Partnership to Improve Patient Care

A Procedural Framework for the Conduct of Comparative Clinical Effectiveness Research

NOVEMBER 2010

Introduction

The *Patient Protection and Affordable Care Act (PPACA)*, at section 6301, authorizes a major new program for comparative clinical effectiveness research.[1] The health reform law establishes a private nonprofit, tax-exempt corporation—a Patient-Centered Outcomes Research Institute—to "assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis…."[2] The *PPACA* specifies that the Institute "shall enter into contracts for the management of funding and conduct of research"[3] with government agencies and academic or private sector research entities, and that it "shall give preference to the Agency for Healthcare Research and Quality and the National Institutes of Health."[4]

The health reform law also lays out a framework for conducting comparative effectiveness reviews that includes several key elements:

- ***Stakeholder Involvement***—a requirement for broad stakeholder representation on the Institute's Board of Governors and other expert advisory panels that carry out its mandate;
- ***Transparency***—a requirement that the Institute's operations and procedures are made clear to the public, and that policy documents are made available in a timely way;
- ***Public Participation***—a requirement that the public is given an opportunity to comment on policy documents, procedures, and reports; and
- ***Open Decision-Making***—a requirement that the public is notified of meetings of the Institute's Board of Governors, that meetings are open, and that decisions on comparative effectiveness research are made in full view.

In some areas, these requirements are set forth explicitly in the health reform law. In other areas, these requirements are identified in statute but not fully defined, and will need to be addressed in the course of the new law's implementation. In both cases, it is expected that putting this framework into operation will be influenced by procedures and approaches that have been developed for federal comparative effectiveness research (CER) efforts currently underway, funded prior to the enactment of the *PPACA*.

Objective

This paper inventories and discusses the basic elements of the framework for CER that are identified in *PPACA*: requirements for stakeholder participation in comparative effectiveness research; requirements for transparency in procedures and operations; requirements for public opportunity to comment on CERs and to be engaged in Patient-Centered Outcomes Research Institute (PCORI) review processes; and requirements for open decision-making processes. This paper also compares these requirements to current procedures developed and used by the Agency for Healthcare Research and Quality (AHRQ) to conduct CER through its Effective Health Care Program[5] and through the funding provided by the *American Recovery and Reinvestment Act* (*ARRA*).

[1]The *Patient Protection and Affordable Care Act* (P.L. 111-148) was signed into law on March 23, 2010. This legislation was modified by the *Health Care and Education Reconciliation Act* (P.L. 111-152), which was signed into law on March 30, 2010.
[2]See the Purpose of the Institute, set forth at Section 1181(c) of the *Social Security Act*.
[3]Section 1181(d)(2)(B)(I) of the *Social Security Act*.
[4]Section 1181(d)(2)(B)(II) of the *Social Security Act*.
[5]This program was authorized by Section 1013 of the *Medicare Modernization Act of 2003.*

The analysis that follows also provides a series of Tables that lay out the key elements of the CER framework specified in *PPACA* and compares them to The Department of Health and Human Services (HHS) CER approaches currently in use. The statutory language authorizing the Effective Health Care Program (Section 1013 of the 2003 *Medicare Modernization Act*) and the CER funding in *ARRA* are provided in Appendices to this paper.

Analysis

Stakeholder Involvement

PPACA. The *PPACA* provides for broad stakeholder participation on both its governing board and its advisory committees. It requires the 21-member Board of Governors of the new PCORI to include a specified number of representatives of patients and consumers, physicians and providers, health insurers, medical technology manufacturers, researchers, and government.[6]

Congress appears to have carefully balanced the composition of the Board. Patients and consumers (3 representatives), physicians (4 representatives), nurses (1 representative), and integrated health care practitioners (1 representative) combine for a total of 9 representatives; government (4 representatives), insurers (3 representatives), and quality improvement and health service researchers (1 representative) have a total of 8 representatives; technology manufacturers and developers have 3 representatives; and hospitals have 1 representative.

While the law identifies the Directors (or designees) of AHRQ and NIH as members of the Board, it delegates responsibility to the Comptroller General to make the other 19 appointments to the Board. The Board of Governors is intended by Congress to "represent a broad range of perspectives and collectively have scientific expertise." Appointments to the Board shall be made for 6-year terms staggered evenly over 2-year increments. No individual shall be appointed for more than 2 terms.

In addition, the law specifies that the Board may make use of both standing and *ad hoc* Expert Advisory Panels to support the Institute's work—identifying research priorities, establishing the research project agenda, and "for other purposes." These panels must have broad representation, including patient and provider representatives.

The *PPACA* requires that two *ad hoc* Expert Advisory Panels be established: a Clinical Trials panel and a panel for each project related to a Rare Disease, and it provides statutory direction on the composition of these panels, as well as other expert advisory panels that the Board chooses to establish. Though precise numbers are not set out, the law states that these panels must include: practicing and research clinicians; patients; and experts in scientific and health services research, health services delivery, and evidence-based medicine who have experience in the topic—and, as appropriate, experts in integrative health and primary prevention strategies.

The law also places an emphasis on effective consumer and patient involvement in PCORI activities by mandating that the Institute provide support and resources to help consumers and patients participate effectively on the Board and the Expert Advisory Panels.

PPACA calls for the establishment of a separate 15-member expert Methodology Committee to be appointed by the Comptroller General to address methodological standards for comparative effectiveness research.

[6]The law requires the Board to be composed of: the Directors of AHRQ and NIH (or their designees) and 19 others appointed by the Comptroller General, as follows: 3 members representing patients and health care consumers; 7 members representing physicians and providers (4 physicians, of whom at least 1 is a surgeon; 1 nurse; 1 state-licensed integrated health care practitioner; and 1 hospital representative); 3 members representing private payers (at least 1 must represent health insurers and at least 1 must represent self-insured employers); 3 members representing pharmaceutical, medical device, and diagnostic manufacturers or developers; 1 member representing quality improvement or independent health service researchers; and 2 members representing the Federal Government or the States (at least 1 member representing a Federal health program or agency).

This Methodology panel is required to be composed of the National Institutes of Health (NIH) and AHRQ Directors (or their designees) and "experts in their scientific field" (e.g., health services research, clinical research, comparative clinical effectiveness research, genomics, biostatistics, and research methodologies). The law specifies that stakeholders with such expertise "may be appointed" to this panel, indicating that Congress recognized that experts eligible for participation need not be restricted to individuals employed by academic research centers. Patients, caregivers, and individuals employed by technology manufacturers could serve as members on this panel if they had the necessary expertise.

The law also places an emphasis on effective consumer and patient involvement in PCORI activities by mandating that the Institute provide support and resources to help consumers and patients participate effectively on the Board and the Expert Advisory Panels.

Section 1013 Effective Health Care Program. By comparison, the CER program authorized by Section 1013 of the *Medicare Modernization Act (MMA)* provides only that AHRQ must ensure that there was "broad and ongoing consultation with relevant stakeholders" in carrying out the program. The statute leaves AHRQ broad discretion in how it implements this requirement. One of AHRQ's responses to this general mandate was the formation of an advisory Stakeholder Group to provide feedback on program initiatives and to serve as a sounding board for interests impacted by the new comparative effectiveness research effort.

