

Patient-Centered Outcomes Research Act of 2009
Section-by-Section Overview
6/9/09

SEC.1. Short Title.

The “Patient-Centered Outcomes Research Act of 2009”

SEC.2. Comparative Effectiveness Research.

- (a) Amends Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) by adding a new part, “Part D-Comparative Effectiveness,” with sections 1181, 1182, and 1183.

Sec. 1181 – Comparative Effectiveness Research

(a) Definitions

Defines the terms “Board”, “comparative clinical effectiveness research”, “comparative effectiveness research”, “medical treatments, services, and items”, and “conflicts of interest”.

(b) Patient-Centered Outcomes Research Institute

Establishment of the Institute

- Authorizes the establishment of a private, nonprofit corporation to be known as the “Patient-Centered Outcomes Research Institute”
- Specifies that the Institute shall be subject to the provisions of this bill and to the extent consistent with this bill, to the District of Columbia Nonprofit Corporation Act.
- Makes amounts in the Patient-Centered Outcomes Research Trust Fund (the ‘PCORTF’) created under section 9511 of the IRC available to the Institute to carry out its duties without further appropriation.

(c) Purpose

States that the purpose of the Institute is to assist patients, clinicians, purchasers, and policy makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative clinical outcomes, clinical effectiveness, and appropriateness of health care strategies.

(d) Duties

Identifying Research Priorities and Establishing Research Agenda

- Charges the Institute with identifying national priorities for comparative clinical effectiveness research and establishing a research project agenda (taking into consideration the relative value of potential studies, among other information) to address such priorities.

- Directs the Institute to consider the need for a systematic review of existing research before providing for the conduct of new research.
- Requires that the Institute take the following factors into account when setting priorities: Disease incidence, prevalence, and burden in the U.S.; evidence gaps, in terms of clinical outcomes; practice variations; the potential of new evidence to improve health and quality of care; expenditures associated with a health care strategy or health condition; patient needs, outcomes, and preferences, including quality of life; and relevance to assisting patients and clinicians in making informed health decisions.

Carrying Out Research Project Agenda

- Requires that the Institute use the following methods to provide for the conduct of research and synthesis of evidence: Systematic reviews and assessments of existing evidence; primary research, such as randomized clinical trials, molecularly informed trials, and observational studies; any other methodologies recommended by the methodology committee and adopted by the Board.
- Requires that such research and evidence synthesis be conducted in accordance with the methodological standards adopted by the Board.
- Allows the Institute to enter into contracts for the management and conduct of research in accordance with the research agenda with federal agencies and instrumentalities with experience in conducting comparative clinical effectiveness research, such as the Agency for Healthcare Research and Quality (AHRQ), to the extent such contracts are authorized under such agencies' governing statutes; as well as with appropriate private sector research or study-conducting entities that have demonstrated the experience and capacity to achieve the goals of comparative effectiveness research.
- Requires that entities under contract with the Institute for research meet the following conditions: Abide by the same transparency and conflicts of interest requirements that apply to the Institute with respect to the management or conduct of research; comply with the methodological standards adopted by the Board; take into consideration public comments, provided for and transmitted by the Institute, on individual study designs before the finalization of such designs, and submit responses to such comments to the Institute, which the Institute shall publish with the comments and finalized study design before the conduct of research; and in the case where the entities are managing or conducting a comparative clinical effectiveness research study for a rare disease, the entities must consult with the expert advisory panel for rare diseases appointed for the relevant study.
- Specifies that contracts may allow for the coverage of cost-sharing of research participants to the extent necessary to preserve the validity of the study results, such as in the case that a study needs to be blinded.
- Requires the Institute to review and update evidence periodically to take into account new research, evolving evidence, advances in medical technology, and changes in the standard of care as they become available, as appropriate.
- Directs the Institute to design research to take into account potential differences in outcomes among different subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and

- molecular sub-types, or quality of life preferences, and to include members of such subpopulations in the research, as feasible and appropriate.
- Requires the Institute to design research that, when appropriate, takes into account different characteristics of treatment modalities that may affect research outcomes.

