

111TH CONGRESS  
1ST SESSION

# H. R. 2502

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.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2009

Mr. SCHRADER (for himself, Mr. McMAHON, Mr. CONNOLLY of Virginia, Mr. KIND, Mrs. HALVORSON, Mr. CROWLEY, Ms. SCHWARTZ, Mr. HIMES, Mr. ALTMIRE, Ms. BEAN, Mrs. TAUSCHER, and Mrs. DAVIS of California) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Comparative Effective-  
3 ness Research Act of 2009”.

4 **SEC. 2. COMPARATIVE EFFECTIVENESS RESEARCH.**

5 (a) IN GENERAL.—Title XI of the Social Security Act  
6 (42 U.S.C. 1301 et seq.) is amended by adding at the end  
7 the following new part:

8 “PART D—COMPARATIVE EFFECTIVENESS RESEARCH

9 “COMPARATIVE EFFECTIVENESS RESEARCH

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

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

13 “(2) COMPARATIVE CLINICAL EFFECTIVENESS  
14 RESEARCH.—

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

21 “(B) MEDICAL TREATMENTS, SERVICES,  
22 AND ITEMS DESCRIBED.—The medical treat-  
23 ments, services, and items described in this sub-  
24 paragraph are health care interventions, proto-  
25 cols for treatment, procedures, medical devices,  
26 diagnostic tools, pharmaceuticals (including

1 drugs and biologicals), and any other processes  
2 or items being used in the treatment and diag-  
3 nosis of, or prevention of illness or injury in,  
4 patients.

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

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

17 “(5) INSTITUTE.—The term ‘Institute’ means  
18 the ‘Health Care Comparative Effectiveness Re-  
19 search Institute’ established under subsection (b)(1).

20 “(b) HEALTH CARE COMPARATIVE EFFECTIVENESS  
21 RESEARCH INSTITUTE.—

22 “(1) ESTABLISHMENT.—There is authorized to  
23 be established a nonprofit corporation, to be known  
24 as the “Health Care Comparative Effectiveness Re-

1 search Institute” which is neither an agency nor es-  
2 tablishment of the United States Government.

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

7 “(3) FUNDING OF COMPARATIVE EFFECTIVE-  
8 NESS RESEARCH.—For fiscal year 2009 and each  
9 subsequent fiscal year, amounts in the Comparative  
10 Effectiveness Research Trust Fund (referred to in  
11 this section as the ‘CERTF’) under section 9511 of  
12 the Internal Revenue Code of 1986 shall be avail-  
13 able, without further appropriation, to the Institute  
14 to carry out this section.

15 “(c) PURPOSE.—The purpose of the Institute is to  
16 improve health care delivered to individuals in the United  
17 States by advancing the quality and thoroughness of evi-  
18 dence concerning the manner in which diseases, disorders,  
19 and other health conditions can effectively and appro-  
20 priately be prevented, diagnosed, treated, and managed  
21 clinically through research and evidence synthesis, and the  
22 dissemination of research findings with respect to the rel-  
23 ative outcomes, effectiveness, and appropriateness of the  
24 medical treatments, services, and items described in sub-  
25 section (a)(2)(B).

1 “(d) DUTIES.—

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

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

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

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

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

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

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

1                   “(B) ESTABLISHING RESEARCH PROJECT  
2                   AGENDA.—

3                   “(i) IN GENERAL.—The Institute shall  
4                   establish and update a research project  
5                   agenda to address the priorities identified  
6                   under subparagraph (A), taking into con-  
7                   sideration the types of research that might  
8                   address each priority and the relative value  
9                   (determined based on the cost of con-  
10                  ducting such research compared to the po-  
11                  tential usefulness of the information pro-  
12                  duced by such research) associated with  
13                  such different types of research, and such  
14                  other factors as the Institute determines  
15                  appropriate.

16                  “(ii) CONSIDERATION OF NEED TO  
17                  CONDUCT A SYSTEMATIC REVIEW.—In es-  
18                  tablishing and updating the research  
19                  project agenda under clause (i), the Insti-  
20                  tute shall consider the need to conduct a  
21                  systematic review of existing research (in-  
22                  cluding research on comparative effective-  
23                  ness conducted with funds provided under  
24                  division A of Public Law 111–5) before

1 providing for the conduct of new research  
2 under paragraph (2)(A).

3 “(2) CARRYING OUT RESEARCH PROJECT AGEN-  
4 DA.—

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

13 “(i) Systematic reviews and assess-  
14 ments of existing research and evidence.

15 “(ii) Clinical research, such as ran-  
16 domized controlled trials and observational  
17 studies.

18 “(iii) Any other methodologies rec-  
19 ommended by the methodology committee  
20 established under paragraph (6) that are  
21 adopted by the Board under paragraph  
22 (9).

23 “(B)(i) CONTRACTS WITH FEDERAL AGEN-  
24 CIES AND INSTRUMENTALITIES.—The Institute  
25 may enter into contracts with agencies and in-

1           strumentalities of the Federal Government that  
2           have experience in conducting comparative clin-  
3           ical effectiveness research, such as the Agency  
4           for Healthcare Research and Quality, for the  
5           management and conduct of research in accord-  
6           ance with the research project agenda estab-  
7           lished under paragraph (1)(B), to the extent  
8           that such contracts are authorized under the  
9           governing statutes of such agencies and instru-  
10          mentalities.

11           “(ii) CONTRACTS WITH OTHER ENTI-  
12          TIES.—The Institute may enter into contracts  
13          with appropriate private sector research or  
14          study-conducting entities for the conduct of re-  
15          search described in clause (i).

