
9 coverage, reimbursement, or other policies for
10 any public or private payer; or

11 “(B) as preventing the Secretary from cov-
12 ering the routine costs of clinical care received
13 by an individual entitled to, or enrolled for, ben-
14 efits under title XVIII, XIX, or XXI in the case
15 where such individual is participating in a clin-
16 ical trial and such costs would otherwise be cov-
17 ered under such title with respect to the bene-
18 ficiary.

19 “(2) REPORTS AND FINDINGS.—None of the re-
20 ports submitted under this section or research find-
21 ings disseminated by the Institute shall be construed
22 as mandates, guidelines, or recommendations for
23 payment, coverage, or treatment.

1 “LIMITATIONS ON USE OF COMPARATIVE EFFECTIVENESS
2 RESEARCH BY THE SECRETARY

3 “SEC. 1182. The Secretary may only use evidence
4 and findings from comparative effectiveness research con-
5 ducted under section 1181 to make a determination re-
6 garding coverage under title XVIII if such use is through
7 an iterative and transparent process which meets the fol-
8 lowing requirements:

9 “(1) Stakeholders and other individuals have
10 the opportunity to provide informed and relevant in-
11 formation with respect to the determination.

12 “(2) Stakeholders and other individuals have
13 the opportunity to review draft proposals of the de-
14 termination and submit public comments with re-
15 spect to such draft proposals.

16 “(3) In making the determination, the Sec-
17 retary considers—

18 “(A) all other relevant evidence, studies,
19 and research in addition to such comparative
20 effectiveness research; and

21 “(B) evidence and research that dem-
22 onstrates or suggests a benefit of coverage with
23 respect to a specific subpopulation of individ-
24 uals, even if the evidence and findings from the
25 comparative effectiveness research demonstrates

1 or suggests that, on average, with respect to the
 2 general population the benefits of coverage do
 3 not exceed the harm.

4 “TRUST FUND TRANSFERS TO PATIENT-CENTERED
 5 OUTCOMES RESEARCH TRUST FUND

6 “SEC. 1183. (a) IN GENERAL.—The Secretary shall
 7 provide for the transfer, from the Federal Hospital Insur-
 8 ance Trust Fund under section 1817 and the Federal Sup-
 9 plementary Medical Insurance Trust Fund under section
 10 1841, in proportion (as estimated by the Secretary) to the
 11 total expenditures during such fiscal year that are made
 12 under title XVIII from the respective trust fund, to the
 13 Patient-Centered Outcomes Research Trust Fund (re-
 14 ferred to in this section as the ‘PCORTF’) under section
 15 9511 of the Internal Revenue Code of 1986, the following:

16 “(1) For fiscal year 2013, an amount equal to
 17 \$1 multiplied by the average number of individuals
 18 entitled to benefits under part A, or enrolled under
 19 part B, of title XVIII during such fiscal year.

20 “(2) For each of fiscal years 2014, 2015, 2016,
 21 2017, 2018, and 2019, an amount equal to \$2 mul-
 22 tiplied by the average number of individuals entitled
 23 to benefits under part A, or enrolled under part B,
 24 of title XVIII during such fiscal year.

25 “(b) ADJUSTMENTS FOR INCREASES IN HEALTH
 26 CARE SPENDING.—In the case of any fiscal year begin-

1 ning after September 30, 2014, the dollar amount in effect
 2 under subsection (a)(2) for such fiscal year shall be equal
 3 to the sum of such dollar amount for the previous fiscal
 4 year (determined after the application of this subsection),
 5 plus an amount equal to the product of—

6 “(1) such dollar amount for the previous fiscal
 7 year, multiplied by

8 “(2) the percentage increase in the projected
 9 per capita amount of National Health Expenditures
 10 from the calendar year in which the previous fiscal
 11 year ends to the calendar year in which the fiscal
 12 year involved ends, as most recently published by the
 13 Secretary before the beginning of the fiscal year.”.

