111TH CONGRESS
1ST SESSION

S. _____

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

Mr. BAUCUS (for himself and Mr. CONRAD) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title XI of the Social Security Act to 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patient-Centered Outcomes Research Act of 2009''.

SEC. 2. COMPARATIVE EFFECTIVENESS RESEARCH.

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

"PART D—COMPARATIVE EFFECTIVENESS RESEARCH

"COMPARATIVE EFFECTIVENESS RESEARCH

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

"(1) BOARD.—The term 'Board' means the Board of Governors established under subsection (f).

"(2) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.—

"(A) IN GENERAL.—The term 'comparative clinical effectiveness research' means research evaluating and comparing the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

"(B) MEDICAL TREATMENTS, SERVICES, AND ITEMS DESCRIBED.—The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), and any other strategies or items being used in the treatment, management, and

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

"(3) COMPARATIVE EFFECTIVENESS RESEARCH.—The term 'comparative effectiveness research' means research evaluating and comparing the implications and outcomes of 2 or more health care strategies to address a particular medical condition for specific patient populations.

"(4) CONFLICTS OF INTEREST.—The term 'conflicts of interest' means associations, including financial and personal, that may be reasonably assumed to have the potential to bias an individual's decisions in matters related to the Institute or the conduct of activities under this section.

"(5) INSTITUTE.—The term 'Institute' means the 'Patient-Centered Outcomes Research Institute' established under subsection (b)(1).

"(b) PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—

"(1) ESTABLISHMENT.—There is authorized to be established a nonprofit corporation, to be known as the "Patient-Centered Outcomes Research Institute" which is neither an agency nor establishment of the United States Government.

"(2) APPLICATION OF PROVISIONS.—The Institute shall be subject to the provisions of this section, and, to the extent consistent with this section, to the District of Columbia Nonprofit Corporation Act.

"(3) FUNDING OF COMPARATIVE EFFECTIVENESS RESEARCH.—For fiscal year 2010 and each subsequent fiscal year, amounts in the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the 'PCORTF') under section 9511 of the Internal Revenue Code of 1986 shall be available, without further appropriation, to the Institute to carry out this section.

"(c) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative clinical outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).

"(d) DUTIES.—

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

"(A) IDENTIFYING RESEARCH PRIORITIES.—The Institute shall identify national priorities for comparative clinical effectiveness research, taking into account factors, including—

"(i) disease incidence, prevalence, and burden in the United States;

"(ii) evidence gaps in terms of clinical outcomes;

"(iii) practice variations, including variations in delivery and outcomes by geography, treatment site, provider type, and patient subgroup;

"(iv) the potential for new evidence concerning certain categories of health care services or treatments to improve patient health and well-being, and the quality of care;

"(v) the effect or potential for an effect on health expenditures associated with a health condition or the use of a particular medical treatment, service, or item;

"(vi) the effect or potential for an effect on patient needs, outcomes, and preferences, including quality of life; and

"(vii) the relevance to assisting patients and clinicians in making informed health decisions.

"(B) ESTABLISHING RESEARCH PROJECT AGENDA.—

"(i) IN GENERAL.—The Institute shall establish and update a research project agenda for comparative clinical effectiveness research to address the priorities identified under subparagraph (A), taking into consideration the types of such research that might address each priority and the relative value (determined based on the cost of conducting such research compared to the potential usefulness of the information produced by such research) associated with the different types of research, and such other factors as the Institute determines appropriate.

"(ii) CONSIDERATION OF NEED TO CONDUCT A SYSTEMATIC REVIEW.—In establishing and updating the research

project agenda under clause (i), the Institute shall consider the need to conduct a systematic review of existing research before providing for the conduct of new research under paragraph (2)(A).

"(2) CARRYING OUT RESEARCH PROJECT AGENDA.—

"(A) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.—In carrying out the research project agenda established under paragraph (1)(B), the Institute shall provide for the conduct of appropriate research and the synthesis of evidence, in accordance with the methodological standards adopted under paragraph (10), using methods, including the following:

"(i) Systematic reviews and assessments of existing research and evidence.

"(ii) Primary research, such as randomized clinical trials, molecularly informed trials, and observational studies.

"(iii) Any other methodologies recommended by the methodology committee established under paragraph (7) that are adopted by the Board under paragraph (10).

"(B) CONTRACTS FOR THE MANAGEMENT AND CONDUCT OF RESEARCH.—

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

"(I) Agencies and instrumentalities of the Federal Government that have experience in conducting comparative clinical effectiveness research, such as the Agency for Healthcare Research and Quality, to the extent that such contracts are authorized under the governing statutes of such agencies and instrumentalities.