Three Stakeholder Group panels have been formed to date to advise AHRQ. The first panel met on a quarterly basis from early 2005 to mid-2007. The second panel met from the Fall of 2007 through early 2010. The second Stakeholder Group was organized into work groups (Product Development, Program Priorities, and Product Dissemination), and these work groups sometimes met via conference call between the face-to-face meetings.

AHRQ solicited nominations for a third Stakeholder Group in a January 7, 2010 *Federal Register* notice, and this new group began meeting in the Fall of 2010. As was the case with the two previous Stakeholder Groups, this third panel will meet for a two-year period. In the *Federal Register* notice, AHRQ stated that the role of the Stakeholder Group will be to:

- Provide guidance on program implementation, including:
  - Quality improvement;
  - Opportunities to maximize impact and expand program reach;
  - Ensuring stakeholder interests are considered and included; and
  - Evaluating success.
- Provide input on implementing Effective Health Care Program reports and findings in practice and policy settings.
- Identify options and recommend solutions to issues identified by Effective Health Care Program staff.
- Provide input on critical research information gaps for practice and policy, as well as research methods to address them. Specifically:
  - Information needs and types of products most useful to consumers, clinicians, and policy makers.
  - Feedback on Effective Health Care Program reports, reviews, and summary guides.
  - Scientific methods and applications.
- Champion objectivity, accountability, and transparency in the Effective Health Care Program.

As constituted by AHRQ, the Stakeholder Group has no fixed or specified number of members. It is composed of individuals drawn from constituencies impacted by the comparative effectiveness program, including patients, consumers, and employers, and it meets

in private.[7] No formal votes are taken, and discussions are based both on AHRQ requests for input and individual member suggestions on all aspects of the program and its implementation.

At AHRQ's request, the first two Stakeholder Groups discussed the need for public comment periods and program transparency, the program's research priorities, project selection criteria and the process of evaluating research suggestions, research methods, the need for enhancing consumer participation, opportunities to increase program impact, approaches to program evaluation, and product dissemination strategies. The Stakeholder Group is not a formal advisory committee, and is not operated according to requirements of the *Federal Advisory Committee Act*[8] concerning open meetings.

AHRQ is currently combining the management of the new Stakeholder Group (which will begin in the Fall of 2010) with an initiative to increase consumer input into CER operations and processes. AHRQ has solicited proposals to establish and support a Community Forum on Effective Health Care to formally engage stakeholders. According to AHRQ, this initiative "will build on the smaller initiative that has guided AHRQ's Effective Health Care Program and will be an important component for a larger and more sustained national initiative in comparative effectiveness research, translation, and use."[9] According to the Center for Medical Technology Policy (CMTP), this project has been awarded to the American Institutes for Research (AIR), AcademyHealth, CMTP, and several other organizations under a multi-year, $10 million per year contract.

ARRA CER Funding. *The American Recovery and Reinvestment Act of 2009* made available $1.1 billion to accelerate the development and dissemination of CER. Of the $1.1 billion, $300 million was allocated to AHRQ, $400 million to the NIH, and $400 million to the Office of the Secretary of HHS for disbursement.

The *ARRA* legislation required that a Federal Coordinating Council for Comparative Effectiveness Research (composed of senior federal officials with responsibility for health-related programs located in the HHS Department, as well as the Department of Veterans Affairs and the Department of Defense) be created to guide and coordinate the use of these funds. The legislation also called on the Institute of Medicine (IOM) to recommend national research priorities for the comparative effectiveness research conducted or supported by *ARRA* funds after considering stakeholder input. IOM formed a committee for this purpose, funded by a contract with the HHS Department. Neither the Federal Coordinating Committee nor the IOM Committee was required by *ARRA* to include stakeholders. However, the 23-person IOM Committee did include 3 consumer and patient advocacy representatives in its membership. ■

[7]The January 7, 2010 *Federal Register* notice soliciting stakeholder nominations states that the "Stakeholder Group will be composed of up to 20 members with a diversity of perspectives and opinions." The notice goes on to say that this panel "will represent several broad constituencies of stakeholders and decision-makers at the policy, system, and clinical levels, which will include:

- Patient/caregiver/consumer.
- Consumers of Federal and State beneficiary programs.
- Healthcare providers.
- Third party healthcare payers (including, but not limited to public State or Federal Medicare or Medicaid programs, and private insurance health plans and Health Maintenance Organizations).
- Employers and health-related businesses.
- Pharmacy and therapeutic committees.
- Healthcare, industry, and professional organizations.
- Academic researchers (including, but not limited to, those with expertise in evidence-based methods and effectiveness and translational research)."

[8]Public Law 92-463, enacted in 1972.

[9]See the AHRQ fact sheet on a Citizen Forum to be funded by *American Recovery and Reinvestment Act* funds: http://www.ahrq.gov/fund/cerfactsheets/cerfsforum.htm. The fact sheet states that: "The Citizen Forum on Effective Health Care will formally engage stakeholders, through a variety of transparent and inclusive mechanisms, at the critical stages of identifying research needs, study design, interpretation of results, development of products, and research dissemination. Funds will be used to develop formal processes for input, convene citizen panels, and convene a Workgroup on Comparative Effectiveness to provide formal advice and guidance to the program. Funds will also support programs in citizen awareness of the use of comparative effectiveness evidence in health care decisionmaking. These programs, developed under the guidance of the Citizen Forum, may include town hall meetings, Web-based information exchange, and community-based grassroots awareness efforts."

TABLE 1
Framework for Conducting Comparative Effectiveness Reviews: Stakeholder Involvement

PPACA SECTION 6301 PATIENT-CENTERED OUTCOMES RESEARCH	ARRA $1.1 BILLION IN CER SPENDING	MMA SECTION 1013 EFFECTIVE HEALTH CARE PROGRAM
PCORI Board of Governors – 21 members – AHRQ Director and NIH Director specified in law – 19 members appointed by the Comptroller General – Composition of 19 appointed members specified in law: 3 patient reps/consumers; 7 physician/provider reps; 3 payer reps; 3 industry reps; 1 rep for quality improvement or health service researchers; 2 federal government/state reps – [Sec. 1181(f)]	***Federal Coordinating Council*** – specified in law – "not more than 15 members, all of whom are senior Federal officers or employees with responsibility for health-related programs, appointed by the President, acting through the Secretary of Health and Human Services"	***Stakeholder Group*** – not FACA compliant; not required in law; no votes taken; serves as a sounding board – AHRQ is flexible regarding the number of members – AHRQ provides only general selection criteria in public notices soliciting nominations
PCORI Expert Advisory Panels – may be permanent or *ad hoc* – will assist in identifying research priorities, establishing the research project agenda, and for other purposes. [Sec. 1181(d)(4)(A)(i)] *Two Required Panels:* 1. *Clinical Trials Expert Advisory Panel:* – required by statute to provide advice on research questions and research design – serves as technical resource for questions arising during conduct of research [Sec. 1181(d)(4)(A)(ii)] 2. *Expert Advisory Panel for Rare Disease*: – required by statute to assist in research design and to determine relative value and feasibility of conducting the research study [Sec. 1181(d)(4)(A)(iii)]	***IOM Priority-Setting Committee*** – IOM appointed members – no statutory requirement for broad stakeholder representation on panel	

