110TH CONGRESS
2D SESSION

S. 3408

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 Comparative Effectiveness Research Trust Fund, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 31, 2008

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

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A BILL

To amend title XI of the Social Security Act to provide for the conduct of comparative effectiveness research and to amend the Internal Revenue Code of 1986 to establish a Comparative Effectiveness 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 ''Comparative Effectiveness Research Act of 2008''.

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, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), and any other processes or items being used in the treatment and diag-

nosis 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.

''(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 'Health Care Comparative Effectiveness Research Institute' established under subsection (b)(1).

''(b) HEALTH CARE COMPARATIVE EFFECTIVENESS RESEARCH INSTITUTE.—

''(1) ESTABLISHMENT.—There is authorized to be established a nonprofit corporation, to be known as the ''Health Care Comparative Effectiveness 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 2009 and each subsequent fiscal year, amounts in the Comparative Effectiveness Research Trust Fund (referred to in this section as the 'CERTF') 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 improve health care delivered to individuals in the United States by advancing the quality and thoroughness of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, and managed clinically through research and evidence synthesis, and the dissemination of research findings with respect to the relative outcomes, 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; and

''(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.

''(B) ESTABLISHING RESEARCH PROJECT AGENDA.—

''(i) IN GENERAL.—The Institute shall establish and update a research project agenda 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 such research compared to the potential usefulness of the information produced by such research) associated with such 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 (9), using methods, including the following:

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

''(ii) Clinical research, such as randomized controlled 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)(i) CONTRACTS WITH FEDERAL AGENCIES AND INSTRUMENTALITIES.—The Institute shall give preference to 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, when enter-

ing into contracts for the management and conduct of research in accordance with the research project agenda established under paragraph (1)(B), to the extent that such contracts are authorized under the governing statutes of such agencies and instrumentalities.

''(ii) CONTRACTS WITH OTHER ENTITIES.—The Institute may enter into contracts with appropriate private sector research or study-conducting entities for the conduct of research described in clause (i).

''(iii) 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 (9) with respect to such research; and

''(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.

''(iv) 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 and evolving evidence 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, different age groups, and individuals with different comorbidities; and

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

''(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.

''(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 ADVISORY PANELS.—

''(A) IN GENERAL.—The Institute may appoint permanent or ad hoc advisory panels as determined appropriate by the Institute to assist in the establishment and carrying out of the research project agenda under paragraphs (1) and (2), respectively. Panels may advise or guide the Institute in matters such as identifying gaps in and updating medical evidence and identifying research priorities and potential study designs in order to ensure that the information produced from such research is clinically relevant to decisions made by clinicians and pa-

tients at the point of care and may provide advice throughout the conduct of research.

''(B) COMPOSITION.—An advisory panel appointed under subparagraph (A) shall include representatives of clinicians and patients and may include experts in scientific and health services research, health services delivery, and the manufacture of health items who have experience in the relevant topic, project, or category for which the panel is established.

''(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.—Members shall be appointed to the methodology committee established under subparagraph (A) 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, 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 of comparative effectiveness research by undertaking the following activities:

''(i) Not later than 1 year after the date on which the members of the methodology committee are appointed under subparagraph (B), developing and periodically updating methodological standards regarding outcomes measures, risk adjustment, statistical protocols, evaluation of evidence, conduct of research, and other aspects of research and assessment to be used when conducting research on comparative clinical effectiveness (and procedures for the use of such standards) in order to help ensure accurate and effective comparisons. Such standards shall also include methods by which new information, data, or advances in technology are considered and incorporated into ongoing research projects by the Institute, as appropriate. In developing

and updating methodological standards under this clause, the methodology committee shall ensure that such standards are scientifically based.

''(ii) Not later than 5 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, 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 cost-effectiveness and value 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.

"(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 de-

scribed 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.

"(7) PROVIDING FOR A PEER-REVIEW PROCESS.—

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

"(i) evidence from research conducted under this section 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 (11)(D).

"(B) COMPOSITION.—Such peer-review process shall have been 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.—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).

"(8) DISSEMINATION OF RESEARCH FINDINGS.—

"(A) IN GENERAL.—The Institute shall disseminate research findings to clinicians, patients, and the general public in accordance with the dissemination protocols and strategies adopted under paragraph (9). Research findings disseminated—

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

''(ii) shall discuss findings and other considerations specific to certain subpopulations, risk factors, and comorbidities, as appropriate;

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

''(iv) shall not include practice guidelines 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 efficient decisions regarding medical treatments, services, and items. In developing and adopting such protocols and strategies, the Institute shall consult with stakeholders 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, appraisal, or assessment.

''(9) 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 (6)(C)(i), any peer-review process provided under paragraph (7), and dissemination protocols and strategies developed under paragraph (8)(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.

''(10) 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 other relevant research and related efforts through appropriate activities, such as making payments, up to 5 percent of the amounts appropriated or credited to the CERTF under section 9511(b) of the Internal Revenue Code of 1986 with respect to the fiscal year, to The Cochrane Collaboration (or a successor organization) to support the infrastructure of The Cochrane Collaboration (or a successor organization) or to provide for sets of reviews related to a particular topic or associated with a particular review group.