"(II) Appropriate private sector research or study-conducting entities that have demonstrated the experience and capacity to achieve the goals of comparative effectiveness research.

"(ii) CONDITIONS FOR CONTRACTS.—A contract entered into under this subparagraph shall require that the agency, instrumentality, or other entity—

"(I) abide by the transparency and conflicts of interest requirements that apply to the Institute with respect to the research managed or conducted under such contract;

"(II) comply with the methodological standards adopted under paragraph (10) with respect to such research;

"(III) take into consideration public comments on the study design that are transmitted by the Institute to the agency, instrumentality, or other entity under subsection (i)(1)(B) during the finalization of the study design and transmit responses to such comments to the Institute, which will publish such comments, responses, and finalized study design in accordance with subsection (i)(3)(A)(iii) prior to the conduct of such research; and

"(IV) in the case where the agency, instrumentality, or other entity is managing or conducting a compara-

tive effectiveness research study for a rare disease, consult with the expert advisory panel for rare disease appointed under paragraph (5)(A)(iii) with respect to such research study.

"(iii) COVERAGE OF COPAYMENTS OR COINSURANCE.—A contract entered into under this subparagraph may allow for the coverage of copayments or co-insurance, or allow for other appropriate measures, to the extent that such coverage or other measures are necessary to preserve the validity of a research project, such as in the case where the research project must be blinded.

"(C) REVIEW AND UPDATE OF EVIDENCE.—The Institute shall review and update evidence on a periodic basis, in order to take into account new research, evolving evidence, advances in medical technology, and changes in the standard of care as they become available, as appropriate.

"(D) TAKING INTO ACCOUNT POTENTIAL DIFFERENCES.—Research shall—

"(i) be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care treatments, services, and items as used with various subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular subtypes, or quality of life preferences; and

"(ii) include members of such subpopulations as subjects in the research as feasible and appropriate.

"(E) DIFFERENCES IN TREATMENT MODALITIES.—Research shall be designed, as appropriate, to take into account different characteristics of treatment modalities that may affect research outcomes, such as the phase of the treatment modality in the innovation cycle and the impact of the skill of the operator of the treatment modality.

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

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

"(B) REPORT.—Not later than 5 years after the date of enactment of this section, the Institute shall submit a report to Congress containing the results of the study conducted under subparagraph (A).

"(4) DATA COLLECTION.—

"(A) IN GENERAL.—The Secretary shall, with appropriate safeguards for privacy, make available to the Institute such data collected by the Centers for Medicare & Medicaid Services under the programs under titles XVIII, XIX, and XXI as the Institute may require to carry out this section. The Institute may also request and, if such request is granted, obtain data from Federal, State, or private entities, including data from clinical databases and registries.

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

"(5) APPOINTING EXPERT ADVISORY PANELS.—

"(A) APPOINTMENT.—

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

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

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

"(iii) EXPERT ADVISORY PANEL FOR RARE DISEASE.—In the case of a comparative effectiveness research study for rare disease, the Institute shall appoint an expert advisory panel for purposes of assisting in the design of such research study and determining the relative value and feasibility of conducting such research study.

"(B) COMPOSITION.—

"(i) IN GENERAL.—An expert advisory panel appointed under subparagraph (A) shall include individuals who have experience in the relevant topic, project, or category for which the panel is established, including—

"(I) practicing and research clinicians (including relevant specialists and subspecialists), patients, and representatives of patients; and

"(II) experts in scientific and health services research, health serv-

ices delivery, and evidence-based medicine.

"(ii) INCLUSION OF REPRESENTATIVES OF MANUFACTURERS OF MEDICAL TECHNOLOGY.—An expert advisory panel appointed under subparagraph (A) may include a representative of each manufacturer of each medical technology that is included under the relevant topic, project, or category for which the panel is established.

"(6) SUPPORTING PATIENT AND CONSUMER REPRESENTATIVES.—The Institute shall provide support and resources to help patient and consumer representatives on the Board and expert advisory panels appointed by the Institute under paragraph (5) to effectively participate in technical discussions regarding complex research topics. Such support shall include initial and continuing education to facilitate effective engagement in activities undertaken by the Institute and may include regular and ongoing opportunities for patient and consumer representatives to interact with each other and to exchange information and support regarding their involvement in the Institute's activities. The Institute shall provide per diem and other appropriate com-

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

"(7) ESTABLISHING METHODOLOGY COMMITTEE.—

"(A) IN GENERAL.—The Institute shall establish a standing methodology committee to carry out the functions described in subparagraph (C).