16           “(iii) CONDITIONS FOR CONTRACTS.—A  
17          contract entered into under this subparagraph  
18          shall require that the agency, instrumentality,  
19          or other entity—

20           “(I) abide by the transparency and  
21          conflicts of interest requirements that  
22          apply to the Institute with respect to the  
23          research managed or conducted under such  
24          contract;



1           “(II) comply with the methodological  
2 standards adopted under paragraph (9)  
3 with respect to such research; and

4           “(III) take into consideration public  
5 comments on the study design that are  
6 transmitted by the Institute to the agency,  
7 instrumentality, or other entity under sub-  
8 section (i)(1) during the finalization of the  
9 study design and transmit responses to  
10 such comments to the Institute, which will  
11 publish such comments, responses, and fi-  
12 nalized study design in accordance with  
13 paragraph (7)(C) prior to the conduct of  
14 such research.

15           “(iv) COVERAGE OF COPAYMENTS OR COIN-  
16 SURANCE.—A contract entered into under this  
17 subparagraph may allow for the coverage of co-  
18 payments or co-insurance, or allow for other ap-  
19 propriate measures, to the extent that such cov-  
20 erage or other measures are necessary to pre-  
21 serve the validity of a research project, such as  
22 in the case where the research project must be  
23 blinded.

24           “(C) REVIEW AND UPDATE OF EVI-  
25 DENCE.—The Institute shall review and update

1 evidence on a periodic basis, in order to take  
2 into account new research and evolving evidence  
3 as they become available, as appropriate.

4 “(D) TAKING INTO ACCOUNT POTENTIAL  
5 DIFFERENCES.—Research shall—

6 “(i) be designed, as appropriate, to  
7 take into account the potential for dif-  
8 ferences in the effectiveness of health care  
9 treatments, services, and items as used  
10 with various subpopulations, such as racial  
11 and ethnic minorities, women, different age  
12 groups, and individuals with different  
13 comorbidities; and

14 “(ii) seek to include members of such  
15 subpopulations as subjects in the research  
16 as feasible and appropriate.

17 “(3) DATA COLLECTION.—

18 “(A) IN GENERAL.—The Secretary shall,  
19 with appropriate safeguards for privacy, make  
20 available to the Institute such data collected by  
21 the Centers for Medicare & Medicaid Services  
22 under the programs under titles XVIII, XIX,  
23 and XXI as the Institute may require to carry  
24 out this section. The Institute may also request

1 and, if such request is granted, obtain data  
2 from Federal, State, or private entities.

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

9 “(4) APPOINTING ADVISORY PANELS.—

10 “(A) IN GENERAL.—The Institute may ap-  
11 point permanent or ad hoc advisory panels as  
12 determined appropriate by the Institute to as-  
13 sist in the establishment and carrying out of  
14 the research project agenda under paragraphs  
15 (1) and (2), respectively. Panels may advise or  
16 guide the Institute in matters such as identi-  
17 fying gaps in and updating medical evidence  
18 and identifying research priorities and potential  
19 study designs in order to ensure that the infor-  
20 mation produced from such research is clinically  
21 relevant to decisions made by clinicians and pa-  
22 tients at the point of care and may provide ad-  
23 vice throughout the conduct of research.

24 “(B) COMPOSITION.—An advisory panel  
25 appointed under subparagraph (A) shall include

1 representatives of clinicians and patients and  
2 may include experts in scientific and health  
3 services research, health services delivery, and  
4 the manufacture of health items who have expe-  
5 rience in the relevant topic, project, or category  
6 for which the panel is established.

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

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

13 “(B) APPOINTMENT AND COMPOSITION.—  
14 Members shall be appointed to the methodology  
15 committee established under subparagraph (A)  
16 by the Comptroller General of the United  
17 States. Members appointed to the methodology  
18 committee shall be experts in their scientific  
19 field, such as health services research, clinical  
20 research, comparative effectiveness research,  
21 biostatistics, and research methodologies.  
22 Stakeholders with such expertise may be ap-  
23 pointed to the methodology committee.

24 “(C) FUNCTIONS.—Subject to subpara-  
25 graph (D), the methodology committee shall

1 work to develop and improve the science of  
2 comparative effectiveness research by under-  
3 taking the following activities:

4 “(i) Not later than 1 year after the  
5 date on which the members of the method-  
6 ology committee are appointed under sub-  
7 paragraph (B), developing and periodically  
8 updating methodological standards regard-  
9 ing outcomes measures, risk adjustment,  
10 statistical protocols, evaluation of evidence,  
11 conduct of research, and other aspects of  
12 research and assessment to be used when  
13 conducting research on comparative clinical  
14 effectiveness (and procedures for the use of  
15 such standards) in order to help ensure ac-  
16 curate and effective comparisons. Such  
17 standards shall also include methods by  
18 which new information, data, or advances  
19 in technology are considered and incor-  
20 porated into ongoing research projects by  
21 the Institute, as appropriate. In developing  
22 and updating methodological standards  
23 under this clause, the methodology com-  
24 mittee shall ensure that such standards are  
25 scientifically based.

1           “(ii) Not later than 2 years after such  
2           date, examining the following:

3                   “(I) Methods by which various  
4                   aspects of the health care delivery sys-  
5                   tem (such as benefit design and per-  
6                   formance, and health services organi-  
7                   zation, management, and delivery)  
8                   could be assessed and compared for  
9                   their relative effectiveness, benefits,  
10                  risks, advantages, and disadvantages  
11                  in a scientifically valid and standard-  
12                  ized way.

13                  “(II) Methods by which cost-ef-  
14                  fectiveness and value could be as-  
15                  sessed in a scientifically valid and  
16                  standardized way.