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Composition of Panels: – practicing and research physicians, patients, experts with experience in the topic – may include a technical expert of each manufacturer or each medical technology included in the study [Sec. 1181(d)(4)(B)]		
Support for Patient and Consumer Reps: – Institute must "provide support and resources" to help reps participate effectively ***Methodology Committee:*** – required by statute – standing committee – 15 members appointed by Comptroller General – composition: experts in their field; stakeholders with expertise; Directors of NIH and AHRQ – function: to develop and improve science and methods of research by developing and updating methodological standards [Sec. 1181(d)(6)]	***ARRA Funding:*** – ARRA provides funding for AHRQ Citizen Forum Contract	***AHRQ Citizen Forum Contract:*** – AHRQ solicited contracts for a Citizen Forum to engage stakeholders in CER activities – funded by ARRA; $10 million over 5 years – contractor selection forthcoming

Stakeholder Involvement Issues to Monitor. The CER provisions of *PPACA* are unique in the requirements they create for full and active stakeholder participation in both the leadership and the operations of the PCORI. While stakeholder engagement is an important and valuable characteristic of existing HHS programs for CER, it does not have the same central role that is provided by *PPACA*.

- ***PCORI.*** The PCORI will take shape in the coming months, and it will determine how stakeholder participation shapes CER deliberative processes and research objectives. It will be important to monitor both the composition of the Board of Governors selected by the Government Accounting Office (GAO) to represent the various stakeholder interests, as well as this

panel's first organizational meetings and decisions on how to proceed. These first actions and decisions will shape future processes and activities. The PCORI Board is in essence a test of a new model for the conduct of federally-supported, patient-centered CER. The way individual stakeholders work together to define and achieve common goals consistent with the statutory mandate will be crucial to the Institute's success.

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Other important issues to monitor with respect to the new Institute include the selection of staff and the appointment of a CER Methodology Committee by GAO. In addition, the Institute is obligated to establish Expert Advisory Committees for clinical trials and rare diseases. How the Board addresses this task and whether it creates additional expert advisory committees (and creates processes to engage stakeholders) as authorized by statute, will provide an important foundation for its future activities.

It is also important to track the approach the Institute takes in implementing the statute's requirement to provide support to patient and consumer representatives on the Board, and to gauge its impact on the effectiveness of consumer involvement in Board activities.

Finally, it will also be important to follow how the new Institute relies on established federal agencies like AHRQ and NIH to carry out its comparative effectiveness research responsibilities. The *PPACA* authorizes the Institute to enter into contracts with both of these government agencies, as well as academic or private sector research entities. The law suggests that preference be given to these public agencies, but it does not require that they be used exclusively.

- ***AHRQ.*** AHRQ's Effective Health Care Program recently solicited and appointed members for a third Stakeholder Panel. Given the likelihood that the new Institute will rely on AHRQ and the experience it has gained in conducting CER and in engaging stakeholders, it will be important to monitor the new Stakeholder Group to ensure that it is balanced in its composition and that it is not disproportionately weighted toward the payer perspective. Further, given the emphasis in *PPACA* on openness and transparency in CER matters, it might be an opportune time to consider making this panel's operations more open and transparent to the public.

  AHRQ's contract intiative for a Community Forum will also need to be followed closely. The contractor selected for this effort will coordinate the agency's efforts to increase consumer involvement with the Effective Health Care Program, and it will include management of the Stakeholder Group. It will be important to track the level and degree of consumer engagement that results from this effort, whether the full range of stakeholders is represented in activities, and whether the focus of this effort will be on obtaining input on the nature and content of CER, as well as on communicating results and disseminating reports.

Transparency

PPACA. The *PPACA* requires the PCORI Board of Governors to meet in public at the call of the Chair or a majority of its members. The law also specifies that at least 7 days advance notice must be given for these meetings. The law is silent on whether agendas and other meeting materials must be posted, and whether other standing or *ad hoc* committees established by the Board must meet in public.

The law also requires the Institute to use an Internet web site to keep the public informed of its activities and to encourage participation. For example, Institute proceedings must be posted, research findings must be made available in a timely way (within 90 days of completion or receipt of reports), the public must be informed of comment periods and deadlines, and comments that have been submitted by the public must be provided.

It is worth noting that the *PPACA* also requires transparency in the processes and methods used by the Institute to conduct CER. It specifically requires the Institute to identify the research entity and the investigators conducting CER, the research protocols used, any conflicts of interest of these parties, and any other information the Institute determines to be appropriate.

Section 1013 Effective Health Care Program. By comparison, meetings of the Stakeholder Group established by AHRQ as part of the implementation of the *MMA* Section 1013 program are held on a quarterly basis. These meetings are closed, and meeting materials are not posted.

AHRQ encourages the public to visit the Effective Health Care Program web site, and to sign up for Listservs in order to track developments (e.g., opportunity to comment on Key Questions or Draft Reports for Systematic Reviews and to receive notices of new research topics that are underway). While there is no statutory requirement for timely posting of CER reports, it appears that CER studies are posted in a timely way after their completion. AHRQ policy is that all comments (and the report authors' responses to the comments) will be publicly posted on the Effective Health Care Program web site within 3 months after a final report is posted.

As for transparency in the processes and methods used to conduct CER, AHRQ's Effective Health Care Program, as a matter of policy, does not release information on the researchers (or research institution) conducting the CER while the research is ongoing. This information becomes apparent with the publication of final reports. AHRQ does make available research abstracts for the CER studies that are undertaken. However, it does not routinely provide estimated timelines for study completion, a matter of interest to the public.

ARRA CER Funding. Working meetings of the Federal Coordinating Committee and the IOM Priorities Committee were held in private, though the public was asked to provide input for consideration. The Federal Coordinating Committee was eliminated by Section 6302 of *PPACA*. The IOM committee that established CER priorities for *ARRA* funding completed its business when its report was issued on June 30, 2009. ■

TABLE 2
Framework for Conducting Comparative Effectiveness Reviews: Transparency

PPACA SECTION 6301 PATIENT-CENTERED OUTCOMES RESEARCH	ARRA $1.1 BILLION IN CER SPENDING	MMA SECTION 1013 EFFECTIVE HEALTH CARE PROGRAM
PCORI Board of Governors Meetings – meets in public at call of the Chair or a majority of members – public notice requirement for meetings (at least 7 days advance notice) [Sec. 1181(f)(7)]	***Federal Coordinating Council and IOM Committee Meetings*** – working meetings were not open to the public – meeting summaries were included in the report of the Council – stakeholder input was solicited by both the Council and the IOM panel	***Stakeholder Group Meetings*** – meets in private at call of AHRQ
Public Availability of Information via Internet Website – required by statute, includes the following: ***Research Findings:*** – must be made available to clinicians, patients, and the general public within 90 days of the conduct or receipt of findings [Sec. 1181(d)(8)]	***Federal Coordinating Council*** – posted final report on HHS web site ***IOM Committee*** – posted stakeholder open meeting presentations on the IOM web site – posted final report on the IOM web site ***ARRA Contract Solicitations and Funding Awards:*** – posted on AHRQ and NIH web sites	***Public Availability of Information via Internet Website*** – no statutory requirement; AHRQ EHC practice is noted below: ***Research Findings:*** – AHRQ EHC practice is to post research reports, and to notify interested parties of developments through Listservs
Process and Methods for Conduct of Research: – identity of the research entity and the investigators conducting the research – conflicts of interest – direct or indirect links to industry – research protocols – other information the Institute determines appropriate		***Process and Methods for Conduct of Research:*** – MMA Sec. 1013(a)(3)(D)(i) requires "all scientific evidence relied upon and the methodologies employed" to be made publicly available "so that the results… can be evaluated or replicated" – AHRQ EHC practice is not to post the identity of the research entity and the investigators conducting the research