14 (b) COORDINATION WITH PROVIDER EDUCATION
 15 AND TECHNICAL ASSISTANCE.—Section 1889(a) of the
 16 Social Security Act (42 U.S.C. 1395zz(a)) is amended by
 17 inserting “and to enhance the understanding of and utili-
 18 zation by providers of services and suppliers of research
 19 findings disseminated by the Patient-Centered Outcomes
 20 Research Institute established under section 1181” before
 21 the period at the end.

22 (c) PATIENT-CENTERED OUTCOMES RESEARCH
 23 TRUST FUND; FINANCING FOR TRUST FUND.—

24 (1) ESTABLISHMENT OF TRUST FUND.—

1 (A) IN GENERAL.—Subchapter A of chap-
2 ter 98 of the Internal Revenue Code of 1986
3 (relating to establishment of trust funds) is
4 amended by adding at the end the following
5 new section:

6 **“SEC. 9511. PATIENT-CENTERED OUTCOMES RESEARCH**
7 **TRUST FUND.**

8 “(a) CREATION OF TRUST FUND.—There is estab-
9 lished in the Treasury of the United States a trust fund
10 to be known as the ‘Patient-Centered Outcomes Research
11 Trust Fund’ (hereafter in this section referred to as the
12 ‘PCORTF’), consisting of such amounts as may be appro-
13 priated or credited to such Trust Fund as provided in this
14 section and section 9602(b).

15 “(b) TRANSFERS TO FUND.—

16 “(1) APPROPRIATION.—There are hereby ap-
17 propriated to the Trust Fund the following:

18 “(A) For fiscal year 2010, \$10,000,000.

19 “(B) For fiscal year 2011, \$50,000,000.

20 “(C) For fiscal year 2012, \$150,000,000.

21 “(D) For fiscal year 2013—

22 “(i) an amount equivalent to the net
23 revenues received in the Treasury from the
24 fees imposed under subchapter B of chap-
25 ter 34 (relating to fees on health insurance

1 and self-insured plans) for such fiscal year;

2 and

3 “(ii) \$150,000,000.

4 “(E) For each of fiscal years 2014, 2015,
5 2016, 2017, 2018, and 2019—

6 “(i) an amount equivalent to the net
7 revenues received in the Treasury from the
8 fees imposed under subchapter B of chap-
9 ter 34 (relating to fees on health insurance
10 and self-insured plans) for such fiscal year;

11 and

12 “(ii) \$150,000,000.

13 The amounts appropriated under subparagraphs
14 (A), (B), (C), (D)(ii), and (E)(ii) shall be trans-
15 ferred from the general fund of the Treasury, from
16 funds not otherwise appropriated.

17 “(2) TRUST FUND TRANSFERS.—In addition to
18 the amounts appropriated under paragraph (1),
19 there shall be credited to the PCORTF the amounts
20 transferred under section 1183 of the Social Secu-
21 rity Act.

22 “(3) AMERICAN RECOVERY AND REINVESTMENT
23 FUNDS.—In addition to the amounts appropriated
24 under paragraph (1) and the amounts credited
25 under paragraph (2), of amounts appropriated for

1 comparative effectiveness research to be allocated at
2 the discretion of the Secretary of Health and
3 Human Services under the heading Agency for
4 Healthcare Research and Quality under the heading
5 Department of Health and Human Services under
6 title VIII of Division A of the American Recovery
7 and Reinvestment Act of 2009 (Public Law 111–5),
8 \$10,000,000 shall be transferred to the Trust Fund.

9 “(4) LIMITATION ON TRANSFERS TO PCORTF.—

10 No amount may be appropriated or transferred to
11 the PCORTF on and after the date of any expendi-
12 ture from the PCORTF which is not an expenditure
13 permitted under this section. The determination of
14 whether an expenditure is so permitted shall be
15 made without regard to—

16 “(A) any provision of law which is not con-
17 tained or referenced in this chapter or in a rev-
18 enue Act, and

19 “(B) whether such provision of law is a
20 subsequently enacted provision or directly or in-
21 directly seeks to waive the application of this
22 paragraph.

