

SEC. 6301. PATIENT-CENTERED OUTCOMES 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 CLINICAL EFFECTIVENESS RESEARCH

“COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

“SEC. 1181 [42 U.S.C. 1320e]. (a) DEFINITIONS.—In this section:

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

“(2) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH; RESEARCH.—

“(A) IN GENERAL.—The terms ‘comparative clinical effectiveness research’ and ‘research’ mean research evaluating and comparing health outcomes and 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), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.

“(3) CONFLICT OF INTEREST.—The term ‘conflict of interest’ means an association, including a financial or personal association, that have the potential to bias or have the appearance of biasing an individual’s decisions in matters related to the Institute or the conduct of activities under this section.

“(4) REAL CONFLICT OF INTEREST.—The term ‘real conflict of interest’ means any instance where a member of the Board, the methodology committee established under subsection (d)(6), or an advisory panel appointed under subsection (d)(4), or a close relative of such member, has received or could receive either of the following:

“(A) A direct financial benefit of any amount deriving from the result or findings of a study conducted under this section.

“(B) A financial benefit from individuals or companies that own or manufacture medical treatments, services, or items to be studied under this section that in the aggregate exceeds \$10,000 per year. For purposes of the preceding sentence, a financial benefit includes honoraria, fees, stock, or other financial benefit and the current value of the member or close relative’s already existing stock holdings, in addition to any direct financial benefit deriving from the results or findings of a study conducted under this section.

“(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’ (referred to in this section as the ‘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 CLINICAL 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 health 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 research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as

well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions, and priorities in the National Strategy for quality care established under section 399H of the Public Health Service Act that are consistent with this section.

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

“(2) CARRYING OUT RESEARCH PROJECT AGENDA.—

“(A) RESEARCH.—The Institute shall carry out the research project agenda established under paragraph (1)(B) in accordance with the methodological standards adopted under paragraph (9) using methods, including the following:

“(i) Systematic reviews and assessments of existing and future research and evidence including original research conducted subsequent to the date of the enactment of this section.

“(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 (6) that are adopted by the Board under paragraph (9).

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

“(i) CONTRACTS.—

“(I) IN GENERAL.—In accordance with the research project agenda established under paragraph (1)(B), the Institute shall enter into contracts for the management of funding and conduct of research in accordance with the following:

“(aa) Appropriate agencies and instrumentalities of the Federal Government.

“(bb) Appropriate academic research, private sector research, or study-conducting entities.

“(II) PREFERENCE.—In entering into contracts under subclause (I), the Institute shall give preference to the Agency for Healthcare Research and Quality and the National Institutes of Health, but only if the research to be conducted or managed under such contract is authorized by the governing statutes of such Agency or Institutes.

“(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 under subsection (h) 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 (9) with respect to such research;

“(III) consult with the expert advisory panels for clinical trials and rare disease appointed under clauses (ii) and (iii), respectively, of paragraph (4)(A);

“(IV) subject to clause (iv), permit a researcher who conducts original research, as described in subparagraph (A)(ii), under the contract for the agency, instrumentality, or other entity to have such research published in a peer-reviewed journal or other publication, as long as the researcher enters into a data use agreement with the Institute for use of the data from the original research, as appropriate; *[As revised by section 10602(1)(A)(i) and (ii)]*

“(V) have appropriate processes in place to manage data privacy and meet ethical standards for the research;

“(VI) comply with the requirements of the Institute for making the information available to the public under paragraph (8); and

“(VII) comply with other terms and conditions determined necessary by the Institute to carry out the research agenda adopted under paragraph (2).

“(iii) COVERAGE OF COPAYMENTS OR COINSURANCE.—A contract entered into under this subparagraph may allow for the coverage of copayments or coinsurance, 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.

“(iv) SUBSEQUENT USE OF THE DATA.—The Institute shall not allow the subsequent use of data from original research in work-for-hire contracts with individuals, entities, or instrumentalities that have a financial interest in the results, unless approved under a data use agreement with the Institute. *[Replaced by section 10602(1)(B)]*

“(C) REVIEW AND UPDATE OF EVIDENCE.—The Institute shall review and update evidence on a periodic basis as appropriate.

