COMPARATIVE EFFECTIVENESS RESEARCH:
UPDATE ON FEDERAL PROGRAMS
January 12, 2010

The American Recovery and Reinvestment Act of 2009 (ARRA) allocated over $166.6 billion to the Department of Health and Human Services (HHS) in eight areas, of which $1.1 billion was designated for comparative effectiveness. For context, amounts allocated for the seven other areas of ARRA funding were as follows: improving and preserving health care ($48.8 billion), health information technology ($48.8 billion), children and community services ($12.4 billion), scientific research and facilities ($10 billion), community health ($2.8 billion), prevention and wellness ($1 billion), and accountability and information technology security ($0.1 billion).

Status of CER Funding
For comparative effectiveness, ARRA provided $400 million to the Office of the HHS Secretary, $300 million for the Agency for Healthcare Research and Quality (AHRQ), and $400 million for the National Institutes of Health (NIH). The law stated that these funds are to support 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.

Office of the HHS Secretary - In FY 2009, HHS obligated $1.5 million for the Institute of Medicine (IOM) study on comparative effectiveness research (CER) and $1.1 million for logistical and research support for the Federal Coordinating Council for Comparative Effectiveness Research. The Council, informed by the IOM report, provided the basis for HHS-initiated FY 2010 activities in CER. Both NIH and AHRQ have representation on the Council, and their recent funding opportunities have been deployed in that context. HHS has just issued its first funding opportunity, and more are anticipated (see table on page 3). General information on HHS's CER activities can be found here: http://www.hhs.gov/recovery/programs/cer/index.html.

National Institutes of Health – For grant competitions under ARRA in the spring and summer of 2009, NIH listed CER as one of its priority areas. In that regard, NIH awarded 82 Challenge Grants (RC1) and 31 Grand Opportunity grants (RC2) that focused on CER. In addition, NIH provided supplements to 23 previously awarded cooperative agreements for research activities specifically focused on comparative effectiveness. An additional 28 projects were either newly funded under ARRA or were supplemented for CER activities. These 164 grants totaled $193 million. A complete listing of these projects, along with abstracts, may be obtained from the RePORTER database at http://projectreporter.nih.gov/reporter.cfm by checking the "comparative effectiveness" option in the upper left of the query form. NIH has also issued a number of new solicitations (with more than $100 million available), summarized in the table on page 3.

Agency for Healthcare Research and Quality – Because much of AHRQ's FY 2009 effort was focused on health information technology issues, the agency was a bit later than NIH in issuing its CER solicitations. Also, AHRQ was forced to wait on the outcomes of the IOM study and subsequent report of the Federal Coordinating Council for Comparative Effectiveness Research before it could issue targeted requests for applications. Two major solicitations, the Clinical and Health Outcomes Initiatives in Comparative Effectiveness (CHOICE) grants and the Innovative Adaptation and Dissemination of AHRQ CER Products (ADAPT) grants, had receipt dates in December 2009; funding decisions are a few months away for this pot totaling $129.5 million. AHRQ has six more active solicitations, with a closing date of January 20, summarized in the table on page 3. These funding opportunities will devote $86 million to CER funding.

A Look toward the Future

A significant portion of the CER activity over the next few months will involve the peer review and subsequent funding of announced initiatives to meet the deadlines mandated by ARRA. As with other funding under ARRA, the agencies will be aggressively monitoring the outcomes of the recently funded, and soon to be funded, projects. These outcomes will inform the future directions of CER that the agencies undertake. The role of the Federal Coordinating Committee on Comparative Effectiveness Research has been minimal in recent months, and its role will be significantly modified in the context of health care reform, as noted below.