Study and Report on Feasibility of Conducting Research In-House

Requires the Institute to conduct a study on the feasibility of conducting research in-house and to report to Congress on the results of such study within 5 years of the date of enactment.

Data Collection

Requires the Secretary of HHS to make appropriate CMS data available to the Institute with appropriate safeguards for privacy and confidentiality, and allows the Institute to request and obtain data from Federal, State, and private entities, including data from clinical databases and registries, if the request is granted by the entity. Requires that the use of such data be in accordance with requirements, laws, and regulations of CMS or the data-granting entity with respect to the release, use, confidentiality, and privacy of the data.

Appointing Advisory Panels

- Requires the Institute, as appropriate, to appoint expert advisory panels to assist in identifying research priorities and establishing the research project agenda. These panels shall advise the Institute to ensure that information produced from such research is clinically relevant to decisions made by clinicians and patients at the point of care.
- Specifies that the Institute shall appoint expert advisory panels to assist in carrying out the research project agenda with respect to primary research. Such panels shall, upon request, advise on the research question, design, or protocol of the study and be available as a resource for technical questions that may arise during the conduct of the research.
- Specifies that in the event of a comparative clinical effectiveness study on a rare disease, the Institute shall appoint an expert advisory panel for purposes of designing research studies for rare diseases, and determining the relative value and feasibility of conducting such research on a particular rare disease.
- Requires that such panels include representatives of practicing and research clinicians, patients, and experts in scientific and health services research, health services delivery, and evidence-based medicine who have experience in the relevant topic. Panels may also include a representative of each manufacturer of each medical technology that is included under the relevant topic, project, or category for which the panel is established.

Supporting Patient and Consumer Representatives

- Requires the Institute to provide support and resources, including initial and continuing education and the potential for regular and ongoing interactions between patients and consumer representatives, to help patient and consumer

representatives on the Board and expert advisory panels to effectively participate in technical discussions regarding complex research topics. The Institute shall also provide a per diem and other appropriate compensation to the patient and consumer representatives for their time.

Establishing Methodology Committee

- Requires the Institute to establish a standing methodology committee, with no more than 17 members, who are to be appointed by the Comptroller General of the U.S.
- Specifies that members of the methodology committee be experts in their scientific field, such as health services, clinical, and comparative effectiveness research, biostatistics, genomics, and research methodology. Stakeholders with such expertise may be appointed to the methodology committee.
- Charges the methodology committee with developing and improving the science and methods of comparative effectiveness research by developing within 2 years of enactment (and periodically updating), both a process to establish and maintain detailed methodological standards for comparative clinical effectiveness studies. Specifies that the standards provide criteria for study design that balance generalizability, timeliness and other factors and a translation table that links comparative effectiveness research methods with specific types of research questions. The standards must also include standards regarding clinical outcomes measures, risk adjustment, and other aspects of research and assessment. Specifies that such standards shall be scientifically based and include methods by which new information, data, or advances in technology may be considered and incorporated into ongoing research. Requires that the process for developing these standards include input and allow for public comment from all relevant experts, stakeholders, and decision-makers. Requires that standards include methods by which patient subpopulations can be accounted for and evaluated. Directs the committee, where appropriate, to build on existing work on methodological and reporting standards. Directs the Institute, in developing and updating such standards, to consult or contract with one or more of the Institute of Medicine (IOM), the AHRQ, the National Institutes of Health (NIH), and academic, non-profit, or other private entities with relevant expertise.
- Requires the methodology committee to contract with the IOM for the conduct of two examinations within 3 years after the methodology committee members are appointed: (1) Methods by which aspects of health care delivery systems, such as benefit design, could be assessed and compared for effectiveness, risks, benefits, advantages, and disadvantages in a scientifically valid and standardized way; and (2) Methods by which efficiency and value could be assessed in a scientifically valid and standardized way.
- Requires the methodology committee to submit reports to the Board concerning the committee's activities and, except for the latter two (3-year study) activities, to include recommendations for the Institute to adopt methodological and reporting standards and for other actions the committee determines necessary to comply with such standards.