“(D) TAKING INTO ACCOUNT POTENTIAL DIFFERENCES.—Research shall 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 sub-types, or quality of life preferences and 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) 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 well as provide access to the data networks developed under section 937(f) of the Public Health Service Act, as the Institute and its contractors may require to carry out this section. The Institute may also request and 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.

“(4) APPOINTING EXPERT ADVISORY PANELS.—

“(A) APPOINTMENT.—

“(i) IN GENERAL.—The Institute may appoint permanent or ad hoc expert advisory panels as determined appropriate to assist in identifying research priorities and establishing the research project agenda under paragraph (1) and for other purposes.

“(ii) EXPERT ADVISORY PANELS FOR CLINICAL TRIALS.—The Institute shall appoint expert advisory panels in carrying out randomized clinical trials under the research project agenda under paragraph (2)(A)(ii). Such expert advisory panels shall advise the Institute and the agency, instrumentality, or entity conducting the research on the research question involved and the research design or protocol, including important patient subgroups and other parameters of the research. 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 research study for rare disease, the Institute shall appoint an expert advisory panel for purposes of assisting in the design of the research study and determining the relative value and feasibility of conducting the research study.

“(B) COMPOSITION.—An expert advisory panel appointed under subparagraph (A) shall include representatives of practicing and research clinicians, patients, and experts in scientific and health services research, health services delivery, and evidence-based medicine who have experience in the relevant topic, and as appropriate, experts in integrative health and primary prevention strategies. The Institute may include a technical expert of each manufacturer or each medical technology that is included under the relevant topic, project, or category for which the panel is established.

“(5) SUPPORTING PATIENT AND CONSUMER REPRESENTATIVES.—The Institute shall provide support and resources to help patient and consumer representatives effectively participate on the Board and expert advisory panels appointed by the Institute under paragraph (4).

“(6) 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 15 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 clinical effectiveness research, biostatistics, genomics, and research methodologies. Stakeholders with such expertise may be appointed to the methodology committee. In addition to the members appointed under the first sentence, the Directors of the National Institutes of Health and the Agency for Healthcare Research and Quality (or their designees) shall each be included as members of the methodology committee.

“(C) FUNCTIONS.—Subject to subparagraph (D), the methodology committee shall work to develop and improve the science and methods of comparative clinical effectiveness research by, not later than 18 months after the establishment of the Institute, directly or through subcontract, developing and periodically updating the following:

“(i) Methodological standards for research. Such methodological standards shall provide specific criteria for internal validity, generalizability, feasibility, and timeliness of research and for health outcomes measures, risk adjustment, and other relevant aspects of research and assessment with respect to the design of research. Any methodological standards developed and updated under this subclause shall be scientifically based and include methods by which new information, data, or advances in technology are considered and incorporated into ongoing research projects by the Institute, as appropriate. The process for developing and updating such standards shall include input from rel-

evant experts, stakeholders, and decisionmakers, and shall provide opportunities for public comment. Such standards shall also include methods by which patient subpopulations can be accounted for and evaluated in different types of research. As appropriate, such standards shall build on existing work on methodological standards for defined categories of health interventions and for each of the major categories of comparative clinical effectiveness research methods (determined as of the date of enactment of the Patient Protection and Affordable Care Act).

“(ii) A translation table that is designed to provide guidance and act as a reference for the Board to determine research methods that are most likely to address each specific research question.

“(D) CONSULTATION AND CONDUCT OF EXAMINATIONS.—

The methodology committee may consult and contract with the Institute of Medicine of the National Academies and academic, nonprofit, or other private and governmental entities with relevant expertise to carry out activities described in subparagraph (C) and may consult with relevant stakeholders to carry out such activities.

“(E) REPORTS.—The methodology committee shall submit reports to the Board on the committee’s performance of the functions described in subparagraph (C). Reports shall contain recommendations for the Institute to adopt methodological standards developed and updated by the methodology committee as well as other actions deemed necessary to comply with such methodological standards.

“(7) 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 primary research described in subparagraph (A)(ii) of paragraph (2) that is conducted under such paragraph. Under such process—

“(i) evidence from such primary research shall be reviewed to assess scientific integrity and adherence to methodological standards adopted under paragraph (9); 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 (10)(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 utilize the peer-review process of appropriate medical journals if such process meets the requirements under subparagraphs (A) and (B).

