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111TH CONGRESS
1ST SESSION

H. R. 2824

To enhance the conduct and support of federally funded comparative effectiveness research relating to health care, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 11, 2009

Mrs. CHRISTENSEN (for herself, Mr. HERGER, and Mr. BOUSTANY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Armed Services, and Veterans' Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To enhance the conduct and support of federally funded comparative effectiveness research relating to health care, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Doctor-Patient Relationship and Research Protection Act''.

SEC. 2. FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH.

(a) AUTHORITY.—Paragraph (1) of section 804(c) of title VIII of division A of the American Recovery and Reinvestment Act of 2009 (42 U.S.C. 299b–8(c)) is amended to read as follows:

''(1) notwithstanding the provisions under the heading 'AGENCY FOR HEALTHCARE RESEARCH AND QUALITY' of this title and any other provision of law, have full authority to direct and coordinate all Federal funding of comparative effectiveness health care research, including such research conducted or supported by the Departments of Health and Human Services, Veterans Affairs, and Defense; and''.

(b) MEMBERSHIP.—Subsection (d) of section 804 of title VIII of division A of the American Recovery and Reinvestment Act of 2009 (42 U.S.C. 299b–8) is amended to read as follows:

''(d) MEMBERSHIP.—

''(1) IN GENERAL.—The members of the Council shall include one senior officer or employee from each of the following agencies:

''(A) The Agency for Healthcare Research and Quality.

''(B) The Secretary of Health and Human Services.

''(C) The Director of the National Institutes of Health.

''(D) 20 members, 9 of whom are not full-time government employees, appointed by the Comptroller General of the United States as follows:

''(i) 3 members representing patients and health care consumers.

''(ii) 3 members representing practicing physicians, including surgeons.

''(iii) 3 members representing agencies that administer public programs, as follows:

''(I) 1 member representing the Centers for Medicare & Medicaid Services who has experience in administering the program under title XVIII of the Social Security Act.

''(II) 1 member representing agencies that administer State health programs (who may represent the Centers for Medicare & Medicaid Services and have experience in administering the program under title XIX or the program under title XXI

of the Social Security Act or be a governor of a State).

''(III) 1 member representing agencies that administer other Federal health programs (such as a health program of the Department of Defense Federal employees health benefits program under chapter 89 of title 5 of the United States Code, a health program of the Department of Veterans Affairs under chapter 17 of title 38 of such Code, or a medical care program of the Indian Health Service or of a tribal organization).

''(iv) 3 members representing private payers, of whom at least 1 member shall represent health insurance issuers and at least 1 member shall represent employers who self-insure employee benefits.

''(v) 3 members representing pharmaceutical, device, and technology manufacturers or developers.

''(vi) 1 member representing nonprofit organizations involved in health services research.

''(vii) 1 member representing organizations that focus on quality measurement and improvement or decision support.

''(viii) 1 member representing independent health services researchers.

''(ix) 1 member representing research in differences in treatment outcomes along the lines of racial and ethnic background, gender, and geography.

''(x) 1 member representing research in treating rural populations.

''(E) QUALIFICATIONS.—At least half of the members of the Council shall be physicians or other experts with clinical expertise.

''(2) CHAIRMAN; VICE CHAIRMAN.—The Secretary shall serve as Chairman of the Council and shall designate a member to serve as Vice Chairman.''.

(c) RULES OF CONSTRUCTION.—Subsection (g) of section 804 of title VIII of division A of the American Recovery and Reinvestment Act of 2009 (42 U.S.C. 299b–8) is amended to read as follows:

''(g) RULES OF CONSTRUCTION.—

''(1) COVERAGE.—Nothing in this section shall be construed—

''(A) to permit the Council to mandate or recommend coverage, reimbursement, or other policies for any public or private payer; or

''(B) as preventing the Secretary of Health and Human Services from covering the routine costs of clinical care received by an individual entitled to, or enrolled for, benefits under title XVIII, XIX, or XXI of the Social Security Act in the case where such individual is participating in a clinical trial and such costs would otherwise be covered under such title with respect to the beneficiary.

''(2) REPORTS AND FINDING.—No report submitted under this section or research findings disseminated by the Council shall be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.''.

(d) TRANSPARENCY, CREDIBILITY, AND ACCESS.—Section 804 of title VIII of division A of the American Recovery and Reinvestment Act of 2009 (42 U.S.C. 299b–8) is amended by adding at the end the following:

''(h) TRANSPARENCY, CREDIBILITY, AND ACCESS.—The Council shall establish procedures to ensure that the following requirements for ensuring transparency, credibility, and access are met:

''(1) PUBLIC COMMENT PERIOD.—

''(A) COMMENT PRIOR TO OBLIGATION OF FUNDS FOR RESEARCH.—Before any Federal funds may be obligated to conduct or support comparative effectiveness research, the Council shall provide for a period of not less than 30 days for the public to comment on the research proposal.

''(B) COMMENT AFTER RESEARCH RESULTS PUBLISHED.—After the publication of the results of research described in subparagraph (A), the Council shall provide for a period of 60 days for the public to comment on such results.

