# Health Care Reform Advisory: Comparative Effectiveness Research Proposals — Potential Implications for Stakeholders

1/4/2010

By Dianne J. Bourque, Deborah A. Daccord, and Karen S. Lovitch

The House and Senate health care reform proposals create federal comparative effectiveness research centers to conduct, support, and disseminate findings from comparative effectiveness research. The Senate bill creates an independent, nonprofit corporation, to be known as the "Patient-Centered Outcomes Research Institute," to identify priorities for and to conduct comparative outcomes research. Similarly, the House bill creates a new center within the Agency for Healthcare Research and Quality, referred to as the "Center for Comparative Effectiveness Research." This new center would be responsible for conducting, supporting, and synthesizing outcomes research to assess the effectiveness and appropriateness of health care services and procedures. Although the goal of both proposals is to identify effective and efficient treatment options, they give rise to questions about exactly how comparative effectiveness research results will be used, and the extent to which they will influence coverage and reimbursement policies or otherwise impact patient care and potentially limit provider treatment choices.

## What is Comparative Effectiveness Research?

Generally, comparative effectiveness research is evidence-based research to evaluate and compare the health outcomes and clinical effectiveness of two or more medical treatments. "Medical treatments" subject to evaluation under the House and Senate bills include medical procedures, medical devices, diagnostic tools, drugs and biologicals, treatment protocols, and other strategies or items used in patient care. The results of comparative effectiveness research are to be publicly disseminated, with the intent of helping providers, patients, and others evaluate various treatments relative to other options. Despite the benign purpose stated in both bills, and the inclusion of provisions prohibiting influence on coverage decisions or the practice of medicine, there is still a great deal of debate over the impact of comparative effectiveness research results on health care policy.

In addition to these concerns, a federal comparative effectiveness research mandate raises issues for a variety of stakeholders in the health care industry:

# Issues for Stakeholders

## Physicians

- **New opportunities to participate in research:** Both the House and Senate bills provide funding for primary research, as well as for the evaluation of existing data.
- **Training opportunities:** The Senate bill includes funding to train researchers in comparative effectiveness research.
- **Consultation opportunities:** The comparative effectiveness research programs established under both bills rely heavily on physician input to identify national priorities and to evaluate findings.
- **Further empowered patients:** Patients are increasingly self-educated, and the public dissemination of comparative effectiveness research findings is likely to further empower patients and prompt new questions for their providers.
- **Practice of medicine boundary issues:** Both the House and Senate bills expressly state that findings cannot infringe on the practice of medicine. However, in practice, bright lines may be difficult to draw when certain treatments are determined to be superior to others.

## Drug, Device, and Biotech Companies

- **Dissemination of negative research findings:** Both bills emphasize the importance of disseminating findings from clinical trials—both successful and unsuccessful—as well as published and unpublished research results. The process to be used for gathering this information is unclear, and whether it will include results from private as well as government-funded research remains to be seen. In any event, the dissemination of unfavorable clinical trial results could create issues for both publicly and privately held companies.
- **Limited opportunities for participation:** Both bills limit participation by drug and device companies on federal comparative effectiveness research advisory panels.
- **More sunshine:** Both bills require that physician relationships with industry be disclosed and that potential conflicts be managed, reduced, or eliminated.

## Payors

- **Reimbursement:** Both bills expressly state that comparative effectiveness research findings are not to be construed as coverage, payment, or reimbursement mandates. However one of the goals of comparative effectiveness research is to make health care more cost-effective. It is unclear how the House or Senate proposal would avoid coverage mandates or whether such a result truly is intended.

Improving quality and efficiency in health care delivery is a key goal of the health care reform effort, but the role of comparative effectiveness research in this effort remains to be seen. Stakeholders should closely monitor how these provisions develop as the House and Senate move toward a final bill, and how they ultimately are implemented to see how concerns related to coverage and provider decision-making are addressed.

* * *

***For up-to-date information regarding health care reform, please visit our Health Care Reform: Analysis & Perspectives page.***

***Please click here to learn more about our health care reform practice.***

For further information regarding this or any issue related to Health Care Reform, please contact one of the attorneys listed below or the Mintz Levin attorney who ordinarily handles your legal affairs.

**Alden J. Bianchi**
*Chair, Employee Benefits and Executive Compensation*
(617) 348-3057
AJBianchi@mintz.com

**Karen S. Lovitch**
*Manager, Health Law Practice*
(202) 434-7324
KSLovitch@mintz.com

**Jeremy Rabinovitz**
*Senior Executive Vice President of Government Relations, ML Strategies*
(202) 434-7443
JRabinovitz@mlstrategies.com

**Stephen M. Weiner**
*Chair, Health Law Practice*
(617) 348-1757
SWeiner@mintz.com