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105TH CONGRESS
1ST SESSION

H. R. 1069

To permit individuals to continue health plan coverage of services while participating in approved clinical studies.

IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 1997

Mrs. LOWEY introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To permit individuals to continue health plan coverage of services while participating in approved clinical studies.

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 ''Improved Patient Access to Clinical Studies Act of 1997''.

SEC. 2. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL STUDIES.

(a) PERMITTING PARTICIPATION IN APPROVED CLINICAL STUDIES.—A health plan 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 plan except for the fact that they are provided in connection with participation in such a study.

A health plan 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 health plan to provide for payment for items and services normally paid for as part of an approved clinical study.

(c) APPROVED CLINICAL STUDY DEFINED.—In this section, 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 de-

fined 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.

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