HemOncToday.com

Volume 10 • Number 18
SEPTEMBER 25, 2009

HemOnc today
CLINICAL NEWS IN ONCOLOGY AND HEMATOLOGY

REGULATORY & LEGISLATIVE ISSUES

Impact of comparative effectiveness research

by Jennifer Newberger

Although the concept of comparative effectiveness research is not new, politicians and medical providers alike have recently been paying increased attention to it.

So far, Congress has considered four comparative effectiveness research (CER) bills in the 111th Congress, and included funding for CER in the American Reinvestment and Recovery Act (Recovery Act) passed in February 2009. Part of the funding provided in the Recovery Act was used to establish the Federal Coordinating Council for Comparative Effectiveness Research, which issued its first "Report to the President and the Congress" on June 30, 2009. The Council Report defined CER as:

[T]he conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, in order to respond to their expressed needs about which interventions are most effective for which patients under specific circumstances.

In order to provide this information, the Report stated that CER must "assess a comprehensive array of health-related outcomes for diverse patient populations and subgroups," and that the interventions compared "may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies."

It is important to note that the definition provided by the Council includes only clinical comparative effectiveness, without taking into account the costs associated with those treatments. Nevertheless, the provision of funding by the federal government to support this research has led to debate about whether CER should be provided by the federal government and whether CER will in fact affect medical treatment and reduce health care spending. To achieve these changes, "the results of comparative effectiveness analyses would ultimately have to change the behavior of doctors and patients." It is perhaps this concern — federally-funded health care research intended to affect the behavior of doctors and patients — that have led some to fear that federal government involvement in CER will lead to "government rationing of medical care."

Rationing care

Possibly in response to such concerns expressed prior to enactment of the Recovery Act, the Recovery Act CER provisions specifically prohibit the Council from mandating "coverage, reimbursement, or other policies for any public or private payer," and likewise provides that none of the reports or recommendations made by the Council "shall be construed as mandates or clinical guidelines for payment, coverage, or treatment." Nevertheless, the Report of the Council expresses intent to "provide information that helps clinicians and patients choose which option best fits a patient's needs and preferences" and to help them determine "which interventions work best for specific types of patients (eg, the elderly, racial and ethnic minorities)."

Providing information to physicians and patients about the comparative effectiveness of certain types of treatments is not, however, the same as mandating clinical decision-making; nor does it necessarily involve requiring or prohibiting coverage by public or private payers of specified treatments analyzed in the CER. As required by the Recovery Act on June 30, 2009, the Institute of Medicine released its recommendations on which study topics related to certain diseases, research methods, and health care models should be priorities for CER funding. The Report notes that although "the overall value of a strategy can be understood best by considering costs and benefits together," and that "[m]any stakeholders thought CER might persuade payers to support or improve reimbursement for particu-

The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers.

lar services," the committee "did not discuss leveraging research findings to payment policy."

However, even if payers were to use CER results to make coverage determinations, it is not clear that these determinations would negatively impact the availability of health care services. Presumably, the coverage determinations would be based on what is "effective," taking into consideration both cost and clinical effectiveness, rather than making coverage determinations based solely on cost, as insurance companies often do. And, as today, if a patient seeks or a provider recommends a service that is not covered by insurance, the patient may independently pay for that service.

None of the reports or recommendations made by the Council "shall be construed as mandates or clinical guidelines for payment, coverage, or treatment."

Physicians may want to consider the CER results when making treatment decisions. CER will inform physicians of the many varied treatment options available for particular conditions, and those options that tend to work most effectively with certain patients. CER will not, however, mandate that clinicians follow any specific recommendations, nor will CER prohibit clinicians from utilizing a method or service they deem most suitable, even if that method was deemed "ineffective" by CER. ■

Preserving Access to Targeted, Individualized, and Effective New Treatments and Services (PATIENTS) Act of 2009, S 1259, 111th Cong (2009).

Doctor-Patient Relationship and Research Protection Act, HR 2824, 111th Cong (2009).

Patient-Centered Outcomes Research Act of 2009, S 1213, 111th Cong (2009).

Comparative Effectiveness Research Act of 2009, HR 2502, 111th Cong (2009).

Michael F. Cannon. A Better Way to Generate and Use Comparative-Effectiveness Research, Cato Institute, Policy Analysis, No. 632, at 1 (Feb. 6, 2009).

American Recovery and Reinvestment Act of 2009, HR 1, 111th Cong, §701 (2009).

HR 1 §804.

Federal Coordinating Council for Comparative Effectiveness Research, Report to the President and the Congress, at 16 (June 30, 2009).

Scott Gottlieb. Promoting and Using Comparative Research: What Are the Promises and Pitfalls of a New Federal Effort? American Enterprise Institute for Public Policy Research, Health Policy Outlook, No. 2 (Feb. 2009).

Congressional Budget Office. Research on the Comparative Effectiveness of Medical Treatments, at 25-26 (December 2007).

Institute of Medicine. Initial National Priorities for Comparative Effectiveness Research, Executive Summary, at S-2 (June 30, 2009).

Jennifer Newberger is an Associate at Arnold & Porter LLP in Washington, DC. Allison Weber Shuren, MSN, JD, assigned, coordinated and edited this article prior to publication. Ms. Shuren may be reached at Arnold & Porter LLP, Washington DC.