17                  “(D) CONSULTATION AND CONDUCT OF  
18                  EXAMINATIONS.—

19                   “(i) IN GENERAL.—Subject to clause  
20                   (iii), in undertaking the activities described  
21                   in subparagraph (C), the methodology  
22                   committee shall—

23                           “(I) consult or contract with 1 or  
24                           more of the entities described in  
25                           clause (ii); and

1                   “(II) consult with stakeholders  
2                   and other entities knowledgeable in  
3                   relevant fields, as appropriate.

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

6                   “(I) The Institute of Medicine of  
7                   the National Academies.

8                   “(II) The Agency for Healthcare  
9                   Research and Quality.

10                  “(III) The National Institutes of  
11                  Health.

12                  “(iii) CONDUCT OF EXAMINATIONS.—  
13                  The methodology committee shall contract  
14                  with the Institute of Medicine of the Na-  
15                  tional Academies for the conduct of the ex-  
16                  aminations described in subclauses (I) and  
17                  (II) of subparagraph (C)(ii).

18                  “(E) REPORTS.—The methodology com-  
19                  mittee shall submit reports to the Board on the  
20                  committee’s performance of the functions de-  
21                  scribed in subparagraph (C). Reports submitted  
22                  under the preceding sentence with respect to  
23                  the functions described in clause (i) of such  
24                  subparagraph shall contain recommendations—

1           “(i) for the Institute to adopt meth-  
2           odological standards developed and up-  
3           dated by the methodology committee under  
4           such subparagraph; and

5           “(ii) for such other action as the  
6           methodology committee determines is nec-  
7           essary to comply with such methodological  
8           standards.

9           “(6) PROVIDING FOR A PEER-REVIEW PROC-  
10          ESS.—

11           “(A) IN GENERAL.—The Institute shall en-  
12           sure that there is a process for peer review of  
13           the research conducted under this section.  
14           Under such process—

15           “(i) evidence from research conducted  
16           under this section shall be reviewed to as-  
17           sess scientific integrity and adherence to  
18           methodological standards adopted under  
19           paragraph (8); and

20           “(ii) a list of the names of individuals  
21           contributing to any peer-review process  
22           during the preceding year or years shall be  
23           made public and included in annual reports  
24           in accordance with paragraph (10)(D).



1           “(B) COMPOSITION.—Such peer-review  
2 process shall have been designed in a manner so  
3 as to avoid bias and conflicts of interest on the  
4 part of the reviewers and shall be composed of  
5 experts in the scientific field relevant to the re-  
6 search under review.

7           “(C) USE OF EXISTING PROCESSES.—In  
8 the case where the Institute enters into a con-  
9 tract or other agreement with another entity for  
10 the conduct or management of research under  
11 this section, the Institute may utilize the peer-  
12 review process of such entity if such process  
13 meets the requirements under subparagraphs  
14 (A) and (B).

15           “(7) DISSEMINATION OF RESEARCH FIND-  
16 INGS.—

17           “(A) IN GENERAL.—The Institute shall  
18 disseminate research findings to clinicians, pa-  
19 tients, and the general public in accordance  
20 with the dissemination protocols and strategies  
21 adopted under paragraph (8). Research findings  
22 disseminated—

23                   “(i) shall convey findings of research  
24 so that they are comprehensible and useful

1 to patients and providers in making health  
2 care decisions;

3 “(ii) shall discuss findings and other  
4 considerations specific to certain sub-  
5 populations, risk factors, and  
6 comorbidities, as appropriate;

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

10 “(iv) shall not include practice guide-  
11 lines or policy recommendations; and

12 “(v) shall not include any data the  
13 dissemination of which would violate the  
14 privacy of research participants or violate  
15 any confidentiality agreements made with  
16 respect to the use of data under this sec-  
17 tion.

18 “(B) DISSEMINATION PROTOCOLS AND  
19 STRATEGIES.—The Institute shall develop pro-  
20 tocols and strategies for the appropriate dis-  
21 semination of research findings in order to en-  
22 sure effective communication of such findings  
23 and the use and incorporation of such findings  
24 into relevant activities for the purpose of in-  
25 forming higher quality and more effective and

1 efficient decisions regarding medical treat-  
2 ments, services, and items. In developing and  
3 adopting such protocols and strategies, the In-  
4 stitute shall consult with stakeholders con-  
5 cerning the types of dissemination that will be  
6 most useful to the end users of the information  
7 and may provide for the utilization of multiple  
8 formats for conveying findings to different audi-  
9 ences.

10 “(C) PUBLIC AVAILABILITY.—The Insti-  
11 tute shall make available to the public and dis-  
12 close through the official public Internet website  
13 of the Institute, and through other forums and  
14 media the Institute determines appropriate, the  
15 following:

16 “(i) The process and methods for the  
17 conduct of research under this section, in-  
18 cluding—

19 “(I) the identity of the entity  
20 conducting such research;

21 “(II) any links the entity has to  
22 industry (including such links that are  
23 not directly tied to the particular re-  
24 search being conducted under this sec-  
25 tion);

1                   “(III) draft study designs (in-  
2                   cluding research questions and the fi-  
3                   nalized study design, together with  
4                   public comments on such study design  
5                   and responses to such comments);

6                   “(IV) research protocols (includ-  
7                   ing measures taken, methods of re-  
8                   search, methods of analysis, research  
9                   results, and such other information as  
10                  the Institute determines appropriate);

11                  “(V) the identity of investigators  
12                  conducting such research and any  
13                  conflicts of interest of such investiga-  
14                  tors; and

15                  “(VI) any progress reports the  
16                  Institute determines appropriate.

17                  “(ii) Public comments submitted dur-  
18                  ing each of the public comment periods  
19                  under subsection (i)(1).

20                  “(iii) Bylaws, processes, and pro-  
21                  ceedings of the Institute, to the extent  
22                  practicable and as the Institute determines  
23                  appropriate.

24                  “(iv) Not later than 90 days after re-  
25                  ceipt by the Institute of a relevant report

1 or research findings, appropriate informa-  
2 tion contained in such report or findings.