23 “(c) TRUSTEE.—The Secretary of Health and
24 Human Services shall be a trustee of the PCORTF.

1 “(d) EXPENDITURES FROM FUND.—Amounts in the
 2 PCORTF are available, without further appropriation, to
 3 the Patient-Centered Outcomes Research Institute estab-
 4 lished by section 2(a) of the Patient-Centered Outcomes
 5 Research Act of 2009 for carrying out part D of title XI
 6 of the Social Security Act (as in effect on the date of en-
 7 actment of the Patient-Centered Outcomes Research Act
 8 of 2009).

9 “(e) NET REVENUES.—For purposes of this section,
 10 the term ‘net revenues’ means the amount estimated by
 11 the Secretary of the Treasury based on the excess of—

12 “(1) the fees received in the Treasury under
 13 subchapter B of chapter 34, over

14 “(2) the decrease in the tax imposed by chapter
 15 1 resulting from the fees imposed by such sub-
 16 chapter.

17 “(f) TERMINATION.—No amounts shall be available
 18 for expenditure from the PCORTF after September 30,
 19 2019, and any amounts in such Trust Fund after such
 20 date shall be transferred to the general fund of the Treas-
 21 ury.”.

22 (B) CLERICAL AMENDMENT.—The table of
 23 sections for subchapter A of chapter 98 of such
 24 Code is amended by adding at the end the fol-
 25 lowing new item:

“Sec. 9511. Patient-Centered Outcomes Research Trust Fund.”.

1 (2) FINANCING FOR FUND FROM FEES ON IN-
2 SURED AND SELF-INSURED HEALTH PLANS.—

3 (A) GENERAL RULE.—Chapter 34 of the
4 Internal Revenue Code of 1986 is amended by
5 adding at the end the following new subchapter:

6 **“Subchapter B—Insured and Self-Insured**
7 **Health Plans**

“Sec. 4375. Health insurance.

“Sec. 4376. Self-insured health plans.

“Sec. 4377. Definitions and special rules.

8 **“SEC. 4375. HEALTH INSURANCE.**

9 “(a) IMPOSITION OF FEE.—There is hereby imposed
10 on each specified health insurance policy for each policy
11 year ending after September 30, 2012, a fee equal to the
12 product of \$2 (\$1 in the case of policy years ending during
13 fiscal year 2013) multiplied by the average number of lives
14 covered under the policy.

15 “(b) LIABILITY FOR FEE.—The fee imposed by sub-
16 section (a) shall be paid by the issuer of the policy.

17 “(c) SPECIFIED HEALTH INSURANCE POLICY.—For
18 purposes of this section:

19 “(1) IN GENERAL.—Except as otherwise pro-
20 vided in this section, the term ‘specified health in-
21 surance policy’ means any accident or health insur-
22 ance policy (including a policy under a group health
23 plan) issued with respect to individuals residing in
24 the United States.

1 “(2) EXEMPTION FOR CERTAIN POLICIES.—The
 2 term ‘specified health insurance policy’ does not in-
 3 clude any insurance if substantially all of its cov-
 4 erage is of excepted benefits described in section
 5 9832(e).

6 “(3) TREATMENT OF PREPAID HEALTH COV-
 7 ERAGE ARRANGEMENTS.—

8 “(A) IN GENERAL.—In the case of any ar-
 9 rangement described in subparagraph (B)—

10 “(i) such arrangement shall be treated
 11 as a specified health insurance policy, and

12 “(ii) the person referred to in such
 13 subparagraph shall be treated as the
 14 issuer.

