Funds for Allocation by the Office of the Secretary through the Agency for Healthcare Research and Quality (AHRQ): Comparative Effectiveness Research

The Department of Health and Human Services (HHS) has developed a comprehensive plan and a corresponding funding allocation for dollars appropriated for Comparative Effectiveness Research (CER). The American Recovery and Reinvestment Act (Recovery Act) appropriated $1.1 billion for Comparative Effectiveness Research (CER), 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 $400 million to be allocated by AHRQ at the discretion of the Secretary.

A. Funding Table—Dollars in millions

Table 1

Program/ Project/Activity:	Comparative Effectiveness Research
Total Appropriated	$400.0
FY 2009 Actual Obligations[1]	$1.6
FY 2010 Estimated Obligations	$398.4

B. Objectives

The overarching goal of this activity is to improve health outcomes by producing evidence to enhance medical decisions made by patients and their medical providers. This goal will be achieved by the Secretary by allocating funds appropriated for comparative effectiveness research (CER) to help produce and provide information and research on the relative strengths and weaknesses of various medical interventions.

The current definition of CER used by HHS as developed by the Federal Coordinating Council is: "Comparative Effectiveness Research" Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are

[1] Please note: The amounts reported for OS CER Obligations and Outlays do not tie to the Treasury Reports as of September 30, 2009. One OS CER Inter-Departmental Delegation of Authority (with an obligation $599,458 and an outlay of $190,747) was mistakenly included in AHRQ's totals. The error has been corrected in subsequent reports.

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 and sub-groups. Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results."

This research will give clinicians and patients' accurate information that can facilitate decision making and improve the performance of the U.S. health care system. This comparative effectiveness research has the potential to improve health outcomes and the safety, quality, affordability and accessibility of health care, including behavioral health care and long-term care.

C. Activities

The Council developed the priority investment portfolio for OS funds with the purpose of making an unprecedented impact on the foundation and future of comparative effectiveness research. While any single investment in an activity can leave its mark, an investment that crosses activities or builds the foundation for multiple research or dissemination efforts will have a far more profound effect on health outcomes. Proposals that leverage multiple activities or themes will have greater value than those that focus on a single area. For example, OS investments in Human and Scientific Capital are imbedded in many of the specific projects (such as the FDA proposal outlined below). Similarly, projects that emphasize comparative effectiveness for priority populations were targeted for OS investment.

HHS has developed a plan that specifies the kind and scope of activities that will achieve the program's objectives. To facilitate the implementation of this plan, the Secretary developed and implemented the Comparative Effectiveness Research-Coordination and Implementation Team (CER-CIT). The CER-CIT has reviewed and approved HHS funded program applications, thus preventing undue duplication of CER activities within HHS. Additionally, the CER-CIT ensures that, consistent with the Recovery Act, funds will be used to accelerate the development and dissemination of research by assessing the comparative effectiveness of health care treatments and strategies. These efforts will 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. Further, the Secretary has allocated funds to 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.

The funds are allocated into the following categories:

Table 2

Investment (categorization is for primary focus)	FY 09 Funding (M)	FY 10 Funding (M)	Total Funding (M)
A. Data Infrastructure	$0M	$219M	$219M
B. Dissemination and Translation	$0M	$93.1M	$93.1M
C. Research	$0M	$75.5M	$75.5M
D. Inventory and Evaluation	$1.6M	$7.65M	$8.25M
E. Administrative Costs	$0M	$4M	$4M
F. Funds for Future Allocation	$0M	$.150	$.150
Total	**$1.6M**	**398.4M**	**$400M**

Data Infrastructure

HHS CER funds provide a unique opportunity for a meaningful and sustainable investment in building the foundation for CER infrastructure. Significant investment in this activity is unlikely to come from any other source, and will fundamentally change the landscape for CER. Through enhancement of existing infrastructure as well as development of new databases, networks, and registries, both public and private CER endeavors will be sustainable and multiplicative. Importantly, investment in data infrastructure can align with investments in health information technology (HIT), providing a platform for research endeavors that can strongly impact broad populations and conditions. Sub-categories of investment that the Federal Coordinating Council considered essential were:

