LegalNotes

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LegalNotes is a regular online *Aligning Forces for Quality* (AF4Q) publication that provides readers with short, readable summaries of developments in the law that collectively shape the broader legal environment for efforts to improve quality, reduce health care disparities, and improve the transparency of price and quality information.

The American Recovery and Reinvestment Act of 2009

Part III - Comparative Effectiveness Provisions

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On February 17, 2009, President Barack Obama signed the American Recovery and Reinvestment Act of 2009 (ARRA), also called the "Recovery Act," into law.[1] ARRA provides hundreds of billions of dollars in new health and health care spending, including more than $19 billion to support and promote the adoption of electronic health records. In three short briefs, we address key areas of the law: health information technology, privacy and comparative effectiveness.

This third and final brief of the **Legal**Notes three-part series on ARRA focuses on the law's comparative effectiveness provisions.

Significant Funding for Comparative Effectiveness

Comparative effectiveness research (CER) compares treatments and strategies for improving health outcomes. This information is essential for clinicians, patients and policy makers to determine the best course of care. ARRA appropriates significant funding totaling $1.1 billion to support CER and creates a Federal Coordinating Council for CER. These funds are allocated as follows:

- U.S. Department of Health and Human Services (HHS)–$400 million
- National Institutes of Health (NIH)–$400 million
- Agency for Healthcare Research and Quality (AHRQ)–$300 million

With these funds, the Recovery Act requires HHS, NIH and AHRQ to accelerate the development and dissemination of research that compares the effectiveness of health care treatments and strategies by:

1. conducting, supporting or synthesizing research that compares the clinical outcomes, effectiveness and appropriateness of items, services and procedures that are used to prevent, diagnose or treat diseases, disorders and other health conditions; and
2. encouraging the development and use of clinical registries, clinical data networks and other forms of electronic health data that can be used to generate or obtain outcomes data.[2]

This is not a new role for AHRQ, which was authorized under Section 1013 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) to conduct and support evidence reviews and research on high priority for Medicare, Medicaid and the State Children's Health Insurance Program.[3] Through its Effective Health Care Program, AHRQ has since focused its research on a priority list of conditions and to date, has issued 10 comparative effectiveness reports.[4] In addition, AHRQ has released numerous related consumer and clinician-focused summary guides as well as summaries of research in progress. The AHRQ National Advisory Council for Healthcare Research and Quality also held a public meeting on April 3, 2009 to gather input to identify priorities for the use of ARRA's CER funding.

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For HHS and NIH, ARRA creates new responsibilities; the NIH addition signals an interest in comparing not only existing care processes, but also clinical and scientific innovation against current practice.

The Conference Committee report on ARRA provides clarification of these government activities, explaining that CER funds are to be used to "conduct or support research to evaluate and compare the clinical outcomes, effectiveness, risk, and benefits of two or more medical treatments and services that address a particular medical condition." They may not be used to "mandate coverage or reimbursement" policies for any public or private payer, thus extending existing provisions from MMA that prohibit HHS from limiting payments to certain procedural approaches or from mandating particular clinical approaches as a condition of participation or payment.[5] The House and Senate conferees also indicated that, similar to provisions in MMA, ARRA funding is not intended to foster a "one-size-fits-all" approach to patient treatment, recognizing that patient and clinical treatment options and preferences may vary and thus, payment approaches must be able to tolerate variation as well.[6] Despite these assurances, the debate continues on whether CER may ultimately limit patient care and treatment choice.

The one notable difference between the prior House and Senate versions of the bill relates to the term "comparative effectiveness." The Senate bill included the word "clinical" before "comparative effectiveness" throughout the bill, which indicates an intention to ensure that CER is used to determine the more appropriate medical treatment and not the more cost-efficient treatment. The term "clinical" was removed from the final bill "without prejudice" (i.e., without making a judgment about the use of the term), and the final bill does not include any reference to the consideration of cost in conducting CER. Thus, while the Conference Report clearly indicates a focus on *clinical* comparative effectiveness, exclusion of the term "clinical" from the language of the final bill does leave the door open for future debate over the role of cost in CER.

Federal Coordinating Council for CER

ARRA also creates a Federal Coordinating Council for CER responsible for fostering coordination of comparative effectiveness activities conducted or supported by relevant federal departments and agencies.[7] This council is specifically tasked with:

1. assisting the federal government, including HHS, the U.S. Department of Veterans Affairs (VA) and the U.S. Department of Defense (DOD), to coordinate the conduct or support of comparative effectiveness and related health services research; and
2. advising the President and Congress on strategies to support the federal government's infrastructure for CER and organizational expenditures for CER by relevant federal departments and agencies.[8]

On March 20, 2009, HHS announced the members of the new Council, including representatives from AHRQ, NIH, Centers for Medicare and Medicaid Services, Food and Drug Administration, Centers for Disease Control and Prevention, and the Office of the National Coordinator for Health Information Technology, among others within HHS, as well as the VA, DOD and the Office of Management and Budget.[9]

Under ARRA, the Council must submit an initial report before June 30, 2009, describing current federal CER efforts and recommendations for CER research to be conducted using ARRA funds. Subsequently, the Council must submit an annual report of its activities and recommendations related to the infrastructure and funding needed for the federal government to coordinate CER. The legislation makes clear, however, that nothing in these reports shall be construed as mandates or clinical guidelines for payment, coverage or treatment.[10]

Funding Requirements

In funding CER activities, either by grant or contract, ARRA requires HHS to take into consideration the recommendations of both the Federal Coordinating Council for CER and the Institute of Medicine (IOM). HHS must also publish information on CER grants and contracts awarded with the funds provided under the Recovery Act; ensure that any grantees or contractors provide an opportunity for public comment on their research as feasible; ensure that research findings are made available to clinicians, patients and the general public; and ensure that all grantees and contractors include women and minorities in their research as appropriate.