3 “(v) All reports, findings, results, and  
4 studies conducted by or through the Insti-  
5 tute.

6 The Institute shall obtain and incorporate pub-  
7 lic feedback through media (such as an Internet  
8 website) on the information disclosed.

9 “(D) FUNDING.—At least 5 percent of the  
10 funds made available each fiscal year under the  
11 CERTF shall be expended on activities under  
12 this paragraph.

13 “(E) DEFINITION OF RESEARCH FIND-  
14 INGS.—In this paragraph, the term ‘research  
15 findings’ means the results of a study, ap-  
16 praisal, or assessment.

17 “(8) ADOPTION.—Subject to subsection (i)(1),  
18 the Institute shall adopt the national priorities iden-  
19 tified under paragraph (1)(A), the research project  
20 agenda established under paragraph (1)(B), the  
21 methodological standards developed and updated by  
22 the methodology committee under paragraph  
23 (5)(C)(i), any peer-review process provided under  
24 paragraph (6), and dissemination protocols and  
25 strategies developed under paragraph (7)(B) by ma-

1 jority vote. In the case where the Institute does not  
2 adopt such national priorities, research project agen-  
3 da, methodological standards, peer-review process, or  
4 dissemination protocols and strategies in accordance  
5 with the preceding sentence, the national priorities,  
6 research project agenda, methodological standards,  
7 peer-review process, or dissemination protocols and  
8 strategies shall be referred to the appropriate staff  
9 or entity within the Institute (or, in the case of the  
10 methodological standards, the methodology com-  
11 mittee) for further review.

12 “(9) COORDINATION OF RESEARCH AND RE-  
13 SOURCES AND BUILDING CAPACITY FOR RE-  
14 SEARCH.—

15 “(A) COORDINATION OF RESEARCH AND  
16 RESOURCES.—The Institute shall coordinate re-  
17 search conducted, commissioned, or otherwise  
18 funded under this section with comparative clin-  
19 ical effectiveness and other relevant research  
20 and related efforts conducted by public and pri-  
21 vate agencies and organizations in order to en-  
22 sure the most efficient use of the Institute’s re-  
23 sources and that research is not duplicated un-  
24 necessarily.

1 “(B) INCLUSION IN ANNUAL REPORTS.—

2 The Institute shall report on any coordination  
3 and capacity building conducted under this  
4 paragraph in annual reports in accordance with  
5 paragraph (10)(E).

6 “(10) ANNUAL REPORTS.—The Institute shall  
7 submit an annual report to Congress and the Presi-  
8 dent, and shall make the annual report available to  
9 the public. Such report shall contain—

10 “(A) a description of the activities con-  
11 ducted under this section during the preceding  
12 year, including the use of amounts appropriated  
13 or credited to the CERTF under section  
14 9511(b) of the Internal Revenue Code of 1986  
15 to carry out this section, research projects com-  
16 pleted and underway, and a summary of the  
17 findings of such projects;

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

20 “(C) a description of research priorities  
21 identified under paragraph (1)(A), dissemina-  
22 tion protocols and strategies developed by the  
23 Institute under paragraph (7)(B), and meth-  
24 odological standards developed and updated by  
25 the methodology committee under paragraph

1 (5)(C)(i) that are adopted under paragraph (8)  
2 during the preceding year;

3 “(D) the names of individuals contributing  
4 to any peer-review process provided under para-  
5 graph (6) during the preceding year or years, in  
6 a manner such that those individuals cannot be  
7 identified with a particular research project;

8 “(E) a description of efforts by the Insti-  
9 tute under paragraph (9) to—

10 “(i) coordinate the research con-  
11 ducted, commissioned, or otherwise funded  
12 under this section and the resources of the  
13 Institute with research and related efforts  
14 conducted by other private and public enti-  
15 ties; and

16 “(ii) build capacity for comparative  
17 clinical effectiveness research and other  
18 relevant research and related efforts  
19 through appropriate activities; and

20 “(F) any other relevant information (in-  
21 cluding information on the membership of the  
22 Board, advisory panels appointed under para-  
23 graph (4), the methodology committee estab-  
24 lished under paragraph (6), and the executive  
25 staff of the Institute, any conflicts of interest



1 with respect to the members of such Board, ad-  
2 visory panels, and methodology committee, or  
3 with respect to any individuals selected for em-  
4 ployment as executive staff of the Institute, and  
5 any bylaws adopted by the Board during the  
6 preceding year).

7 “(11) CONFLICTS OF INTEREST.—The Institute  
8 shall—

9 “(A) in appointing members to an advisory  
10 panel under subsection (d)(4) and the method-  
11 ology committee under subsection (d)(5), and in  
12 selecting individuals to contribute to any peer-  
13 review process under subsection (d)(6) and for  
14 employment as executive staff of the Institute,  
15 take into consideration any conflicts of interest  
16 of potential appointees, participants, and staff;  
17 and

18 “(B) include a description of any such con-  
19 flicts of interest and conflicts of interest of  
20 Board members in the annual report under sub-  
21 section (d)(10), except that, in the case of indi-  
22 viduals contributing to any such peer review  
23 process, such description shall be in a manner  
24 such that those individuals cannot be identified  
25 with a particular research project.

1 “(e) ADMINISTRATION.—

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

4 “(2) NONDELEGABLE DUTIES.—The activities  
5 described in subsections (b)(3)(D), (d)(1), and  
6 (d)(8) are nondelegable.

7 “(f) BOARD OF GOVERNORS.—

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

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

13 “(B) The Director of the Agency for  
14 Healthcare Research and Quality (or the Direc-  
15 tor’s designee).

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

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

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

24 “(ii) 3 members representing prac-  
25 ticing physicians, including surgeons.

