

110TH CONGRESS
2^D SESSION

S. 2999

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to require group and individual health insurance coverage and group health plans to provide coverage for individuals participating in approved cancer clinical trials.

IN THE SENATE OF THE UNITED STATES

MAY 8, 2008

Mr. BROWN (for himself, Mr. SPECTER, and Mr. WHITEHOUSE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 require group and individual health insurance coverage and group health plans to provide coverage for individuals participating in approved cancer clinical trials.

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 “Access to Cancer Clin-
5 ical Trials Act of 2008”.

1 **SEC. 2. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
 2 **APPROVED CANCER CLINICAL TRIALS.**

3 (a) GROUP HEALTH PLANS.—

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

8 **“SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING**
 9 **IN APPROVED CANCER CLINICAL TRIALS.**

10 “(a) COVERAGE.—

11 “(1) IN GENERAL.—If a group health plan (or
 12 a health insurance issuer offering health insurance
 13 coverage in connection with the plan) provides cov-
 14 erage to a qualified individual (as defined in sub-
 15 section (b)), the plan or issuer—

16 “(A) may not deny the individual partici-
 17 pation in the clinical trial referred to in sub-
 18 section (b)(2);

19 “(B) subject to subsection (c), may not
 20 deny (or limit or impose additional conditions
 21 on) the coverage of routine patient costs for
 22 items and services furnished in connection with
 23 participation in the trial; and

24 “(C) may not discriminate against the in-
 25 dividual on the basis of the individual’s partici-
 26 pation in such trial.

1 “(2) EXCLUSION OF CERTAIN COSTS.—

2 “(A) IN GENERAL.—For purposes of para-
3 graph (1)(B), subject to subparagraph (B), rou-
4 tine patient costs include all items and services
5 provided in the clinical trial that are otherwise
6 generally available to the qualified individual,
7 except—

8 “(i) in the cases of drugs and devices,
9 the investigational item or service, itself; or

10 “(ii) items and services that are pro-
11 vided solely to satisfy data collection and
12 analysis needs and that are not used in the
13 direct clinical management of the patient.

14 “(B) INCLUSIONS.—Such routine patient
15 costs include costs for items or services that are
16 typically provided absent a clinical trial.

17 “(3) USE OF IN-NETWORK PROVIDERS.—If one
18 or more participating providers is participating in a
19 clinical trial, nothing in paragraph (1) shall be con-
20 strued as preventing a plan or issuer from requiring
21 that a qualified individual participate in the trial
22 through such a participating provider if the provider
23 will accept the individual as a participant in the
24 trial.

1 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
2 poses of subsection (a), the term ‘qualified individual’
3 means an individual who is a participant or beneficiary
4 in a group health plan and who meets the following condi-
5 tions:

6 “(1)(A) The individual has been diagnosed with
7 cancer.

8 “(B) The individual is eligible to participate in
9 an approved clinical trial according to the trial pro-
10 tocol with respect to treatment of such illness.

11 “(2) Either—

12 “(A) the referring physician is a partici-
13 pating health care professional and has con-
14 cluded that the individual’s participation in
15 such trial would be appropriate based upon the
16 individual meeting the conditions described in
17 paragraph (1); or

18 “(B) the participant or beneficiary pro-
19 vides medical and scientific information estab-
20 lishing that the individual’s participation in
21 such trial would be appropriate based upon the
22 individual meeting the conditions described in
23 paragraph (1).

24 “(c) PAYMENT.—

1 “(1) IN GENERAL.—Under this section a group
2 health plan (or health insurance issuer offering
3 health insurance coverage in connection with the
4 plan) shall provide for payment for routine patient
5 costs described in subsection (a)(2) but is not re-
6 quired to pay for costs of items and services that are
7 customarily provided by the research sponsors free
8 of charge for individuals participating in the trial.

