



## Agency for Healthcare Research and Quality: Comparative Effectiveness Research

The Department of Health and Human Services (HHS) is currently developing a plan and a corresponding funding allocation for dollars appropriated to the Agency for Healthcare Research and Quality (AHRQ) for comparative effectiveness research. The American Recovery and Reinvestment Act (Recovery Act) appropriated \$1.1 billion for comparative effectiveness research, of which \$300 million is for AHRQ, \$400 million is for the National Institutes of Health, and \$400 million is for allocation at the discretion of the Secretary.

This implementation plan focuses on the \$300 million to be obligated by AHRQ.

### A. Funding Table

(Dollars in Millions)

	<b>Total Appropriated</b>	<b>Planned Obligations FY 2009</b>	<b>Planned Obligations FY 2010</b>
Comparative Effectiveness Research	\$300.0	*	*
<b>Total</b>	<b>\$300.00</b>		

\*HHS is currently developing a plan that specifies the kind and scope of activities that will be funded to achieve the program's objectives. Planned obligations are not yet determined.

### B. Objectives

The overarching goal of this program is to improve health outcomes by providing evidence to enhance medical decisions made by patients and their medical providers. This goal is achieved by conducting and supporting comparative effectiveness research. The Department of Health and Human Services uses the definition of comparative effectiveness research as set forth by the Federal Coordinating Council for CER:

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations. Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.



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Systematic research methods can include randomized controlled trials, meta-analyses, observational cohort analyses, and other new and emerging methodologies. Comparative effectiveness studies may compare similar treatments, such as competing drugs, or analyze very different approaches, such as surgery and drug therapy. Evaluation of treatments includes any potential medical intervention under consideration, whether prognostic, preventive, diagnostic, therapeutic, or palliative. Comparative effectiveness research may also address public health or systems interventions that affect health outcomes. Comparative effectiveness research is designed to inform patient and clinician decisions relevant to the unique circumstances of individual patients.

AHRQ will spend appropriated funds to research and provide information on the relative strengths and weaknesses of various medical interventions. Such research will give clinicians and patients valid information with which to make decisions that will improve the performance of the U.S. health care system. AHRQ's comparative effectiveness research will support HHS strategic plan goal 1<sup>1</sup>: improve the safety, quality, affordability and accessibility of health care, including behavioral health care and long-term care.

### **C. Activities**

AHRQ is currently developing a plan that specifies the kind and scope of activities that AHRQ will fund to achieve the program's objectives. AHRQ is considering various approaches for this program, such as expanding and broadening comparative effectiveness research activities initiated at AHRQ in response to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Section 1013 legislation was designed, in part, to increase the availability of research that would inform the real-world decisions facing patients and clinicians. Specifically, AHRQ's investments using Recovery Act funds may expand its Effective Health Care (EHC) Program, which supports research activities performed using rigorous scientific methods within a previously-established process that emphasizes stakeholder involvement and transparency, that is designed to prioritize among pressing health issues, and whose products are designed for maximum usefulness for health care decision makers.

### **D. Characteristics**

AHRQ is currently developing a plan that specifies the financial award mechanisms that AHRQ will use to execute the program and that specify the recipients and beneficiaries of the program funds. AHRQ is considering various competitive award mechanisms, such as grants, contracts, and cooperative agreements. All eligible applications will undergo a competitive review process in order to evaluate scientific and technical merit. AHRQ is also considering the appropriate intended recipients for each type of award, such as researchers, academic institutions, states, community-based organizations, national organizations, DEClIDE consortium<sup>2</sup>, John

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<sup>1</sup> HHS Strategic Plan Goals and Objectives - FY 2007-2012 available at [http://www.hhs.gov/strategic\\_plan/](http://www.hhs.gov/strategic_plan/)

<sup>2</sup> The DEClIDE (Developing Evidence to Inform Decisions about Effectiveness) Network is a new network of research centers that AHRQ created in 2005 to generate new knowledge. The DEClIDE Network conducts accelerated practical studies about the outcomes, comparative clinical effectiveness, safety, and appropriateness of health care items and services. The network is comprised of research-based health



M. Eisenberg Clinical Decisions and Communications Science Center communities<sup>3</sup>, and private or non-profit organizations.

## E. Delivery Schedule

AHRQ is currently developing a schedule with milestones and planned delivery dates for major phases of the program's activities. As the Recovery Act requires, AHRQ will submit an operating plan for this program to the House and Senate Appropriation Committees prior to obligating Federal funds and not later than July 30, 2009. All funds available for AHRQ for comparative effectiveness research will be awarded in fiscal years 2009 and 2010.

## F. Environmental Review Compliance

The Implementation Plan for AHRQ's Recovery Act comparative effectiveness research activity has been reviewed in accordance with the Chapter 30-20-40 of the HHS General Administration Manual (<http://www.hhs.gov/hhsmanuals/read/gam/part30/>) and has been determined that the activity falls under Category 2 Functional Exclusions a., c., d., e., f., and i., and there are no additional extraordinary circumstances that may cause significant effects.

There will be no construction or renovation funded under this activity.