"(B) APPOINTMENT AND COMPOSITION.—The methodology committee established under subparagraph (A) shall be composed of not more than 17 members appointed by the Comptroller General of the United States. Members appointed to the methodology committee shall be experts in their scientific field, such as health services research, clinical research, comparative effectiveness research, biostatistics, genomics, and research methodologies. Stakeholders with such expertise may be appointed to the methodology committee.

"(C) FUNCTIONS.—Subject to subparagraph (D), the methodology committee shall work to develop and improve the science and methods of comparative effectiveness research

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

"(i) Not later than 2 years after the date on which the members of the methodology committee are appointed under subparagraph (B), developing and periodically updating the following:

"(I) Establish and maintain methodological standards for comparative clinical effectiveness research on major categories of interventions to prevent, diagnose, or treat a clinical condition or improve the delivery of care. Such methodological standards shall provide specific criteria for internal validity, generalizability, feasibility, and timeliness of such research and for clinical outcomes measures, risk adjustment, and other relevant aspects of research and assessment with respect to the design of such research. Any methodological standards developed and updated under this subclause shall be scientifically based and 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-

mine research methods that are most likely to address each specific comparative clinical effectiveness research question.

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

"(I) Methods by which various aspects of the health care delivery system (such as benefit design and performance, and health services organization, management, information communication, and delivery) could be assessed and compared for their relative effectiveness, benefits, risks, advantages, and disadvantages in a scientifically valid and standardized way.

"(II) Methods by which efficiency and value (including the full range of harms and benefits, such as quality of life) could be assessed in a scientifically valid and standardized way.

"(D) CONSULTATION AND CONDUCT OF EXAMINATIONS.—

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

in subparagraph (C), the methodology committee shall—

"(I) consult or contract with 1 or more of the entities described in clause (ii); and

"(II) consult with stakeholders and other entities knowledgeable in relevant fields, as appropriate.

"(ii) ENTITIES DESCRIBED.—The following entities are described in this clause:

"(I) The Institute of Medicine of the National Academies.

"(II) The Agency for Healthcare Research and Quality.

"(III) The National Institutes of Health.

"(IV) Academic, non-profit, or other private entities with relevant expertise.

"(iii) CONDUCT OF EXAMINATIONS.—The methodology committee shall contract with the Institute of Medicine of the National Academies for the conduct of the examinations described in subclauses (I) and (II) of subparagraph (C)(ii).

"(E) REPORTS.—The methodology committee shall submit reports to the Board on the committee's performance of the functions described in subparagraph (C). Reports submitted under the preceding sentence with respect to the functions described in clause (i) of such subparagraph shall contain recommendations—

"(i) for the Institute to adopt methodological standards developed and updated by the methodology committee under such subparagraph; and

"(ii) for such other action as the methodology committee determines is necessary to comply with such methodological standards.

"(8) PROVIDING FOR A PEER-REVIEW PROCESS FOR PRIMARY RESEARCH.—

"(A) IN GENERAL.—The Institute shall ensure that there is a process for peer review of the research conducted under paragraph (2)(A)(ii). Under such process—

"(i) evidence from research conducted under such paragraph shall be reviewed to assess scientific integrity and adherence to

methodological standards adopted under paragraph (10); and

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

"(B) COMPOSITION.—Such peer-review process shall be designed in a manner so as to avoid bias and conflicts of interest on the part of the reviewers and shall be composed of experts in the scientific field relevant to the research under review.

"(C) USE OF EXISTING PROCESSES.—

"(i) PROCESSES OF ANOTHER ENTITY.—In the case where the Institute enters into a contract or other agreement with another entity for the conduct or management of research under this section, the Institute may utilize the peer-review process of such entity if such process meets the requirements under subparagraphs (A) and (B).

"(ii) PROCESSES OF APPROPRIATE 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;

"(iv) shall not include practice guidelines, coverage recommendations, or policy recommendations; and

"(v) shall not include any data the dissemination of which would violate the privacy of research participants or violate any confidentiality agreements made with respect to the use of data under this section.

"(B) DISSEMINATION PROTOCOLS AND STRATEGIES.—The Institute shall develop protocols and strategies for the appropriate dissemination of research findings in order to ensure effective communication of such findings and the use and incorporation of such findings into relevant activities for the purpose of informing higher quality and more effective and timely decisions regarding medical treatments, services, and items. In developing and adopting such protocols and strategies, the Institute shall consult with stakeholders, including practicing clinicians and patients, concerning the types of dissemination that will be most useful to the end users of the information and may provide

for the utilization of multiple formats for conveying findings to different audiences.