1           “(iii) 3 members representing agen-  
2           cies that administer public programs, as  
3           follows:

4                   “(I) 1 member representing the  
5                   Centers for Medicare & Medicaid  
6                   Services who has experience in admin-  
7                   istering the program under title  
8                   XVIII.

9                   “(II) 1 member representing  
10                  agencies that administer State health  
11                  programs (who may represent the  
12                  Centers for Medicare & Medicaid  
13                  Services and have experience in ad-  
14                  ministering the program under title  
15                  XIX or the program under title XXI  
16                  or be a governor of a State).

17                  “(III) 1 member representing  
18                  agencies that administer other Fed-  
19                  eral health programs (such as a  
20                  health program of the Department of  
21                  Defense under chapter 55 of title 10,  
22                  United States Code, the Federal em-  
23                  ployees health benefits program under  
24                  chapter 89 of title 5 of such Code, a  
25                  health program of the Department of

1 Veterans Affairs under chapter 17 of  
2 title 38 of such Code, or a medical  
3 care program of the Indian Health  
4 Service or of a tribal organization).

5 “(iv) 3 members representing private  
6 payers, of whom at least 1 member shall  
7 represent health insurance issuers and at  
8 least 1 member shall represent employers  
9 who self-insure employee benefits.

10 “(v) 3 members representing pharma-  
11 ceutical, device, and technology manufac-  
12 turers or developers.

13 “(vi) 1 member representing nonprofit  
14 organizations involved in health services re-  
15 search.

16 “(vii) 1 member representing organi-  
17 zations that focus on quality measurement  
18 and improvement or decision support.

19 “(viii) 1 member representing inde-  
20 pendent health services researchers.

21 “(2) QUALIFICATIONS.—

22 “(A) DIVERSE REPRESENTATION OF PER-  
23 SPECTIVES.—The Board shall represent a broad  
24 range of perspectives and collectively have sci-  
25 entific expertise in clinical practice and clinical

1 health sciences research, including epidemi-  
2 ology, decisions sciences, health economics, and  
3 statistics.

4 “(B) CONFLICTS OF INTEREST.—

5 “(i) IN GENERAL.—In appointing  
6 members of the Board under paragraph  
7 (1)(D), the Comptroller General of the  
8 United States shall take into consideration  
9 any conflicts of interest of potential ap-  
10 pointees. Any conflicts of interest of mem-  
11 bers appointed to the Board under para-  
12 graph (1) shall be disclosed in accordance  
13 with subsection (d)(7).

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

25 “(3) TERMS.—

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

6                   “(i) 6 shall be appointed for a term of  
7 6 years;

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

10                   “(iii) 6 shall be appointed for a term  
11 of 2 years.

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

15           “(C) EXPIRATION OF TERM.—Any member  
16 of the Board whose term has expired may serve  
17 until such member’s successor has taken office,  
18 or until the end of the calendar year in which  
19 such member’s term has expired, whichever is  
20 earlier.

21           “(D) VACANCIES.—

22                   “(i) IN GENERAL.—Any member ap-  
23 pointed to fill a vacancy prior to the expi-  
24 ration of the term for which such mem-

1           ber’s predecessor was appointed shall be  
2           appointed for the remainder of such term.

3           “(ii) VACANCIES NOT TO AFFECT  
4           POWER OF BOARD.—A vacancy on the  
5           Board shall not affect its powers, but shall  
6           be filled in the same manner as the origi-  
7           nal appointment was made.

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

9           “(A) IN GENERAL.—From among the  
10          members of the Board appointed under para-  
11          graph (1)(D), the Comptroller General of the  
12          United States shall designate a member who is  
13          a physician with national research credentials  
14          as Chairperson of the Board and another mem-  
15          ber as Vice-Chairperson of the Board.

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

19          “(5) COMPENSATION.—

20          “(A) IN GENERAL.—A member of the  
21          Board shall be entitled to compensation at the  
22          per diem equivalent of the rate provided for  
23          level IV of the Executive Schedule under section  
24          5315 of title 5, United States Code.

1           “(B) TRAVEL EXPENSES.—While away  
2           from home or regular place of business in the  
3           performance of duties for the Board, each mem-  
4           ber of the Board may receive reasonable travel,  
5           subsistence, and other necessary expenses.

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

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

12          “(B) seek such assistance and support as  
13          may be required in the performance of the du-  
14          ties of the Institute from appropriate depart-  
15          ments and agencies of the Federal Government;

16          “(C) enter into contracts or make other ar-  
17          rangements and make such payments as may  
18          be necessary for performance of the duties of  
19          the Institute;

20          “(D) provide travel, subsistence, and per  
21          diem compensation for individuals performing  
22          the duties of the Institute, including members  
23          of any advisory panel appointed under sub-  
24          section (d)(4), members of the methodology  
25          committee established under subsection (d)(5),



1 and individuals selected to contribute to any  
2 peer-review process under subsection (d)(6);  
3 and

4 “(E) prescribe such rules, regulations, and  
5 bylaws as the Board determines necessary with  
6 respect to the internal organization and oper-  
7 ation of the Institute.

8 “(7) MEETINGS AND HEARINGS.—The Board  
9 shall meet and hold hearings at the call of the  
10 Chairperson or a majority of its members. In the  
11 case where the Board is meeting on matters not re-  
12 lated to personnel, Board meetings shall be open to  
13 the public and advertised.