15 “(B) DESCRIPTION OF ARRANGEMENTS.—

16 An arrangement is described in this subpara-
 17 graph if under such arrangement fixed pay-
 18 ments or premiums are received as consider-
 19 ation for any person’s agreement to provide or
 20 arrange for the provision of accident or health
 21 coverage to residents of the United States, re-
 22 gardless of how such coverage is provided or ar-
 23 ranged to be provided.

24 “(d) ADJUSTMENTS FOR INCREASES IN HEALTH
 25 CARE SPENDING.—In the case of any policy year ending

1 in any fiscal year beginning after September 30, 2014, the
 2 dollar amount in effect under subsection (a) for such pol-
 3 icy year shall be equal to the sum of such dollar amount
 4 for policy years ending in the previous fiscal year (deter-
 5 mined after the application of this subsection), plus an
 6 amount equal to the product of—

7 “(1) such dollar amount for policy years ending
 8 in the previous fiscal year, multiplied by

9 “(2) the percentage increase in the projected
 10 per capita amount of National Health Expenditures
 11 from the calendar year in which the previous fiscal
 12 year ends to the calendar year in which the fiscal
 13 year involved ends, as most recently published by the
 14 Secretary of Health and Human Services before the
 15 beginning of the fiscal year.

16 “(e) TERMINATION.—This section shall not apply to
 17 policy years ending after September 30, 2019.

18 **“SEC. 4376. SELF-INSURED HEALTH PLANS.**

19 “(a) IMPOSITION OF FEE.—In the case of any appli-
 20 cable self-insured health plan for each plan year ending
 21 after September 30, 2012, there is hereby imposed a fee
 22 equal to \$2 (\$1 in the case of plan years ending during
 23 fiscal year 2013) multiplied by the average number of lives
 24 covered under the plan.

25 “(b) LIABILITY FOR FEE.—

1 “(1) IN GENERAL.—The fee imposed by sub-
2 section (a) shall be paid by the plan sponsor.

3 “(2) PLAN SPONSOR.—For purposes of para-
4 graph (1) the term ‘plan sponsor’ means—

5 “(A) the employer in the case of a plan es-
6 tablished or maintained by a single employer,

7 “(B) the employee organization in the case
8 of a plan established or maintained by an em-
9 ployee organization,

10 “(C) in the case of—

11 “(i) a plan established or maintained
12 by 2 or more employers or jointly by 1 or
13 more employers and 1 or more employee
14 organizations,

15 “(ii) a multiple employer welfare ar-
16 rangement, or

17 “(iii) a voluntary employees’ bene-
18 ficiary association described in section
19 501(c)(9),

20 the association, committee, joint board of trust-
21 ees, or other similar group of representatives of
22 the parties who establish or maintain the plan,
23 or

24 “(D) the cooperative or association de-
25 scribed in subsection (c)(2)(F) in the case of a

1 plan established or maintained by such a coop-
2 erative or association.

3 “(c) APPLICABLE SELF-INSURED HEALTH PLAN.—

4 For purposes of this section, the term ‘applicable self-in-
5 sured health plan’ means any plan for providing accident
6 or health coverage if—

7 “(1) any portion of such coverage is provided
8 other than through an insurance policy, and

9 “(2) such plan is established or maintained—

10 “(A) by one or more employers for the
11 benefit of their employees or former employees,

12 “(B) by one or more employee organiza-
13 tions for the benefit of their members or former
14 members,

15 “(C) jointly by 1 or more employers and 1
16 or more employee organizations for the benefit
17 of employees or former employees,

18 “(D) by a voluntary employees’ beneficiary
19 association described in section 501(c)(9),

20 “(E) by any organization described in sec-
21 tion 501(c)(6), or

22 “(F) in the case of a plan not described in
23 the preceding subparagraphs, by a multiple em-
24 ployer welfare arrangement (as defined in sec-
25 tion 3(40) of Employee Retirement Income Se-

1 curity Act of 1974), a rural electric cooperative
2 (as defined in section 3(40)(B)(iv) of such Act),
3 or a rural telephone cooperative association (as
4 defined in section 3(40)(B)(v) of such Act).

5 “(d) ADJUSTMENTS FOR INCREASES IN HEALTH
6 CARE SPENDING.—In the case of any plan year ending
7 in any fiscal year beginning after September 30, 2014, the
8 dollar amount in effect under subsection (a) for such plan
9 year shall be equal to the sum of such dollar amount for
10 plan years ending in the previous fiscal year (determined
11 after the application of this subsection), plus an amount
12 equal to the product of—

13 “(1) such dollar amount for plan years ending
14 in the previous fiscal year, multiplied by

15 “(2) the percentage increase in the projected
16 per capita amount of National Health Expenditures
17 from the calendar year in which the previous fiscal
18 year ends to the calendar year in which the fiscal
19 year involved ends, as most recently published by the
20 Secretary of Health and Human Services before the
21 beginning of the fiscal year.

22 “(e) TERMINATION.—This section shall not apply to
23 plan years ending after September 30, 2019.

1 **“SEC. 4377. DEFINITIONS AND SPECIAL RULES.**

2 “(a) DEFINITIONS.—For purposes of this sub-
3 chapter—

4 “(1) ACCIDENT AND HEALTH COVERAGE.—The
5 term ‘accident and health coverage’ means any cov-
6 erage which, if provided by an insurance policy,
7 would cause such policy to be a specified health in-
8 surance policy (as defined in section 4375(c)).

9 “(2) INSURANCE POLICY.—The term ‘insurance
10 policy’ means any policy or other instrument where-
11 by a contract of insurance is issued, renewed, or ex-
12 tended.

13 “(3) UNITED STATES.—The term ‘United
14 States’ includes any possession of the United States.

15 “(b) TREATMENT OF GOVERNMENTAL ENTITIES.—

16 “(1) IN GENERAL.—For purposes of this sub-
17 chapter—

18 “(A) the term ‘person’ includes any gov-
19 ernmental entity, and

20 “(B) notwithstanding any other law or rule
21 of law, governmental entities shall not be ex-
22 empt from the fees imposed by this subchapter
23 except as provided in paragraph (2).

24 “(2) TREATMENT OF EXEMPT GOVERNMENTAL
25 PROGRAMS.—In the case of an exempt governmental
26 program, no fee shall be imposed under section 4375

1 or section 4376 on any covered life under such pro-
2 gram.

3 “(3) EXEMPT GOVERNMENTAL PROGRAM DE-
4 FINED.—For purposes of this subchapter, the term
5 ‘exempt governmental program’ means—

6 “(A) any insurance program established
7 under title XVIII of the Social Security Act,

8 “(B) the medical assistance program es-
9 tablished by title XIX or XXI of the Social Se-
10 curity Act,

11 “(C) any program established by Federal
12 law for providing medical care (other than
13 through insurance policies) to individuals (or
14 the spouses and dependents thereof) by reason
15 of such individuals being—

16 “(i) members of the Armed Forces of
17 the United States, or

18 “(ii) veterans, and

19 “(D) any program established by Federal
20 law for providing medical care (other than
21 through insurance policies) to members of In-
22 dian tribes (as defined in section 4(d) of the In-
23 dian Health Care Improvement Act).

1 “(c) TREATMENT AS TAX.—For purposes of subtitle
2 F, the fees imposed by this subchapter shall be treated
3 as if they were taxes.

4 “(d) NO COVER OVER TO POSSESSIONS.—Notwith-
5 standing any other provision of law, no amount collected
6 under this subchapter shall be covered over to any posses-
7 sion of the United States.”.