9 “(2) PAYMENT RATE.—In the case of covered
10 items and services provided by—

11 “(A) a participating provider, the payment
12 rate shall be at the agreed upon rate, or

13 “(B) a nonparticipating provider, the pay-
14 ment rate shall be at the rate the plan would
15 normally pay for comparable items and services
16 under subparagraph (A).

17 “(d) APPROVED CLINICAL TRIAL DEFINED.—

18 “(1) IN GENERAL.—In this section, the term
19 ‘approved clinical trial’ means a clinical research
20 study or clinical investigation that relates to the
21 treatment of cancer (including related symptoms)
22 and is described in any of the following subpara-
23 graphs:

24 “(A) FEDERALLY FUNDED TRIALS.—The
25 study or investigation is approved or funded

1 (which may include funding through in-kind
2 contributions) by one or more of the following:

3 “(i) NIH.—The National Institutes of
4 Health.

5 “(ii) CDC.—The Centers for Disease
6 Control and Prevention.

7 “(iii) AHRQ.—The Agency for Health
8 Care Research and Quality.

9 “(iv) CMS.—The Centers for Medi-
10 care & Medicaid Services.

11 “(v) COOPERATIVE CENTER.—A coop-
12 erative group or center of any of the enti-
13 ties described in clauses (i) through (iv) or
14 the Departments of Defense or Veterans
15 Affairs.

16 “(vi) CENTER SUPPORT GRANTEES.—
17 A qualified non-governmental research en-
18 tity identified in the guidelines issued by
19 the National Institutes of Health for cen-
20 ter support grants.

21 “(vii) DOD; VA; DOE.—Any of the fol-
22 lowing if the conditions described in para-
23 graph (2) are met:

24 “(I) The Department of Veterans
25 Affairs.

1 “(II) The Department of De-
2 fense.

3 “(III) The Department of En-
4 ergy.

5 “(B) FDA DRUG TRIAL UNDER IND.—The
6 study or investigation is conducted under an in-
7 vestigational new drug application reviewed by
8 the Food and Drug Administration.

9 “(C) EXEMPT DRUG TRIAL.—The study or
10 investigation is a drug trial that is exempt from
11 having such an investigational new drug appli-
12 cation.

13 “(2) CONDITIONS FOR DEPARTMENTS.—The
14 conditions described in this paragraph, for a study
15 or investigation conducted by a Department, are
16 that the study or investigation has been reviewed
17 and approved through a system of peer review that
18 the Secretary determines—

19 “(A) to be comparable to the system of
20 peer review of studies and investigations used
21 by the National Institutes of Health, and

22 “(B) assures unbiased review of the high-
23 est scientific standards by qualified individuals
24 who have no interest in the outcome of the re-
25 view.

1 “(e) CONSTRUCTION.—Nothing in this section shall
 2 be construed to limit a plan’s or issuer’s coverage with
 3 respect to clinical trials.”.

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

8 **“SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
 9 **APPROVED CANCER CLINICAL TRIALS.**

10 “(a) COVERAGE.—

11 “(1) IN GENERAL.—If a group health plan (or
 12 a health insurance issuer offering health insurance
 13 coverage in connection with the plan) provides cov-
 14 erage to a qualified individual (as defined in sub-
 15 section (b)), the plan or issuer—

16 “(A) may not deny the individual partici-
 17 pation in the clinical trial referred to in sub-
 18 section (b)(2);

19 “(B) subject to subsection (c), may not
 20 deny (or limit or impose additional conditions
 21 on) the coverage of routine patient costs for
 22 items and services furnished in connection with
 23 participation in the trial; and

1 “(C) may not discriminate against the in-
2 dividual on the basis of the individual’s partici-
3 pation in such trial.

4 “(2) EXCLUSION OF CERTAIN COSTS.—

5 “(A) IN GENERAL.—For purposes of para-
6 graph (1)(B), subject to subparagraph (B), rou-
7 tine patient costs include all items and services
8 provided in the clinical trial that are otherwise
9 generally available to the qualified individual,
10 except—

11 “(i) in the cases of drugs and devices,
12 the investigational item or service, itself; or

13 “(ii) items and services that are pro-
14 vided solely to satisfy data collection and
15 analysis needs and that are not used in the
16 direct clinical management of the patient.