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PPACA SECTION 6301 PATIENT-CENTERED OUTCOMES RESEARCH	ARRA $1.1 BILLION IN CER SPENDING	MMA SECTION 1013 EFFECTIVE HEALTH CARE PROGRAM
Notice of Public Comment Periods: – includes posting deadlines for public comments ***Comments Received During Public Comment Periods*** ***Institute Proceedings*** [Sec. 1181(h)(3)]		***Notice of Public Comment Periods:*** – AHRQ EHC practice is to post information on the review process and notify interested parties of opportunity to comment via Listservs ***Comments Received During Public Comment:*** – AHRQ EHC practice is to solicit public suggestions for research proposals, and to post suggestions them – AHRQ EHC policy is to post comments (and report authors' responses to comments) within 3 months after a final report is posted ***Stakeholder Group Proceedings:*** – AHRQ EHC practice is not to post meeting agendas, minutes, or proceedings of these meetings
Peer Reviewers: – a list of those contributing to any peer review process shall be made public and included in annual reports – PCORI may utilize the peer review processes of contractors or other entities, as well as medical journals [Sec. 1181(d)(7)]		***Peer Reviewers:*** – peer reviewers for systematic reviews are noted in the Appendix of Final Reports and posted on the web site – published reports, including DEcIDE network reports, have been subject to peer review processes of the applicable journal

Transparency Issues to Monitor.

- ***PCORI.*** As it begins its operations, the new PCORI will make a number of important decisions bearing on how transparent its activities will be to the public.

  First, it will have to decide how to notify the public of upcoming meetings of the PCORI Board of Governors, and it will have to determine what information to provide in advance of meetings. AHRQ's experience with Listservs and Internet postings might prove to be valuable in notifying the public of developments. Information that might be made available to the public prior to Board meetings could include agendas, as well as draft policies and reports to be discussed.

  Second, the Institute will have to determine whether or not time will be allocated for public comment during the meetings of the Board of Governors. The Medicare Evidence Development and Coverage Advisory Committee (MedCAC) and the Medicare Payment Advisory Commission (MedPAC) both provide for public comment periods at their meetings, and this pattern might be followed by the Institute.

  Third, the Institute will have to determine whether meetings of the standing and *ad hoc* Expert Advisory Committees established by the Board of Governors, including the Methodology Committee, will meet in public, and, if so, whether these meetings will be conducted with a degree of transparency comparable to what is established for Board meetings. The Institute will have to decide whether transcripts or minutes of meetings will be made public following the meetings, and whether public comments submitted to the Board or its Committees or matters under consideration will be made public.

  Fourth, and most important, the Institute will have to determine if it chooses to contract with public, academic, or private research entities to conduct CER. If the Institute chooses to do so, the transparency, public participation, and conflict of interest requirements set out in *PPACA* would be extended to the public and private entities that conduct CER on its behalf.

- ***AHRQ.*** In carrying out the Effective Health Care Program, AHRQ could continue with the policies it has already put into place, or it could make changes to become more consistent with the transparency requirements that are put into place at the Institute. For example, AHRQ could provide more information to the public on Stakeholder Group meetings by posting agendas and discussion topics.

  In addition, given the emphasis on transparency in the *PPACA*, AHRQ could reverse its current policy of not identifying the researchers (or research institutions) conducting CER, while research is underway. It could also provide other information that would help the public track CER activities, like posting expected completion dates for studies and projects.

Public Participation

PPACA. The *PPACA* provides a series of detailed specifications for engaging the public in PCORI operations. It specifies that a public comment period of between 45 and 60 days must be used in several areas: setting national priorities for CER; establishing a CER project agenda; determining methodological standards for CERs; developing a peer review process; and arriving at findings for systematic reviews.

Beyond this, the *PPACA* specifies that PCORI should consider making use of public forums to increase public awareness of its operations and to incorporate public input into its activities. It also requires that the Methodology Committee consult with relevant stakeholders as it carries out its duties. It specifically requires that

the process of developing and updating methodological standards must include input from experts, stakeholders, and decision-makers, as well as an opportunity for public comment.

Section 1013 Effective Health Care Program. Shortly after this program began, AHRQ took steps to engage the public in identifying research priorities for CER, including a public listening session in May 2004. Based on this input and internal discussion by a steering committee of representatives from the HHS Department, the HHS Secretary identified an initial set of 10 priority conditions focusing on the needs of Medicare populations in December 2004. A second listening session was held on January 11, 2006. In 2008, the Secretary expanded this CER priorities list to 14 conditions to include conditions also relevant to Medicaid and State Child Health Insurance Program (SCHIP) programs.

In addition, AHRQ has encouraged public participation in Effective Health Care Program activities by encouraging the public to submit research topics for CER projects, by establishing a four-week public comment period for all draft reports, and by posting for comment the key questions for systematic reviews performed by Evidence-based Practice Centers. However, AHRQ typically does not disclose the research center (or individual researchers) undertaking specific CER studies.

Although public comment is solicited for CER key questions and draft reports that are systematic reviews of the literature on a given topic, AHRQ does not permit public comment on the projects undertaken by the Effective Health Care Program's Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) research network. The DEcIDE research centers, which have access to electronic health information databases, generate new scientific information to fill knowledge gaps or address methodological issues (as opposed to performing systematic reviews of existing literature). AHRQ posts research abstracts for DEcIDE studies to inform the public of research undertaken, but it does not post (or solicit public comment on) draft key questions for this research, and does not post draft final reports for comment. Instead, most studies appear first in the published literature, where they have been subject to a particular journal's peer review process.

ARRA CER Funding. *ARRA* established a 15-member Federal Coordinating Council to coordinate CER activities at the federal level and to advise the President and Congress on infrastructure needs within the federal government, including expenditures for CER by these federal agencies and departments. Membership on the Council was specified in the law; it included representatives from the various federal agencies engaged in comparative effectiveness research.

The Council held 3 listening sessions (April 14, 2009 in Washington, D.C.; May 13, 2009 in Chicago; and June 10, 2010 in Washington, D.C.) to receive public comment. Comments were also solicited through the HHS web site for the Recovery Act. Ninety-two speakers participated in the listening sessions, and more than 300 individuals and organizations submitted comments. The Council issued its report to the President and Congress on June 30, 2010, as required by *ARRA*.

ARRA also directed HHS to contract with the IOM to prepare a report on national priorities for comparative effectiveness research conducted with the funds made available by the Recovery Act. *ARRA* specified that the IOM committee must consider "input from stakeholders" in identifying national priority topics for CER. The committee used three avenues to secure this input: direct correspondence with the IOM committee; oral and written presentations at an open stakeholders meeting; and the submission by the public of specific CER topics.

