

Summary of Comparative Effectiveness Research Legislation in the 110th Congress*



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	S. 3408 Comparative Effectiveness Research Act of 2008 (“Baucus/Conrad”) Introduced August 8, 2008	H.R. 3162, Sec. 904 Children’s Health and Medicare Protection Act (“CHAMP”) Passed House August 1, 2007	H.R. 2184 Enhanced Health Care Value for All Act (“Allen/Emerson”) Introduced May 7, 2007	S.3, Sec. 4 & 5 Medicare Prescription Drug Price Negotiation Act (Chairman’s Mark) Rejected in Senate April 2007
Scope of Work	<p>Comparative clinical effectiveness research:</p> <ul style="list-style-type: none"> Broad spectrum of treatments—drugs, devices, procedures Broad spectrum of methods—randomized control trials (RCT), observational studies, research syntheses 	<p>Comparative clinical effectiveness research:</p> <ul style="list-style-type: none"> Broad spectrum of treatments—drugs, devices, procedures Broad spectrum of methods—randomized control trials (RCT), observational studies, research syntheses 	<p>Comparative effectiveness research (Did not specify clinical and/or cost effectiveness):</p> <ul style="list-style-type: none"> Broad spectrum of treatments—drugs, devices, procedures Broad spectrum of methods—RCTs, observational studies, research syntheses 	<p>Comparative clinical effectiveness research:</p> <ul style="list-style-type: none"> Comparing Part D drugs to a broad spectrum of treatments—drugs, devices, procedures—covered under Medicare Broad spectrum of methods—RCTs, observational studies, research syntheses
Placement	<p>Within a newly established nonprofit corporation, the Health Care Comparative Effectiveness Research Institute. The Institute is neither an agency nor establishment of the U.S. government</p>	<p>Within AHRQ, under a newly established Center for Comparative Effectiveness Research</p>	<p>Initially within AHRQ; governing Board evaluates by FY 2010 where to house long-term</p>	<p>Within AHRQ under existing program established through Section 1013 of MMA</p>
Dissemination & Use	<p>Specific provisions to guide dissemination included:</p> <ul style="list-style-type: none"> Institute must disseminate findings to providers and patients that are comprehensible and discuss additional considerations and limitations Institute shall establish, in consultation with stakeholders, dissemination protocols and strategies to ensure effective communication <p>No restrictions on use of research findings, though Institute explicitly prohibited from issuing practice or policy recommendations, or coverage guidelines.</p>	<p>No specific provisions or restrictions on dissemination and use, but directs Commission, Center, and Secretary to disseminate information to public and coordinate with stakeholders to do so</p>	<p>No specific provisions or restrictions on dissemination and use, but directs AHRQ and Board to disseminate information to public and coordinate with stakeholders to do so</p>	<p>Would require pharmacy and therapeutic committees to take relevant comparative effectiveness studies into account when deciding which drugs in a therapeutic class should be included or excluded from a formulary</p>

*The scope of this analysis includes comprehensive authorizing legislation; it does not include de minimus references to comparative effectiveness research in legislation. Nor does it include language related to comparative effectiveness research contained in the budget resolutions, appropriations bills, or related committee reports of the 110th Congress.
Source: S. 3408, H.R. 3162, H.R. 2184, S. 3, all accessible at <http://thomas.loc.gov>.

	S. 3408	H.R. 3162, Sec. 904	H.R. 2184	S.3, Sec. 4 & 5
Governance	<p>Board of Governors to oversee research prioritization, conduct, and dissemination activities of the Institute</p> <ul style="list-style-type: none"> • Standing seats for Secretary of HHS, Director of AHRQ, Director of NIH (or designees) • Comptroller General appoints 18 members representing patients, physicians, public and private payers, health industry (pharma, device, technology), and health services researchers • Members must represent “diverse perspectives” and collectively have scientific expertise in epidemiology, decisions sciences, health economics, and statistics • Six year terms, with staggered terms for the first appointed Board • Comptroller General appoints Chair and Vice Chair for three year terms <p>Institute shall establish a standing methodology committee</p> <ul style="list-style-type: none"> • Appointed by Comptroller General, with expertise in health services research, clinical research, CER, biostatistics, and research methods • Committee shall “work to develop and improve the science of CER” by developing and updating methodological standards, and over time, exploring how to evaluate comparative system and cost effectiveness <p>Institute may establish other advisory committees as appropriate</p>	<p>Comparative Effectiveness Advisory Commission to oversee research prioritization, conduct, and dissemination</p> <ul style="list-style-type: none"> • Comptroller General appoints 17 members, with Director of AHRQ and Chief Medical Officer of CMS being two. Remaining 15 would represent patients, providers, payers, and industry researchers • Members must represent “diverse perspectives,” including epidemiology, health services research, bioethics, decision sciences, and economics • Four year terms <p>Commission would appoint a clinical perspective advisory panel for each research priority that would frame the research inquiry to ensure it’s clinically relevant</p> <p>Provides \$7 million to support governance in FY 2008, \$9 million in FY 2009, and \$10 million in FY 2010 from the Comparative Effectiveness Research Trust Fund</p>	<p>Comparative Effectiveness Advisory Board to oversee research prioritization, conduct, and dissemination, and evaluate long-term placement of comparative effectiveness program</p> <ul style="list-style-type: none"> • Comptroller General appoints up to 15 members, with one being Director of AHRQ. Up to 14 members would represent patients, providers, payers, and researchers • Two year terms <p>Board would appoint clinical peer review advisory panel (composed of methodologists, health services researchers, and medical experts) for each research priority that would validate the science and methods used to conduct studies</p>	<p>No governance, per se</p> <p>The Secretary of HHS would develop a list of research priorities that are “most critical to building the evidence needed to advance value-based purchasing of covered part D drugs...”</p> <p>The Secretary would establish an Advisory Committee to provide advice on setting the comparative effectiveness research priorities</p> <p>The Committee would include a diverse group of public and private clinical experts, stakeholders, and interests representing medical and health industries, patients, researchers, and government</p> <p>The Committee would provide “substantial opportunity” for public comment prior to making recommendations to Secretary</p>

