

106TH CONGRESS
1ST SESSION

H. R. 2769

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to permit individuals to continue health coverage of services while participating in approved clinical studies.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 5, 1999

Mrs. LOWEY introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Education and the Workforce, and Ways and Means, 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

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to permit individuals to continue health 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 1999”.

1 **SEC. 2. CONTINUING COVERAGE FOR INDIVIDUALS PAR-**
 2 **TICIPATING IN APPROVED CLINICAL STUD-**
 3 **IES.**

4 (a) GROUP HEALTH PLANS.—

5 (1) PUBLIC HEALTH SERVICE ACT AMEND-
 6 MENTS.—(A) Subpart 2 of part A of title XXVII of
 7 the Public Health Service Act is amended by adding
 8 at the end the following new section:

9 **“SEC. 2707. CONTINUING COVERAGE FOR INDIVIDUALS**
 10 **PARTICIPATING IN APPROVED CLINICAL**
 11 **STUDIES.**

12 “(a) PERMITTING PARTICIPATION IN APPROVED
 13 CLINICAL STUDIES.—A group health plan, and a health
 14 insurance issuer offering group health insurance
 15 coverage—

16 “(1) may not deny (or limit or impose addi-
 17 tional conditions on) coverage of items and services
 18 furnished to a participant or beneficiary if—

19 “(A) the participant or beneficiary is par-
 20 ticipating in an approved clinical study;

21 “(B) the items and services are furnished
 22 according to the design of the study or to treat
 23 conditions resulting from participation in the
 24 study; and

25 “(C) the items and services would other-
 26 wise be covered under the plan except for the

1 fact that they are provided in connection with
2 participation in such a study; and

3 “(2) may not discriminate against a participant
4 or beneficiary on the basis of the participant’s or
5 beneficiary’s participation in such a study.

6 “(b) CONSTRUCTION.—Nothing in subsection (a)
7 shall be construed as requiring a group health plan or
8 health insurance issuer to provide for payment for items
9 and services normally paid for as part of an approved clin-
10 ical study.

11 “(c) NOTICE.—A group health plan under this part
12 shall comply with the notice requirement under section
13 714(c) of the Employee Retirement Income Security Act
14 of 1974 with respect to the requirements of this section
15 as if such section applied to such plan.

16 “(d) APPROVED CLINICAL STUDY DEFINED.—In this
17 section, the term ‘approved clinical study’ means—

18 “(1) a research study approved by the Sec-
19 retary of Health and Human Services, the Director
20 of the National Institutes of Health, the Commis-
21 sioner of the Food and Drug Administration, the
22 Secretary of Veterans Affairs, the Secretary of De-
23 fense, or a qualified nongovernmental research entity
24 (as defined in guidelines of the National Institute of
25 Health); or

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

9 (B) Section 2723(c) of such Act (42 U.S.C.
 10 300gg-23(c)) is amended by striking “section 2704”
 11 and inserting “sections 2704 and 2707”.

12 (2) ERISA AMENDMENTS.—(A) Subpart B of
 13 part 7 of subtitle B of title I of the Employee Re-
 14 tirement Income Security Act of 1974 is amended by
 15 adding at the end the following new section:

16 **“SEC. 714. CONTINUING COVERAGE FOR INDIVIDUALS PAR-**
 17 **TICIPATING IN APPROVED CLINICAL STUD-**
 18 **IES.**

19 “(a) PERMITTING PARTICIPATION IN APPROVED
 20 CLINICAL STUDIES.—A group health plan, and a health
 21 insurance issuer offering group health insurance
 22 coverage—

23 “(1) may not deny (or limit or impose addi-
 24 tional conditions on) coverage of items and services
 25 furnished to a participant or beneficiary if—

1 “(A) the participant or beneficiary is par-
2 ticipating in an approved clinical study;

3 “(B) the items and services are furnished
4 according to the design of the study or to treat
5 conditions resulting from participation in the
6 study; and

7 “(C) the items and services would other-
8 wise be covered under the plan except for the
9 fact that they are provided in connection with
10 participation in such a study; and

11 “(2) may not discriminate against a participant
12 or beneficiary on the basis of the participant’s or
13 beneficiary’s participation in such a study.

14 “(b) CONSTRUCTION.—Nothing in subsection (a)
15 shall be construed as requiring a group health plan or
16 health insurance issuer to provide for payment for items
17 and services normally paid for as part of an approved clin-
18 ical study.

19 “(c) NOTICE UNDER GROUP HEALTH PLAN.—The
20 imposition of the requirement of this section shall be treat-
21 ed as a material modification in the terms of the plan de-
22 scribed in section 102(a)(1), for purposes of assuring no-
23 tice of such requirements under the plan; except that the
24 summary description required to be provided under the
25 last sentence of section 104(b)(1) with respect to such

1 modification shall be provided by not later than 60 days
2 after the first day of the first plan year in which such
3 requirement apply.”.

4 “(d) 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 the Food and Drug Administration, the
10 Secretary of Veterans Affairs, the Secretary of De-
11 fense, or a qualified nongovernmental research entity
12 (as defined in guidelines of the National Institute of
13 Health); or

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

22 (B) Section 731(c) of such Act (29 U.S.C.
23 1191(c)) is amended by striking “section 711” and
24 inserting “sections 711 and 714”.

1 (C) Section 732(a) of such Act (29 U.S.C.
 2 1191a(a)) is amended by striking “section 711” and
 3 inserting “sections 711 and 714”.

4 (D) The table of contents in section 1 of such
 5 Act is amended by inserting after the item relating
 6 to section 713 the following new item:

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

7 (3) INTERNAL REVENUE CODE AMEND-
 8 MENTS.—

9 (A) IN GENERAL.—Subchapter B of chap-
 10 ter 100 of the Internal Revenue Code of 1986
 11 is amended—

12 (i) in the table of sections, by insert-
 13 ing after the item relating to section 9812
 14 the following new item:

“Sec. 9813. Continuing coverage for individuals participating in approved clinical studies.”; and

15 (ii) by inserting after section 9812 the
 16 following:

17 **“SEC. 9813. CONTINUING COVERAGE FOR INDIVIDUALS**
 18 **PARTICIPATING IN APPROVED CLINICAL**
 19 **STUDIES.**

20 “(a) PERMITTING PARTICIPATION IN APPROVED
 21 CLINICAL STUDIES.—A group health plan—

1 “(1) may not deny (or limit or impose addi-
2 tional conditions on) coverage of items and services
3 furnished to a participant or beneficiary if—

4 “(A) the participant or beneficiary is par-
5 ticipating in an approved clinical study;

6 “(B) the items and services are furnished
7 according to the design of the study or to treat
8 conditions resulting from participation in the
9 study; and

10 “(C) the items and services would other-
11 wise be covered under the plan except for the
12 fact that they are provided in connection with
13 participation in such a study; and

14 “(2) may not discriminate against a participant
15 or beneficiary on the basis of the participant’s or
16 beneficiary’s participation in such a study.

17 “(b) CONSTRUCTION.—Nothing in subsection (a)
18 shall be construed as requiring a group health plan to pro-
19 vide for payment for items and services normally paid for
20 as part of an approved clinical study.

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

23 “(1) a research study approved by the Sec-
24 retary of Health and Human Services, the Director
25 of the National Institutes of Health, the Commis-

1 sioner of the Food and Drug Administration, the
2 Secretary of Veterans Affairs, the Secretary of De-
3 fense, or a qualified nongovernmental research entity
4 (as defined in guidelines of the National Institute of
5 Health); or

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

14 (B) CONFORMING AMENDMENT.—Section
15 4980D(d)(1) of such Code is amended by strik-
16 ing “section 9811” and inserting “sections
17 9811 and 9813”.

18 (b) INDIVIDUAL HEALTH INSURANCE.—(1) Part B
19 of title XXVII of the Public Health Service Act is amend-
20 ed by inserting after section 2752 the following new sec-
21 tion:

1 **“SEC. 2753. CONTINUING COVERAGE FOR INDIVIDUALS**
2 **PARTICIPATING IN APPROVED CLINICAL**
3 **STUDIES.**

4 “(a) IN GENERAL.—The provisions of section 2707
5 (other than subsection (c)) shall apply to health insurance
6 coverage offered by a health insurance issuer in the indi-
7 vidual market in the same manner as they apply to health
8 insurance coverage offered by a health insurance issuer
9 in connection with a group health plan in the small or
10 large group market.

11 “(b) NOTICE.—A health insurance issuer under this
12 part shall comply with the notice requirement under sec-
13 tion 714(c) of the Employee Retirement Income Security
14 Act of 1974 with respect to the requirements referred to
15 in subsection (a) as if such section applied to such issuer
16 and such issuer were a group health plan.”.

17 (2) Section 2762(b)(2) of such Act (42 U.S.C.
18 300gg–62(b)(2)) is amended by striking “section 2751”
19 and inserting “sections 2751 and 2753”.

20 (c) EFFECTIVE DATES.—

21 (1) GROUP HEALTH PLANS AND GROUP
22 HEALTH INSURANCE COVERAGE.—Subject to para-
23 graph (3), the amendments made by subsection (a)
24 apply with respect to group health plans for plan
25 years beginning on or after January 1, 2000.

1 (2) INDIVIDUAL HEALTH INSURANCE COV-
2 ERAGE.—The amendments made by subsection (b)
3 apply with respect to health insurance coverage of-
4 fered, sold, issued, renewed, in effect, or operated in
5 the individual market on or after such date.

6 (3) COLLECTIVE BARGAINING EXCEPTION.—In
7 the case of a group health plan maintained pursuant
8 to 1 or more collective bargaining agreements be-
9 tween employee representatives and 1 or more em-
10 ployers ratified before the date of enactment of this
11 Act, the amendments made subsection (a) shall not
12 apply to plan years beginning before the later of—

13 (A) the date on which the last collective
14 bargaining agreements relating to the plan ter-
15 minates (determined without regard to any ex-
16 tension thereof agreed to after the date of en-
17 actment of this Act), or

18 (B) January 1, 2000.

19 For purposes of subparagraph (A), any plan amend-
20 ment made pursuant to a collective bargaining
21 agreement relating to the plan which amends the
22 plan solely to conform to any requirement added by
23 subsection (a) shall not be treated as a termination
24 of such collective bargaining agreement.

1 (d) COORDINATION OF ADMINISTRATION.—The Sec-
2 retary of Labor, the Secretary of the Treasury, and the
3 Secretary of Health and Human Services shall ensure,
4 through the execution of an interagency memorandum of
5 understanding among such Secretaries, that—

6 (1) regulations, rulings, and interpretations
7 issued by such Secretaries relating to the same mat-
8 ter over which two or more such Secretaries have re-
9 sponsibility under the provisions of this Act (and the
10 amendments made thereby) are administered so as
11 to have the same effect at all times; and

12 (2) coordination of policies relating to enforcing
13 the same requirements through such Secretaries in
14 order to have a coordinated enforcement strategy
15 that avoids duplication of enforcement efforts and
16 assigns priorities in enforcement.

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