IOM to Recommend CER Priorities

Building on existing work undertaken by IOM, ARRA requires HHS to enter into an additional contract with IOM (up to $1.5 million of the allocation to HHS) to develop recommended national priorities for CER. These recommendations must be included in a report submitted to Congress and the Secretary of HHS by June 30, 2009. In developing these recommendations, IOM must consider stakeholder input. Towards this end, IOM held a public meeting on March 20, 2009 to gather public input. More than 35 organizations representing a wide variety of stakeholders from physicians to device and drug manufacturers to consumers provided comments, and the IOM also accepted written comments through March 27, 2009.

Ensuring Appropriate Use of Funds

To ensure appropriate use of funds, ARRA requires the Secretary to prepare an annual report on the research conducted or supported by ARRA funds. Furthermore, the Recovery Act requires that the Secretary, jointly with the AHRQ and NIH Directors, provide a report on the planned and actual use of ARRA funds, including the type of research conducted, primary conditions addressed, and allocations of resources within HHS, prior to making any obligations for fiscal years 2009 and 2010.[11]

Conclusion

Although ARRA provides funding for research and coordination of federal government activities, the larger issues of how CER will be coordinated across the public and private sectors and how information generated by CER will be used remain undetermined. Specifically, the Recovery Act does not address the following issues:

1. *Should a single entity be responsible for conducting and disseminating CER?* Some organizations, such as IOM and MedPAC, have recommended that Congress create a single entity with authority, resources and capacity to produce unbiased information about clinical effectiveness.[12] Others, such as the American Medical Association, oppose the creation of a single federal entity that would make or recommend coverage or payment decisions based on CER.[13]
2. *If there is a single entity, should it be based in government, the private sector or a public-private venture?* The IOM recommendations do not address whether a single CER entity should be based in the public or private sectors, or a public-private collaborative effort.[14] In contrast, MedPAC recommends a public-private approach governed by an independent board of directors.[15]
3. *How should the results of CER be used?* While there is clear consensus that the results of CER should be made available to clinicians, patients and payers, there is less consensus for how the information should be used. ARRA clearly indicates that CER should be used to inform clinical practice and patient choice; however, concern remains that CER could be used to dictate coverage and reimbursement decisions which may lead to limitations on patient access to care. MedPAC is clear that the single entity should not play a role in determining how public and private payers use CER information.[16]
4. *Should cost information be included in CER?* MedPAC recognizes that while clinical comparative effectiveness is the primary goal, cost may be an important factor for end users of the information, regardless of whether two or more treatments or services are equally effective.[17] However, while both IOM and ARRA focus on clinical effectiveness comparisons, the language of ARRA does not rule out inclusion of cost information in CER.

While some of these issues will be addressed in the numerous reports required from IOM and the Federal Coordinating Council for CER under ARRA, resolution of these fundamental issues can be expected to evolve over time.

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[1]The American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111-5, 111th Cong., 1st sess. (2009).

[2]*Id.*

[3]Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Public Law 108-173 (2003), § 1013.

[4]Agency for Healthcare Research and Quality, "Effective Health Care Research Reviews," U.S. Department of Health and Human Services, *http://effectivehealthcare.ahrq.gov* (accessed April 30, 2009).

[5]MMA, § 1013(b).

[6]U.S. House of Representatives, "Joint Explanatory Statement of the Committee of the Conference," *http://www.house.gov/billtext/hr1_cr_jes.pdf* (accessed April 30, 2009); MMA §1013(b)(2).

[7]ARRA, § 804(a).

[8]*Id.*

[9]"Federal Coordinating Council for Comparative Effectiveness Research Membership," U.S. Department of Health and Human Services, *http://www.hhs.gov/recovery/programs/os/cerbios.html* (accessed April 30, 2009).

[10]ARRA, § 804(g).

[11]ARRA, Title VIII.

[12] Committee on Reviewing Evidence to Identify Highly Effective Clinical Services, Institute of Medicine. *Knowing What Works in Health Care: A Roadmap for the Nation*. Washington: National Academies Press, 2008; *Report to the Congress: Promoting Greater Efficiency in Medicare*. Washington: Medicare Payment Advisory Commission, 2007. (No authors given.)

[13]"H.R. 1, the 'American Recovery and Reinvestment Act of 2009' Explanation of Comparative Effectiveness Research (CER) Provisions," American Medical Association, *http://www.ama-assn.org/ama1/pub/upload/mm/399/arra-cer-provisions.pdf* (accessed April 30, 2009).

[14]Committee on Reviewing Evidence to Identify Highly Effective Clinical Services, Institute of Medicine. *Knowing What Works in Health Care: A Roadmap for the Nation*. Washington: National Academies Press, 2008.

[15]*Report to the Congress: Promoting Greater Efficiency in Medicare*. Washington: Medicare Payment Advisory Commission, 2007. (No authors given.)

[16]*Id.*

[17]*Id.*