"(C) DEFINITION OF RESEARCH FINDINGS.—In this paragraph, the term 'research findings' means the results of a study or assessment.

"(10) ADOPTION.—Subject to subsection (i)(1)(A)(i), the Institute shall adopt the national priorities identified under paragraph (1)(A), the research project agenda established under paragraph (1)(B), the methodological standards developed and updated by the methodology committee under paragraph (7)(C)(i), any peer-review process provided under paragraph (8), and dissemination protocols and strategies developed under paragraph (9)(B) by majority vote. In the case where the Institute does not adopt such national priorities, research project agenda, methodological standards, peer-review process, or dissemination protocols and strategies in accordance with the preceding sentence, the national priorities, research project agenda, methodological standards, peer-review process, or dissemination protocols and strategies shall be referred to the appropriate staff or entity within the Institute (or, in the

case of the methodological standards, the methodology committee) for further review.

"(11) COORDINATION OF RESEARCH AND RESOURCES AND BUILDING CAPACITY FOR RESEARCH.—

"(A) COORDINATION OF RESEARCH AND RESOURCES.—The Institute shall coordinate research conducted, commissioned, or otherwise funded under this section with comparative clinical effectiveness and other relevant research and related efforts conducted by public and private agencies and organizations in order to ensure the most efficient use of the Institute's resources and that research is not duplicated unnecessarily.

"(B) BUILDING CAPACITY FOR RESEARCH.—The Institute may build capacity for comparative clinical effectiveness research and methodologies, including research training and development of data resources (such as clinical registries), through appropriate activities, including using up to 20 percent of the amounts appropriated or credited to the PCORTF under section 9511(b) of the Internal Revenue Code of 1986 with respect to a fiscal year to fund ex-

tramural efforts of organizations such as the Cochrane Collaboration (or a successor organization) and other organizations that develop and maintain a data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.

"(C) INCLUSION IN ANNUAL REPORTS.—The Institute shall report on any coordination and capacity building conducted under this paragraph in annual reports in accordance with paragraph (12)(E).

"(12) ANNUAL REPORTS.—The Institute shall submit an annual report to Congress and the President, and shall make the annual report available to the public. Such report shall contain—

"(A) a description of the activities conducted under this section during the preceding year, including the use of amounts appropriated or credited to the PCORTF under section 9511(b) of the Internal Revenue Code of 1986 to carry out this section, research projects completed and underway, and a summary of the findings of such projects;

"(B) the research project agenda and budget of the Institute for the following year;

"(C) a description of research priorities identified under paragraph (1)(A), dissemination protocols and strategies developed by the Institute under paragraph (9)(B), and methodological standards developed and updated by the methodology committee under paragraph (7)(C)(i) that are adopted under paragraph (10) during the preceding year;

"(D) the names of individuals contributing to any peer-review process provided under paragraph (8) during the preceding year or years, in a manner such that those individuals cannot be identified with a particular research project; and

"(E) a description of efforts by the Institute under paragraph (11) to—

"(i) coordinate the research conducted, commissioned, or otherwise funded under this section and the resources of the Institute with research and related efforts conducted by other private and public entities; and

"(ii) build capacity for comparative clinical effectiveness research and other relevant research and related efforts through appropriate activities.

"(F) any other relevant information (including information on the membership of the Board, expert advisory panels appointed under paragraph (5), the methodology committee established under paragraph (7), and the executive staff of the Institute, any conflicts of interest with respect to the members of such Board, expert advisory panels, and methodology committee, or with respect to any individuals selected for employment as executive staff of the Institute, and any bylaws adopted by the Board during the preceding year).

"(e) ADMINISTRATION.—

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

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

"(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

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

"(v) 3 members representing pharmaceutical, device, and diagnostic manufacturers or developers.

"(vi) 1 member representing nonprofit organizations involved in health services research.

"(vii) 1 member representing organizations that focus on quality measurement and improvement or decision support.

"(viii) 1 member representing independent health services researchers.

"(2) QUALIFICATIONS.—

"(A) DIVERSE REPRESENTATION OF PERSPECTIVES.—The Board shall represent a broad range of perspectives and collectively have scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics.

"(B) CONFLICTS OF INTEREST.—

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

United States shall take into consideration any conflicts of interest of potential appointees. Any conflicts of interest of members appointed to the Board under paragraph (1) shall be disclosed in accordance with subsection (i)(4)(B).

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

"(3) TERMS.—

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

"(i) 6 shall be appointed for a term of 6 years;

"(ii) 6 shall be appointed for a term of 4 years; and

"(iii) 6 shall be appointed for a term of 2 years.