“(8) RELEASE OF RESEARCH FINDINGS.—

“(A) IN GENERAL.—The Institute shall, not later than 90 days after the conduct or receipt of research findings under this part, make such research findings available to clinicians, patients, and the general public. The Institute shall ensure that the research findings—

“(i) convey the findings of research in a manner that is comprehensible and useful to patients and providers in making health care decisions;

“(ii) fully convey findings and discuss considerations specific to certain subpopulations, risk factors, and comorbidities, as appropriate;

“(iii) include limitations of the research and what further research may be needed as appropriate;

“(iv) do not include practice guidelines, coverage recommendations, payment, or policy recommendations; and *As revised by section 10602(2)*]

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

“(B) DEFINITION OF RESEARCH FINDINGS.—In this paragraph, the term ‘research findings’ means the results of a study or assessment.

“(9) ADOPTION.—Subject to subsection (h)(1), 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 (6)(C)(i), and any peer-review process provided under paragraph (7) by majority vote. In the case where the Institute does not adopt such processes in accordance with the preceding sentence, the processes 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.

“(10) 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, research priorities identified under paragraph (1)(A) and methodological standards developed and updated by the methodology committee under paragraph (6)(C)(i) that are adopted under paragraph (9) during the preceding year;

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

“(C) any administrative activities conducted by the Institute during the preceding year;

“(D) the names of individuals contributing to any peer-review process under paragraph (7), without identifying them with a particular research project; and

“(E) any other relevant information (including information on the membership of the Board, expert advisory panels, methodology committee, and the executive staff of the Institute, any conflicts of interest with respect to these individuals, 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 (d)(1) and (d)(9) are nondelegable.

“(f) BOARD OF GOVERNORS.—

“(1) IN GENERAL.—The Institute shall have a Board of Governors, which shall consist of the following members:

“(A) The Director of Agency for Healthcare Research and Quality (or the Director’s designee).

“(B) The Director of the National Institutes of Health (or the Director’s designee).

“(C) Seventeen members appointed, not later than 6 months after the date of enactment of this section, by the Comptroller General of the United States as follows:

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

“(ii) 7 members representing physicians and providers, including 4 members representing physicians (at least 1 of whom is a surgeon), 1 nurse, 1 State-licensed integrative health care practitioner, and 1 representative of a hospital. *[Replaced by section 10602(3)]*

“(iii) 3 members representing private 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.

“(iv) 3 members representing pharmaceutical, device, and diagnostic manufacturers or developers.

“(v) 1 member representing quality improvement or independent health service researchers.

“(vi) 2 members representing the Federal Government or the States, including at least 1 member representing a Federal health program or agency.

“(2) QUALIFICATIONS.—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. In appointing the Board, the Comptroller General of the United States shall consider and disclose any conflicts of interest in accordance with subsection (h)(4)(B). Members of the Board shall be recused from relevant Institute activities in the case where the member (or an immediate family member of such member) has

a real conflict of interest directly related to the research project or the matter that could affect or be affected by such participation.

“(3) TERMS; VACANCIES.—A member of the Board shall be appointed for a term of 6 years, except with respect to the members first appointed, whose terms of appointment shall be staggered evenly over 2-year increments. No individual shall be appointed to the Board for more than 2 terms. Vacancies shall be filled in the same manner as the original appointment was made.

“(4) CHAIRPERSON AND VICE-CHAIRPERSON.—The Comptroller General of the United States shall designate a Chairperson and Vice Chairperson of the Board from among the members of the Board. Such members shall serve as Chairperson or Vice Chairperson for a period of 3 years.

“(5) COMPENSATION.—Each member of the Board who is not an officer or employee of the Federal Government shall be entitled to compensation (equivalent to the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code) and expenses incurred while performing the duties of the Board. An officer or employee of the Federal government who is a member of the Board shall be exempt from compensation.

“(6) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—The Board may 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 and may seek such assistance and support of, or contract with, experts and consultants that may be necessary for the performance of the duties 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. Meetings not solely concerning matters of personnel shall be advertised at least 7 days in advance and open to the public. A majority of the Board members shall constitute a quorum, but a lesser number of members may meet and hold hearings.