Providing for a Peer-Review Process for Primary Research

- Requires the Institute to ensure that there is a process for peer-review of primary research, under which evidence shall be reviewed to assess scientific integrity and adherence to the methodological standards adopted by the Institute.
- Requires that a list of names of individuals contributing to any peer-review process during the preceding year or years be made public and included in the Institute's annual reports.
- Requires that any peer-review process be designed in a manner so as to avoid bias and conflicts of interest on the part of the reviewers, and that such review be conducted by experts in the scientific field relevant to the research under review.
- Allows the Institute to utilize existing peer-review processes which are already utilized by entities with which the Institute contracts, including the option to utilize the peer-review process of appropriate medical journals, if such processes meet the Institute's own requirements for a peer review process.

Dissemination of Research Findings

- Requires the Institute to disseminate the findings of research to clinicians, patients, and the public so that they are comprehensible and useful to patients and providers in making health care decisions.
- Specifies that such dissemination of research shall (1) discuss conclusions and considerations specific to certain subpopulations, comorbidities, or risk factors, as appropriate, and (2) include considerations such as limitations of research and discuss what further research may be needed, as appropriate.
- Prohibits disseminated findings from including practice guidelines, coverage recommendations, or policy recommendations.
- Prohibits inclusion of data the dissemination of which would violate the privacy of research participants or violate any confidentiality agreements made with respect to use of the data.
- Requires the Institute to develop protocols and strategies for the dissemination of research findings in order to ensure effective communication for the purpose of informing higher quality, more effective, and more timely medical decisions. The Institute is required to consult with stakeholders in determining the types of dissemination that will be most useful to the stakeholders and is allowed to utilize multiple formats for conveying findings to different audiences.
- Defines "research findings" as the results of a study or assessment.

Adoption of Priorities, Standards, Processes, and Protocols

Requires the Institute to adopt priorities, the research project agenda, methodological standards, peer review process(es), and dissemination protocols and strategies by majority vote. The Institute is required to refer any of the above back to staff or to the methodology committee, where appropriate, for further review in the case where adoption is not granted.

Coordination of Research and Resources and Building Capacity for Research

- Directs the Institute to coordinate its own activities and resources with that of other public and private agencies to ensure the most efficient use of the Institute's resources and to ensure that research is not unnecessarily duplicated.
- Permits the Institute to build capacity for comparative clinical effectiveness research and related efforts through activities such as supporting the Cochrane Collaboration and other organizations that develop and maintain a data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records. Allows such payments to be up to 20% of the PCORTF amounts for a year.

Annual Reports

Requires the Institute to submit an annual report to Congress, the President, and the public. The report must contain a description of the activities conducted during the previous year, including the use of funds, research projects completed and underway, and a summary of the findings of such projects; the research agenda and budget of the coming year; a description of research priorities, dissemination protocols, and methodological standards adopted by the Institute; a list of names of individuals participating in any peer-review process during a preceding year or years; a description of the Institute's coordination with other private and public entities and capacity-building activities for the year; and any other relevant information such as membership and conflicts of interest of Board members, Institute staff, advisory panels, and methodology committees, and any bylaws adopted by the Board during the previous year.

(e) Administration.

This subsection designates the Board responsible for carrying out the duties of the Institute. The Board is specifically prohibited from delegating the following duties to staff: approving and monitoring disbursements from the PCORTF; identifying research priorities; and adopting priorities, methodological standards, peer review processes, dissemination protocols.

(f) Board of Governors.

The membership of the Board is specified. The Board shall have 21 members, including the Secretary of Health and Human Services, the Director of AHRQ, and the Director of NIH. The other 18 members are to be appointed by the Comptroller General of the United States within 6 months after enactment and shall include 3 members representing each of the following groups: patients and health care consumers; physicians, including surgeons; agencies administering public health programs (including 1 member each representing CMS, a state health program (including Medicaid/CHIP or a state governor), and other Federal health programs); private payers (including at least 1 health insurance plan and 1 self-insuring employer); pharmaceutical, device, and diagnostic manufacturers; and others (including 1 member representing each of nonprofit health services research organization, quality improvement and decision support organizations, and independent health services researchers.)