- Longitudinal Claims Databases—research database that links claims data for single patients over a long period of time
- Distributed Data Networks—clinical electronic health record (EHR) data networks and health information exchanges for CER purposes
- Patient Registries—databases that prospectively collect clinical data on patients with a specific disease or on a specific test or procedure

Dissemination, Translation, and Implementation

The FCC recognized that currently most research funds are directed towards evidence generation rather than the application of evidence "at the bedside." Without significant investment in evidence dissemination and implementation into practice, the goal of the Comparative Effectiveness Research – improved health outcomes – could go unrealized. Several Federal agencies currently engage in dissemination and translation activities, with inconsistent results. Innovative methods and strategies for these activities are therefore essential, both for patients and providers.

Priority Populations and Interventions

Another core investment for the OS funds is within the cross-cutting themes of priority populations and interventions. Investment in these areas requires coordination of efforts across multiple activities, and can therefore have a broad impact. Priority populations include:

- Racial and Ethnic Minorities
- Elderly
- Children
- People with Disabilities
- People with Multiple Chronic Conditions

These sub-groups have historically been under-represented in research activity to date, and describe a large segment of the U.S. population.

The Council specified the following interventions as lacking in clinical certainty, affecting a large population, and insufficiently addressed by other agencies. Thus, the Council recommended that OS funds could be used to address gaps in research addressing these comparative effectiveness questions:

- Medical and Assistive Devices (e.g., comparing rehabilitative devices)
- Procedures and Surgeries (e.g., evaluating surgical options or surgery versus medical management)
- Medications (e.g., comparing the effectiveness of 2 drugs from different classes on a specific disease)
- Diagnostic Testing (e.g. comparing imaging modalities for evaluating certain types of cancer)
- Behavioral Change (e.g., developing and assessing smoking cessation programs)
- Delivery System Strategies (e.g., testing two different discharge process care models on readmission rates
- Prevention (e.g., comparing two interventions to prevent or decrease obesity)

Research

Another core investment for the OS funds is research. The ARRA will produce an array of new CER findings for physicians.

Many of these topics are larger foci for investment within NIH and AHRQ, and therefore represent supporting investments for the OS spending plan. The Office of the Secretary investments in these CER questions are specifically designed to address these questions in a way to complement the NIH and AHRQ operational plans.

Inventory and Evaluation

The CER inventory analysis outlined in the Federal Coordinating Council's Report to Congress identified current gaps in the CER landscape. This process of cataloguing CE research activities and infrastructure is ongoing, and will be crucial to tracking

investments in CER going forward. Public and private investments across the major activities will need to be assessed collectively, to capture the entire spectrum of this important work. Through an iterative process, current and future CER efforts will be routinely evaluated, so as to rapidly identify gaps in knowledge and inform future priority-setting.

Administrative Costs

Section 804(f) of the Recovery Act addressed the Federal Coordinating Council for Comparative Effectiveness Research and instructed the Secretary to make no more than $4 million available to the Council for staff and administrative support.

D. Characteristics

A total of $1.6 million of the total funds available were obligated in FY 2009, and $398.4 million will be obligated in FY 2010. To achieve the goals of comparative effectiveness research, HHS will use a variety of funding mechanisms including grants and contracts. HHS anticipates that award recipients will include a combination of researchers, academic institutions, States, community-based organizations, private or non-profit national organizations, and Federal agencies. Descriptions of all OS ARRA CER funded programs are as follows:

Data Infrastructure

A1. Enhance Availability and Use of Medicare Data to Support Comparative Effectiveness Research

Centers for Medicare & Medicaid Services

This program will enhance the Chronic Conditions Warehouse to support CER by adding Medicare and Medicaid data back to 1999 with census track and race and ethnicity codes to facilitate study of health disparities. Enhancement of this data warehouse will also enable research on the elderly and persons with multiple chronic conditions, two populations historically under-represented in research.

A2. Build a Medicaid Analytic eXtract (MAX) Data Repository Designed to Support Comparative Effectiveness Research for Medicaid and Children's Health Insurance Program Populations

Centers for Medicare & Medicaid Services

This program will focus on building a parallel Medicaid and Children's Health Insurance Program research database with data dissemination capability to support CER projects.