The environmental impact for acquisition of IT and other products and equipment will be mitigated by compliance with criteria described in Executive Order 13423 and the HHS Affirmative Procurement Plan (APP) and written guidance to this effect will be provided to grantees as appropriate.

- Specifically, E.O. 13423 requires that preference be given to the purchase of EPEAT-registered electronic products and at least 95 percent of electronic products be EPEAT-registered unless there is no EPEAT standard. When available, the purchase of EPEAT Silver-rated electronic products or higher is required. EPEAT is intended to help purchasers in the public and private sectors evaluate, compare and select desktop computers, notebooks and monitors based on their environmental attributes. The EPEAT website is: <http://www.epeat.net/>.
- The HHS Affirmative Procurement Plan (APP) applies to: a) All agency acquisitions, including micro-purchases and purchase card transactions, in which an EPA-designated item is acquired; b) Contractor Operated, Government-owned (GOCO) HHS facilities; and c) State and local recipients of assistance funding. The latest version (April 2009) of the HHS' APP is available by contacting Dennise March, Director, Division of Acquisition Program Support, at (202)205-0722, [Dennise.March@hhs.gov](mailto:Dennise.March@hhs.gov) or Lydina Battle, Procurement Analyst, at (202) 205-4512, [Lydina.Battle@hhs.gov](mailto:Lydina.Battle@hhs.gov).

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organizations with access to electronic health information databases and the capacity to conduct rapid turnaround research.

<sup>3</sup> The John M. Eisenberg Clinical Decisions and Communications Science Center translates complex scientific research produced in the Effective Healthcare Program into short, clear and actionable materials and products that can be used by three primary audiences: clinicians, consumers and policymakers.



## G. Measures

HHS is working to develop cross-cutting outcome measures for comparative effectiveness research activities across the Department. Initial outcome measures will be developed by December 1, 2009. Current measures for AHRQ's comparative effectiveness program are below. A new output measure has been established for funding appropriated under the Recovery Act - Number of competitive contracts and grants awarded to support AHRQ's Recovery Act comparative effectiveness research activities (Output).

We will report outcome and outputs, to the extent possible, supported with funding appropriated under the Recovery Act as an incremental change from those supported by regular appropriations. See Table 1 below.

Table 1

Outcome/Output	Reporting Period	Methodology	Target (not including ARRA funds) <sup>4</sup>	Target with ARRA funds <sup>5</sup>
Increase number of systematic reviews and summary guides available to patients, providers and policymakers to make health care decisions (Output)	Quarterly	All AHRQ systematic reviews and summary guides are posted on the AHRQ Effective Health Care Program Web site, <a href="http://effectivehealthcare.ahrq.gov/">http://effectivehealthcare.ahrq.gov/</a> .	TBD	TBD
Increase number of organizations disseminating systematic reviews and summary guides to their constituents (Output)	Bi-annually due to availability of data	Requests for copies of AHRQ publications (ordered by title and publication number), are made to the AHRQ Publications Clearinghouse. Data will be provided bi-annually from the Publications Clearinghouse on the number of organizations requesting more than 50 copies of AHRQ comparative effectiveness research reports and summary guides.	TBD	TBD
Increase amount of evidence from the CE Portfolio policymakers use as a foundation for population-base policies	Annually due to availability of data	Data for this output is available from AHRQ's Medicaid Medical Director's Learning Network (MMDLN). At an annual meeting, members of MMDLN report on how they use AHRQ's comparative effectiveness research reports and summary guides.	TBD	TBD

<sup>4</sup> Targets listed as to be determined (TBD) will be available on October 31, 2009. This is consistent with the information provided in the DHHS Fiscal Year 2010 AHRQ Justification of Estimates for Appropriations Committees.

<sup>5</sup> Targets listed as to be determined (TBD) will be available on October 31, 2009.



Outcome/Output	Reporting Period	Methodology	Target (not including ARRA funds) <sup>4</sup>	Target with ARRA funds <sup>5</sup>
(Developmental/ Interim Output)				
Number of competitive contracts and grants awarded to support AHRQ's Recovery Act comparative effectiveness research activities (Output) <sup>6</sup>	Quarterly	Data for this output is available from AHRQ's accounting system - the Unified Financial Management System (UFMS).	TBD	TBD

## H. Monitoring and Evaluation

All Recovery Act programs will be assessed by AHRQ staff on a quarterly basis for risk and to ensure that appropriate processes by which an organization's resources are directed, monitored, and measured are in place throughout the entire funding cycle. These assessments will be done consistent with the statutory requirements of the Federal Manager's Financial Integrity Act and the Improper Payments Information Act, as well as OMB's circular A-123 "Management's Responsibility for Internal Control".

AHRQ will build on current internal controls activities in accordance with both the Federal Managers' Financial Integrity Act (FMFIA) and Appendix A of OMB Circular A-123 to protect Recovery Act funds from misappropriation, mismanagement, waste, and abuse. During the A-123 review AHRQ will provide additional testing of key controls (if necessary) to ensure Recovery Act funds are included in AHRQ's testing sample. Finally, AHRQ is in the process of drafting a comprehensive Risk Management Plan to identify, prioritize, and mitigate AHRQ and program specific risks.

