

# Bill Summary



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## BCBSA Summary of Key Legislative Proposal

### Comparative Effectiveness Research Act of 2008

On August 1, 2008, Senators Baucus (D-MT) and Conrad (D-ND) introduced S. 3408, the Comparative Effectiveness Research Act of 2008. This bill amends the Social Security Act to establish a private, nonprofit corporation to support comparative effectiveness research funded by federal appropriations, transfers from the Medicare Trust Funds, and a new fee on insured and self-funded health coverage.

Key elements of the bill include the following: (1) the establishment of an independent research entity outside the federal government; (2) a public-private board of governors for the entity; (3) discretion for the entity to support a broad range of comparative clinical effectiveness research; and (4) an emphasis on the entity producing and disseminating research relevant to provider and patient needs.

The bill specifies that none of the entity's reports or research findings shall be construed as mandates, guidelines, or policy recommendations for payment, coverage, or treatment.

#### Key Provisions

Authorizes the establishment of a private, nonprofit corporation to be known as the Health Care Comparative Effectiveness Research Institute (Institute) to compare and evaluate the clinical outcomes of different approaches to addressing particular medical conditions. Allows research comparing different interventions, treatment protocols, procedures, medical devices, diagnostic tools, and pharmaceuticals (including biologics).

**Duties.** Sets the following duties for the Institute:

- *Identify National Priorities/Research Agenda.* Requires the Institute to identify national priorities for comparative clinical effectiveness research and establish a research project agenda. Requires the following factors be taken into account when setting priorities: evidence gaps; disease incidence, prevalence, and burden in the U.S.; practice variations; the potential of new evidence to improve health and quality of care; and expenditures associated with a health condition or health care treatment, service, or item. (New SSA § 1181(d)(1))
- *Establish Research Agenda.*
  - Provides for consideration of the need to systematically review existing research before providing for new research.
  - Provides for clinical research such as randomized controlled trials and observational studies.
  - Gives contracting preference to federal agencies with experience in conducting comparative effectiveness research, such as the Agency for Healthcare Research and Quality (ARHQ). Also permits the Institute to contract with private entities to conduct

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- research.
- Requires contracting entities to meet specified conditions, including transparency and conflict of interest standards and methodological standards.
  - Permits contracts to cover cost-sharing of research participants.
  - Requires the Institute to review and update evidence periodically to take into account new studies and evolving evidence.
  - Requires the Institute to design research so that it takes into account potential differences in outcomes among different subpopulations, and includes members of such subpopulations in the research, as feasible and appropriate. (New SSA § 1181(d)(2))
  - *Feasibility Study of In-House Research.* Requires the Institute to study the feasibility of conducting research in-house and to report back to Congress within 5 years of enactment. (New SSA § 1181(d)(3))
  - *Data Collection.* Requires that CMS data (Medicare, Medicaid and SCHIP) be made available to the Institute and allows the Institute to request and obtain data from Federal, State, and private entities if the request is granted by the entity and if the Institute meets the entity's requirements for the release, use, confidentiality, and privacy of the data. (New SSA § 1181(d)(4))
  - *Advisory Panels.* Allows the Institute to appoint advisory panels to assist in the establishment and carrying out the research agenda. (New SSA § 1181(d)(5))
  - *Methodology Committee.* Requires the Institute to establish a standing methodology committee appointed by the Comptroller General. Members must be experts in their scientific field (e.g., health services research, clinical research, or comparative effectiveness research). Requires this committee to:
    - Consult with stakeholders and other entities knowledgeable in relevant fields.
    - Develop and periodically update scientifically based methodological standards for comparative effectiveness research, including standards regarding outcomes measures, risk adjustment, statistical protocols, evaluation of evidence, conduct of research, and other aspects of research and assessment. Standards shall include methods by which new information, data, or advances in technology may be considered and incorporated into ongoing research. Requires the first set of standards be developed within 1 year after enactment. Requires the committee to consult or contract with the Institute of Medicine (IOM), AHRQ, and/or the National Institutes of Health (NIH) in developing such standards.
    - Within 5 years after the committee is appointed, contract with the IOM to examine the methods by which: (1) various aspects of the delivery system (such as benefit design and health services delivery) could be assessed and compared for their relative effectiveness, risk, benefits, etc.; and (2) cost-effectiveness and value can be assessed in a scientifically valid and standardized way.
    - Submit reports to the Board regarding the committee's activities and make recommendations for the Institute to adopt methodological standards. (New SSA § 1181(d)(6))
  - *Peer Review.* Requires the Institute to ensure there is a process for peer review of the research. (New SSA § 1181(d)(7))

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- *Dissemination of Findings.* Requires the Institute to disseminate the findings of research to clinicians, patients, and the public in ways that are comprehensible and useful in making health care decisions. Requires the Institute to consult with stakeholders in determining the types of dissemination that will be most useful. Reports may describe research limitations, need for further research, and considerations specific to subpopulations, risk factors, and comorbidities. Prohibits disseminated findings from including practice guidelines or policy recommendations or including data that would violate the privacy of study participants or violate any confidentiality agreements made with respect to use of the data. (New SSA § 1181(d)(8))
- *Adoption by Majority Vote.* Requires the Institute to adopt research priorities, research project agenda, methodological standards, peer review processes and dissemination protocols by majority vote. (New SSA § 1181(d)(9))
- *Coordination of Research and Resources.* 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. Permits the Institute to build capacity for comparative effectiveness research through activities such as making payments of up to 5% of the amounts available to the Institute to the Cochrane Collaboration (an independent, non-profit organization with significant expertise in drafting systematic reviews) to support its infrastructure to provide for sets of reviews on a particular topic. (New SSA § 1181(d)(10))
- *Annual Reports.* Requires the Institute to submit annual reports to Congress, the President, and the public describing the activities conducted during the previous year and any other relevant information such as the research agenda and budget for the following year. (New SSA § 1181(d)(11))