Qualifications

Requires that the Board have collective scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics. Requires the Comptroller General to take into consideration and disclose any conflicts of interest of potential Board appointees. Also requires recusal by members with conflicts of interest from participation in Board activities to which such interest is directly related and could affect or be affected by such participation.

Terms

Specifies that members will be appointed for 6 years, except for those first appointments, of whom 6 shall be appointed for 6 years, 6 for 4 years, and 6 for 2 years. Limits individuals from serving more than 2 Board terms. Specifies protocols for expirations of terms and for vacancies.

Chair and Vice-Chair

Specifies that the Comptroller General designate a Chairperson and Vice-Chairperson from among the Board members to serve a 3-year term.

Compensation, etc.

Entitles Board members to compensation at the per diem equivalent of the level IV Executive Schedule rate. Also allows travel, subsistence, and other necessary expense compensation. Allows the Board to employ and set the compensation for an executive director and other personnel as necessary, seek support from appropriate departments and agencies of the Federal Government, make arrangements and payments necessary for the performance of the Institute's duties, and prescribe such rules and bylaws as it deems necessary.

Meetings and Hearings

Allows the Board to hold hearings and meetings at the call of the Chairperson or a majority of the members. Requires that meetings not solely concerning matters of personnel be advertised and open to the public at least 7 days in advance. Specifies that a majority of the Board members shall constitute a quorum, but that a lesser number of members may meet and hold hearings.

(g) Financial Oversight

Requires the Institute to provide for the annual conduct of financial audits of the Institute by a private entity. Requires the Comptroller General to review the results of the audit and submit a report to Congress on the audit and its report.

(h) Governmental Oversight

- Directs the Comptroller General to review the processes established by the Institute, including those regarding the identification of research priorities and the conduct of research, in order to determine whether such research is objective and credible, produced in a manner consistent with the requirements of this section, and developed in a transparent process.

- Directs the Comptroller General to review the overall effectiveness of the Institute and its activities, including the utilization of the research findings by health care decision makers, and any effect on innovation.
- Mandates that the Comptroller General submit a report to Congress at least every 5 years on the above reviews, along with recommendations for any such legislative and administrative action as the Comptroller determines appropriate.

Funding Assessment

Mandates that the Comptroller General also assess the adequacy and use of funding for the Institute under the PCORTF, including a determination of whether, based on utilization of the Institute’s findings by public and private payers, funding from private-sector contributions, the Medicare Trust Funds, and general revenues are appropriate and should be continued or adjusted. Requires the Comptroller to submit a report to Congress, together with any recommendations, on this assessment not later than 8 years after the date of enactment.

(i) Ensuring Transparency, Credibility, and Access

This section requires the Institute to establish procedures to ensure transparency, credibility, and access through public comment periods, forums, public availability of information, and protocols for conflicts of interest

Public Comment Periods

- Requires the Institute to provide for public comment periods of not less than 45 and not more than 60 days at the following times: prior to the adoption of national priorities, a research project agenda, methodological standards, the peer-review process, and dissemination protocols and strategies; prior to the finalization of individual study designs; and after the release of draft findings from systematic reviews and assessments of existing research and evidence.
- Directs the Institute to transmit any public comments received in relation to draft study designs to the entity conducting the research.

Additional Forums

Directs the Institute to support additional forums to increase public awareness and obtain and incorporate public input and feedback on the identification of research priorities, including research topics, and the establishment of the research agenda, research findings, and any other duties, activities, or processes the Institute determines appropriate.