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

"(C) EXPIRATION OF TERM.—Any member of the Board whose term has expired may serve until such member's successor has taken office, or until the end of the calendar year in which such member's term has expired, whichever is earlier.

"(D) VACANCIES.—

"(i) IN GENERAL.—Any member appointed to fill a vacancy prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of such term.

"(ii) VACANCIES NOT TO AFFECT POWER OF BOARD.—A vacancy on the Board shall not affect its powers, but shall be filled in the same manner as the original appointment was made.

"(4) CHAIRPERSON AND VICE-CHAIRPERSON.—

"(A) IN GENERAL.—The Comptroller General of the United States shall designate a Chairperson and Vice-Chairperson of the Board from among the members of the Board appointed under paragraph (1)(D).

"(B) TERM.—The members so designated shall serve as Chairperson and Vice-Chairperson of the Board for a period of 3 years.

"(5) COMPENSATION.—

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

"(B) TRAVEL EXPENSES.—While away from home or regular place of business in the performance of duties for the Board, each member of the Board may receive reasonable travel, subsistence, and other necessary expenses.

"(6) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—The Board may—

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

"(B) seek such assistance and support as may be required in the performance of the duties of the Institute from appropriate departments and agencies of the Federal Government;

"(C) enter into contracts or make other arrangements and make such payments as may be necessary for performance of the duties of the Institute;

"(D) provide travel, subsistence, and per diem compensation for individuals performing the duties of the Institute, including members of any expert advisory panel appointed under subsection (d)(5), members of the methodology committee established under subsection (d)(7), and individuals selected to contribute to any peer-review process under subsection (d)(8); and

"(E) prescribe such rules, regulations, and bylaws as the Board determines necessary with respect to the internal organization and operation of the Institute.

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

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

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

"(g) FINANCIAL OVERSIGHT.—

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

"(2) REVIEW OF AUDIT AND REPORT TO CONGRESS.—The Comptroller General of the United States shall—

"(A) review the results of the audits conducted under paragraph (1); and

"(B) submit a report to Congress containing the results of such audits and review.

"(h) GOVERNMENTAL OVERSIGHT.—

"(1) REVIEW AND REPORTS.—

"(A) IN GENERAL.—The Comptroller General of the United States shall review the following:

"(i) Processes established by the Institute, including those with respect to the identification of research priorities under subsection (d)(1)(A) and the conduct of research projects under this section. Such review shall determine whether information produced by such research projects—

"(I) is objective and credible;

"(II) is produced in a manner consistent with the requirements under this section; and

"(III) is developed through a transparent process.

"(ii) The overall effect of the Institute and the effectiveness of activities conducted under this section, including an assessment of—

"(I) the utilization of the findings of research conducted under this section by health care decision makers; and

"(II) the effect of the Institute and such activities on innovation and on the health economy of the United States.

"(B) REPORTS.—Not later than 5 years after the date of enactment of this section, and not less frequently than every 5 years thereafter, the Comptroller General of the United States shall submit a report to Congress containing the results of the review conducted under subparagraph (A), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

"(2) FUNDING ASSESSMENT.—

"(A) IN GENERAL.—The Comptroller General of the United States shall assess the adequacy and use of funding for the Institute and activities conducted under this section under the PCORTF under section 9511 of the Internal Revenue Code of 1986. Such assessment shall include a determination as to whether, based on the utilization of findings by public and private payers, each of the following are appropriate sources of funding for the Institute, including a determination of whether such sources of funding should be continued or adjusted, or whether other sources of funding not

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

"(i) The transfer of funds from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the PCORTF under section 1183.

"(ii) The amounts appropriated under subparagraphs (A), (B), (C), (D)(ii), and (E)(ii) of subsection (b)(1) of such section 9511.

"(iii) Private sector contributions under subparagraphs (D)(i) and (E)(i) of such subsection (b)(1).

"(B) REPORT.—Not later than 8 years after the date of enactment of this section, the Comptroller General of the United States shall submit a report to Congress containing the results of the assessment conducted under subparagraph (A), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

"(i) ENSURING TRANSPARENCY, CREDIBILITY, AND ACCESS.—The Institute shall establish procedures to ensure that the following requirements for ensuring transparency, credibility, and access are met:

"(1) PUBLIC COMMENT PERIODS.—

"(A) IN GENERAL.—The Institute shall provide for a public comment period of not less than 45 and not more than 60 days at the following times:

"(i) Prior to the adoption of the national priorities identified under subsection (d)(1)(A), the research project agenda established under subsection (d)(1)(B), the methodological standards developed and updated by the methodology committee under subsection (d)(7)(C)(i), the peer-review process generally provided under subsection (d)(8), and dissemination protocols and strategies developed by the Institute under subsection (d)(9)(B) in accordance with subsection (d)(10).