Historically, most of AHRQ's grant awards are made to institutions that have had prior Federal funding and have demonstrated their ability to administer Federal funds. In accordance with HHS policy, for recipients that have not received prior Federal funding, non-profit status will be confirmed and a cursory assessment of the organization's financial status will be made by AHRQ staff. These grants would be deemed high risk. Subsequent to funding, AHRQ will request that the OIG perform an audit to assess the recipients' ability to properly expend and monitor grant funds

<sup>6</sup> This new output measure and the targets listed are for ARRA funds only. Once the spend plan is approved, we will finalize the target numbers of competitive contracts and grants to be awarded. AHRQ also reserves the right to shift target numbers as our priorities shift.



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where there are concerns. AHRQ anticipates that the majority of large grants will be awarded to institutions that have had prior Federal funding and have demonstrated their ability to administer Federal funds.

Contract awards are made to organizations that must demonstrate that they have an adequate accounting system that has been approved by a Federal agency. This accounting system must allow the organization to track Federal obligations, expenses, and reimbursements for each project funded. The adequacy of the accounting system is verified prior to award. AHRQ also provides a two level review of each invoice received to ensure that the expenses are allowable and appropriate to be distributed.

From a program standpoint, a potential risk for ineffective spending or waste is through non-performance of funded projects. To minimize this risk, AHRQ will carefully review and select projects for funding. The following criteria may be reviewed for each proposed project: understanding of the purpose and objectives of AHRQ's comparative effectiveness research programs, technical approach, management plan, organizational experience, key personnel, stakeholder engagement, and facilities and database characteristics. AHRQ will also continue to standardize training required for program officials at the Agency working on contracts and grants. This will ensure effective oversight and management of contracts and grants and will decrease the risk of non-performance. AHRQ program officials will implement processes for identifying high and low performance which may include program officials overseeing project management plans and awardees submitting monthly status reports and quarterly self-assessments.

## **I. Transparency**

AHRQ will be open and transparent in all of its grants competitions that involve spending of Recovery Act funding consistent with statutory and OMB guidance.

AHRQ will ensure that recipient reporting required by Section 1512 of the Recovery Act and OMB guidance is made available to the public on Recovery.gov by October 10, 2009. AHRQ will inform recipients of their reporting obligation through standard terms and conditions, grant announcements, contract solicitations, and other program guidance. AHRQ will provide technical assistance to grantees and contractors and fully utilize Project officers to ensure compliance with reporting requirements.

AHRQ will include in all grants and contract funding announcements the standard terms and conditions for Recovery Act funds. These terms and conditions will convey to recipients the reporting requirements that are outlined in Section 2.9 of the OMB February 18 Guidance. In addition, AHRQ grants and contracts management will be available for technical assistance.

## **J. Accountability**

To ensure that managers are held to high standards of accountability in achieving program goals under the Recovery Act, HHS will build on and strengthen existing processes. Senior OS officials will meet regularly with senior Department officials to



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ensure that projects are meeting their program goals, assessing and mitigating risks, ensuring transparency, and incorporating corrective actions. The personnel performance appraisal system will also incorporate corrective actions - processes to fix problems and to ensure that such problems do not recur. The personnel performance appraisal system will also incorporate Recovery Act program stewardship responsibilities for program and business function managers.

Accountability in terms of business functions will be monitored and documented through performance plans. AHRQ's Office and Center Directors, Portfolio Leaders, Financial Management Staff, Recovery Act Contracting Officer's Technical Representatives (COTRs) and Recovery Act Project Officers will have a specific element in their performance plan related to oversight of Recovery Act funds. At the Comparative Effectiveness program level, recipients will be required to provide quarterly reports on progress. Following a thorough review of the progress reports, selected site visits will be taken if progress in meeting stated goals is delayed. In addition, Recovery Act awardees will be required to attend AHRQ's annual meeting and participate in a specific session on Recovery Act awards.

### **K. Barriers to Effective Implementation**

One potential barrier/risk to effective implementation is funding projects that do not meet the needs of stakeholders. To minimize this risk, AHRQ will continue to increase the transparency and explicit process for comparative effectiveness research and will continue to engage stakeholders throughout the research process. Currently, there are many ways for stakeholders to get involved in AHRQ's comparative effectiveness research, including:

- Submitting suggestions for research topics.
- Commenting on draft key questions before research has begun.
- Commenting on draft Research Reviews and Comparative Effectiveness Reviews.
- Providing expert input / scientific information to inform a report.
- Participating in a listening session. These sessions allow participants to provide focused comments on issues important to the EHC Program, such as research topics, program structure, and scientific methods.

AHRQ will include in all funding announcements the requirement to accelerate work wherever possible. In addition, all grantees will be required to report quarterly to both AHRQ (through our reporting system) and through Recovery Act channels. The use of multi-year funding will also be reflected in AHRQ's risk management plan and will include risk mitigation strategies.

### **L. Federal Infrastructure**

AHRQ will ensure that it complies with energy efficiency and green building requirements, if applicable. Little, if any, Recovery Act funds are expected to be used to fund equipment purchases. No Recovery Act funds will be used to fund construction projects.