Public Availability

Requires the Institute to make publicly available and disclose through the official public Internet site, and any other forums the Institute deems appropriate, the following:

- The process and methods for the conduct of research, including
 - the identity of the entity conducting research,

- any links the entity has to industry (including links that are not directly tied to particular research being conducted under contract with the Institute),
- draft study designs, including research questions and the finalized study design together with associated public comments and responses to such comments,
- research protocols, including measures taken, methods of research and analysis used, research results, and such other information as the Institute determines appropriate,
- any key decisions made by the Institute and any appropriate committees of the Institute,
- the identity of investigators conducting such research and any associated conflicts of interest,
- any progress reports the Institute determines appropriate;
- Notice of each of the public comments periods established by the Institute, along with any deadlines for public comments for such periods;
- Public comments submitted during each of the public comment periods;
- Bylaws, processes, and proceedings of the Institute, as feasible and appropriate; and
- Any report, research findings, and appropriate related information within 90 days after the receipt of such article by the Institute.

Conflicts of Interest

Requires the Institute to take into consideration any conflicts of interest of potential appointees, participants, and staff in appointing members to advisory panels and the methodology committee, in selecting individuals to contribute to any peer-review process, and in employing executive staff. Further requires a description of any such conflicts of interest (and in the case of peer-reviewers, in a manner such that peer-reviewers cannot be associated with a particular study) in the annual report.

(j) Rules

Prohibits the Institute, its Board or staff from accepting gifts, bequeaths, or donations. Prohibits the Institute from establishing a corporation or generating revenues from activities other than as provided for under this section.

(k) Rules of Construction

Clarifies that the Institute shall not mandate coverage, reimbursement, or other policies for any public or private payer. States that none of the reports or research findings shall be construed as mandates, guidelines, or policy recommendations. Clarifies that this section does not prevent the Secretary from covering the routine costs of clinical care for Medicare beneficiaries participating in research provided for by the Institute for whom such costs would normally be covered under Medicare.”

Sec.1182. Special Rules for the Use of Studies by the HHS Secretary

Requires an iterative and transparent process for the use of comparative clinical effectiveness research by the Secretary in making coverage determinations. The

process requires that stakeholders and other individuals have the opportunity to provide informed and relevant information with respect to the determination and to review draft proposals of the determination and submit public comments with respect to such draft proposals. It also requires the Secretary to consider all other relevant evidence, studies, and research in addition to such comparative clinical effectiveness research and any evidence and research that demonstrates or suggests a benefit of coverage with respect to specific subpopulations, even if the evidence of the findings demonstrate or suggest, that on average, with respect to the general population the benefits of coverage do not exceed the harm.

Sec.1183. Trust Fund Transfers to Patient-Centered Outcomes Research Trust Fund

(a) Directs the Secretary to transfer amounts from the Medicare Federal Hospital Insurance and the Federal Supplemental Medical Trust Funds to the new Patient-Centered Outcomes Research Trust Fund (the ‘PCORTF’) created to fund the Institute. Specifies that in FY2013, such amount will be equivalent to 1 dollar multiplied by the average number of individuals entitled to benefits under Part A or enrolled under Part B of Medicare; in FY2014 through FY2019, amounts will be equivalent to 2 dollars, increased by annual medical inflation after FY2014, multiplied by the average number of such individuals for the given year. Specifies that the transfers will come from the Medicare Trust Funds in proportion to total Medicare expenditures that come from each Fund for a given year.”

(b) Coordination with Provider Education and Technical Assistance

Amends Section 1889(a) of the Social Security Act, relating to educational activities provided through Medicare contractors to Medicare providers and suppliers, to include as part of such activities the objective of enhancing the understanding of and utilization by such providers and suppliers of findings produced by the Institute.

(c) Patient-Centered Outcomes Research Trust Fund; Financing for Trust Fund

Establishes a new trust fund in the Internal Revenue Code:

Sec. 9511. Patient-Centered Outcomes Research Trust Fund.

(a) Creation of Trust Fund

Creates the new Patient-Centered Outcomes Research Trust Fund (the ‘PCORTF’) in the U.S. Treasury.

