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Healthcare Reform Law: Comparative Effectiveness Provisions Concerning Healthcare Products and Services

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The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law), contains provisions supporting the development of comparative effectiveness research (CER). Section 6301 of the Healthcare Reform Law authorizes the establishment of a nonprofit corporation known as the Patient-Centered Outcome Research Institute (Institute), whose purpose is to "assist patients, clinicians, purchasers, and policy-makers in making informed health decisions" through conducting CER and disseminating research findings. The Institute replaces the Federal Coordinating Council for Comparative Effectiveness Research that was established under the American Recovery and Reinvestment Act of 2009 (ARRA), which allocated $1.1 billion for comparative effectiveness research.[1] Medical product manufacturers and healthcare providers should closely monitor the development and implementation of CER because of the interest shown by certain groups and government entities in using CER to assist with respect to healthcare cost-containment efforts. In view of this interest, cost/comparative effectiveness elements must be assessed by product developers at an earlier stage, including during clinical trials; claims and comparisons derived from CER will need to be considered as part of product promotion and marketing; and changes in valuation of medical products manufacturers and healthcare service providers will have to be assessed with respect to acquisitions and collaboration agreements.

CER Development Under the Healthcare Reform Law

As defined under section 6301(a) of the Healthcare Reform Law, CER involves comparison of the health outcomes and clinical effectiveness of two or more medical treatments, including healthcare intervention, medical devices, drugs, and biologics. The Institute's major activities will include identifying national research priorities, establishing a methodology committee, establishing and carrying out research project agenda, and disseminating the research findings. The Institute is to contract with federal agencies and academic and private sector research institutes to manage funding and conduct research, with preference given to the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH).

Although CER findings can be potentially used by private payers as a basis for product and service approval or reimbursement decisions, the immediate impact of the CER provisions will likely be limited due to a number of factors, including statutory restrictions, lack of CER studies, the absence of any consensus on protocols to study comparative effectiveness or how to apply CER studies in treatment

[1] Section 6302 of the Healthcare Reform Law.

decisions, and the usefulness of CER results in certain areas such as cancer treatment. These issues are discussed briefly below.

Statutory Restrictions. The Healthcare Reform Law requires the Institute to "ensure that the [comparative effectiveness] research findings not be construed as mandates for practice guidelines, coverage recommendations, payment, or policy recommendations."[2] The Institute is also prohibited from developing or employing a "dollars-per-quality adjusted life year" or similar measures as a threshold to establish what type of healthcare is cost effective and recommended. These statutory restrictions establish a tension with the interest in the use of CER as a significant element of healthcare cost containment. The potential for significant controversy was illustrated by the rejection at the end of 2009 of recommendations by the U.S. Preventive Services Task Force to end routine mammograms for women in their forties and for less frequent testing for women 50 and older based on review of various studies.

Lack of Historical CER Studies. As a significant portion of CER involves analysis of existing clinical trials, the lack of studies that compare the effectiveness of one medical product to another, or a product to a medical treatment option, will likely lead to a delay in the development of CER findings acceptable for treatment decisions. It will also be challenging to compare different trials that have very different enrollment criteria and study populations. For these and other reasons—including the absence of any widely accepted protocols as to the conduct of CER—physicians, hospitals, and patients will likely be slow to adopt CER findings that suggest a medical product or treatment is less effective with respect to costs or patient outcomes.

Research Limitations. In certain areas where research is advancing rapidly, such as cancer treatment, the acceptability of CER findings, which are typically derived from analysis of older, previously completed studies, also may be quite limited because the physician and patient may have access to treatment options that were not available a few years ago. In addition, where a person's genetic background may affect the treatment outcome, it is questionable whether CER results derived from studies of the general population would help an individual or a subpopulation who may have different expressions of cancer-related genes to make "informed health decisions." This limitation would particularly affect the development of personalized medicines.

CER Results Uncertain. There is also an unavoidable and significant level of uncertainty concerning the results of CER studies. This is due in part to the difficulties of analyzing different clinical trials, as discussed above, as well as a relative lack of experience by AHRQ or NIH in conducting primary research (such as randomized clinical trials) that compare two treatments head to head. For example, NIH's first comparative drug study, a multicenter clinical trial comparing the relative safety and effectiveness of two drugs, Lucentis and Avastin, was begun only in 2008, with the results not expected until 2011.[3]

Absence of Accepted CER Protocols. The absence of a widely accepted CER protocols or methodology also contributes to the level of uncertainty—under the Healthcare Reform Law, CER methodological standards shall be developed by a methodology committee within 18 months after the establishment of the Institute, a process that is likely to generate considerable controversy among medical product manufacturers and healthcare providers as well as professional medical specialty groups. Similarly, critical questions such as whether a comparison should be between two drugs, or a drug and a device, or a medical treatment and nontreatment (e.g., diet and lifestyle changes), and

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[2] Section 6301(a) of the Healthcare Reform Law, adding section 1181(d)(8)(iv) of Title XI of the Social Security Act.

[3] NIH National Eye Institute Press Release, Feb. 22, 2008, available at http://www.nei.nih.gov/news/pressreleases/022208.asp.

whether the objective of the CER is to identify a treatment with a lower cost or one with superior patient outcomes, will also generate significant controversy.

Immediate and Future Implications

The development and implementation of CER should be closely monitored by medical product manufacturers and healthcare providers because of the interest among certain groups and government entities in using CER to assist with respect to healthcare cost-containment efforts. For example, the Healthcare Reform Law allows the Secretary of the Department of Health and Human Services to use CER results to make a determination concerning Medicare coverage, if such use is through an iterative and transparent process, and if a determination to deny coverage is not based solely on CER.[4] In addition, the statutory restrictions on the use of CER results are not applicable to private payers. AHRQ noted recently that some CER findings obtained through its Effective Health Care Program have been used to provide employers and their employees with the best available evidence for designing benefits and making treatment choices.[5] Many organizations already have used CER results "in their deliberations of patient care, formulary design, and areas for needed research."[6] AHRQ itself is actively seeking to improve methods of dissemination of the CER results to healthcare providers.[7] CER thus may influence a number of policies and guidelines in the United States, including payers' reimbursement policies, as it has the decisions of the UK's National Institute for Health and Clinical Excellence (NICE).

Consequently, medical product manufacturers and healthcare providers should consider other activities and issues relating to CER in addition to monitoring developments, including (1) providing comments regarding the Institute's proposed adoption of certain agenda and standards, such as national priorities, research project agenda, and methodological standards; (2) incorporating cost/comparative effectiveness aspects into clinical trials of drugs, biologics, and medical devices; (3) assessing how to use cost/comparative effectiveness trials and studies in the promotion of drugs, biologics, and medical devices; and (4) assessing CER as part of the valuation of medical products or medical product manufacturers and healthcare providers in the context of corporate transactions and collaboration agreements.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the author of this LawFlash, **Stephen Paul Mahinka** (202.739.5205; smahinka@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

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4 Section 6301(c) of the Healthcare Reform Law, amending Part D of title XI of the Social Security Act by adding section 1182.

5 *See* Agency for Healthcare Research and Quality, FY 2011 Online Performance Appendix.

6 *Id*.

7 *Id*.

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