''(C) TRANSMISSION OF PUBLIC COMMENTS.—The Council shall ensure the transmission of public comments submitted under subparagraph (A) to the entity conducting the research with respect to which the individual study design is being finalized.

''(2) ADDITIONAL FORUMS.—The Council shall, in addition to the public comment period described in paragraph (1), support forums to increase public awareness and obtain and incorporate public feed-

back through media (such as an Internet website) on the following:

''(A) The identification of comparative effectiveness research priorities.

''(B) Comparative effectiveness research findings.

''(C) Any other duties, activities, or processes the Council determines appropriate.

''(3) PUBLIC AVAILABILITY.—The Council shall make available to the public and disclose through the official public Internet website of the Council, and through other forums and media the Council determines appropriate, the following:

''(A) The process and methods for the conduct of comparative effectiveness research pursuant to this section, including—

''(i) the identity of the entity conducting any such research;

''(ii) any links the entity has to industry (including such links that are not directly tied to the particular research);

''(iii) draft study designs (including research questions and the finalized study design, together with public comments on

such study design and responses to such comments);

''(iv) research protocols (including measures taken, methods of research, methods of analysis, research results, and such other information as the Council determines appropriate);

''(v) the identity of investigators conducting such research and any conflicts of interest of such investigators; and

''(vi) any progress reports the Council determines appropriate.

''(B) Public comments submitted during each public comment period under paragraph (1)(A).

''(C) Bylaws, processes, and proceedings of the Council, to the extent practicable and as the Council determines appropriate.

''(D) Not later than 60 days after receipt by the Council of a relevant report or comparative effectiveness research finding, appropriate information contained in such report or finding.

''(4) CONFLICTS OF INTEREST.—

''(A) IN GENERAL.—The Council shall—

''(i) in appointing members to an advisory panel, and in selecting individuals to contribute to any peer-review process and for employment as executive staff of the Council, take into consideration any conflicts of interest of potential appointees, participants, and staff; and

''(ii) include a description of any such conflicts of interest and conflicts of interest of Council members in an annual report to the Congress, except that, in the case of individuals contributing to any such peer review process, such description shall be in a manner such that those individuals cannot be identified with a particular research project.

''(B) DEFINITION.—In this subsection, the term 'conflict of interest' means associations, including financial and personal, that may be reasonably assumed to have the potential to bias an individual's decisions in matters related to the Council or the conduct of the comparative effectiveness research.''.

SEC. 3. APPLICATION OF FEDERALLY FUNDED CLINICAL COMPARATIVE EFFECTIVENESS RESEARCH.

(a) LIMITATION ON CMS.—The Administrator of the Centers for Medicare & Medicaid Services may not use federally funded clinical comparative effectiveness research data to make coverage determinations under title XVIII of the Social Security Act for medical treatments, services, and items on the basis of cost.

(b) REQUIREMENT FOR IMPLEMENTATION.—Federally funded clinical comparative effectiveness research and related evaluation and communication activities shall reflect the principle that clinicians and patients should have the best available evidence upon which to make choices in health care items and services, in providers, and in health care delivery systems, recognizing that patient subpopulations and patient and physician preferences may vary.

(c) APPEALS OF CERTAIN MEDICARE COVERAGE DETERMINATIONS.—In the case of a national or local coverage determination under title XVIII of the Social Security Act that has been made utilizing federally funded comparative effectiveness research, an individual entitled to benefits under such title shall—

(1) be an eligible requester under section 1869(h)(1)(B) of such Act in relation;

(2) have expedited access (as specified by the Secretary) to coverage determinations, redeterminations, and appeals relating to such determinations; and

(3) have full access to all administrative or judicial review under section 1869 of such Act with respect to such determinations.

(d) RULE OF CONSTRUCTION.—Nothing in this Act or the amendments made by this Act shall be construed to require coverage of any drug, biological product, device, or treatment that has been determined by the Food and Drug Administration to be unsafe.

(e) DISAGGREGATION OF RESEARCH RESULTS.—No Federal funds may be made available to any person for any federally funded clinical comparative effectiveness research, unless the person agrees to ensure that, whenever possible, the methodology and research protocols will include variables that not only measure, but can be disaggregated to analyze and identify, any differences along the lines of racial and ethnic background, gender, and geography that may exist among and within patient subpopulations.

(f) DEFINITIONS.—In this section:

(1) The term ''federally funded clinical comparative effectiveness research'' means research that—

(A) evaluates and compares the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items; and

(B) is conducted or supported in accordance with provisions of title VIII of division A of the American Recovery and Reinvestment Act of 2009 or with the use of other Federal funds.

(2) The term ''medical treatments, services, and items'' means health care interventions, protocols for treatment, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), and any other processes or items being used in the treatment and diagnosis of, or prevention of illness or injury in, patients.

(3) The term ''patient subpopulations'' means populations of patients of different racial and ethnic backgrounds, genders, and geographic locations.

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