A3. Clinically Enhanced State Data for Analysis and Tracking of Comparative Effectiveness Impact

Agency for Healthcare Research and Quality

This program will provide organizations that collect statewide all-payer, hospital-based encounter-level data (inpatient, emergency department, and ambulatory surgery) capacity to significantly broaden and supplement existing population-based data for producing the evidence base for comparative effectiveness and evaluating efforts to implement comparative effectiveness where the evidence already exists.

A4. Creation of an All-Payer, All-Claims Database to Enable Innovative Comparative Effectiveness Research

Office of the Assistant Secretary for Planning and Evaluation, Centers for Medicare & Medicaid Services

This program will focus on the creation of an all-payer database that builds on existing claims streams to support research to allow for the greatest power in analysis, ensuring that the data infrastructure is equipped to address the needs of multiple priority populations, multiple priority types of interventions, and a breadth of conditions.

A5. Distributed Data Research Networks, Including Linking Data

Agency for Healthcare Research and Quality

This program will focus on electronic health record-driven distributed research networks along with linking clinical and administrative data to investigate comparative effectiveness of medications, treatments, and strategies to improve health outcomes.

A6. Community Health Applied Research Network

Health Resources and Services Administration

This program will provide funds for research nodes, that will serve as a platform from which to conduct investigations on treatments, interventions, and models of care.

A7. Building Patient Registries to Track Health Outcomes and Measure Quality and Performance

Agency for Healthcare Research and Quality

This program will focus on developing registries for researching health outcomes for effectiveness research and performance measurement and benchmarking.

A8. Enhancing Cancer Registry Data Systems for Comparative Effectiveness Research

Centers for Disease Control and Prevention

This program will focus on the power of cancer surveillance systems that can be significantly enhanced for comparative effectiveness analyses and clinical research by expanding the current infrastructure.

A9. Registry of Patient Registries

Agency for Healthcare Research and Quality

This program will establish a registry of patient registries with research purposes, thus enabling researchers who are considering a new registry to identify similar studies and avoid unnecessary duplication of research questions or populations.

A10. Building U.S. Food and Drug Administration Comparative Effectiveness Research Clinical Data and Standards Infrastructure, Tools, Skills, and Capacity

U.S. Food and Drug Administration

Under this program, the U.S. Food and Drug Administration will develop policies, standards, infrastructure, and tools for standardizing clinical study data to enable analyses across multiple studies. This activity will support scientifically sound assessments of medical interventions consistent with FDA's public health responsibility. Although current FDA regulations generally limit public sharing of the primary data from commercial sponsors, FDA has options for supporting CER including sharing of data with sponsor permission.

A11. Persons with Multiple Chronic Conditions Data and Research

Agency for Healthcare Research and Quality, Indian Health Service

- 11A – Expansion of Research Capability to Study Complex Patients — The Agency for Healthcare Research and Quality will solicit grant applications from organizations that propose to build or enhance partnerships and datasets that will improve the capacity to study comparative effectiveness of different management strategies for patient-centered care of patients with multiple chronic illnesses.
- 11B – Comparative Effectiveness Research to Optimize Prevention and Health Care Management for the Complex Patient — This program will focus on the priority conditions as detailed in Agency for Healthcare Research and Quality's comparative effectiveness program.
- 11C– Creating and Disseminating Public Use Data Sets — This program will address the specific priority population of patients with multiple chronic conditions. Investment in infrastructure should permit performance of high-

quality research on complex patient populations to provide evidence for which interventions are most valuable and how a patient's particular circumstances determine these relative values.

- 11D – Comparative Effectiveness Research to Enhance the Delivery of Services Within the Indian Health Service — This program will be conducted within existing Special Diabetes Program for Indians grantee sites to compare the effectiveness of disease treatment and prevention strategies for diabetes and cardiovascular disease as provided by physicians, nurse practitioners, physician assistants, advanced practice pharmacists, and registered dieticians.
- 11E – Comparative Effectiveness of Quality Improvement Efforts Focused on Chronically Ill Adults among American Indian/Alaska Native Communities — This program focuses on evaluation of prevention and treatment strategies for chronic diseases within American Indian/Alaska Native communities.

