Comparative Effectiveness Research – Health Care Reform Law (111-148)

Background: Comparative effectiveness research (CER) gained a great deal of momentum through the American Recovery and Reinvestment Act (ARRA) (PL 111-5). ARRA invested $1.1 billion in CER that was to be administered by the Agency for Health Research and Quality, the National Institutes of Health, and the Office of the Secretary of the Department of Health and Human Services. These invested funds were intended to drive the movement toward more evidence-based health care through services that demonstrate cost-effectiveness and high quality. Accompanying the infusion of funding in CER were two reports that were to be completed by the Institute of Medicine and a newly created Federal Coordinating Council on CER to identify priority areas and generate guidance for the investment of funding. The reports each acknowledged the necessity and importance of further study on the effects of low-technology, high-value treatments versus alternative approaches.

ACNM Position/Policy: ACNM is a strong supporter of this provision of the health care reform law.

Impact on Nurse Midwives: Competitive effectiveness research can assist midwifery in demonstrating value and cost effectiveness in the services that are provided by CNMs and CMs.

Summary of Provisions

Section 6302 calls for the immediate dissolution of the Federal Coordinating Council for CER, which was created through ARRA. Section 6301 creates a new Patient-Centered Outcomes Research Institute (PCORI) as a private, nonprofit corporation to assist patients, clinicians, purchasers, and policy makers in making informed health decisions by advancing the quality and relevance of clinical evidence through research and evidence synthesis. PCORI will conduct research that compares the health outcomes and clinical effectiveness, risks, and benefits of two or more medical treatments, services, or items. PCORI must identify research priorities, establish a research project agenda, adopt methodological standards, provide for a peer-review process for primary research, and provide for a public comment forum.

PCORI may not mandate coverage, reimbursement, or other policies for any public or private payer. The reports or research findings that the research institute generates must not include practice guidelines, coverage recommendations, or payment/policy
recommendations. The Secretary of Health and Human Services is prohibited from denying Medicare coverage based solely on a study conducted by PCORI, and the Secretary may only use evidence and findings from PCORI research to make a Medicare coverage decision if such use is through an iterative and transparent process that includes public comment and considers the effect on subpopulations.

A Patient-Centered Outcomes Research Trust Fund is to be created through contributions from Medicare, private insurers, and self-insured health plans, beginning at $1 per capita in FY2013, rising to $2 per capita in FY2014, and increasing at a rate relative to increases in the National Health Expenditures for FY2015-FY2019. Additional financing is provided through appropriations, beginning with $10 million for FY2010 and increasing to $150 million per year for FY2012-FY2019.

References: