

107TH CONGRESS  
1ST SESSION

# S. 257

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

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 6, 2001

Ms. SNOWE 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 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 2001”.

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

8       (a) AMENDMENTS TO ERISA.—

9               (1) IN GENERAL.—Subpart B of part 7 of sub-  
10       title B of title I of the Employee Retirement Income

1 Security Act of 1974 (29 U.S.C. 1185 et seq.) is  
2 amended by adding at the end the following:

3 **“SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**  
4 **APPROVED CLINICAL STUDIES.**

5 “(a) PERMITTING PARTICIPATION IN APPROVED  
6 CLINICAL STUDIES.—A group health plan, and a health  
7 insurance issuer offering health insurance coverage in con-  
8 nection with a group health plan, may not deny (or limit  
9 or impose additional conditions on) the coverage of items  
10 and services furnished to an enrollee if—

11 “(1) the enrollee is participating in an approved  
12 clinical study;

13 “(2) the items and services are furnished ac-  
14 cording to the design of the study or to treat condi-  
15 tions resulting from participation in the study; and

16 “(3) the items and services would otherwise be  
17 covered under the plan except for the fact that the  
18 items and services are provided in connection with  
19 participation in such a study.

20 Such a plan or issuer may not discriminate against an  
21 enrollee on the basis of the enrollee’s participation in such  
22 a study.

23 “(b) CONSTRUCTION.—Nothing in subsection (a)  
24 shall be construed as requiring a group health plan, or  
25 a health insurance issuer offering health insurance cov-

1 erage in connection with a group health plan, to provide  
 2 for payment for items and services normally paid for as  
 3 part of an approved clinical study.

4 “(c) APPROVED CLINICAL STUDY DEFINED.—In this  
 5 section, the term ‘approved clinical study’ means—

6 “(1) a research study approved by the Sec-  
 7 retary of Health and Human Services, the Director  
 8 of the National Institutes of Health, the Commis-  
 9 sioner of Food and Drugs, the Secretary of Veterans  
 10 Affairs, the Secretary of Defense, or a qualified non-  
 11 governmental research entity (as defined in guide-  
 12 lines of the National Institutes of Health); or

13 “(2) a peer-reviewed and approved research  
 14 program, as defined by the Secretary of Health and  
 15 Human Services, conducted for the primary purpose  
 16 of determining whether or not a treatment is safe,  
 17 is efficacious, or has any other characteristic of a  
 18 treatment that must be demonstrated in order for  
 19 the treatment to be medically necessary or appro-  
 20 priate.”.

21 (2) TABLE OF CONTENTS.—The table of con-  
 22 tents in section 1 of the Employee Retirement In-  
 23 come Security Act of 1974 (29 U.S.C. prec. 1001)  
 24 is amended by inserting after the item relating to  
 25 section 713 the following:

“Sec. 714. Coverage for individuals participating in approved clinical studies.”.

1 (b) AMENDMENTS TO PHSA.—

2 (1) GROUP MARKET.—Subpart 2 of part A of  
3 title XXVII of the Public Health Service Act (29  
4 U.S.C. 300gg–4 et seq.) is amended by adding at  
5 the end the following:

6 **“SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING**  
7 **IN APPROVED CLINICAL STUDIES.**

8 “(a) PERMITTING PARTICIPATION IN APPROVED  
9 CLINICAL STUDIES.—A group health plan, and a health  
10 insurance issuer offering health insurance coverage in con-  
11 nection with a group health plan, may not deny (or limit  
12 or impose additional conditions on) the coverage of items  
13 and services furnished to an enrollee if—

14 “(1) the enrollee is participating in an approved  
15 clinical study;

16 “(2) the items and services are furnished ac-  
17 cording to the design of the study or to treat condi-  
18 tions resulting from participation in the study; and

19 “(3) the items and services would otherwise be  
20 covered under the plan except for the fact that the  
21 items and services are provided in connection with  
22 participation in such a study.

23 Such a plan or issuer may not discriminate against an  
24 enrollee on the basis of the enrollee’s participation in such  
25 a study.

1       “(b) CONSTRUCTION.—Nothing in subsection (a)  
2 shall be construed as requiring a group health plan, or  
3 a health insurance issuer offering health insurance cov-  
4 erage in connection with a group health plan, to provide  
5 for payment for items and services normally paid for as  
6 part of an approved clinical study.

7       “(c) APPROVED CLINICAL STUDY DEFINED.—In this  
8 section, the term ‘approved clinical study’ means—

9               “(1) a research study approved by the Sec-  
10 retary of Health and Human Services, the Director  
11 of the National Institutes of Health, the Commis-  
12 sioner of Food and Drugs, the Secretary of Veterans  
13 Affairs, the Secretary of Defense, or a qualified non-  
14 governmental research entity (as defined in guide-  
15 lines of the National Institutes of Health); or

16               “(2) a peer-reviewed and approved research  
17 program, as defined by the Secretary of Health and  
18 Human Services, conducted for the primary purpose  
19 of determining whether or not a treatment is safe,  
20 is efficacious, or has any other characteristic of a  
21 treatment that must be demonstrated in order for  
22 the treatment to be medically necessary or appro-  
23 priate.”.

1           (2) INDIVIDUAL MARKET.—The first subpart 3  
2           of part B of title XXVII of the Public Health Serv-  
3           ice Act (29 U.S.C. 300gg–51 et seq.) is amended—

4           (1) by adding at the end the following:

5   **“SEC. 2753. COVERAGE FOR INDIVIDUALS PARTICIPATING**  
6                           **IN APPROVED CLINICAL STUDIES.**

7           “The provisions of section 2707 shall apply to health  
8           insurance coverage offered by a health insurance issuer  
9           in the individual market in the same manner as the provi-  
10          sions apply to health insurance coverage offered by a  
11          health insurance issuer in connection with a group health  
12          plan in the small or large group market.”; and

13          (2) by redesignating such subpart 3 as subpart  
14          2.

15   **SEC. 3. EFFECTIVE DATE.**

16          The amendments made by this Act shall apply—

17          (1) with respect to group health plans for plan  
18          years beginning on or after January 1, 2002; and

19          (2) with respect to health insurance coverage  
20          offered, sold, issued, renewed, in effect, or operated  
21          in the individual market on or after January 1,  
22          2002.

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