17 “(B) EXCLUSION.—Such routine patient
18 costs do include costs for items or services that
19 are typically provided absent a clinical trial.

20 “(3) USE OF IN-NETWORK PROVIDERS.—If one
21 or more participating providers is participating in a
22 clinical trial, nothing in paragraph (1) shall be con-
23 strued as preventing a plan or issuer from requiring
24 that a qualified individual participate in the trial
25 through such a participating provider if the provider

1 will accept the individual as a participant in the
2 trial.

3 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
4 poses of subsection (a), the term ‘qualified individual’
5 means an individual who is a participant or beneficiary
6 in a group health plan and who meets the following condi-
7 tions:

8 “(1)(A) The individual has been diagnosed with
9 cancer.

10 “(B) The individual is eligible to participate in
11 an approved clinical trial according to the trial pro-
12 tocol with respect to treatment of such illness.

13 “(2) Either—

14 “(A) the referring physician is a partici-
15 pating health care professional and has con-
16 cluded that the individual’s participation in
17 such trial would be appropriate based upon the
18 individual meeting the conditions described in
19 paragraph (1); or

20 “(B) the participant or beneficiary pro-
21 vides medical and scientific information estab-
22 lishing that the individual’s participation in
23 such trial would be appropriate based upon the
24 individual meeting the conditions described in
25 paragraph (1).

1 “(c) PAYMENT.—

2 “(1) IN GENERAL.—Under this section a group
3 health plan (or health insurance issuer offering
4 health insurance coverage in connection with the
5 plan) shall provide for payment for routine patient
6 costs described in subsection (a)(2) but is not re-
7 quired to pay for costs of items and services that are
8 customarily provided by the research sponsors free
9 of charge for individuals participating in the trial.

10 “(2) PAYMENT RATE.—In the case of covered
11 items and services provided by—

12 “(A) a participating provider, the payment
13 rate shall be at the agreed upon rate, or

14 “(B) a nonparticipating provider, the pay-
15 ment rate shall be at the rate the plan would
16 normally pay for comparable items and services
17 under subparagraph (A).

18 “(d) APPROVED CLINICAL TRIAL DEFINED.—

19 “(1) IN GENERAL.—In this section, the term
20 ‘approved clinical trial’ means a clinical research
21 study or clinical investigation that relates to the
22 treatment of cancer (including related symptoms)
23 and is described in any of the following subpara-
24 graphs:

1 “(A) FEDERALLY FUNDED TRIALS.—The
2 study or investigation is approved or funded
3 (which may include funding through in-kind
4 contributions) by one or more of the following:

5 “(i) NIH.—The National Institutes of
6 Health.

7 “(ii) CDC.—The Centers for Disease
8 Control and Prevention.

9 “(iii) AHRQ.—The Agency for Health
10 Care Research and Quality.

11 “(iv) CMS.—The Centers for Medi-
12 care & Medicaid Services.

13 “(v) COOPERATIVE CENTER.—A coop-
14 erative group or center of any of the enti-
15 ties described in clauses (i) through (iv) or
16 the Departments of Defense or Veterans
17 Affairs.

18 “(vi) CENTER SUPPORT GRANTEES.—
19 A qualified non-governmental research en-
20 tity identified in the guidelines issued by
21 the National Institutes of Health for cen-
22 ter support grants.

23 “(vii) DOD; VA; DOE.—Any of the fol-
24 lowing if the conditions described in para-
25 graph (2) are met:

1 “(I) The Department of Veterans
2 Affairs.

3 “(II) The Department of De-
4 fense.

5 “(III) The Department of En-
6 ergy.