''(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 (11)(E).

''(11) 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 CERTF 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 (8)(B), 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;

''(D) the names of individuals contributing to any peer-review process provided under paragraph (7) 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 (10) 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, advisory panels appointed under paragraph (5), the methodology committee established under paragraph (6), and the executive staff of the Institute, any conflicts of interest with respect to the members of such Board, 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)(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 Secretary of Health and Human Services (or the Secretary's designee).

"(B) The Director of the Agency for Healthcare Research and Quality (or the Director's designee).

"(C) The Director of the National Institutes of Health (or the Director's designee).

"(D) 18 members appointed by the Comptroller General of the United States not later than 6 months after the date of enactment of this section, as follows:

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

"(ii) 3 members representing practicing physicians, including surgeons.

"(iii) 3 members representing agencies that administer public programs, as follows:

"(I) 1 member representing the Centers for Medicare & Medicaid Services who has experience in administering the program under title XVIII.

"(II) 1 member representing agencies that administer State health programs (who may represent the Centers for Medicare & Medicaid Services and have experience in administering the program under title XIX or the program under title XXI or be a governor of a State).

"(III) 1 member representing agencies that administer other Federal health programs (such as a health program of the Department of Defense under chapter 55 of title 10, United States Code, the Federal employees health benefits program under chapter 89 of title 5 of such Code, a health program of the Department of Veterans Affairs under chapter 17 of title 38 of such Code, or a medical

care program of the Indian Health Service or of a tribal organization).

''(iv) 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.

''(v) 3 members representing pharmaceutical, device, and technology 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 advisory panel appointed under subsection (d)(5), members of the methodology committee established under subsection (d)(6), and individuals selected to contribute to any peer-review process under subsection (d)(7); 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 related to personnel, Board meetings shall be open to the public and advertised.

''(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 CERTF 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:

"(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 CERTF under section 1182.

"(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 30 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)(6)(C)(i), the peer-review process generally provided under subsection (d)(7), and dissemination protocols and strategies developed by the Institute under subsection (d)(8)(B) in accordance with subsection (d)(9).

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

''(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 feedback through media (such as an Internet website) on the following:

''(A) The identification of research priorities 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);

''(v) the identity of investigators conducting such research and any conflicts of interest of such investigators; and

''(vi) any progress reports the Institute determines appropriate.

''(B) Public comments submitted during each of the public comment periods under paragraph (1)(A).

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

"(D) 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 advisory panel under subsection (d)(5) and the methodology committee under subsection (d)(6), and in selecting individuals to contribute to any peer-review process under subsection (d)(7) 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)(11), 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—

''(A) establish a corporation other than as provided under this section; or

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

''(k) 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 clin-

ical trial and such costs would otherwise be covered under such title with respect to the beneficiary.

''(2) REPORTS AND FINDINGS.—None of the reports submitted under this section or research findings disseminated by the Institute shall be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.

''TRUST FUND TRANSFERS TO COMPARATIVE EFFECTIVENESS RESEARCH TRUST FUND

''SEC. 1182. (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 Comparative Effectiveness Research Trust Fund (referred to in this section as the 'CERTF') under section 9511 of the Internal Revenue Code of 1986, the following:

''(1) For fiscal year 2012, an amount equal to 50 cents 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 2013, 2014, 2015, 2016, 2017, and 2018, an amount equal to $1 mul-

tiplied 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, 2013, 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 Health Care Comparative Ef-

fectiveness Research Institute established under section 1181'' before the period at the end.

(c) COMPARATIVE EFFECTIVENESS 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. COMPARATIVE EFFECTIVENESS 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 'Comparative Effectiveness Research Trust Fund' (hereafter in this section referred to as the 'CERTF'), 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 2009, $5,000,000.

''(B) For fiscal year 2010, $25,000,000.

''(C) For fiscal year 2011, $75,000,000.

''(D) For fiscal year 2012—

''(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) $75,000,000.

''(E) For each of fiscal years 2013, 2014, 2015, 2016, 2017, and 2018—

''(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) $75,000,000.

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 CERTF the amounts

transferred under section 1182 of the Social Security Act.

''(3) LIMITATION ON TRANSFERS TO CERTF.—No amount may be appropriated or transferred to the CERTF on and after the date of any expenditure from the CERTF 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 CERTF.

''(d) EXPENDITURES FROM FUND.—Amounts in the CERTF are available, without further appropriation, to the Health Care Comparative Effectiveness Research Institute established by section 2(a) of the Comparative Effectiveness Research Act of 2008 for carrying out part D of title XI of the Social Security Act (as in effect on the

date of enactment of the Comparative Effectiveness Research Act of 2008).

''(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 CERTF after September 30, 2018, 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. Comparative Effectiveness 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, 2011, a fee equal to the product of $1 (50 cents in the case of policy years ending during fiscal year 2012) 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, 2013, 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 (deter-

mined 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, 2018.

''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, 2011, there is hereby imposed a fee equal to $1 (50 cents in the case of plan years ending during fiscal year 2012) 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-in-

sured 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 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, 2013, 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 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 plan years ending after September 30, 2018.

''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. 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.

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