A12. Pediatric Care Networks and Comparative Effectiveness Research

Health Resources and Services Administration

This program will enhance the electronic health record infrastructure of pediatric care networks for comparative effectiveness research.

A13. Public Use Data Files

Centers for Medicare & Medicaid Services

Consistent with the confidentiality requirements of the Privacy Act and the Health Insurance Portability and Accountability Act, the Centers for Medicare & Medicaid Services propose to create public use files containing detailed but de-identified data for the Medicare population, including claims (inpatient and outpatient hospital, skilled nursing facilities, home health, hospice, physician/suppliers, durable medical equipment, and prescription drugs), beneficiary-level enrollment/entitlement/demographic information, and data from the Medicare Current Beneficiary Survey.

A14. Strategic Plan for Developing Comparative Effectiveness Research Data Sets

Centers for Medicare & Medicaid Services

This project will be used to develop a strategic plan for the use of all types of Centers for Medicare & Medicaid Services data, including Medicare fee-for-service claims, Medicare Advantage encounter data, and Medicaid claims. The analysis would focus on maximizing Centers for Medicare & Medicaid Services data in all formats for comparative effectiveness research, including the public use files, limited data sets, and research-identifiable files. Contracts will be awarded for this opportunity.

Dissemination and Translation

B1. Dissemination of Comparative Effectiveness Research to Physicians, Providers, Patients, and Consumers Through Multiple Vehicles

Agency for Healthcare Research and Quality, Office of the Assistant Secretary for Planning and Evaluation, Assistant Secretary for Public Affairs

This project includes multiple sub-proposals that seek to bring innovative, effective, and user-friendly methods to advancing the dissemination of comparative effectiveness concepts and content to patients and providers.

B2. Assessing and Accelerating Implementation Strategies in Agency for Healthcare Research and Quality Networks

Agency for Healthcare Research and Quality

This project funds the development and implementation of strategies for promoting the use of comparative effectiveness findings at the delivery system and community levels, along with an evaluation designed to assess the effectiveness of the interventions themselves and their potential for broader spread.

B3. Accelerating Dissemination and Adoption of Comparative Effectiveness Research by Delivery Systems

Office of the Assistant Secretary for Planning and Evaluation

This project will fund both Federal and non-Federal comparative effectiveness research dissemination and translation efforts.

B4. Enhancing the Adoption of Comparative Effectiveness Research in the Treatment of Serious Mental Illnesses in Medicaid

Office of the Assistant Secretary for Planning and Evaluation

This project will identify the combinations of benefit design, payment, and organizational arrangements that best support the use of evidence-based practices for the severely and persistently mentally ill population in Medicaid, recognizing that Medicaid is the single largest payer of services for this population. The study will evaluate State Medicaid programs' use of effective pharmacotherapy to treat serious mental disorders and will be part of evaluating "benefit design."

Research

C1. Optimizing the Impact of Comparative Effectiveness Research Findings through Behavioral Economic Randomized Controlled Trial Experiments

National Institutes of Health, Agency for Healthcare Research and Quality

The National Institutes of Health and Agency for Healthcare Research and Quality will collaborate to develop, apply, and compare behavioral economic approaches to encourage rapid and widespread uptake of CER recommendations.

C2. Comparative Effectiveness Research on Delivery Systems

Agency for Healthcare Research and Quality

The demonstrations and evaluations funded under this initiative will rapidly build and deploy an evidence base for successful, large-scale delivery system transformation and lay the infrastructure for further work in this area.

C3. Effective Use of Regionalized Emergency Care Delivery

Office of the Assistant Secretary for Preparedness and Response

This proposal will focus on the evaluation of established models of regional emergency care delivery, identify best practices and opportunities for networking State-level regionalized services, and identify the limitations of such care delivery systems.