7 “(B) FDA DRUG TRIAL UNDER IND.—The
8 study or investigation is conducted under an in-
9 vestigational new drug application reviewed by
10 the Food and Drug Administration.

11 “(C) EXEMPT DRUG TRIAL.—The study or
12 investigation is a drug trial that is exempt from
13 having such an investigational new drug appli-
14 cation.

15 “(2) CONDITIONS FOR DEPARTMENTS.—The
16 conditions described in this paragraph, for a study
17 or investigation conducted by a Department, are
18 that the study or investigation has been reviewed
19 and approved through a system of peer review that
20 the Secretary determines—

21 “(A) to be comparable to the system of
22 peer review of studies and investigations used
23 by the National Institutes of Health, and

24 “(B) assures unbiased review of the high-
25 est scientific standards by qualified individuals

1 who have no interest in the outcome of the re-
2 view.

3 “(e) CONSTRUCTION.—Nothing in this section shall
4 be construed to limit a plan’s or issuer’s coverage with
5 respect to clinical trials.”.

6 (B) Section 732(a) of such Act (29 U.S.C.
7 1191a(a)) is amended by striking “section 711” and
8 inserting “sections 711 and 714”.

9 (C) The table of contents in section 1 of such
10 Act is amended by inserting after the item relating
11 to section 713 the following new item:

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

12 (3) INTERNAL REVENUE CODE AMEND-
13 MENTS.—

14 (A) IN GENERAL.—Subchapter B of chap-
15 ter 100 of the Internal Revenue Code of 1986
16 is amended—

17 (i) in the table of sections, by insert-
18 ing after the item relating to section 9812
19 the following new item:

“Sec. 9813. Coverage for individuals participating in approved cancer clinical
trials.”;

20 and

21 (ii) by inserting after section 9812 the
22 following:

1 **“SEC. 9813. COVERAGE FOR INDIVIDUALS PARTICIPATING**
2 **IN APPROVED CANCER CLINICAL TRIALS.**

3 “(a) COVERAGE.—

4 “(1) IN GENERAL.—If a group health plan pro-
5 vides coverage to a qualified individual (as defined in
6 subsection (b)), the plan—

7 “(A) may not deny the individual partici-
8 pation in the clinical trial referred to in sub-
9 section (b)(2);

10 “(B) subject to subsection (c), may not
11 deny (or limit or impose additional conditions
12 on) the coverage of routine patient costs for
13 items and services furnished in connection with
14 participation in the trial; and

15 “(C) may not discriminate against the in-
16 dividual on the basis of the individual’s partici-
17 pation in such trial.

18 “(2) EXCLUSION OF CERTAIN COSTS.—

19 “(A) IN GENERAL.—For purposes of para-
20 graph (1)(B), subject to subparagraph (B), rou-
21 tine patient costs include all items and services
22 provided in the clinical trial that are otherwise
23 generally available to the qualified individual,
24 except—

25 “(i) in the cases of drugs and devices,
26 the investigational item or service, itself; or

1 “(ii) items and services that are pro-
2 vided solely to satisfy data collection and
3 analysis needs and that are not used in the
4 direct clinical management of the patient.

5 “(B) EXCLUSION.—Such routine patient
6 costs do include costs for items or services that
7 are typically provided absent a clinical trial.

8 “(3) USE OF IN-NETWORK PROVIDERS.—If one
9 or more participating providers is participating in a
10 clinical trial, nothing in paragraph (1) shall be con-
11 strued as preventing a plan from requiring that a
12 qualified individual participate in the trial through
13 such a participating provider if the provider will ac-
14 cept the individual as a participant in the trial.

15 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
16 poses of subsection (a), the term ‘qualified individual’
17 means an individual who is a participant or beneficiary
18 in a group health plan and who meets the following condi-
19 tions:

20 “(1)(A) The individual has been diagnosed with
21 cancer.

22 “(B) The individual is eligible to participate in
23 an approved clinical trial according to the trial pro-
24 tocol with respect to treatment of such illness.