(b) Transfers to Fund

Appropriates from general funds in the Treasury \$10 million in FY2010, \$50 million in FY2011, \$150 million in FY2012, and \$150 million for each of FY2013 through FY2019. Also appropriates the net revenues received from the new fee on insurance policies and plans, specified below, to the PCORTF for the years FY2013 through FY2019. Additionally, credits the amounts transferred from the Medicare Trust Funds in Section 1183 of the Social Security Act to the PCORTF. In addition to amount appropriated and credited, \$10 million shall be transferred to the PCORTF from funds appropriated to the Secretary under title VIII of Division A of the American Recovery

and Reinvestment Act of 2009 (Public Law 111-5). Specifies that no amounts may be appropriated or transferred to the PCORTF if any amounts expended from the PCORTF are used for a purpose that is not permitted.

(c) Trustee

Names the Secretary of Health and Humans Services as the trustee of the PCORTF.

(d) Expenditures from Fund

Makes amounts in the PCORTF available to the Institute to carry out Title IV, Part D of the Social Security Act.

(e) Net Revenues

Defines net revenues as the amount of the fees received from insurance policies and plans minus the income tax on those fees.

(f) Termination

Sunsets all funding after FY2019.

Financing for Fund from Fees on Insured and Self-Insured Health Plans

Creates a new Subchapter B of Chapter 34 of the Internal Revenue Code, with new sections 4375-4377.

Sec.4375. Health Insurance

Imposes a fee of 1 dollar in FY2013 and 2 dollars (growing at the rate of medical inflation in FY2014 and after) in FY2014 through FY2019, on each health insurance policy multiplied by the number of lives covered under that policy. Exempts insurance policies that provide chiefly non-health benefits. Sunsets fee after FY2019.

Sec.4376. Self-Insured Health Plans

Imposes a fee of 1 dollar in FY2013 and 2 dollars (growing at the rate of medical inflation in FY2014 and after) in FY2014 through FY2019, on each self-insured health plan multiplied by the number of lives covered under that plan. Defines applicable self-insured health plans as plans providing accident or health coverage provided other than through an insurance policy and maintained by a plan sponsor for the benefit of members, employees or former employees, or maintained by a multiple employer welfare arrangement of ERISA, or a rural electric or telephone cooperative. Defines plan sponsors as employers, employer organizations, or groups or associations maintaining a plan; or the entity maintaining a plan for 2 or more employers, joint employer-employee groups, or employee organizations, welfare arrangements, or voluntary employee's beneficiary associations (VEBAs) maintaining such plans. Sunsets fee after FY2019.

Sec.4377. Definitions and Special Rules

Defines accident and health coverage that is not of chiefly excepted benefits; insurance policy as any policy or instrument whereby a health insurance contract is issued, renewed, or extended; and the United States as including an possession of the

U.S. Includes government entities as subject to fees, but exempts Medicare, Medicaid, SCHIP, Federal health programs established for veterans, members of the U.S. Armed Forces, or members of Indian Tribes. States that fees imposed by this subchapter shall be treated as if they were taxes.

SEC.3. Coordination with Federal Coordinating Council for Comparative Effectiveness.

This section amends the American Recovery and Reinvestment Act of 2009 in the following ways:

- by adding a duty that the Federal Coordinating Council (FCC) shall provide support to the Institute;
- by including the Chairperson of the Institute, to the extent such person is a Federal officer or employee, to the Board of the FCC;
- by requiring the FCC to include an inventory of its activities with respect to comparative effectiveness research conducted by relevant Federal departments and agencies, in the FCC's annual report; and
- by requiring the FCC to coordinate its duties with the Institute.

SEC.4. GAO Report on National Coverage Determinations Process.

This section instructs the Comptroller General to submit a report to Congress within 18 months after the date of enactment on the process for making national coverage determinations under the Medicare program. The section specifies that the report shall include a determination of whether the Secretary of HHS has complied with applicable law and regulations, including requirements for consultation with outside experts, providing appropriate public notice and comment opportunities, and making appropriate information and data available to the public and to nonvoting members of advisory committees.