"(ii) Prior to the finalization of individual study designs.

"(iii) After the release of draft findings with respect to a systematic review

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

"(B) TRANSMISSION OF PUBLIC COMMENTS ON STUDY DESIGN.—The Institute shall transmit public comments submitted during the public comment period described in subparagraph (A)(ii) to the entity conducting research with respect to which the individual study design is being finalized.

"(2) ADDITIONAL FORUMS.—The Institute shall, in addition to the public comment periods described in paragraph (1)(A), support forums to increase public awareness and obtain and incorporate public input and feedback through media (such as an Internet website) on the following:

"(A) The identification of research priorities, including research topics, and the establishment of the research project agenda under subparagraphs (A) and (B), respectively, of subsection (d)(1).

"(B) Research findings.

"(C) Any other duties, activities, or processes the Institute determines appropriate.

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

through the official public Internet website of the Institute, and through other forums and media the Institute determines appropriate, the following:

"(A) The process and methods for the conduct of research under this section, including—

"(i) the identity of the entity conducting such research;

"(ii) any links the entity has to industry (including such links that are not directly tied to the particular research being conducted under this section);

"(iii) draft study designs (including research questions and the finalized study design, together with public comments on such study design and responses to such comments);

"(iv) research protocols (including measures taken, methods of research, methods of analysis, research results, and such other information as the Institute determines appropriate) with respect to each medical treatment, service, and item described in subsection (a)(2)(B);

"(v) any key decisions made by the Institute and any appropriate committees of the Institute;

"(vi) the identity of investigators conducting such research and any conflicts of interest of such investigators; and

"(vii) any progress reports the Institute determines appropriate.

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

"(C) Public comments submitted during each of the public comment periods under paragraph (1)(A), including such public comments submitted on draft findings under clause (iii) of such paragraph.

"(D) Bylaws, processes, and proceedings of the Institute, to the extent practicable and as the Institute determines appropriate.

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

"(4) CONFLICTS OF INTEREST.—The Institute shall—

"(A) in appointing members to an expert advisory panel under subsection (d)(5) and the methodology committee under subsection (d)(7), and in selecting individuals to contribute to any peer-review process under subsection (d)(8) and for employment as executive staff of the Institute, take into consideration any conflicts of interest of potential appointees, participants, and staff; and

"(B) include a description of any such conflicts of interest and conflicts of interest of Board members in the annual report under subsection (d)(12), except that, in the case of individuals contributing to any such peer review process, such description shall be in a manner such that those individuals cannot be identified with a particular research project.

"(j) RULES.—

"(1) GIFTS.—The Institute, or the Board and staff of the Institute acting on behalf of the Institute, may not accept gifts, bequeaths, or donations of services or property.

"(2) ESTABLISHMENT AND PROHIBITION ON ACCEPTING OUTSIDE FUNDING OR CONTRIBUTIONS.—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.

"LIMITATIONS ON USE OF COMPARATIVE EFFECTIVENESS RESEARCH BY THE SECRETARY

"SEC. 1182. The Secretary may only use evidence and findings from comparative effectiveness research conducted under section 1181 to make a determination regarding coverage under title XVIII if such use is through an iterative and transparent process which meets the following requirements:

"(1) Stakeholders and other individuals have the opportunity to provide informed and relevant information with respect to the determination.

"(2) Stakeholders and other individuals have the opportunity to review draft proposals of the determination and submit public comments with respect to such draft proposals.

"(3) In making the determination, the Secretary considers—

"(A) all other relevant evidence, studies, and research in addition to such comparative effectiveness research; and

"(B) evidence and research that demonstrates or suggests a benefit of coverage with respect to a specific subpopulation of individuals, even if the evidence and findings from the comparative effectiveness research demonstrates

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

"TRUST FUND TRANSFERS TO PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND

"SEC. 1183. (a) IN GENERAL.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841, in proportion (as estimated by the Secretary) to the total expenditures during such fiscal year that are made under title XVIII from the respective trust fund, to the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the 'PCORTF') under section 9511 of the Internal Revenue Code of 1986, the following:

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

"(2) For each of fiscal years 2014, 2015, 2016, 2017, 2018, and 2019, an amount equal to $2 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of title XVIII during such fiscal year.

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

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

"(1) such dollar amount for the previous fiscal year, multiplied by

"(2) the percentage increase in the projected per capita amount of National Health Expenditures from the calendar year in which the previous fiscal year ends to the calendar year in which the fiscal year involved ends, as most recently published by the Secretary before the beginning of the fiscal year.".