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

18 “(g) FINANCIAL OVERSIGHT.—

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

23 “(2) REVIEW OF AUDIT AND REPORT TO CON-  
24 GRESS.—The Comptroller General of the United  
25 States shall—

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

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

5           “(h) GOVERNMENTAL OVERSIGHT.—

6           “(1) REVIEW AND REPORTS.—

7           “(A) IN GENERAL.—The Comptroller Gen-  
8           eral of the United States shall review the fol-  
9           lowing:

10           “(i) Processes established by the In-  
11           stitute, including those with respect to the  
12           identification of research priorities under  
13           subsection (d)(1)(A) and the conduct of re-  
14           search projects under this section. Such re-  
15           view shall determine whether information  
16           produced by such research projects—

17                   “(I) is objective and credible;

18                   “(II) is produced in a manner  
19                   consistent with the requirements  
20                   under this section; and

21                   “(III) is developed through a  
22                   transparent process.

23           “(ii) The overall effect of the Institute  
24           and the effectiveness of activities con-

1                   ducted under this section, including an as-  
2                   sessment of—

3                   “(I) the utilization of the find-  
4                   ings of research conducted under this  
5                   section by health care decision mak-  
6                   ers; and

7                   “(II) the effect of the Institute  
8                   and such activities on innovation and  
9                   on the health economy of the United  
10                  States.

11                 “(B) REPORTS.—Not later than 5 years  
12                 after the date of enactment of this section, and  
13                 not less frequently than every 5 years there-  
14                 after, the Comptroller General of the United  
15                 States shall submit a report to Congress con-  
16                 taining the results of the review conducted  
17                 under subparagraph (A), together with rec-  
18                 ommendations for such legislation and adminis-  
19                 trative action as the Comptroller General deter-  
20                 mines appropriate.

21                 “(2) FUNDING ASSESSMENT.—

22                 “(A) IN GENERAL.—The Comptroller Gen-  
23                 eral of the United States shall assess the ade-  
24                 quacy and use of funding for the Institute and  
25                 activities conducted under this section under

1 the CERTF under section 9511 of the Internal  
2 Revenue Code of 1986. Such assessment shall  
3 include a determination as to whether, based on  
4 the utilization of findings by public and private  
5 payers, each of the following are appropriate  
6 sources of funding for the Institute, including a  
7 determination of whether such sources of fund-  
8 ing should be continued or adjusted:

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

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

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

25 “(i) PUBLIC COMMENT PERIODS.—

1           “(1) IN GENERAL.—The Institute shall provide  
2 for a public comment period of not less than 30 and  
3 not more than 60 days at the following times:

4           “(A) Prior to the adoption of the national  
5 priorities identified under subsection (d)(1)(A),  
6 the research project agenda established under  
7 subsection (d)(1)(B), the methodological stand-  
8 ards developed and updated by the methodology  
9 committee under subsection (d)(5)(C)(i), the  
10 peer-review process generally provided under  
11 subsection (d)(6), and dissemination protocols  
12 and strategies developed by the Institute under  
13 subsection (d)(7)(B) in accordance with sub-  
14 section (d)(8).

15           “(B) Prior to the finalization of individual  
16 study designs.

17           “(2) TRANSMISSION OF PUBLIC COMMENTS ON  
18 STUDY DESIGN.—The Institute shall transmit public  
19 comments submitted during the public comment pe-  
20 riod described in paragraph (1)(B) to the entity con-  
21 ducting research with respect to which the individual  
22 study design is being finalized.

23           “(j) RULES.—

24           “(1) GIFTS.—The Institute, or the Board and  
25 staff of the Institute acting on behalf of the Insti-

1 tute, may not accept gifts, bequeaths, or donations  
2 of services or property.

3 “(2) ESTABLISHMENT AND PROHIBITION ON  
4 ACCEPTING OUTSIDE FUNDING OR CONTRIBU-  
5 TIONS.—The Institute may not—

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

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

10 “(k) RULES OF CONSTRUCTION.—

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

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

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

24 “(2) REPORTS AND FINDINGS.—None of the re-  
25 ports submitted under this section or research find-

1        ings disseminated by the Institute shall be construed  
 2        as mandates, guidelines, or recommendations for  
 3        payment, coverage, or treatment.

4            “(3) PHYSICIAN OUT.—None of the reports  
 5        submitted under this section or research findings  
 6        disseminated by the Institute shall be construed to  
 7        prevent the physician and patient to ultimately de-  
 8        termine what is best for the patient involved given  
 9        the individual circumstances of different patients.”.

10        (b) COORDINATION WITH PROVIDER EDUCATION  
 11        AND TECHNICAL ASSISTANCE.—Section 1889(a) of the  
 12        Social Security Act (42 U.S.C. 1395zz(a)) is amended by  
 13        inserting “and to enhance the understanding of and utili-  
 14        zation by providers of services and suppliers of research  
 15        findings disseminated by the Health Care Comparative Ef-  
 16        fectiveness Research Institute established under section  
 17        1181” before the period at the end.

18        (c) COMPARATIVE EFFECTIVENESS RESEARCH  
 19        TRUST FUND; FINANCING FOR TRUST FUND.—

20            (1) ESTABLISHMENT OF TRUST FUND.—

21            (A) IN GENERAL.—Subchapter A of chap-  
 22        ter 98 of the Internal Revenue Code of 1986  
 23        (relating to establishment of trust funds) is  
 24        amended by adding at the end the following  
 25        new section:

1 **“SEC. 9511. COMPARATIVE EFFECTIVENESS RESEARCH**  
2 **TRUST FUND.**

3 “(a) CREATION OF TRUST FUND.—There is estab-  
4 lished in the Treasury of the United States a trust fund  
5 to be known as the ‘Comparative Effectiveness Research  
6 Trust Fund’ (hereafter in this section referred to as the  
7 ‘CERTF’), consisting of such amounts as may be appro-  
8 priated or credited to such Trust Fund as provided in this  
9 section and section 9602(b).