On March 20, 2009, the IOM committee conducted an open stakeholders meeting to receive stakeholder input. During this meeting, 54 speakers made presentations. Written statements made at this meeting were made publicly available on the committee's web site. The committee also solicited input through a web-based questionnaire, open for three weeks, from March 6 to March 27, 2009. There were 1,758 respondents to this questionnaire, and 2,606 suggestions for CER research. The IOM committee's final report for the President and Congress, issued June 30, 2009, identified 100 priority topics for CER.

AHRQ based its initial *ARRA* funding determinations on the 14 priority conditions established for the Effective Health Care Program, but stated[10] it would also make use of the priorities set by the IOM committee to allocate funds; NIH began obligating its *ARRA* funds before the IOM report on CER priorities was issued. ■

TABLE 3
Framework for Conducting Comparative Effectiveness Reviews: Public Participation

PPACA SECTION 6301 PATIENT-CENTERED OUTCOMES RESEARCH	ARRA $1.1 BILLION IN CER SPENDING	MMA SECTION 1013 EFFECTIVE HEALTH CARE PROGRAM
Public Comment Period – 45-60 days comment period required by statute for: ✔ national priorities ✔ research project agenda ✔ methodological standards ✔ peer review process ✔ draft findings for systematic reviews [Sec. 1181(h)(1)]		***Public Comment Period*** – 4 week comment period established by AHRQ/EHC Program for: ✔ Key Questions (for systematic reviews only) ✔ Draft Reports (both systematic reviews and DEcIDE Network reports)
Forums – required to increase public awareness and obtain and incorporate public input and feedback on research priorities, research findings, and other duties, activities, or processes the Institute determines appropriate [Sec. 1181(h)(2)]	***Federal Coordinating Council*** – 3 public listening sessions – received comments filed through the public web site for 2 months – posted interim working documents for feedback: ✔ definition of CER ✔ prioritization criteria ✔ strategic framework – open door meetings held to inform deliberations	***Public Meetings*** – comments were solicited and reviewed, and listening sessions were held on identifying research priorities – final decisions were made by an HHS committee – no public comment on HHS committee determination

[10]See *Operating Plan for American Recovery and Reinvestment Act Funds for Comparative Effectiveness Research at the Agency for Healthcare Research and Quality (2009)*.

TABLE 3
Framework for Conducting Comparative Effectiveness Reviews: Public Participation

PPACA SECTION 6301 PATIENT-CENTERED OUTCOMES RESEARCH	ARRA $1.1 BILLION IN CER SPENDING	MMA SECTION 1013 EFFECTIVE HEALTH CARE PROGRAM
	IOM Priority-Setting Committee – legislation required priorities to be based on "input from stakeholders" – three avenues: ✔ direct correspondence with the committee ✔ written and oral presentations at an open stakeholder's meeting ✔ submission of specific CER topics	
Other Consultations – Methodology Committee may consult with relevant stakeholders to carry out its activities [Sec. 1181(d)(6)(D) – Process of Developing and Updating Methodological Standards ✔ include input from experts, stakeholders, and decision makers ✔ provide opportunity for public comment [Sec. 1181(d)(6)(C)(i)]		

Public Participation Issues to Monitor. Opportunities for public participation in the activities of the PCORI authorized by the *PPACA* exceed those that have been available for CER projects undertaken by AHRQ in the Effective Health Care program, or by AHRQ and NIH with *ARRA* CER funding.

For example, the law mandates longer public comment periods than those currently available for systematic reviews by AHRQ's Effective Health Care Program. In addition, the law directs that public comments must be sought on a number of other important matters which to date have not been subject to public notice-and-comment procedures in the AHRQ CER program—e.g., establishing a CER project agenda, determining methodological standards for CERs, and developing a peer review process.

Beyond this, the *PPACA* requirement for the use of public forums to increase public awareness and stimulate input, and for Methodology Committee consultation with stakeholders, will open new doors for public participation. However, the mandates set forth in the health reform legislation are general and must be addressed by the Board of Governors soon after its formation. The public will benefit from this engagement, and it is pos-

sible that some outreach techniques used by AHRQ for the Effective Health Care Program may be of use in soliciting this public input (e.g., the use of listening sessions and Listservs).

Opportunities for public participation in the activities of the PCORI authorized by the *PPACA* exceed those that have been available for CER projects undertaken by AHRQ in the Effective Health Care program, or by AHRQ and NIH with *ARRA* CER funding.

- ***PCORI***. The Institute's Board of Governors will have to decide in its first months how to address the following specific matters:
  - It will have to establish a precise comment period during which public input is solicited, since the *PPACA* provides only a range (between 45 and 60 days), and it will have to decide if the same time period will apply to all situations in which public comments are sought.
  - It will have to decide whether a public comment period will be required for those CER activities not clearly specified in law as requiring a public comment period (e.g., only systematic reviews of existing research and evidence require public comment; the law is silent on other research studies, like primary research and methodological inquiries that are not systematic reviews, as well as other PCORI activities).
  - It will have to decide whether (and in what circumstances) it will make use of public forums to engage stakeholders and the public in its activities, particularly whether forums will be held to solicit public input for key methodological issues and research topics that prove to be controversial—for example, how patient subpopulations can be accounted for and evaluated in different types of research.
  - It will have to determine the situations and methods in which the Methodology Committee consults with stakeholders, or it could choose to defer that matter to the Methodology Committee itself.
  - It will have to decide whether peer reviewers will be identified for individual CER reports and whether peer review processes of CER contractors and medical journals that publish CERs should be used.
  - It will have to decide whether it will enter into contracts with federal agencies (e.g., AHRQ, NIH) and/or academic or private-sector research entities to conduct CER. As mentioned above (under the discussion of "Transparency"), if the Institute chooses to enter into contracts, the transparency, public participation, and conflict of interest requirements set out in *PPACA* would be extended to AHRQ, NIH, or other public and private entities that conduct CER on its behalf.
- ***AHRQ***. The opportunity for public participation in the CER activities of the AHRQ Effective Health Care Program are not uniform for all research projects (DEcIDE network studies are currently not subject to public comment, while systematic reviews are), and the public comment periods that are provided are not as generous as those mandated in the *PPACA*. In addition, AHRQ does not currently meet the transparency, public participation, and conflicts of interest requirements set forth in *PPACA* for CER studies.

  If AHRQ enters into a contract with the Institute to conduct CER projects, it must abide by the *PPACA* requirements. It is likely, then, that AHRQ will adjust its transparency, public participation, and conflict of interest requirements to be consistent with those required by the Institute. This argues for close

attention to what the Institute spells out its requirements for contractors. Through these Institute requirements, more light can be placed on both public and non-public input into research funding determinations.

Open Decision-Making

PPACA. The *PPACA* requires decisions of the PCORI Board to be made in public, by majority vote. The law also specifies that there will be votes on national priorities for CER, the CER research project agenda, methodological standards for CER, and the CER peer review process. The law does not address the decision-making process for standing and *ad hoc* committees of the Board of Governors.