“(g) FINANCIAL AND GOVERNMENTAL 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 AND ANNUAL REPORTS.—

“(A) REVIEW.—The Comptroller General of the United States shall review the following:

“(i) Not less frequently than on an annual basis, the financial audits conducted under paragraph (1).

“(ii) Not less frequently than every 5 years, the processes established by the Institute, including the research priorities and the conduct of research projects, in order to determine whether information produced by such research projects is objective and credible, is produced in a manner consistent with the

requirements under this section, and is developed through a transparent process.

“(iii) Not less frequently than every 5 years, the dissemination and training activities and data networks established under section 937 of the Public Health Service Act, including the methods and products used to disseminate research, the types of training conducted and supported, and the types and functions of the data networks established, in order to determine whether the activities and data are produced in a manner consistent with the requirements under such section.

“(iv) Not less frequently than every 5 years, the overall effectiveness of activities conducted under this section and the dissemination, training, and capacity building activities conducted under section 937 of the Public Health Service Act. Such review shall include an analysis of the extent to which research findings are used by health care decision-makers, the effect of the dissemination of such findings on reducing practice variation and disparities in health care, and the effect of the research conducted and disseminated on innovation and the health care economy of the United States.

“(v) Not later than 8 years after the date of enactment of this section, the adequacy and use of the funding for the Institute and the activities conducted under section 937 of the Public Health Service Act, including a determination as to whether, based on the utilization of research findings by public and private payers, funding sources for the Patient-Centered Outcomes Research Trust Fund under section 9511 of the Internal Revenue Code of 1986 are appropriate and whether such sources of funding should be continued or adjusted.

“(B) ANNUAL REPORTS.—Not later than April 1 of each year, the Comptroller General of the United States shall submit to Congress a report containing the results of the review conducted under subparagraph (A) with respect to the preceding year (or years, if applicable), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

“(h) 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.—The Institute shall provide for a public comment period of not less than 45 days and not more than 60 days prior to the adoption under subsection (d)(9) 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)(6)(C)(i), and the peer-review process provided under para-

graph (7), and after the release of draft findings with respect to systematic reviews of existing research and evidence.

“(2) ADDITIONAL FORUMS.—The Institute shall support forums to increase public awareness and obtain and incorporate public input and feedback through media (such as an Internet website) on research priorities, research findings, and 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 the following:

“(A) Information contained in research findings as specified in subsection (d)(9).

“(B) The process and methods for the conduct of research, including the identity of the entity and the investigators conducting such research and any conflicts of interests of such parties, any direct or indirect links the entity has to industry, and research protocols, including measures taken, methods of research and analysis, research results, and such other information the Institute determines appropriate) concurrent with the release of research findings.

“(C) Notice of public comment periods under paragraph (1), including deadlines for public comments.

“(D) Subsequent comments received during each of the public comment periods.

“(E) In accordance with applicable laws and processes and as the Institute determines appropriate, proceedings of the Institute.

“(4) DISCLOSURE OF CONFLICTS OF INTEREST.—

“(A) IN GENERAL.—A conflict of interest shall be disclosed in the following manner:

“(i) By the Institute in appointing members to an expert advisory panel under subsection (d)(4), in selecting individuals to contribute to any peer-review process under subsection (d)(7), and for employment as executive staff of the Institute.

“(ii) By the Comptroller General in appointing members of the methodology committee under subsection (d)(6);

“(iii) By the Institute in the annual report under subsection (d)(10), 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.

“(B) MANNER OF DISCLOSURE.—Conflicts of interest shall be disclosed as described in subparagraph (A) as soon as practicable on the Internet web site of the Institute and of the Government Accountability Office. The information disclosed under the preceding sentence shall include the type, nature, and magnitude of the interests of the individual involved, except to the extent that the individual recuses himself or herself from participating in the consid-

eration of or any other activity with respect to the study as to which the potential conflict exists.

“(i) RULES.—The Institute, its Board or staff, shall be prohibited from accepting gifts, bequeaths, or donations of services or property. In addition, the Institute shall be prohibited from establishing a corporation or generating revenues from activities other than as provided under this section.