25 “(2) Either—

1 “(A) the referring physician is a partici-
2 pating health care professional and has con-
3 cluded that the individual’s participation in
4 such trial would be appropriate based upon the
5 individual meeting the conditions described in
6 paragraph (1); or

7 “(B) the participant or beneficiary pro-
8 vides medical and scientific information estab-
9 lishing that the individual’s participation in
10 such trial would be appropriate based upon the
11 individual meeting the conditions described in
12 paragraph (1).

13 “(c) PAYMENT.—

14 “(1) IN GENERAL.—Under this section a group
15 health plan shall provide for payment for routine pa-
16 tient costs described in subsection (a)(2) but is not
17 required to pay for costs of items and services that
18 are customarily provided by the research sponsors
19 free of charge for individuals participating in the
20 trial.

21 “(2) PAYMENT RATE.—In the case of covered
22 items and services provided by—

23 “(A) a participating provider, the payment
24 rate shall be at the agreed upon rate, or

1 “(B) a nonparticipating provider, the pay-
2 ment rate shall be at the rate the plan would
3 normally pay for comparable items and services
4 under subparagraph (A).

5 “(d) APPROVED CLINICAL TRIAL DEFINED.—

6 “(1) IN GENERAL.—In this section, the term
7 ‘approved clinical trial’ means a clinical research
8 study or clinical investigation that relates to the
9 treatment of cancer (including related symptoms)
10 and is described in any of the following subpara-
11 graphs:

12 “(A) FEDERALLY FUNDED TRIALS.—The
13 study or investigation is approved or funded
14 (which may include funding through in-kind
15 contributions) by one or more of the following:

16 “(i) NIH.—The National Institutes of
17 Health.

18 “(ii) CDC.—The Centers for Disease
19 Control and Prevention.

20 “(iii) AHRQ.—The Agency for Health
21 Care Research and Quality.

22 “(iv) CMS.—The Centers for Medi-
23 care & Medicaid Services.

24 “(v) COOPERATIVE CENTER.—A coop-
25 erative group or center of any of the enti-

1 ties described in clauses (i) through (iv) or
2 the Departments of Defense or Veterans
3 Affairs.

4 “(vi) CENTER SUPPORT GRANTEES.—
5 A qualified non-governmental research en-
6 tity identified in the guidelines issued by
7 the National Institutes of Health for cen-
8 ter support grants.

9 “(vii) DOD; VA; DOE.—Any of the fol-
10 lowing if the conditions described in para-
11 graph (2) are met:

12 “(I) The Department of Veterans
13 Affairs.

14 “(II) The Department of De-
15 fense.

16 “(III) The Department of En-
17 ergy.

18 “(B) FDA DRUG TRIAL UNDER IND.—The
19 study or investigation is conducted under an in-
20 vestigational new drug application reviewed by
21 the Food and Drug Administration.

22 “(C) EXEMPT DRUG TRIAL.—The study or
23 investigation is a drug trial that is exempt from
24 having such an investigational new drug appli-
25 cation.

1 “(2) CONDITIONS FOR DEPARTMENTS.—The
2 conditions described in this paragraph, for a study
3 or investigation conducted by a Department, are
4 that the study or investigation has been reviewed
5 and approved through a system of peer review that
6 the Secretary determines—

7 “(A) to be comparable to the system of
8 peer review of studies and investigations used
9 by the National Institutes of Health, and

10 “(B) assures unbiased review of the high-
11 est scientific standards by qualified individuals
12 who have no interest in the outcome of the re-
13 view.

14 “(e) CONSTRUCTION.—Nothing in this section shall
15 be construed to limit a plan’s coverage with respect to clin-
16 ical trials.”.

17 (B) CONFORMING AMENDMENT.—Section
18 4980D(d)(1) of such Code is amended by strik-
19 ing “section 9811” and inserting “sections
20 9811 and 9813”.