C4. Informing Clinical and Public Health Approaches to Chronic Disease Prevention

Centers for Disease Control and Prevention

This program seeks to enhance clinical and community linkages to perform CER on community interventions that are designed to work in concert with clinical interventions, to perform CER that addresses both primary prevention and secondary prevention and optimum delivery of quality health care in underserved populations, and to leverage the community engagement that Prevention Research Centers possess to advance translation and dissemination of CER findings.

C5. Linked HHS longitudinal claims data sets for comparative effectiveness research on medications and devices (ASPE/CMS)

Office of the Assistant Secretary for Planning and Evaluation, Centers for Medicare & Medicaid Services

Due to ARRA time constraints this program was withdrawn.

C6. Centers for Racial and Ethnic Minority-Focused Comparative Effectiveness Research

Office of Minority Health, National Institutes of Health

The Office of Minority Health will partner with the National Center on Minority Health and Health Disparities, under the aegis of the Federal Collaboration for Health Disparities Research, to create Centers on Comparative Effectiveness Research. These centers will complement existing peer-reviewed Centers of Excellence at the National Institutes of Health and other Federal agencies focusing on the health of racial and ethnic minority populations.

C7. Center of Excellence for Research on Disability Care Coordination

Office of the Director, Office of the Assistant Secretary for Planning and Evaluation

This program will establish the Center of Excellence for Research on Disability Care Coordination.

Inventory and Evaluation

D1. Inventory of Ongoing Comparative Effectiveness Research and Evaluation of Impact

Office of the Assistant Secretary for Planning and Evaluation

This program will focus on an iterative process through which current and future CER efforts will need to be routinely evaluated so as to rapidly identify gaps in knowledge and inform future priority setting.

D2. Evaluation and Impact Assessment

Office of the Assistant Secretary for Planning and Evaluation

The objective of these assessments is to ensure that the complete portfolio of efforts is collectively achieving impact. Its purpose is not to evaluate the performance of specific projects or grants.

D3. Federal Coordinating Council Support for Inventory and Listening Sessions

Office of the Assistant Secretary for Planning and Evaluation

This program provided support for the Federal Coordinating Council for Comparative Effectiveness Research and the development of recommended research priorities for the Office of the Secretary's Comparative Effectiveness Research funds.

D4. Institute of Medicine Report-Initial National Priorities for Comparative Effectiveness Research

Agency for Healthcare Research and Quality

This program provided support for an independent committee convened by the IOM, to develop a report on comparative effectiveness research priority topics. In addition to the FCC findings, this report further informs how the Office of the Secretary's comparative effectiveness research funds are distributed.

E. Delivery Schedule

The table below includes the anticipated award dates for the items identified in Section D.

Table 3

Investment	Primary Division	Type of Award	Est. Date of Award
A. Data Infrastructure			
A1. Medicare claims	CMS	Task Order Contracts	April and June 2010
A2. Medicaid claims	CMS	Task Order Contracts	March (awarded) and Sept 2010
A3. Clinically enhanced state data	AHRQ	Contracts and/or grants, cooperative agreements	July and Sept 2010
A4. All-Payor, All-Claims Design and Implementation	ASPE/CMS	Task Order Contracts	January, April and Sept 2010
A5. Distributed clinical data networks	AHRQ	Grants, Task Order Contracts	Sept 2010
A6. Community Health Applied Research Network	HRSA	Cooperative agreements	Sept 2010
A7. Patient Registries	AHRQ	Task Order Contracts or Grants	Sept 2010
A8. Cancer Registries	CDC	Task Order Contracts, cooperative agreements	May 2010
A9.Registry of Registries	AHRQ	Contract	Sept 2010
A10. Building FDA infrastructure and skills for medication and device CER	FDA	Task Order Contracts,	August and Sept 2010
A11. Persons with multiple chronic conditions Data and Research	AHRQ/IHS	Grants and/or Task Order Contracts	July and Sept 2010
A12. Pediatric care networks and CER	HRSA	Grants and/or cooperative agreements	Sept 2010

