

“Comparative Effectiveness Research Act of 2008”

Finding Out What Works in Health Care

The Comparative Effectiveness Research Act of 2008 establishes a private, nonprofit corporation, called the Health Care Comparative Effectiveness Research Institute to generate evidence on which health care interventions and services work and which ones don't. Comparative effectiveness research compares clinical outcomes, or the “clinical effectiveness,” of alternative therapies for the same condition. More evidence on what works and doesn't work can lead to better health care decisions and thus to improved quality of care, improved efficiency, and ultimately to the potential for cost savings throughout the health system. The Institute will establish a national agenda of research priorities, based on the need for better evidence, disease burden, practice variations, the potential for improved care, and expenditures associated with a given health condition or care strategy. The Institute can contract with federal agencies, such as the Agency for Healthcare Research and Quality (AHRQ), and appropriate private entities to conduct the research, which will include systematic reviews, observational studies, clinical trials, and randomized controlled trials. Research findings will be peer-reviewed and publicly disseminated in ways patients and healthcare providers can easily understand. The Institute will be governed by a multi-stakeholder Board of Governors, including the Secretary of Health and Human Services (HHS), the Directors of AHRQ and the National Institutes of Health (NIH), and 18 additional members representing diverse public and private sector expertise and interests. These members will be appointed by the Comptroller General of the United States.

Ensuring Credible and Objective Research

A critical component of the Institute's mission will be to develop the field of comparative effectiveness research. To accomplish this, the bill requires the Institute to establish an expert methodology committee that is charged with developing the standards which must be used in the conduct of the Institute's research. To ensure adherence to these methodological standards and to the principles of scientific integrity, all research conducted through the Institute will be subject to a peer review process. The methodology committee is also charged with examining whether scientifically valid methods exist for including cost and health plan design in comparative effectiveness research. Cost and health plan design factors will not be used by the Institute, but a future Congress may decide to incorporate these factors into the Institute's research down the road. Furthermore, the Institute's placement outside of the government ensures that undue political influence is minimized, while regular reviews by the Government Accountability Office (GAO) ensure accountability.

Transparency and Public Input

The Institute will seek input from a broad array of stakeholders on a continuous basis throughout its activities, ensuring that the Institute's research is relevant to the needs of patients, physicians, and other stakeholders and that the research is disseminated in ways most useful to health care decision-makers. The Institute may establish expert advisory panels to make certain that its research and findings are relevant to decision-makers at the point of service. Furthermore, the Institute is encouraged to design research that looks at differences in clinical outcomes among patient subgroups, such as racial and ethnic minorities, because their response to medical treatments may vary. The Institute is also required to establish formal public comment periods regarding many of its activities and to host periodic forums for public input. Ultimately, the Institute will disseminate research findings, but will be prohibited from issuing practice or policy recommendations or coverage guidelines.

Funding

The Institute and its activities will be funded by contributions from both public and private payers, made available to the Institute through a Comparative Effectiveness Research Trust Fund (CERTF). Contributions to the CERTF will include general revenues, amounts from the Medicare Trust Funds phased-in to \$1 per beneficiary annually, and amounts from a \$1 fee per-covered-life assessed annually on insured and self-insured health plans. Five years after enactment, total annual funding for the Institute will exceed \$300 million, with the Medicare Trust Fund transfer and annual fee on insured and self-insured plans not taking effect until 2012.