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104TH CONGRESS
2D SESSION

H. R. 3958

To permit individuals to continue coverage under Federal health care programs of services while participating in approved clinical studies and to require the Secretary of Health and Human Services to make publicly available information on clinical trials.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 1996

Mrs. JOHNSON of Connecticut introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Ways and Means, National Security, Veterans' Affairs, and Government Reform and Oversight, 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 permit individuals to continue coverage under Federal health care programs of services while participating in approved clinical studies and to require the Secretary of Health and Human Services to make publicly available information on clinical trials.

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 ''Federal Coverage for Clinical Trials Act of 1996''.

SEC. 2. COVERAGE UNDER CERTAIN FEDERAL HEALTH CARE PROGRAMS FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL STUDIES.

(a) PERMITTING PARTICIPATION IN APPROVED CLINICAL STUDIES.—A Federal health care program may not deny (or limit or impose additional conditions on) coverage of items and services furnished to an enrollee if—

(1) the enrollee is participating in an approved clinical study,

(2) the items and services are furnished according to the design of the study or to treat conditions resulting from participation in the study, and

(3) the items and services would otherwise be covered under the program except for the fact that they are provided in connection with participation in such a study.

Such a program may not discriminate against an enrollee on the basis of the enrollee's participation in such a study.

(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed as requiring a Federal health care program to provide for payment for items and services normally paid for as part of an approved clinical study, such as the experimental therapy or drug itself.

(c) APPROVED CLINICAL STUDY DEFINED.—In this Act, the term ''approved clinical study'' means—

(1) a research study approved by the Secretary of Health and Human Services, the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, the Secretary of Veterans Affairs, the Secretary of Defense, or a qualified nongovernmental research entity (as defined in guidelines of the National Institute of Health), or

(2) a peer-reviewed and approved research program, as defined by the Secretary of Health and Human Services, conducted for the primary purpose of determining whether or not a treatment is safe, efficacious, or having any other characteristic of a treatment which must be demonstrated in order for the treatment to be medically necessary or appropriate.

(d) FEDERAL HEALTH CARE PROGRAM DEFINED.—In this section, the term ''Federal health care program'' means the following:

(1) MEDICARE.—The medicare program under title XVIII of the Social Security Act.

(2) FEHBP.—Health benefits plans offered under the Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code.

(3) VA HEALTH CARE.—The veterans health care program under chapter 17 of title 38, United States Code.

(4) DOD-RELATED PROGRAMS.—The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in section 1072(4) of title 10, United States Code.

(e) COVERAGE UNDER MEDICAID PROGRAM.—Nothing in title XIX of the Social Security Act shall be construed as preventing a State from receiving Federal financial participation with respect to medical assistance for which coverage is otherwise required to be provided by a Federal health care program under this section.

SEC. 3. MAKING PUBLICLY AVAILABLE INFORMATION ON RESULTS OF APPROVED CLINICAL STUDIES.

The Secretary of Health and Human Services shall make available to the public information about clinical investigations and results obtained from approved clinical studies (as defined in section 2(c)).

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