Section 1013 Effective Health Care Program. Program decisions that are made by AHRQ concerning this CER program are not readily identifiable, except as part of documents prepared for Congress. It is not clear to members of the public how research priorities are determined, how decisions are made to fund specific CER projects (both DEcIDE projects and systematic reviews), and why public comments are solicited and considered on some CER projects and not others. Further, there is no information on how non-public meetings with particular stakeholder groups impact Agency decision-making.

ARRA CER Funding. A summary of the Federal Coordinating Council's meetings and deliberations is contained in its June 30, 2009 report for the President and Congress. The IOM report on priorities for CER provides information on the panel's decision-making process. Although *ARRA* requires the HHS Secretary and the Directors of NIH and AHRQ to submit an Operating Plan for the CER funds appropriated to the Appropriations Committees of Congress that detail the type of research being conducted and the priority conditions addressed, these reports provide only general information on the priorities addressed. They do not identify which priority each particular study addresses.

TABLE 4
Framework for Conducting Comparative Effectiveness Reviews: Open Decision Making

PPACA SECTION 6301 PATIENT-CENTERED OUTCOMES RESEARCH	ARRA $1.1 BILLION IN CER SPENDING	MMA SECTION 1013 EFFECTIVE HEALTH CARE PROGRAM
PCORI Board of Governors – specifies votes on: ✔ national priorities ✔ research project agenda ✔ methodological standards ✔ peer review process [Sec. 1181(d)(9)]	***Federal Coordinating Council; IOM Priority-Setting Committee*** – decisions were not made in public – NIH took steps to obligate *ARRA* funds prior to publication of IOM priorities	***Stakeholder Group*** – advisory group – provides sounding board
Voting – decisions made by majority vote [Sec. 1181(d)(9)]		***Voting*** – no votes taken

Open Decision-Making Issues to Monitor.

- ***PCORI.*** The Institute's Board of Governors will have to set the ground rules for the decision-making process that will be used by both standing and *ad hoc* committees. Because CER decisions to date have been made by federal officials, there has not been an opportunity for the public to witness how important determinations are made—e.g., how research priorities are set, how funding decisions are made, how research gaps and methodological challenges are considered and addressed, and how non-public meetings with particular stakeholders impact decisions. A more open decision-making process might enhance the credibility of these determinations.

  The Board will also have to address how it will handle situations where its members disagree on important matters. Given the broad representation of stakeholders on the Board, it is likely that disagreements will occur on matters like the methodological approaches taken in specific research efforts and the interpretation of research findings.

  For example, the law specifically directs that expert advisory panels should provide advice on research designs and protocols, including patient subgroups, and it requires that the Methodology Committee develop methodological standards for conducting CER that account for and evaluate patient subpopulations. Although CER involves a consideration of the impact that various alternative technologies, procedures, and services can have for both populations and individuals,[11] it is possible that, in practice, CER may not sufficiently emphasize patient subgroup and individual patient impact, and that research findings may tend to be population-based, primarily addressing the impact on "average" patients.

  Given the importance and sensitivity of this matter, it will be important to closely monitor the work of expert advisory committees, especially the methodological standards developed by the Methodology Committee, and the first CER studies that are undertaken.

  Because the first CER studies will set precedents and might address particularly difficult matters, the Board could choose to permit Board members, or members of other standing and *ad hoc* expert advisory committees, to submit, and have published, their dissenting opinions on controversial matters (e.g., the degree to which studies address the needs of particular subpopulations and individuals) in meeting minutes and even in reports.

- ***ARRA.*** This legislation authorizing $1.1 billion in CER funding requires HHS to send a number of reports to Congress, with particular detail required to be submitted to the House and Senate Appropriations Committees. In order to keep the public informed, each of these communications should be posted on the HHS Department web site.

  As mentioned earlier, the *ARRA* legislation requires that the Operating Plans required of the HHS Secretary, and the Directors of AHRQ and NIH "detail the type of research being conducted or supported, including the priority conditions addressed; and specify the allocation of resources within the Department of Health and Human Services." Given the investment the public has made in suggesting priority conditions to the IOM to guide the allocation of *ARRA* funds, the HHS Secretary and the Directors of AHRQ and NIH should identify which priority is addressed by each

[11]The Institute of Medicine, in its June 2009 report on national priorities for comparative effectiveness research conducted with the funds made available by *ARRA*, defined CER as: "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels." IOM, *Initial National Priorities for Comparative Effectiveness Research* (Washington, DC: National Academies Press, 2009), p. 13.

project funded through *ARRA*. Doing so will identify gaps in research that might be addressed by PCORI. A start can be made in this area by including this information in the "Inventory of Comparative Effectiveness Research" that is currently being prepared by the Office of the Assistant Secretary for Planning Evaluation (ASPE) within the HHS Department.

Conclusion

The *PPACA* represents a significant and qualitative shift in the way decisions will be made with respect to comparative effectiveness research. For the first time, stakeholder representatives—including patients, consumers, and care-givers—will be decision-makers, instead of advisors, in a federal program to conduct comparative effectiveness research on a wide range of medical items, treatments, and services.

The Board's first decisions will be especially important because many of the Institute's responsibilities are only generally addressed in *PPACA*. The first actions of the Board of Governors in the coming months will need to address important procedural and operational issues that will shape the program for years to come.

As members of the Board of Governors of the PCORI, these stakeholder representatives will give patients and consumers, physicians and providers, health insurers, medical technology manufacturers, and researchers responsibilities previously reserved for government officials. Government agency officials from AHRQ and NIH will be involved as well on the Board, but they will be in the minority, and their agencies will serve as possible contractors (eligible to conduct the research that the Board determines to be appropriate). The multi-stakeholder Board will have the opportunity to determine program priorities, research methods, and deliberative procedures. Patient, consumer, and caregiver representatives will be engaged in these processes in sufficient numbers to have a clear impact on the CER program.

The Board's first decisions will be especially important because many of the Institute's responsibilities are only generally addressed in *PPACA*. The first actions of the Board of Governors in the coming months will need to address important procedural and operational issues that will shape the program for years to come.

As the Board determines its priorities, identifies its research agenda, selects contractors, establishes a peer review process, and resolves methodological questions, it will be setting important precedents. Its actions will indicate if stakeholders will accept the *PPACA* framework for conducting comparative effectiveness—requirements for stakeholder involvement, transparency, public participation, and open decision-making—as a starting point for even greater consumer engagement and participation, or if this framework will be viewed, instead, as a burdensome statutory requirement meriting only minimal compliance.

APPENDIX A

[**DOCID: f:publ173.108]**

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

(Source: http://www.medicare.gov/medicarereform/108s1013.htm)

Public Law 108-173
108th Congress

SEC. 1013. <> RESEARCH ON OUTCOMES OF HEALTH CARE ITEMS AND SERVICES.

(a) Research, Demonstrations, and Evaluations.--

(1) Improvement of effectiveness and efficiency.--

(A) In general.--To improve the quality, effectiveness, and efficiency of health care delivered pursuant to the programs established under titles XVIII, XIX, and XXI of the Social Security Act, the Secretary acting through the Director of the Agency for Healthcare Research and Quality (in this section referred to as the "Director"), shall conduct and support research to meet the priorities and requests for scientific evidence and information identified by such programs with respect to--

(i) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs); and

(ii) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs.