### **Governance**

- *Board.* Creates a 21-member Board, including the HHS Secretary, AHRQ Director, the NIH Director, along with the other 18 members to be appointed by the Comptroller General representing: patients and health care consumers (3 members); practicing physicians, including surgeons (3 members); CMS (1 member), State health programs (1 member), and other Federal health programs (1 member); private payers (3 members) (including a health insurance plan and a self-funded employer); pharmaceutical, device, and technology manufacturers (3 members); nonprofit organizations involved in health services research (1 member); organizations focusing on quality measurement or decision support (1 member); and independent health services researchers (1 member). Provides for 6-year terms for appointed members. Provides for the Comptroller General to designate the Board's chair and co-chair for 3-year terms. Establishes conflict of interest and recusal policy for members. Requires that the Board have collective scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics. (New SSA § 1181(f))
- *Executive Director and Staff.* Authorizes the Board to hire an Executive Director and other staff as necessary to carry out the Institute's duties. (New SSA § 1181(f)(6))
- *Annual Audit.* 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. (New SSA § 1181(g))
- *Oversight.* Directs the Comptroller General to:
  - Review the processes established by the Institute to determine whether the research produced is objective and credible, consistent with the bill's requirements, and

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developed in a transparent process.

- Review the overall effectiveness of the Institute and its activities, including the use of the research findings by health care decision makers and its effect on innovation and on the health economy of the U.S.
- Submit a report to Congress at least every 5 years on the above reviews, along with any recommendations for legislative and/or administrative action.
- Directs the Comptroller General to assess the adequacy and use of Institute funding, including a determination of whether each funding source (public and private) should be continued or adjusted. Requires the Comptroller to submit a report to Congress, together with any recommended action on this assessment not later than 8 years after enactment. (New SSA § 1181(h))

### Transparency

- *Public Comment.* Requires the Institute to provide public comment periods at several stages: (1) prior to the adoption of the research priorities and research project agenda, the methodological standards, the peer review process, and the dissemination protocols; and (2) prior to the finalization of individual study designs. Directs the Institute to support additional forums to increase public awareness of and obtain and incorporate public input on key Institute activities.
- *Disclosure via Internet and Other Means.* 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 not directly tied to the particular study being conducted for the Institute);
    - Draft study designs, including study questions and the finalized study design together with related public comments and responses to such comments;
    - Research protocols;
    - The identity of investigators conducting such research and any associated conflicts of interest;
    - Appropriate progress reports;
  - Public comments submitted during each of the public comment periods;
  - Bylaws, processes, and proceedings of the Institute; and
  - Any report, research findings and other appropriate information, within 90 days after receipt by the Institute. (New SSA § 1181(i))

### Funding

- Establishes the Health Care Comparative Effectiveness Research Trust Fund and provides for \$5 million in public funding in the first year, rising to \$300 million by FY 2013. Appoints the HHS Secretary as the trustee.
  - *General Revenues.* Appropriates \$5 million in FY2009, \$25 million in FY2010, and \$75 million for each of FYs 2011-2018.

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- *Medicare.* Transfers from the Medicare Trust Funds amounts equal to a \$.50 per beneficiary fee in FY 2012, increasing to a \$1.00 per beneficiary fee in FYs 2013-2018. Increases these amounts by the per capita percentage increase in National Health Expenditures, starting with FY 2014.
- *Fees from health care coverage.* Imposes uniform fees on the average number of covered lives covered under insured and self-funded coverage policies, starting at \$.50 in FY 2012, increasing to \$1.00 in FYs 2013-2018. Increases these amounts by the per capita percentage increase in National Health Expenditures, starting with FY 2014. (These fees are the same as are paid by Medicare.)
- *Coverage sources exempt from fees.* Exempts from the fees: policies and self-funded plans that provide HIPAA exempted benefits (e.g., dental, vision, Medicare supplement, etc.); Medicaid and SCHIP coverage; coverage for members of the Armed Forces and veterans; and federal programs providing coverage for members of Indian tribes.
- *Sunset.* Sunsets funding sources after FY 2018. (New SSA § 1182 and new IRC § 4375-4377)

### **Additional Provisions**

- *Prohibitions.* Prohibits the Institute, its Board and/or staff from accepting gifts or donations of services or property. Prohibits the Institute from establishing a corporation or accepting any funds or contributions other than as provided under the legislation. (New SSA § 1181(j))
- *Clarification.*
  - Clarifies that the Institute shall not mandate coverage, reimbursement, or other policies for any public or private payer.
  - Clarifies that the Medicare, Medicaid and SCHIP may cover the routine costs of clinical care received by enrollees where such individuals are participating in clinical trials and such costs would otherwise be covered.
  - States that none of the reports or research findings shall be construed as mandates, guidelines, or policy recommendations for payment, coverage or treatment. (New SSA § 1181(k))
- *GAO Report on National Coverage Determinations under Medicare.* Directs the Comptroller General to submit a report to Congress within 18 months after enactment on the process for making national coverage determinations under the Medicare program. (Bill § 3)