111TH CONGRESS
1ST SESSION

S. 1259

To protect all patients by prohibiting the use of data obtained from comparative effectiveness research to deny coverage of items or services under Federal health care programs and to ensure that comparative effectiveness research accounts for advancements in personalized medicine and differences in patient treatment response.

IN THE SENATE OF THE UNITED STATES

JUNE 15, 2009

Mr. KYL (for himself, Mr. MCCONNELL, Mr. ROBERTS, and Mr. CRAPO) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To protect all patients by prohibiting the use of data obtained from comparative effectiveness research to deny coverage of items or services under Federal health care programs and to ensure that comparative effectiveness research accounts for advancements in personalized medicine and differences in patient treatment response.

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 ''Preserving Access to Targeted, Individualized, and Effective New Treatments

and Services (PATIENTS) Act of 2009'' or the ''PATIENTS Act of 2009''.

SEC. 2. PROHIBITION ON CERTAIN USES OF DATA OBTAINED FROM COMPARATIVE EFFECTIVENESS RESEARCH; ACCOUNTING FOR PERSONALIZED MEDICINE AND DIFFERENCES IN PATIENT TREATMENT RESPONSE.

(a) IN GENERAL.—Notwithstanding any other provision of law, the Secretary of Health and Human Services—

(1) shall not use data obtained from the conduct of comparative effectiveness research, including such research that is conducted or supported using funds appropriated under the American Recovery and Reinvestment Act of 2009 (Public Law 111–5), to deny coverage of an item or service under a Federal health care program (as defined in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b(f))); and

(2) shall ensure that comparative effectiveness research conducted or supported by the Federal Government accounts for factors contributing to differences in the treatment response and treatment preferences of patients, including patient-reported outcomes, genomics and personalized medicine, the

unique needs of health disparity populations, and indirect patient benefits.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as affecting the authority of the Commissioner of Food and Drugs under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

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