(B) Specification.--To respond to priorities and information requests in subparagraph (A), the Secretary may conduct or support, by grant, contract, or interagency agreement, research, demonstrations, evaluations, technology assessments, or other activities, including the provision of technical assistance, scientific expertise, or methodological assistance.

(2) Priorities.--

(A) In general.--The Secretary shall establish a process to develop priorities that will guide the research, demonstrations, and evaluation activities undertaken pursuant to this section.

(B) Initial list.--Not later than 6 months after the date of the enactment of this Act, the Secretary shall establish an initial list of priorities for research related to health care items and services (including prescription drugs).

(C) Process.--In carrying out subparagraph (A), the Secretary--

(i) shall ensure that there is broad and ongoing consultation with relevant stakeholders in identifying the highest priorities for research, demonstrations, and evaluations to support and improve the programs established under titles XVIII, XIX, and XXI of the Social Security Act;

(ii) may include health care items and services which impose a high cost on such programs, as well as those which may be underutilized or overutilized and which may significantly improve the prevention, treatment, or cure of diseases and conditions (including chronic conditions) which impose high direct or indirect costs on patients or society; and

(iii) shall ensure that the research and activities undertaken pursuant to this section are responsive to the specified priorities and are conducted in a timely manner.

(3) Evaluation and synthesis of scientific evidence.--

(A) In general.--The Secretary shall--

(i) evaluate and synthesize available scientific evidence related to health care items and services (including prescription drugs) identified as priorities in accordance with paragraph (2) with respect to the comparative clinical effectiveness, outcomes, appropriateness, and provision of such items and services (including prescription drugs);

(ii) identify issues for which existing scientific evidence is insufficient with respect to such health care items and services (including prescription drugs);

(iii) disseminate to prescription drug plans and MA-PD plans under part D of title XVIII of the Social Security Act, other health plans, and the

public the findings made under clauses (i) and (ii); and

(iv) work in voluntary collaboration with public and private sector entities to facilitate the development of new scientific knowledge regarding health care items and services (including prescription drugs).

(B) Initial research.--The Secretary shall complete the evaluation and synthesis of the initial research required by the priority list developed under paragraph (2)(B) not later than 18 months after the development of such list.

(C) Dissemination.--

(i) In general.--To enhance patient safety and the quality of health care, the Secretary shall make available and disseminate in appropriate formats to prescription drugs plans under part D, and MA-PD plans under part C, of title XVIII of the Social Security Act, other health plans, and the public the evaluations and syntheses prepared pursuant to subparagraph (A) and the findings of research conducted pursuant to paragraph (1). In carrying out this clause the Secretary, in order to facilitate the availability of such evaluations and syntheses or findings at every decision point in the health care system, shall--

(I) present such evaluations and syntheses or findings in a form that is easily understood by the individuals receiving health care items and services (including prescription drugs) under such plans and periodically assess that the requirements of this subclause have been met; and

(II) provide such evaluations and syntheses or findings and other relevant information through easily accessible and searchable electronic mechanisms, and in hard copy formats as appropriate.

(ii) Rule of construction.--Nothing in this section shall be construed as--

(I) affecting the authority of the Secretary or the Commissioner of Food and Drugs under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act; or

(II) conferring any authority referred to in subclause (I) to the Director.

(D) Accountability.--In carrying out this paragraph, the Secretary shall implement activities in a manner that--

(i) makes publicly available all scientific evidence relied upon and the methodologies employed, provided such evidence and method are not protected from public disclosure by section 1905 of title 18, United States Code, or other applicable law so that the results of the research, analyses, or syntheses can be evaluated or replicated; and

(ii) ensures that any information needs and unresolved issues identified in subparagraph (A)(ii) are taken into account in priority-setting for future research conducted by the Secretary.

(4) Confidentiality.--

(A) In general.--In making use of administrative, clinical, and program data and information developed or collected with respect to the programs established under titles XVIII, XIX, and XXI of the Social Security Act, for purposes of carrying out the requirements of this section or the activities authorized under title IX of the Public Health Service Act (42 U.S.C. 299 et seq.), such data and information shall be protected in accordance with the confidentiality requirements of title IX of the Public Health Service Act.

(B) Rule of construction.--Nothing in this section shall be construed to require or permit the disclosure of data provided to the Secretary that is otherwise protected from disclosure under the Federal Food, Drug, and Cosmetic Act, section 1905 of title 18, United States Code, or other applicable law.

(5) Evaluations.--The Secretary shall conduct and support evaluations of the activities carried out under this section to determine the extent to which such activities have had an effect on outcomes and utilization of health care items and services.

(6) Improving information available to health care providers, patients, and policymakers.--Not later than 18 months after the date of enactment of this Act, the Secretary shall identify options that could be undertaken in voluntary collaboration with private and public entities (as appropriate) for the--

(A) provision of more timely information through the programs established under titles XVIII, XIX, and XXI of

the Social Security Act, regarding the outcomes and quality of patient care, including clinical and patient-reported outcomes, especially with respect to interventions and conditions for which clinical trials would not be feasible or raise ethical concerns that are difficult to address;

(B) acceleration of the adoption of innovation and quality improvement under such programs; and

(C) development of management tools for the programs established under titles XIX and XXI of the Social Security Act, and with respect to the programs established under such titles, assess the feasibility of using administrative or claims data, to--

(i) improve oversight by State officials;

(ii) support Federal and State initiatives to improve the quality, safety, and efficiency of services provided under such programs; and

(iii) provide a basis for estimating the fiscal and coverage impact of Federal or State program and policy changes.

(b) Recommendations.--

(1) Disclaimer.--In carrying out this section, the Director shall--

(A) not mandate national standards of clinical practice or quality health care standards; and

(B) include in any recommendations resulting from projects funded and published by the Director, a corresponding reference to the prohibition described in subparagraph (A).

(2) Requirement for implementation.--Research, evaluation, and communication activities performed pursuant to this sec tion shall reflect the principle that clinicians and patients should have the best available evidence upon which to make choices in health care items and services, in providers, and in health care delivery systems, recognizing that patient subpopulations and patient and physician preferences may vary.

(3) Rule of construction.--Nothing in this section shall be construed to provide the Director with authority to mandate a national standard or require a specific approach to quality measurement and reporting.

(c) Research With Respect to Dissemination.--The Secretary, acting through the Director, may conduct or support research with respect to improving methods of disseminating information in accordance with subsection (a)(3)(C).

(d) Limitation on CMS.--The Administrator of the Centers for Medicare & Medicaid Services may not use data obtained in accordance with this section to withhold coverage of a prescription drug.

(e) Authorization of Appropriations.--There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2004, and such sums as may be necessary for each fiscal year thereafter.

APPENDIX B

Text of the Recovery Act Related to Comparative Effectiveness Funding

(Source: http://www.hhs.gov/recovery/programs/cer/recoveryacttext.html)

American Recovery and Reinvestment Act of 2009

An Act making supplemental appropriations for job preservation and creation, infrastructure investment, energy efficiency and science, assistance to the unemployed, and State and local fiscal stabilization, for the fiscal year ending September 30, 2009, and for other purposes.

