

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.

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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

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## 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) 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(c).

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 sserting 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.

○