

104TH CONGRESS
2D SESSION

H. R. 3582

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 5, 1996

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Improved Patient Ac-
5 cess to Clinical Studies Act of 1996”.

6 **SEC. 2. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
7 **APPROVED CLINICAL STUDIES.**

8 (a) **PERMITTING PARTICIPATION IN APPROVED CLIN-**
9 **ICAL STUDIES.**—A health plan may not deny (or limit or

1 impose additional conditions on) coverage of items and
2 services furnished to an enrollee if—

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

5 (2) the items and services are furnished accord-
6 ing to the design of the study or to treat conditions
7 resulting from participation in the study, and

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

12 A health plan may not discriminate against an enrollee
13 on the basis of the enrollee’s participation in such a study.

14 (b) CONSTRUCTION.—Nothing in subsection (a) shall
15 be construed as requiring a health plan to provide for pay-
16 ment for items and services normally paid for as part of
17 an approved clinical study.

18 (c) APPROVED CLINICAL STUDY DEFINED.—In this
19 section, the term “approved clinical study” means—

20 (1) a research study approved by the Secretary
21 of Health and Human Services, the Director of the
22 National Institutes of Health, the Commissioner of
23 the Food and Drug Administration, the Secretary of
24 Veterans Affairs, the Secretary of Defense, or a
25 qualified nongovernmental research entity (as de-

1 fined in guidelines of the National Institute of
2 Health), or

3 (2) a peer-reviewed and approved research pro-
4 gram, as defined by the Secretary of Health and
5 Human Services, conducted for the primary purpose
6 of determining whether or not a treatment is safe,
7 efficacious, or having any other characteristic of a
8 treatment which must be demonstrated in order for
9 the treatment to be medically necessary or appro-
10 priate.

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