

## Comparative Effectiveness Sections American Recovery and Reinvestment Act

### **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 H. R. 1—63 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.

#### **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 healthrelated 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.