(b) COORDINATION WITH PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Section 1889(a) of the Social Security Act (42 U.S.C. 1395zz(a)) is amended by inserting "and to enhance the understanding of and utilization by providers of services and suppliers of research findings disseminated by the Patient-Centered Outcomes Research Institute established under section 1181" before the period at the end.

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

(1) ESTABLISHMENT OF TRUST FUND.—

(A) IN GENERAL.—Subchapter A of chapter 98 of the Internal Revenue Code of 1986 (relating to establishment of trust funds) is amended by adding at the end the following new section:

"SEC. 9511. PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND.

"(a) CREATION OF TRUST FUND.—There is established in the Treasury of the United States a trust fund to be known as the 'Patient-Centered Outcomes Research Trust Fund' (hereafter in this section referred to as the 'PCORTF'), consisting of such amounts as may be appropriated or credited to such Trust Fund as provided in this section and section 9602(b).

"(b) TRANSFERS TO FUND.—

"(1) APPROPRIATION.—There are hereby appropriated to the Trust Fund the following:

"(A) For fiscal year 2010, $10,000,000.

"(B) For fiscal year 2011, $50,000,000.

"(C) For fiscal year 2012, $150,000,000.

"(D) For fiscal year 2013—

"(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance

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

"(ii) $150,000,000.

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

"(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and

"(ii) $150,000,000.

The amounts appropriated under subparagraphs (A), (B), (C), (D)(ii), and (E)(ii) shall be transferred from the general fund of the Treasury, from funds not otherwise appropriated.

"(2) TRUST FUND TRANSFERS.—In addition to the amounts appropriated under paragraph (1), there shall be credited to the PCORTF the amounts transferred under section 1183 of the Social Security Act.

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

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

"(4) LIMITATION ON TRANSFERS TO PCORTF.—No amount may be appropriated or transferred to the PCORTF on and after the date of any expenditure from the PCORTF which is not an expenditure permitted under this section. The determination of whether an expenditure is so permitted shall be made without regard to—

"(A) any provision of law which is not contained or referenced in this chapter or in a revenue Act, and

"(B) whether such provision of law is a subsequently enacted provision or directly or indirectly seeks to waive the application of this paragraph.

"(c) TRUSTEE.—The Secretary of Health and 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.".

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

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

"Subchapter B—Insured and Self-Insured Health Plans

"SEC. 4375. HEALTH INSURANCE.

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

"(b) LIABILITY FOR FEE.—The fee imposed by subsection (a) shall be paid by the issuer of the policy.

"(c) SPECIFIED HEALTH INSURANCE POLICY.—For purposes of this section:

"(1) IN GENERAL.—Except as otherwise provided in this section, the term 'specified health insurance policy' means any accident or health insurance policy (including a policy under a group health plan) issued with respect to individuals residing in the United States.

"(2) EXEMPTION FOR CERTAIN POLICIES.—The term 'specified health insurance policy' does not include any insurance if substantially all of its coverage is of excepted benefits described in section 9832(c).

"(3) TREATMENT OF PREPAID HEALTH COVERAGE ARRANGEMENTS.—

"(A) IN GENERAL.—In the case of any arrangement described in subparagraph (B)—

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

"(ii) the person referred to in such subparagraph shall be treated as the issuer.

"(B) DESCRIPTION OF ARRANGEMENTS.—An arrangement is described in this subparagraph if under such arrangement fixed payments or premiums are received as consideration for any person's agreement to provide or arrange for the provision of accident or health coverage to residents of the United States, regardless of how such coverage is provided or arranged to be provided.

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

in any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a) for such policy year shall be equal to the sum of such dollar amount for policy years ending in the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

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

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

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

"SEC. 4376. SELF-INSURED HEALTH PLANS.

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

"(b) LIABILITY FOR FEE.—

"(1) IN GENERAL.—The fee imposed by subsection (a) shall be paid by the plan sponsor.

"(2) PLAN SPONSOR.—For purposes of paragraph (1) the term 'plan sponsor' means—

"(A) the employer in the case of a plan established or maintained by a single employer,

"(B) the employee organization in the case of a plan established or maintained by an employee organization,

"(C) in the case of—

"(i) a plan established or maintained by 2 or more employers or jointly by 1 or more employers and 1 or more employee organizations,

"(ii) a multiple employer welfare arrangement, or

"(iii) a voluntary employees' beneficiary association described in section 501(c)(9),

the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, or

"(D) the cooperative or association described in subsection (c)(2)(F) in the case of a

plan established or maintained by such a cooperative or association.