“(j) RULES OF CONSTRUCTION.—

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

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

“(B) as preventing the Secretary from covering the routine costs of clinical care received by an individual entitled to, or enrolled for, benefits under title XVIII, XIX, or XXI in the case where such individual is participating in a clinical trial and such costs would otherwise be covered under such title with respect to the beneficiary.”.

(b) DISSEMINATION AND BUILDING CAPACITY FOR RESEARCH.—Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.), as amended by section 3606, is further amended by inserting after section 936 the following:

“SEC. 937 [42 U.S.C. 299b–37]. DISSEMINATION AND BUILDING CAPACITY FOR RESEARCH.

“(a) IN GENERAL.—

“(1) DISSEMINATION.—The Office of Communication and Knowledge Transfer (referred to in this section as the ‘Office’) at the Agency for Healthcare Research and Quality (or any other relevant office designated by Agency for Healthcare Research and Quality), in consultation with the National Institutes of Health, shall broadly disseminate the research findings that are published by the Patient Centered Outcomes Research Institute established under section 1181(b) of the Social Security Act (referred to in this section as the ‘Institute’) and other government-funded research relevant to comparative clinical effectiveness research. The Office shall create informational tools that organize and disseminate research findings for physicians, health care providers, patients, payers, and policy makers. The Office shall also develop a publicly available resource database that collects and contains government-funded evidence and research from public, private, not-for profit, and academic sources.

“(2) REQUIREMENTS.—The Office shall provide for the dissemination of the Institute’s research findings and government-funded research relevant to comparative clinical effectiveness research to physicians, health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans. Materials, forums, and media used to disseminate the findings, informational tools, and resource databases shall—

“(A) include a description of considerations for specific subpopulations, the research methodology, and the limita-

tions of the research, and the names of the entities, agencies, instrumentalities, and individuals who conducted any research which was published by the Institute; and

“(B) not be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.

“(b) INCORPORATION OF RESEARCH FINDINGS.—The Office, in consultation with relevant medical and clinical associations, shall assist users of health information technology focused on clinical decision support to promote the timely incorporation of research findings disseminated under subsection (a) into clinical practices and to promote the ease of use of such incorporation.

“(c) FEEDBACK.—The Office shall establish a process to receive feedback from physicians, health care providers, patients, and vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans about the value of the information disseminated and the assistance provided under this section.

“(d) RULE OF CONSTRUCTION.—Nothing in this section shall preclude the Institute from making its research findings publicly available as required under section 1181(d)(8) of the Social Security Act.

“(e) TRAINING OF RESEARCHERS.—The Agency for Health Care Research and Quality, in consultation with the National Institutes of Health, shall build capacity for comparative clinical effectiveness research by establishing a grant program that provides for the training of researchers in the methods used to conduct such research, including systematic reviews of existing research and primary research such as clinical trials. At a minimum, such training shall be in methods that meet the methodological standards adopted under section 1181(d)(9) of the Social Security Act.

“(f) BUILDING DATA FOR RESEARCH.—The Secretary shall provide for the coordination of relevant Federal health programs to build data capacity for comparative clinical effectiveness research, including the development and use of clinical registries and health outcomes research data networks, in order to develop and maintain a comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.

“(g) AUTHORITY TO CONTRACT WITH THE INSTITUTE.—Agencies and instrumentalities of the Federal Government may enter into agreements with the Institute, and accept and retain funds, for the conduct and support of research described in this part, provided that the research to be conducted or supported under such agreements is authorized under the governing statutes of such agencies and instrumentalities.”.

(c) IN GENERAL.—Part D of title XI of the Social Security Act, as added by subsection (a), is amended by adding at the end the following new section:

“LIMITATIONS ON CERTAIN USES OF COMPARATIVE CLINICAL
EFFECTIVENESS RESEARCH

“SEC. 1182 [42 U.S.C. 1320e–1]. (a) The Secretary may only use evidence and findings from 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 includes public comment and considers the effect on subpopulations.

“(b) Nothing in section 1181 shall be construed as—

“(1) superceding or modifying the coverage of items or services under title XVIII that the Secretary determines are reasonable and necessary under section 1862(l)(1); or

“(2) authorizing the Secretary to deny coverage of items or services under such title solely on the basis of comparative clinical effectiveness research.