Sec. 804. Federal Coordinating Council for Comparative Effectiveness Research

(a) ESTABLISHMENT— There is hereby established a Federal Coordinating Council for Comparative Effectiveness Research (in this section referred to as the 'Council').

(b) PURPOSE— The Council shall foster optimum coordination of comparative effectiveness and related health services research conducted or supported by relevant Federal departments and agencies, with the goal of reducing duplicative efforts and encouraging coordinated and complementary use of resources.

(c) DUTIES— The Council shall—

(1) assist the offices and agencies of the Federal Government, including the Departments of Health and Human Services, Veterans Affairs, and Defense, and other Federal departments or agencies, to coordinate the conduct or support of comparative effectiveness and related health services research; and

2) advise the President and Congress on—

(A) strategies with respect to the infrastructure needs of comparative effectiveness research within the Federal Government; and
(B) organizational expenditures for comparative effectiveness research by relevant Federal departments and agencies.

(d) MEMBERSHIP—

(1) NUMBER AND APPOINTMENT— The Council shall be composed of not more than 15 members, all of whom are senior Federal officers or employees with responsibility for health-related programs, appointed by the President, acting through the Secretary of Health and Human Services (in this section referred to as the 'Secretary'). Members shall first be appointed to the Council not later than 30 days after the date of the enactment of this Act.

(2) MEMBERS—
(A) IN GENERAL— The members of the Council shall include one senior officer or employee from each of the following agencies:
(i) The Agency for Healthcare Research and Quality.
(ii) The Centers for Medicare and Medicaid Services.
(iii) The National Institutes of Health.
(iv) The Office of the National Coordinator for Health Information Technology.
(v) The Food and Drug Administration.
(vi) The Veterans Health Administration within the Department of Veterans Affairs.
(vii) The office within the Department of Defense responsible for management of the Department of Defense Military Health Care System.
(B) QUALIFICATIONS— At least half of the members of the Council shall be physicians or other experts with clinical expertise.
(3) CHAIRMAN; VICE CHAIRMAN— The Secretary shall serve as Chairman of the Council and shall designate a member to serve as Vice Chairman.

(e) REPORTS—

(1) INITIAL REPORT— Not later than June 30, 2009, the Council shall submit to the President and the Congress a report containing information describing current Federal activities on comparative effectiveness research and recommendations for such research conducted or supported from funds made available for allotment by the Secretary for comparative effectiveness research in this Act.

2) ANNUAL REPORT— The Council shall submit to the President and Congress an annual report regarding its activities and recommendations concerning the infrastructure needs, organizational expenditures and opportunities for better coordination of comparative effectiveness research by relevant Federal departments and agencies.

(f) STAFFING; SUPPORT— From funds made available for allotment by the Secretary for comparative effectiveness research in this Act, the Secretary shall make available not more than 1 percent to the Council for staff and administrative support.

(g) RULES OF CONSTRUCTION—

(1) COVERAGE— Nothing in this section shall be construed to permit the Council to mandate coverage, reimbursement, or other policies for any public or private payer.

(2) REPORTS AND RECOMMENDATIONS— None of the reports submitted under this section or recommendations made by the Council shall be construed as mandates or clinical guidelines for payment, coverage, or treatment.

Title VIII—Departments of Labor, Health And Human Services, and Education, and Related Agencies

Department of Health and Human Services

Agency for Healthcare Research and Quality

Healthcare Research and Quality (Including Transfer of Funds)

For an additional amount for 'Healthcare Research and Quality' to carry out titles III and IX of the Public Health Service Act, part A of title XI of the Social Security Act, and section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, $700,000,000 for comparative effectiveness research: *Provided*, That of the amount appropriated in this paragraph, $400,000,000 shall be transferred to the Office of the Director of the National Institutes of Health ('Office of the Director') to conduct or support comparative effectiveness research under section 301 and title IV of the Public Health Service Act: *Provided further*, That funds transferred to the Office of the Director may be transferred to the Institutes and Centers of the National Institutes of Health and to the Common Fund established under section 402A(c)(1) of the Public Health Service Act: *Provided further*, That this transfer authority is in addition to any other transfer authority available to the National

Institutes of Health: *Provided further*, That within the amount available in this paragraph for the Agency for Healthcare Research and Quality, not more than 1 percent shall be made available for additional full-time equivalents.

In addition, $400,000,000 shall be available for comparative effectiveness research to be allocated at the discretion of the Secretary of Health and Human Services ('Secretary'): *Provided*, That the funding appropriated in this paragraph shall be used to accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies, through efforts that: (1) conduct, support, or synthesize 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) encourage 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: *Provided further*, That the Secretary shall enter into a contract with the Institute of Medicine, for which no more than $1,500,000 shall be made available from funds provided in this paragraph, to produce and submit a report to the Congress and the Secretary by not later than June 30, 2009, that includes recommendations on the national priorities for comparative effectiveness research to be conducted or supported with the funds provided in this paragraph and that considers input from stakeholders: *Provided further*, That the Secretary shall consider any recommendations of the Federal Coordinating Council for Comparative Effectiveness Research established by section 804 of this Act and any recommendations included in the Institute of Medicine report pursuant to the preceding proviso in designating activities to receive funds provided in this paragraph and may make grants and contracts with appropriate entities, which may include agencies within the Department of Health and Human Services and other governmental agencies, as well as private sector entities, that have demonstrated experience and capacity to achieve the goals of comparative effectiveness research: *Provided further*, That the Secretary shall publish information on grants and contracts awarded with the funds provided under this heading within a reasonable time of the obligation of funds for such grants and contracts and shall disseminate research findings from such grants and contracts to clinicians, patients, and the general public, as appropriate: *Provided further*, That, to the extent feasible, the Secretary shall ensure that the recipients of the funds provided by this paragraph offer an opportunity for public comment on the research: *Provided further*, That research conducted with funds appropriated under this paragraph shall be consistent with Departmental policies relating to the inclusion of women and minorities in research: *Provided further*, That the Secretary shall provide the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate with an annual report on the research conducted or supported through the funds provided under this heading: *Provided further*, That the Secretary, jointly with the Directors of the Agency for Healthcare Research and Quality and the National Institutes of Health, shall provide the Committees on Appropriations of the House of Representatives and the Senate a fiscal year 2009 operating plan for the funds appropriated under this heading prior to making any Federal obligations of such funds in fiscal year 2009, but not later than July 30, 2009, and a fiscal year 2010 operating plan for such funds prior to making any Federal obligations of such funds in fiscal year 2010, but not later than November 1, 2009, that detail the type of research being conducted or supported, including the priority conditions addressed; and specify the allocation of resources within the Department of Health and Human Services: *Provided further*, That the Secretary, jointly with the Directors of the Agency for Healthcare Research and Quality and the National Institutes of Health, shall provide to the Committees on Appropriations of the House of Representatives and the Senate a report on the actual obligations, expenditures, and unobligated balances for each activity funded under this heading not later than November 1, 2009, and every 6 months thereafter as long as funding provided under this heading is available for obligation or expenditure.

Current as of March 2009

Internet Citation:
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http://www.hhs.gov/recovery/programs/cer/recoveryacttext.html