10 “(b) TRANSFERS TO FUND.—

11 “(1) FROM ARRA FUNDING FOR CER.—There  
12 are hereby transferred to the CERTF the amounts  
13 appropriated to carry out comparative effectiveness  
14 research under division A of Public Law 111–5.  
15 whether appropriated for the National Institutes of  
16 Health, the Secretary of Health and Human Serv-  
17 ices, or the Agency for Healthcare Research and  
18 Quality, which are not otherwise obligated or ex-  
19 pended as of the date of the enactment of this sec-  
20 tion.

21 “(2) FROM MEDICARE TRUST FUNDS.—

22 “(A) IN GENERAL.—The Secretary of  
23 Health and Human Services shall provide for  
24 the transfer, from the Federal Hospital Insur-  
25 ance Trust Fund under section 1817 of the So-  
26 cial Security Act and the Federal Supple-



1           mentary Medical Insurance Trust Fund under  
2           section 1841 of such Act, in proportion (as esti-  
3           mated by the Secretary) to the total expendi-  
4           tures during such fiscal year that are made  
5           under title XVIII of such title from the respec-  
6           tive trust fund, to the CERTF the following:

7                   “(i) For fiscal year 2010, an amount  
8                   equal to 50 cents multiplied by the average  
9                   number of individuals entitled to benefits  
10                  under part A, or enrolled under part B, of  
11                  title XVIII of such Act during such fiscal  
12                  year.

13                  “(ii) For each of fiscal years 2011  
14                  through 2020, an amount equal to \$1 mul-  
15                  tiplied by the average number of individ-  
16                  uals entitled to benefits under part A, or  
17                  enrolled under part B, of such title XVIII  
18                  during such fiscal year.

19                  “(B) ADJUSTMENTS FOR INCREASES IN  
20                  HEALTH CARE SPENDING.—In the case of any  
21                  fiscal year beginning after September 30, 2011,  
22                  the dollar amount in effect under subparagraph  
23                  (A)(ii) for such fiscal year shall be equal to the  
24                  sum of such dollar amount for the previous fis-  
25                  cal year (determined after the application of

1           this subparagraph), plus an amount equal to  
2           the product of—

3                   “(i) such dollar amount for the pre-  
4                   vious fiscal year; multiplied by

5                   “(ii) the percentage increase in the  
6                   projected per capita amount of National  
7                   Health Expenditures from the calendar  
8                   year in which the previous fiscal year ends  
9                   to the calendar year in which the fiscal  
10                  year involved ends, as most recently pub-  
11                  lished by the Secretary before the begin-  
12                  ning of the fiscal year.

13                  “(3) ADDITIONAL TRANSFERS FOR FISCAL  
14                  YEARS 2010 THROUGH 2020.—There are hereby ap-  
15                  propriated to the CERTF for each of fiscal years  
16                  2010 through 2020, an amount equivalent to the net  
17                  revenues received in the Treasury from the fees im-  
18                  posed under subchapter B of chapter 34 (relating to  
19                  fees on health insurance and self-insured plans) for  
20                  such fiscal year.

21                  “(4) LIMITATION ON TRANSFERS TO CERTF.—  
22                  No amount may be appropriated or transferred to  
23                  the CERTF on and after the date of any expendi-  
24                  ture from the CERTF which is not an expenditure  
25                  permitted under this section. The determination of

1 whether an expenditure is so permitted shall be  
2 made without regard to—

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

6 “(B) whether such provision of law is a  
7 subsequently enacted provision or directly or in-  
8 directly seeks to waive the application of this  
9 paragraph.

10 “(c) TRUSTEE.—The Secretary of Health and  
11 Human Services shall be a trustee of the CERTF.

12 “(d) EXPENDITURES FROM FUND.—Amounts in the  
13 CERTF are available, without further appropriation, to  
14 the Health Care Comparative Effectiveness Research In-  
15 stitute established by section 2(a) of the Comparative Ef-  
16 fectiveness Research Act of 2009 for carrying out part D  
17 of title XI of the Social Security Act (as in effect on the  
18 date of enactment of the Comparative Effectiveness Re-  
19 search Act of 2009).

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

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

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

4           “(f) TERMINATION.—No amounts shall be available  
5 for expenditure from the CERTF after September 30,  
6 2020, and any amounts in such Trust Fund after such  
7 date shall be transferred to the general fund of the Treas-  
8 ury.”.

9                   (B) CLERICAL AMENDMENT.—The table of  
10                   sections for subchapter A of chapter 98 of such  
11                   Code is amended by adding at the end the fol-  
12                   lowing new item:

“Sec. 9511. Comparative Effectiveness Research Trust Fund.”.

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

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

18                   **“Subchapter B—Insured and Self-Insured**  
19                   **Health Plans**

“Sec. 4375. Health insurance.

“Sec. 4376. Self-insured health plans.

“Sec. 4377. Definitions and special rules.

20                   **“SEC. 4375. HEALTH INSURANCE.**

21                   “(a) IMPOSITION OF FEE.—There is hereby imposed  
22 on each specified health insurance policy for each policy  
23 year ending after September 30, 2009, a fee equal to the

1 product of \$1 (50 cents in the case of policy years ending  
2 during fiscal year 2010) multiplied by the average number  
3 of lives covered under the policy.

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

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

8 “(1) IN GENERAL.—Except as otherwise pro-  
9 vided in this section, the term ‘specified health in-  
10 surance policy’ means any accident or health insur-  
11 ance policy (including a policy under a group health  
12 plan) issued with respect to individuals residing in  
13 the United States.

14 “(2) EXEMPTION FOR CERTAIN POLICIES.—The  
15 term ‘specified health insurance policy’ does not in-  
16 clude any insurance if substantially all of its cov-  
17 erage is of excepted benefits described in section  
18 9832(c).

