



H.R. 1, the “American Recovery and Reinvestment Act of 2009” Explanation of Comparative Effectiveness Research (CER) Provisions¹

There is widespread consensus, driven in part by the Institute of Medicine (IOM) and other prominent health stakeholders, that physicians and patients would benefit from research on the relative clinical benefits of various treatment and diagnostic modalities. As a result, IOM’s recommendation that the government should increase support for comparative effectiveness research (CER) has been met with widespread support. (See CMS Report 5 (A-08)). The AMA opposes conferring a federal CER entity with the authority to make or recommend coverage or payment decisions for payers.

When implemented consistent with AMA policy, CER should improve health care value by enhancing physician clinical decision-making—not dictating it—and fostering the delivery of patient-centered care.

The “American Recovery and Reinvestment Act of 2009” (ARRA) provides a meaningful, initial down payment on CER that will strengthen the delivery of evidence-based medicine while preserving physician decision-making autonomy. Title VIII of ARRA includes a \$1.1 billion appropriation to fund additional CER administered by the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH), and the Secretary of the Department of Health & Human Services (HHS). This funding will “be used to conduct or support research to evaluate and compare clinical outcomes, effectiveness, risk, and benefits of two or more medical treatments and services that address a particular medical condition” as specified in the Conference Report concerning the CER provisions. The corresponding statutory language of ARRA signifies the preeminence of clinical outcome-based research and analysis (as opposed to research driven by cost analysis and cost containment). Also, the Conference Report “recognizes that ‘a one-size-fits-all’ approach to patient treatment is not medically appropriate.”

ARRA incorporates existing provisions in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that prohibit HHS from including national clinical guidelines or coverage determinations in CER. As a result, contrary to some inaccurate media reports, this new law does not appropriate funds to support federal agency mandates that specify the course of treatment for individual patients and deprive physicians of discretion.

ARRA establishes a new advisory council called the Federal Coordinating Council for Comparative Effectiveness Research. The authority and responsibilities of this advisory council are limited. The essential function of this advisory council is to coordinate CER and related health services research among federal agencies in order to reduce “duplicative efforts,” and encourage “coordinated and complementary use of resources.” Membership on the advisory council would be comprised of senior representatives of federal agencies, of which at least half

¹ This summary will be updated when additional details become available during the rule-making process.

would be physicians or others with clinical expertise. The scope of the advisory council's work is strictly limited to CER. ARRA includes explicit language that the advisory council does not have the authority to mandate coverage, reimbursement, or other policies for any public or private payer.

AHRQ, which already supports CER, will receive an additional \$300 million to scale-up CER and transfer another \$400 million to the National Institutes of Health (NIH) to do the same. The HHS Secretary will receive \$400 million in order "to accelerate the development and dissemination" of CER. ARRA includes a number of specific directives on how some these funds are to be used by the Secretary. First the Secretary must immediately enter into an IOM contract for the preparation of a report that will be submitted by June 30, 2009, to the Secretary and Congress identifying CER priorities. The IOM must consider input from health care stakeholders. The Secretary must also publish information on grants and contracts awarded from the appropriated funds within a reasonable time of the obligation of funds and disseminate the CER findings to clinicians, patients, and the general public. Recipients of the appropriated funds must offer an opportunity for public comment, to the extent feasible, on the research, and the Secretary must report annually on the research conducted or supported through the funds.

The AMA will continue to work with policymakers and stakeholders to ensure that physicians have a central role in CER, and that clinical considerations drive CER analysis, findings, and eventual information disseminated to physicians. While the AMA supports the use of cost-effectiveness considerations by physicians, we emphasize that cost-effectiveness is subordinate to the consideration of safety and clinical effectiveness. Cost-effectiveness must not be used by payers to preclude or limit the availability of a safe and effective technology that is medically indicated.

The AMA strongly supports federal funding to build the clinical evidence base and address knowledge gaps that cannot be undertaken by physicians in isolation. The focus must be on ensuring that physicians have information to enhance the value of medical services, and maximizing health outcomes and quality of care for patients. Physicians should access to the best available evidence at the point of care to ensure that the chosen intervention is the most effective for a given patient and condition. in reducing morbidity and mortality.