8 (B) CLERICAL AMENDMENTS.—

9 (i) Chapter 34 of such Code is amend-
10 ed by striking the chapter heading and in-
11 serting the following:

12 **“CHAPTER 34—TAXES ON CERTAIN**
13 **INSURANCE POLICIES**

 “SUBCHAPTER A. POLICIES ISSUED BY FOREIGN INSURERS

 “SUBCHAPTER B. INSURED AND SELF-INSURED HEALTH PLANS

14 **“Subchapter A—Policies Issued By Foreign**
15 **Insurers”.**

16 (ii) The table of chapters for subtitle
17 D of such Code is amended by striking the
18 item relating to chapter 34 and inserting
19 the following new item:

 “CHAPTER 34—TAXES ON CERTAIN INSURANCE POLICIES”.

1 **SEC. 3. COORDINATION WITH FEDERAL COORDINATING**
 2 **COUNCIL FOR COMPARATIVE EFFECTIVE-**
 3 **NESS RESEARCH.**

4 Section 804 of Division A of the American Recovery
 5 and Reinvestment Act of 2009 (42 U.S.C. 299b–8) is
 6 amended—

7 (1) in subsection (c)—

8 (A) in paragraph (1), by striking “and” at
 9 the end;

10 (B) in paragraph (2), by striking the pe-
 11 riod at the end and inserting “; and”; and

12 (C) by adding at the end the following new
 13 paragraph:

14 “(3) provide support to the Patient-Centered
 15 Outcomes Research Institute established under sec-
 16 tion 1181(b)(1) of the Social Security Act (referred
 17 to in this section as the ‘Institute’).”;

18 (2) in subsection (d)(2)—

19 (A) by redesignating subparagraph (B) as
 20 subparagraph (C); and

21 (B) by inserting after subparagraph (A)
 22 the following new subparagraph:

23 “(B) INCLUSION OF CHAIRPERSON OF THE
 24 BOARD OF GOVERNORS OF THE PATIENT-CEN-
 25 TERED OUTCOMES RESEARCH INSTITUTE.—In
 26 the case where the Chairperson of the Board of

1 Governors of the Patient-Centered Outcomes
2 Research Institute established under section
3 1181(f) of the Social Security Act is a senior
4 Federal officer or employee with responsibility
5 for a health-related program, the members of
6 the council shall include such Chairperson.”.

7 (3) in subsection (e)(2), by striking “regarding
8 its activities” and all that follows through the period
9 at the end and inserting “containing—

10 “(A) an inventory of its activities with re-
11 spect to comparative effectiveness research con-
12 ducted by relevant Federal departments and
13 agencies; and

14 “(B) recommendations concerning better
15 coordination of comparative effectiveness re-
16 search by such departments and agencies.”;

17 (4) by redesignating subsection (g) as sub-
18 section (h); and

19 (5) by inserting after subsection (f) the fol-
20 lowing new subsection:

21 “(g) COORDINATION WITH THE PATIENT-CENTERED
22 OUTCOMES RESEARCH INSTITUTE.—The Council shall co-
23 ordinate with the Institute in carrying out its duties under
24 this section.”.

1 **SEC. 4. GAO REPORT ON NATIONAL COVERAGE DETER-**
2 **MINATIONS PROCESS.**

3 Not later than 18 months after the date of enactment
4 of this Act, the Comptroller General of the United States
5 shall submit a report to Congress on the process for mak-
6 ing national coverage determinations (as defined in section
7 1869(f)(1)(B) of the Social Security Act (42 U.S.C.
8 1395ff(f)(1)(B))) under the Medicare program under title
9 XVIII of the Social Security Act. Such report shall include
10 a determination whether, in initiating and conducting such
11 process, the Secretary of Health and Human Services has
12 complied with applicable law and regulations, including re-
13 quirements for consultation with appropriate outside ex-
14 perts, providing appropriate notice and comment opportu-
15 nities to the public, and making information and data
16 (other than proprietary data) considered in making such
17 determinations available to the public and to nonvoting
18 members of any advisory committees established to advise
19 the Secretary with respect to such determinations.

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