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42 U.S. Code § 1320e

Comparative clinical effectiveness research

(a) Definitions

In this section:

(1) Board

The term "Board" means the Board of Governors established under subsection (f).

(2) Comparative clinical effectiveness research; research

(A) In general

The terms "comparative clinical effectiveness research" and "research" mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

(B) Medical treatments, services, and items described

The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.

(3) Conflict of interest

The term "conflict of interest" means an association, including a financial or personal association, that have [1] the potential to bias or have the appearance of biasing an individual's decisions in matters related to the Institute or the conduct of activities under this section.

(4) Real conflict of interest

The term "real conflict of interest" means any instance where a member of the Board, the methodology committee established under subsection (d)(6), or an advisory panel appointed under subsection (d)(4), or a close relative of such member, has received or could receive either of the following:

(A) A direct financial benefit of any amount deriving from the result or findings of a study conducted under this section.

(B) A financial benefit from individuals or companies that own or manufacture medical treatments, services, or items to be studied under this section that in the aggregate exceeds $10,000 per year. For purposes of the preceding sentence, a financial benefit includes honoraria, fees, stock, or other financial benefit and the current value of the member or close relative's already existing stock holdings, in addition to any direct financial benefit deriving from the results or findings of a study conducted under this section.

(b) Patient-Centered Outcomes Research Institute

(1) Establishment

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There is authorized to be established a nonprofit corporation, to be known as the "Patient-Centered Outcomes Research Institute" (referred to in this section as the "Institute") which is neither an agency nor establishment of the United States Government.

(2) Application of provisions

The Institute shall be subject to the provisions of this section, and, to the extent consistent with this section, to the District of Columbia Nonprofit Corporation Act.

(3) Funding of comparative clinical effectiveness research

For fiscal year 2010 and each subsequent fiscal year, amounts in the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the "PCORTF") under section 9511 of the Internal Revenue Code of 1986 shall be available, without further appropriation, to the Institute to carry out this section.

(c) Purpose

The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).

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