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# The Comparative Effectiveness Research Act of 2008: Reducing the Uncertainty of the Effectiveness of New Medical Technologies

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In recent years, the United States has spent an exorbitant amount of money on health care;[1] in 2006, alone, Americans spent over two trillion dollars.[2] Those expenditures accounted for sixteen percent of the U.S. economy, which means that "for every $100 in goods and services produced and consumed in American in 2006, $16 were for health care."[3] These high costs are due in part to technological advancements in medical treatments, and these costs have greatly affected the way the U.S. healthcare system functions.[4] Presently, the U.S. healthcare system has become a battleground between patients who want health insurance coverage for new technologies and health insurance companies who do not want to cover untested, experimental, and expensive treatments.[5] To address this tension, Senate Finance Committee Chairman Max Baucus (D - Mont). and Budget Committee Chairman Kent Conrad (D - N.D.) have introduced the Comparative Effectiveness Research Act of 2008 (S. 3408) in the United States

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[1] 154 CONG. REC. S7805, 7960 (daily ed. July 31, 2008) (statement of Sen. Baucus).
[2] *Id.*
[3] *Id.*
[4] Joseph B. Clamon, *Does My Health Insurance Cover It? Using Evidence-Based Medicine and Binding Arbitration Techniques to Determine What Therapies Fall Under Experimental Exclusion Clause in Health Insurance Contracts*, 54 DRAKE L.REV. 473, 474 (2006).
[5] *See* Gina Kolata, *When Doctors Say Yes and Insurers No*, N.Y. TIMES, Aug. 16, 1992, *available at* http://query.nytimes.com/gst/fullpage.html?sec=health&res=9E0CE7D9133CF935A2575BC0A964958260.

Senate, which has the potential to remedy one of the main issues associated with the cost of new technologies in healthcare: the determination of whether a new technology would be effective in treating a patient.[6]

Insurance companies struggle with the cost of medical technology, which "account[s] for [forty] percent of annual increases in health insurance premiums."[7] To combat these high prices, insurance companies have implemented numerous programs and guidelines to address emerging medical technologies.[8] For example, most health insurance companies exclude coverage of "experimental therapy."[9] This exclusion is triggered whenever evidence regarding a new therapy is inconclusive or if a procedure or technology is still being developed.[10] Thus, an insurance company will first determine whether researchers have reviewed the effectiveness of the technology, and, if so, the insurer will only cover the cost of that technology if the research establishes that it is a proven course of therapy.[11] Although this exclusion may benefit the insurance companies, it has significantly affected patients who are forced into a struggle with their insurer to obtain coverage for unproven treatments for their diseases.[12]

To provide better healthcare for these patients, many within the medical industry have called for increased research assessing the effectiveness of new and promising technologies and for government funding of these studies.[13] On July 31, 2008, that call may have finally been answered by Senators Max Baucus and Kent Conrad who introduced the Comparative Effectiveness Research Act of

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[6] *See* 154 CONG. REC. S7805, 7960 (daily ed. July 31, 2008) (statement of Sen. Baucus).
[7] Kolata, *supra* note 5.
[8] *See* Sandra J. Carnahan, *Medicare's Coverage With Study Participation Policy: Clinical Trials or Tribulations?*, 7 YALE J. HEALTH POL'Y, L. & ETHICS 229, 251-56 (2007); *Improving Health Care Quality: Hearing Before Senate Comm. on Finance*, 110th Cong. (2008) (statement of Sen. Baucus, Chairman, Senate Comm. on Finance) *available at* 2008 WLNR 17235017 (Westlaw).
[9] Clamon, *supra* note 4, at 476.
[10] *Id.* at 482.
[11] *Id.*
[12] *Id.* at 481.
[13] Kolata, *supra* note 5; BLUECROSS BLUESHIELD ASSOCIATION, THE PATHWAY TO COVERING AMERICA: ENSURING QUALITY, VALUE AND ACCESS 9 (2008), *available at* http://www.bcbs.com/issues/uninsured/pathway-to-covering-america/pathway-to-covering-america.pdf.

2008.[14] The bill proposes improving the quality of health care in the United States by establishing an organization to collect and distribute information regarding the effectiveness of various healthcare treatments, including new technologies.[15] Operating as the Health Care Comparative Effectiveness Research Institute ("Institute"), this private, nonprofit corporation will research the treatment of various health conditions to determine which treatments are most beneficial to individuals afflicted with specific conditions.[16]

To achieve this goal, the Institute would evaluate all forms of treatments, including medical devices, medical procedures, medical services, and other therapies.[17] The Institute would be overseen by a Board of Governors comprised of the Secretary of Health and Human Services, the Director of Agency for Healthcare Research Quality, the Director of the National Institutes of Health, and eighteen individuals appointed by the Comptroller General of the United States with backgrounds in various areas within the public and private sector.[18] Federal agencies and private entities approved by the Board of Governors would be enlisted to conduct the research.[19] All of the research findings would then be peer-reviewed, and a simplified version would be distributed to the public.[20]

Funding for the Institute would initially derive from general revenues with five million dollars of general funds coming from the Treasury in 2009, twenty-five million dollars in 2010, seventy-five million in 2011, and seventy-five million for each year from 2012 through 2018.[21] Beginning in 2012, funding would also come from revenues generated in the Medicare Trust Fund from fees

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[14] COMMITTEE ON FINANCE, BAUCUS-CONRAD PROPOSAL CAN IMPROVE QUALITY, LOWER COSTS THROUGHOUT AMERICAN HEALTH CARE SYSTEM (2008), http://finance.senate.gov/press/Bpress/2008press/prb080108.pdf.
[15] *Id.;* 154 CONG. REC. S7805, 7960 (daily ed. July 31, 2008) (statement of Sen. Baucus).
[16] COMMITTEE ON FINANCE, *supra* note 14.
[17] 154 CONG. REC. S7805, 7960 (daily ed. July 31, 2008) (statement of Sen. Baucus).
[18] COMMITTEE ON FINANCE, *supra* note 14.
[19] *Id.*
[20] *Id.*
[21] COMPARATIVE EFFECTIVENESS RESEARCH ACT OF 2008 SECTION-BY-SECTION OVERVIEW 9, Aug 1. 2008, http://finance.senate.gov/sitepages/leg/LEG%202008/080108%20CE%20Section-by-Section.pdf.

on private health insurance policies.[22] The private insurance fee would total one dollar per person each year, and the funding from Medicare would equal one dollar per beneficiary annually.[23]

Initial reactions to the bill generally have been positive.[24] Blue Cross Blue Shield Association noted that it has supported the creation of this type of institute for years and commended the Senators for taking the "first step towards creating a knowledge-based health care system where treatment decisions are based on sound clinical data."[25] The president and chief executive officer of the Advanced Medical Technology Association expressed qualified approval of the bill stating that "[i]t is also essential that research recognize the unique iterative nature of device innovation when establishing research priorities and conducting studies."[26] Other reactions, however, were not so positive. David Merritt from the Center for Healthcare Transformation found the amount of funding proposed for the Institute inadequate, especially when compared to the National Institutes of Health's thirty billion dollar budget.[27] He noted that the amount of funding the bill proposed was "not even a drop in the bucket compared to what's needed."[28] Further, several professionals in the medical device and pharmaceutical industries fear that the

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[22] *Baucus Comparative Effectiveness Bill Funded With Private/Public Partnership*, INSIDE CMS, Aug. 7, 2008, *available at* 2008 WLNR 14748807 (Westlaw).
[23] *Id.*
[24] Bureau of Nat'l Affairs, Inc., *Quality Assurance: Senators Propose Nonprofit Institute for Study of Comparative Effectiveness*, BNA MED. RES. L. & POL. REP. NEWS, Aug. 6, 2008, *available at* 7 BNA MRLP No. 15 d13 (Westlaw).
[25] U.S. Insurance News, BCBSA Throws Support Behind Proposed Comparative Effectiveness Research Institute, Aug. 11, 2008, http://www.digitalinsurancenews.com/000000008896/issues/bcbsa-throws-support-behind-proposed-comparative-effectiveness-research-institute.html.
[26] Bureau of Nat'l Affairs, Inc., *supra* note 24.
[27] Mark McCarty, *Washington Roundup: Comparative Effectiveness Bill Appears Aimed at Next Congress*, MED. DEVICE DAILY, Aug. 5, 2008, at 4, *available at* http://faculty.swosu.edu/jerrie.robinson/share/Health%20Care%20Administration/CMS%20declines%20more%20coverage%20for%20CAS.pdf.
[28] *Id.*

research could ultimately be manipulated to deny patients treatment and save government money if it is not properly managed.[29]

The proposed legislation has the potential to decrease tensions between health insurance companies and the insured by providing the evidence required to determine the effectiveness of new technologies.[30] The research conducted by the Institute will not only benefit patients[31] who want the benefits of new medical technology. The research also will assist insurers that are often unwilling to pay for an expensive, new technology due to the uncertainty of its effectiveness[32] when they make coverage decisions. With passage of the bill, not only will patients have better knowledge about the effectiveness of emerging treatments, but insurance companies will have the ability to eliminate coverage for ineffective treatments. These improvements may result in extra funds that both patients and insurance companies could use to pay for expensive but successful treatments and could decrease the healthcare community's hesitancy to embrace new medical technology.

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[29] *Baucus Comparative Effectiveness Bill Funded With Private/Public Partnership*, *supra* note 22; Peter Pitts, *America Shouldn't Repeat Britain's Health-Care Atrocities*, THE VALLEY NEWS, Sept. 13, 2008, *available at* http://www.valleynewsonline.com/viewnews.php?newsid=83411&id=2.
[30] *See* 154 CONG. REC. S7805, 7961 (daily ed. July 31, 2008) (statement of Sen. Baucus).
[31] *Id.* at 7960.
[32] Clamon, *supra* note 4, at 482.