“(c)(1) The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1181 in determining coverage, reimbursement, or incentive programs under title XVIII in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill.

“(2) Paragraph (1) shall not be construed as preventing the Secretary from using evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs under title XVIII based upon a comparison of the difference in the effectiveness of alternative treatments in extending an individual’s life due to the individual’s age, disability, or terminal illness.

“(d)(1) The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1181 in determining coverage, reimbursement, or incentive programs under title XVIII in a manner that precludes, or with the intent to discourage, an individual from choosing a health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability.

“(2)(A) Paragraph (1) shall not be construed to—

“(i) limit the application of differential copayments under title XVIII based on factors such as cost or type of service; or

“(ii) prevent the Secretary from using evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs under such title based upon a comparison of the difference in the effectiveness of alternative health care treatments in extending an individual’s life due to that individual’s age, disability, or terminal illness.

“(3) Nothing in the provisions of, or amendments made by the Patient Protection and Affordable Care Act, shall be construed to limit comparative clinical effectiveness research or any other research, evaluation, or dissemination of information concerning the likelihood that a health care treatment will result in disability.

“(e) The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine

coverage, reimbursement, or incentive programs under title XVIII.”.

(d) IN GENERAL.—Part D of title XI of the Social Security Act, as added by subsection (a) and amended by subsection (c), is amended by adding at the end the following new section:

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

“SEC. 1183 [42 U.S.C. 1320e–2]. (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, of 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 beginning 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, as most recently published by the Secretary before the beginning of the fiscal year.”.

(e) 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) 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 the Treasury shall be a trustee of the PCORTF.

“(d) EXPENDITURES FROM FUND.—

“(1) AMOUNTS AVAILABLE TO THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—Subject to paragraph (2), amounts in the PCORTF are available, without further appropriation, to the Patient-Centered Outcomes Research Institute established under section 1181(b) of the Social Security Act for carrying out part D of title XI of the Social Security Act (as in effect on the date of enactment of such Act).

“(2) TRANSFER OF FUNDS.—

“(A) IN GENERAL.—The trustee of the PCORTF shall provide for the transfer from the PCORTF of 20 percent of the amounts appropriated or credited to the PCORTF for each of fiscal years 2011 through 2019 to the Secretary of

Health and Human Services to carry out section 937 of the Public Health Service Act.

“(B) AVAILABILITY.—Amounts transferred under subparagraph (A) shall remain available until expended.

“(C) REQUIREMENTS.—Of the amounts transferred under subparagraph (A) with respect to a fiscal year, the Secretary of Health and Human Services shall distribute—

“(i) 80 percent to the Office of Communication and Knowledge Transfer of the Agency for Healthcare Research and Quality (or any other relevant office designated by Agency for Healthcare Research and Quality) to carry out the activities described in section 937 of the Public Health Service Act; and

“(ii) 20 percent to the Secretary to carry out the activities described in such section 937.

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

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

“(2) the decrease in the tax imposed by chapter 1 resulting from the fees imposed by such subchapter.

“(f) TERMINATION.—No amounts shall be available for expenditure from the PCORTF after September 30, 2019, and any amounts in such Trust Fund after such date shall be transferred to the general fund of the Treasury.”.

(B) CLERICAL AMENDMENT.—The table of sections for subchapter A of chapter 98 of such Code is amended by adding at the end the following 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.

“Sec. 4376. Self-insured health plans.

“Sec. 4377. Definitions and special rules.

“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), such arrangement shall be treated as a specified health insurance policy, and 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, as most recently published by the Secretary 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 1 or more employers for the benefit of their employees or former employees,

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

“(d) **ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.**—In the case of any plan year ending in any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a) for such plan year shall be equal to the sum of such dollar amount for plan 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 plan years ending in the previous fiscal year, multiplied by

“(2) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.

“(e) **TERMINATION.**—This section shall not apply to 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 members of the Armed Forces of the United States or 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”.

(f) TAX-EXEMPT STATUS OF THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—Subsection 501(l) of the Internal Revenue Code of 1986 is amended by adding at the end the following new paragraph:

“(4) The Patient-Centered Outcomes Research Institute established under section 1181(b) of the Social Security Act.”.