Investment	Primary Division	Type of Award	Est. Date of Award
A13. CMS Public Use Data Files	CMS	Task Order Contracts	Sept 2010
A14. Strategic Plan for Developing CER Data Sets	CMS	Task Order Contract	Sept 2010
B. Dissemination and Translation			
B1. Dissemination of CER to Physicians and other Providers, Patients and Consumers	AHRQ/ASPE	Task Order Contracts	May and Sept 2010
B2. Implementation strategies in AHRQ networks	AHRQ	Grants and/or Task Order Contracts	July and Sept 2010
B3. Accelerating Dissemination and Adoption of CER in Delivery Systems	ASPE	Cooperative agreements Grants and/or Task order contracts	May, July, August and Sept 2010
B4. Enhancing the Adoption of CER in the Treatment of Medicaid Patients with Serious Mental Illness	ASPE	Task Order Contract	July 2010
C. Interventions			
C1. Behavioral Economics and Change	NIH/AHRQ	Grants and Contracts	August 2010
C2. Delivery System	AHRQ	Grants, Task Order Contract	June and Sept 2010
C3. Regionalized Emergency Care delivery	ASPR	Task Order Contracts	June 2010
C4. Comparative effectiveness of chronic disease prevention	CDC	Grants	July 2010
C5. Linked administrative claims research on medications and devices	ASPE Withdrawn	Task Order Contract, cooperative agreements	Withdrawn
C6. Centers of Excellence for Racial and Ethnic Minority-focused CER	NIH/OMH	Cooperative agreements	July 2010
C7. Centers of Excellence for Persons with Disabilities	ASPE/OD	Task Order Contracts, cooperative agreements	April 2010
D. Inventory and Evaluation			
D1. Inventory of CER ongoing	ASPE	Task Order Contract	May 2010
D2. Evaluation and Impact Assessment	ASPE	Task Order Contracts	June 2010
D3. FCC support for inventory and listening sessions	ASPE	Task Order Contracts	Awarded
D4. IOM report	AHRQ	Contract	Awarded

Investment	Primary Division	Type of Award	Est. Date of Award
E. Administrative Costs	Across Divisions	Administrative	Ongoing
F. Funds for Future Allocation			

F. Environment Review Compliance[2],[3]

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.

G. Measures

HHS has developed quantifiable outcomes that will show how execution of this program will improve health outcomes and the quality of health care. Performance indicators are broken into 3 key categories: data infrastructure, dissemination and translation, and research. The AHRQ Program Management Office will collect information to aid HHS with tracking progress toward the program's goals and objectives. The total number of projects on track will indicate the progress towards program completion. Planned measures include the following:

[2] 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/.

[3] 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 or Lydina Battle, Procurement Analyst, at (202) 205-4512, Lydina.Battle@hhs.gov

Table 4

Outcome / Achievement	Units	Type	9/30/09	12/31/09	3/31/10	6/30/10	9/30/10	12/31/10	3/31/11	6/30/11	9/30/11	Program End
ARRA OS CER 1: Evidence[4] available to policymakers, providers and consumers as a foundation for health care decision making[5]	0	TARGET	TBD	N/A[6]	N/A	N/A	N/A	N/A	N/A	N/A	TBD	By 2013, increase by 10%
		ACTUAL										
ARRA OS CER 2: The number of sources[7] available for comparative effectiveness Research[5]	0	TARGET	TBD	N/A	N/A	N/A	N/A	N/A	N/A	N/A	TBD	By 2013, increase by 10%
		ACTUAL										
ARRA OS CER 3: The number of research networks[8] for comparative effectiveness research[5]	0	TARGET	TBD	N/A	N/A	N/A	N/A	N/A	N/A	N/A	TBD	By 2013, increase by 10%
		ACTUAL										
ARRA OS CER 4: Number of contract and grant applications received	#	TARGET	0	0	154	155	155	N/A	N/A	N/A	N/A	Establishing baseline metrics for applicants received.

[4] The type of evidence of CER to be developed includes, but is not limited to literature reviews, peer reviewed journal articles, websites, and presentations.
[5] Performance data sources for the Data Infrastructure, Research and Dissemination and Translation projects are currently under development. Target measurements will be determined by April 2011 and are reported annually.
[6] N/A indicates that target measures will be reported on or by April 2011
[7] Sources for this measure include, but are not limited to the creation of datasets, registries or files to be utilized for CER.
[8] Research networks are designed to increase the availability of researcher access to data by creating data linkages among research institutions for CER work.