Any final healthcare reform bills are likely to have specific implications for CER projects under the HHS agencies' aegis. The House bill would create a Center for Comparative Effectiveness Research (CER) within AHRQ, while the Senate bill would create the Patient-Centered Outcomes Research Institute. Both House and Senate bills would create a CER Commission to oversee and evaluate the Center's activities and a trust fund that would receive contributions from Medicare and private health insurance plans to fund the Center and the research it would conduct. During its debate on the bill, the House also accepted the following amendments to the CER provisions: prohibit research conducted, supported, or developed by the Center, the Commission, or the Federal Coordinating Council for Comparative Effectiveness Research from being used to deny or ration care; prohibit the Centers for Medicare and Medicaid Services (CMS) from using federally-funded CER data to make coverage determinations on the basis of cost; and require that, in developing best practices, the Commission or Center consult with "specialty colleges and academies of medicine." Any recommendations made or best practices developed by the Commission or Center must be based upon evidence-based medicine and must not violate standards and protocols of clinical excellence of the specialty colleges and academies. Both bills have language on transparency of data, access to research performed, and ability of government agencies to collect the data.

In summary, the health care reform bills will extend money and emphasis on comparative effectiveness research begun under ARRA, but would do so under modified means from current efforts. As well, the healthcare bills contain more legislative language than what the stimulus offered and articulate funding in the range of $110 million to $150 million, to be supplemented by fees collected from health insurance plans. It is unclear what prominence comparative effectiveness will have in the President's fiscal year 2011 budget, which will be released on February 1. Nevertheless, it is clear that NIH and AHRQ in particular are committed to support of robust programs in CER that address needs in healthcare and that substantive funding opportunities will continue to emerge over the next few years.

Federal Funding Opportunities for Comparative Effectiveness Research

TOPIC	RFA #	AGENCY	DUE DATES	FUNDING DATE	FUNDS
Accelerating Adoption of CER Results by Providers and Patients (R18)	RFA-AE-10-001	DHHS	March 11	August	$15 M
NIH Director's Opportunity for Research in Five Thematic Areas (RC4) (CER is one of themes)	RFA-OD-10-005	NIH-wide	March 15	September	$80 M
Administrative Supplements for CER Research Workforce Development	NOT-OD-10-037	NIH-wide	March 1	Spring	$8 M
Behavioral Economics for Nudging the Implementation of CER Clinical Trials (RC4)	RFA-OD-10-001	5 NIH Institutes	April 7	August	$15 M
Behavioral Economics for Nudging the Implementation of CER: Pilot Research (RC4)	RFA-OD-10-002	5 NIH Institutes	March 19	August	$5 M
CER on Upper Endoscopy in Gastroesophageal Reflux Disease, Eradication Methods for Methicillin Resistant Staphylococcus aureus (MRSA) & Dementia Detection & Management Strategies (RC4)	RFA-OD-10-008	4 NIH Institutes	February 26	August	$15 M
Methodology Development in CER (RC4)	RFA-OD-10-009	8 NIH Institutes	February 26	August	$10 M
Expansion of Research Capability to Study Comparative Effectiveness in Complex Patients (R24)	RFA-HS-10-001	AHRQ	January 20	September	$12 M
CER Research to Optimize Prevention and Healthcare Management for the Complex Patient (R21)	RFA-HS-10-009	AHRQ	January 20	September	$6 M
Electronic Data Methods Forum for CER (U13)	RFA-HS-10-006	AHRQ	January 20	September	$4 M
Institutional NRSA Postdoctoral CER Training Award (T32)	RFA-HS-10-011	AHRQ	January 20	September	$5 M
Mentored Clinical Scientists CER Development Award (K12)	RFA-HS-10-007	AHRQ	January 20	September	$15 M
PROSPECT Studies: Building New Clinical Infrastructure for CER (R01)	RFA-HS-10-005	AHRQ	January 20	September	$44 M
Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE) (R01)	RFA-HS-10-003	AHRQ	CLOSED	August	$100 M
Innovative Adaptation & Dissemination of AHRQ CER Products (ADAPT) (R18)	RFA-HS-10-004	AHRQ	CLOSED	August	$29.5 M