21 (b) INDIVIDUAL HEALTH INSURANCE.—Part B of
22 title XXVII of the Public Health Service Act is amended—

23 (1) by redesignating the first subpart 3 (relat-
24 ing to other requirements) as subpart 2; and

1 (2) by adding at the end of subpart 2 the fol-
2 lowing new section:

3 **“SEC. 2753. COVERAGE FOR INDIVIDUALS PARTICIPATING**
4 **IN APPROVED CANCER CLINICAL TRIALS.**

5 “The provisions of section 2707 shall apply to health
6 insurance coverage offered by a health insurance issuer
7 in the individual market in the same manner as they apply
8 to health insurance coverage offered by a health insurance
9 issuer in connection with a group health plan in the small
10 or large group market.”.

11 (c) EFFECTIVE DATES.—

12 (1) GROUP HEALTH PLANS AND GROUP
13 HEALTH INSURANCE COVERAGE.—Subject to para-
14 graph (3), the amendments made by subsection (a)
15 apply with respect to group health plans for plan
16 years beginning on or after January 1, 2009.

17 (2) INDIVIDUAL HEALTH INSURANCE COV-
18 ERAGE.—The amendment made by subsection (b)
19 applies with respect to health insurance coverage of-
20 fered, sold, issued, renewed, in effect, or operated in
21 the individual market on or after such date.

22 (3) COLLECTIVE BARGAINING EXCEPTION.—In
23 the case of a group health plan maintained pursuant
24 to one or more collective bargaining agreements be-
25 tween employee representatives and one or more em-

1 ployers ratified before the date of the enactment of
2 this Act, the amendments made by subsection (a)
3 shall not apply to plan years beginning before the
4 later of—

5 (A) the date on which the last collective
6 bargaining agreements relating to the plan ter-
7 minates (determined without regard to any ex-
8 tension thereof agreed to after the date of the
9 enactment of this Act), or

10 (B) January 1, 2009.

11 For purposes of subparagraph (A), any plan amend-
12 ment made pursuant to a collective bargaining
13 agreement relating to the plan which amends the
14 plan solely to conform to any requirement added by
15 subsection (a) shall not be treated as a termination
16 of such collective bargaining agreement.

17 (d) COORDINATION OF ADMINISTRATION.—The Sec-
18 retary of Labor, the Secretary of the Treasury, and the
19 Secretary of Health and Human Services shall ensure,
20 through the execution of an interagency memorandum of
21 understanding among such Secretaries, that—

22 (1) regulations, rulings, and interpretations
23 issued by such Secretaries relating to the same mat-
24 ter over which two or more such Secretaries have re-
25 sponsibility under the provisions of this Act (and the

1 amendments made thereby) are administered so as
2 to have the same effect at all times; and

3 (2) coordination of policies relating to enforcing
4 the same requirements through such Secretaries in
5 order to have a coordinated enforcement strategy
6 that avoids duplication of enforcement efforts and
7 assigns priorities in enforcement.

8 (e) STUDY AND REPORT.—

9 (1) STUDY.—The Secretary of Health and
10 Human Services, jointly with the Secretaries of
11 Labor and the Treasury, shall study the impact on
12 group health plans and health insurance issuers of
13 requiring group health plans and health insurance
14 coverage to cover routine patient care costs for indi-
15 viduals with serious and life threatening diseases
16 other than cancer.

17 (2) REPORT TO CONGRESS.—Not later than
18 January 1, 2012, such Secretary shall submit a re-
19 port to Congress that contains an assessment of—

20 (A) any incremental cost to group health
21 plans and health insurance issuers resulting
22 from the provisions of this section; and

23 (B) a projection of expenditures of such
24 plans and issuers if coverage of routine patient
25 care costs in an approved clinical trial program

1 were extended to individuals entitled to benefits
2 under such plans or health insurance coverage
3 who have a diagnosis other than cancer.

○