Outcome / Achievement	Units	Type	9/30/09	12/31/09	3/31/10	6/30/10	9/30/10	12/31/10	3/31/11	6/30/11	9/30/11	Program End
		ACTUAL	0	0	168							
ARRA OS CER 5: Number of Federal Coordinating Council Meetings (Annual Target)[9]		TARGET		13				2				
		ACTUAL		13								Completed 100% of all council meetings.
ARRA OS CER 6: Number or people and organizations who provided written or verbal comments for Council's consideration (Annual Target)[9]		TARGET		13				2				
		ACTUAL		412								Exceeded target goal for public comments received on CER for FCC consideration.

[9] The Federal Coordinating Council was terminated in the Affordable Care Act.

H. Monitoring and Evaluation

All Recovery Act programs are assessed for risk to ensure that appropriate internal controls are in place throughout the entire lifecycle of the program. These assessments are 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." (including Appendices A, B, and C)

The HHS risk management process fits within the overall governance structure established at HHS to address Recovery Act program risks. The HHS Risk Management and Financial Oversight Board provides executive leadership and establishes accountability for the risk assessment process related to internal controls over financial reporting, and the HHS Senior Assessment Team ensures that risk assessment objectives are clearly communicated throughout the Department. The AHRQ Risk Assessment Team carries out comprehensive annual assessments of its Recovery Act program(s) to identify risks and develop strategies to address them, including those associated with selecting recipients, awarding and overseeing funds, and achieving program goals. The AHRQ Risk Assessment Team meets with OPDIV's weekly to assess the effectiveness of mitigation strategies and identify emerging risks.

In addition, AHRQ has presented its high level risks to the Recovery Act Implementation Team. Chaired by the Deputy Secretary and comprised of senior policy officials from throughout the Department, the Implementation Team convenes monthly to monitor progress in carrying out Recovery Act programs and address the obstacles and risks that could impact on their success.

I. Transparency

The Office of the Secretary is open and transparent in all of its contracting and grant competitions and regulations depending on what is appropriate for program activities that involve spending of Recovery Act funding consistent with statutory and OMB guidance. Contract solicitations can be found via the Federal Business Opportunity website, http://www.fbo.gov, and funding announcements are available via http://www.grants.gov.

HHS ensures that recipient reports required by Section 1512 of the Recovery Act are submitted and reviewed for material omissions and significant errors that would mislead or confuse the public. HHS informs recipients of their reporting obligation through standard terms and conditions, grant announcements, contract solicitations, and other program guidance. In addition, HHS provides key award information to recipients and other technical assistance to grantees and contractors and fully utilizes Project Officers to ensure compliance with reporting requirements.

J. Accountability

To ensure that managers are held to high standards of accountability in achieving program goals under the Recovery Act, HHS has built upon and strengthened existing processes. Senior OS officials meet regularly with senior Department officials to ensure that projects are meeting their program goals, assessing and mitigating risks, ensuring transparency, and incorporating corrective actions. The personnel performance appraisal system also incorporates Recovery Act program stewardship responsibilities for program and business function managers.

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, HHS will continue to increase the transparency and explicit process for comparative effectiveness research and will continue to engage stakeholders throughout the research process.

L. Federal Infrastructure Investments

The OS does not anticipate any construction or renovation funded under this activity. However, HHS will ensure that it complies with energy efficiency and green building requirements, if applicable.

Summary of Significant Changes:

- Added Obligation Funding table to Section A.
- Added table indicating investment levels for data infrastructure, dissemination and translation, research and inventory and evaluation projects in Section C.
- Revised Characteristics section to include numbers from obligation funding table and previously funded inventory (D3 and D4) projects.
- Revised delivery schedule table to include the correct name for the Registry of Registries project.
- Updated Performance Measures Provided in Section G.
- Updated Sections F, H and I to reflect updated HHS policies on Environmental Review Compliance, Monitoring and Evaluation, and Transparency.