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Financing	<p>Comparative Effectiveness Research Trust Fund, with Secretary of HHS designated as the trustee</p> <p>Financed by transfers of general funds from Treasury. Starting in FY 2012, financed by transfer from Medicare Trust Fund and assessment on insured and self-insured plans. Other contributions prohibited</p> <p>Provides from Treasury:</p> <ul style="list-style-type: none"> • \$5 million in FY 2009 • \$25 million in FY 2010 • \$75 million in each of FY 2011-2018 <p>Provides from Medicare Trust:</p> <ul style="list-style-type: none"> • In FY 2012, amount equivalent to 50 cents multiplied by the average number individuals entitled to Part A, or enrolled in Part B • In FY 2013-2018, amount increased to \$1 per average number of individuals • In FY 2014-2028, amount per average number of individuals increases by annual medical inflation <p>Provides from plans:</p> <ul style="list-style-type: none"> • In FY 2012, amount equivalent to 50 cents per policy multiplied by the average number of lives covered under that policy • In FY 2013-2018, amount increased to \$1 per covered life • After year FY 2013, amount per individual increases by annual medical inflation <p>Sunsets all funding after FY 2018</p>	<p>Comparative Effectiveness Research Trust Fund</p> <p>Financed by “fair share” assessment on:</p> <ul style="list-style-type: none"> • Medicare Trust Fund, not to exceed \$90 million in any given fiscal year starting FY 2011 • Insured and self-insured health plans beginning FY 2011 <p>Secretary would determine formula for health plan contributions. Or, the Secretary may use the “default amount” provided in statute of \$2 per covered beneficiary per year in FY 2011, increased for future years by annual percentage increase in medical care component of CPI</p> <p>Provides (from Medicare Trust):</p> <ul style="list-style-type: none"> • \$90 million in FY 2008 • \$100 million in FY 2009 • \$110 million in FY 2010 • Up to \$90 million in FY 2011 <p>Plans begin contributing FY 2011, providing up to \$375 million total from Medicare and plans</p>	<p>Comparative Effectiveness Research Trust Fund</p> <p>Financed by “fair share” assessment on:</p> <ul style="list-style-type: none"> • Medicare Trust Fund, not to exceed \$200 million in any given fiscal year • Insured and self-insured health plans. Secretary would determine formula for health plan contributions <p>Private contributions to begin FY 2008</p> <p>Provides up to \$3 billion over five years:</p> <ul style="list-style-type: none"> • \$100 million FY 2008 • \$200 million FY 2009 • \$900 million FY 2010, 2011, 2012 	<p>“Such sums as may be necessary” through annual appropriations</p> <p>Congressional Budget Office estimates that funding for developing prioritized list of comparative effectiveness studies would be \$2 million in FY 2008 and \$500,000 annually in subsequent years</p>

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Reporting & Transparency	<p>Provides for a peer review process to assess the scientific integrity and rigor of the research</p> <p>Requires the Institute to ensure transparency, credibility, and access, including public comment period, forums to increase public awareness and seek feedback, and public disclosure on processes for research priority setting, conduct, and review</p> <p>Requires annual financial audit by private entity. Requires GAO to review results of audit and submit report to Congress</p> <p>Requires GAO to review processes established by Institute and overall effectiveness of the Institute (including use of findings and impact on innovation), and report to Congress every five years</p> <p>Requires GAO to assess the adequacy and appropriateness of the trust fund not later than eight years after date of enactment and make recommendations for adjustments</p> <p>Requires annual reporting by Institute to Congress and the President on:</p> <ul style="list-style-type: none"> • Activities conducted during the preceding year, including funding, disseminations strategies, methodological standards • Activities to enhance coordination and capacity building • Research agenda and budget for the upcoming year <p>Not later than five years after enactment, Institute provides Congress with feasibility study of conducting intramural research</p>	<p>Requires annual reporting to Congress on status of research activities</p> <p>Not later than Dec. 31, 2011 the Secretary in consultation with the Commission would submit a report to Congress evaluating:</p> <ul style="list-style-type: none"> • The “return on investment” resulting from comparative effectiveness research • The overall costs of the Center’s activities • A list of any research projects not funded. <p>Report would also address whether the Center’s scope of work should be expanded to include studies on the overall effectiveness of the health care system, including ways in which health services are organized, managed, and delivered</p>	<p>Requires annual reporting to Congress on status of research activities</p> <p>In 2012, the Secretary in consultation with the Board would submit a report to Congress evaluating:</p> <ul style="list-style-type: none"> • Overall research, public comment, and dissemination activities and the use of comparative effectiveness research • The “return on investment” resulting from comparative effectiveness research • The overall costs of the program • A list of any research projects not funded 	<p>Not later than one year after the date of the Act’s enactment, the Secretary would submit a report to Congress on:</p> <ul style="list-style-type: none"> • The list of priority research topics and corresponding methods • Plans for conducting the research • An explanation of how this list was developed • The rationale for selecting the priority studies <p>The report would also be made available to the public</p> <p>The Secretary would be required to submit a draft of this report to Congress, and make the draft available to public—providing a 60 day public comment period</p>

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