"(c) APPLICABLE SELF-INSURED HEALTH PLAN.—For purposes of this section, the term 'applicable self-insured health plan' means any plan for providing accident or health coverage if—

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

"(2) such plan is established or maintained—

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

"(B) by one or more employee organizations for the benefit of their members or former members,

"(C) jointly by 1 or more employers and 1 or more employee organizations for the benefit of employees or former employees,

"(D) by a voluntary employees' beneficiary association described in section 501(c)(9),

"(E) by any organization described in section 501(c)(6), or

"(F) in the case of a plan not described in the preceding subparagraphs, by a multiple employer welfare arrangement (as defined in section 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.

"SEC. 4377. DEFINITIONS AND SPECIAL RULES.

"(a) DEFINITIONS.—For purposes of this subchapter—

"(1) ACCIDENT AND HEALTH COVERAGE.—The term 'accident and health coverage' means any coverage which, if provided by an insurance policy, would cause such policy to be a specified health insurance policy (as defined in section 4375(c)).

"(2) INSURANCE POLICY.—The term 'insurance policy' means any policy or other instrument whereby a contract of insurance is issued, renewed, or extended.

"(3) UNITED STATES.—The term 'United States' includes any possession of the United States.

"(b) TREATMENT OF GOVERNMENTAL ENTITIES.—

"(1) IN GENERAL.—For purposes of this subchapter—

"(A) the term 'person' includes any governmental entity, and

"(B) notwithstanding any other law or rule of law, governmental entities shall not be exempt from the fees imposed by this subchapter except as provided in paragraph (2).

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

or section 4376 on any covered life under such program.

"(3) EXEMPT GOVERNMENTAL PROGRAM DEFINED.—For purposes of this subchapter, the term 'exempt governmental program' means—

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

"(B) the medical assistance program established by title XIX or XXI of the Social Security Act,

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

"(i) members of the Armed Forces of the United States, or

"(ii) veterans, and

"(D) any program established by Federal law for providing medical care (other than through insurance policies) to members of Indian tribes (as defined in section 4(d) of the Indian Health Care Improvement Act).

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

"(d) NO COVER OVER TO POSSESSIONS.—Notwithstanding any other provision of law, no amount collected under this subchapter shall be covered over to any possession of the United States.".

(B) CLERICAL AMENDMENTS.—

(i) Chapter 34 of such Code is amended by striking the chapter heading and inserting the following:

"CHAPTER 34—TAXES ON CERTAIN INSURANCE POLICIES

"SUBCHAPTER A. POLICIES ISSUED BY FOREIGN INSURERS

"SUBCHAPTER B. INSURED AND SELF-INSURED HEALTH PLANS

"Subchapter A—Policies Issued By Foreign Insurers".

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

"CHAPTER 34—TAXES ON CERTAIN INSURANCE POLICIES".

SEC. 3. COORDINATION WITH FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH.

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

(1) in subsection (c)—

(A) in paragraph (1), by striking ''and'' at the end;

(B) in paragraph (2), by striking the period at the end and inserting ''; and''; and

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

''(3) provide support to the Patient-Centered Outcomes Research Institute established under section 1181(b)(1) of the Social Security Act (referred to in this section as the 'Institute').'';

(2) in subsection (d)(2)—

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

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

''(B) INCLUSION OF CHAIRPERSON OF THE BOARD OF GOVERNORS OF THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—In the case where the Chairperson of the Board of

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

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

''(A) an inventory of its activities with respect to comparative effectiveness research conducted by relevant Federal departments and agencies; and

''(B) recommendations concerning better coordination of comparative effectiveness research by such departments and agencies.'';

(4) by redesignating subsection (g) as subsection (h); and

(5) by inserting after subsection (f) the following new subsection:

''(g) COORDINATION WITH THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—The Council shall coordinate with the Institute in carrying out its duties under this section.''.

SEC. 4. GAO REPORT ON NATIONAL COVERAGE DETERMINATIONS PROCESS.

Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit a report to Congress on the process for making national coverage determinations (as defined in section 1869(f)(1)(B) of the Social Security Act (42 U.S.C. 1395ff(f)(1)(B)) under the Medicare program under title XVIII of the Social Security Act. Such report shall include a determination whether, in initiating and conducting such process, the Secretary of Health and Human Services has complied with applicable law and regulations, including requirements for consultation with appropriate outside experts, providing appropriate notice and comment opportunities to the public, and making information and data (other than proprietary data) considered in making such determinations available to the public and to nonvoting members of any advisory committees established to advise the Secretary with respect to such determinations.