19 “(3) TREATMENT OF PREPAID HEALTH COV-  
20 ERAGE ARRANGEMENTS.—

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

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

1                   “(ii) the person referred to in such  
2                   subparagraph shall be treated as the  
3                   issuer.

4                   “(B) DESCRIPTION OF ARRANGEMENTS.—  
5                   An arrangement is described in this subpara-  
6                   graph if under such arrangement fixed pay-  
7                   ments or premiums are received as consider-  
8                   ation for any person’s agreement to provide or  
9                   arrange for the provision of accident or health  
10                  coverage to residents of the United States, re-  
11                  gardless of how such coverage is provided or ar-  
12                  ranged to be provided.

13                  “(d) ADJUSTMENTS FOR INCREASES IN HEALTH  
14                  CARE SPENDING.—In the case of any policy year ending  
15                  in any fiscal year beginning after September 30, 2013, the  
16                  dollar amount in effect under subsection (a) for such pol-  
17                  icy year shall be equal to the sum of such dollar amount  
18                  for policy years ending in the previous fiscal year (deter-  
19                  mined after the application of this subsection), plus an  
20                  amount equal to the product of—

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

23                         “(2) the percentage increase in the projected  
24                         per capita amount of National Health Expenditures  
25                         from the calendar year in which the previous fiscal

1 year ends to the calendar year in which the fiscal  
2 year involved ends, as most recently published by the  
3 Secretary of Health and Human Services before the  
4 beginning of the fiscal year.

5 “(e) TERMINATION.—This section shall not apply to  
6 policy years ending after September 30, 2020.

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

8 “(a) IMPOSITION OF FEE.—In the case of any appli-  
9 cable self-insured health plan for each plan year ending  
10 after September 30, 2011, there is hereby imposed a fee  
11 equal to \$1 (50 cents in the case of plan years ending  
12 during fiscal year 2012) multiplied by the average number  
13 of lives covered under the plan.

14 “(b) LIABILITY FOR FEE.—

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

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

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

21 “(B) the employee organization in the case  
22 of a plan established or maintained by an em-  
23 ployee organization,

24 “(C) in the case of—

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

5           “(ii) a multiple employer welfare ar-  
6           rangement, or

7           “(iii) a voluntary employees’ bene-  
8           ficiary association described in section  
9           501(c)(9),

10          the association, committee, joint board of trust-  
11          ees, or other similar group of representatives of  
12          the parties who establish or maintain the plan,  
13          or

14          “(D) the cooperative or association de-  
15          scribed in subsection (c)(2)(F) in the case of a  
16          plan established or maintained by such a coop-  
17          erative or association.

18          “(c) APPLICABLE SELF-INSURED HEALTH PLAN.—  
19          For purposes of this section, the term ‘applicable self-in-  
20          sured health plan’ means any plan for providing accident  
21          or health coverage if—

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

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



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

3           “(B) by one or more employee organiza-  
4 tions for the benefit of their members or former  
5 members,

6           “(C) jointly by 1 or more employers and 1  
7 or more employee organizations for the benefit  
8 of employees or former employees,

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

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

13           “(F) in the case of a plan not described in  
14 the preceding subparagraphs, by a multiple em-  
15 ployer welfare arrangement (as defined in sec-  
16 tion 3(40) of Employee Retirement Income Se-  
17 curity Act of 1974), a rural electric cooperative  
18 (as defined in section 3(40)(B)(iv) of such Act),  
19 or a rural telephone cooperative association (as  
20 defined in section 3(40)(B)(v) of such Act).

21           “(d) ADJUSTMENTS FOR INCREASES IN HEALTH  
22 CARE SPENDING.—In the case of any plan year ending  
23 in any fiscal year beginning after September 30, 2011, the  
24 dollar amount in effect under subsection (a) for such plan  
25 year shall be equal to the sum of such dollar amount for

1 plan years ending in the previous fiscal year (determined  
2 after the application of this subsection), plus an amount  
3 equal to the product of—

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

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

13 “(e) TERMINATION.—This section shall not apply to  
14 plan years ending after September 30, 2020.

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

16 “(a) DEFINITIONS.—For purposes of this sub-  
17 chapter—

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

23 “(2) INSURANCE POLICY.—The term ‘insurance  
24 policy’ means any policy or other instrument where-

1 by a contract of insurance is issued, renewed, or ex-  
2 tended.

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

5 “(b) TREATMENT OF GOVERNMENTAL ENTITIES.—

6 “(1) IN GENERAL.—For purposes of this sub-  
7 chapter—

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

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

14 “(2) TREATMENT OF EXEMPT GOVERNMENTAL  
15 PROGRAMS.—In the case of an exempt governmental  
16 program, no fee shall be imposed under section 4375  
17 or section 4376 on any covered life under such pro-  
18 gram.

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

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

1           “(B) the medical assistance program es-  
2           tablished by title XIX or XXI of the Social Se-  
3           curity Act,

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

9                   “(i) members of the Armed Forces of  
10                   the United States, or

11                   “(ii) veterans, and

12           “(D) any program established by Federal  
13           law for providing medical care (other than  
14           through insurance policies) to members of In-  
15           dian tribes (as defined in section 4(d) of the In-  
16           dian Health Care Improvement Act).

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

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

24                   (B) CLERICAL AMENDMENTS.—

1 (i) Chapter 34 of such Code is amend-  
2 ed by striking the chapter heading and in-  
3 serting the following:

4 **“CHAPTER 34—TAXES ON CERTAIN**  
5 **INSURANCE POLICIES**

“SUBCHAPTER A. Policies issued by foreign insurers.

“SUBCHAPTER B. Insured and self-insured health plans.

6 **“Subchapter A—Policies Issued By Foreign**  
7 **Insurers”.**

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

“CHAPTER 34—TAXES ON CERTAIN INSURANCE POLICIES”.

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