

111TH CONGRESS
1ST SESSION

S. 488

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

FEBRUARY 26, 2009

Mr. BROWN 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 **§ 1. Short title**

4 This Act may be cited as the “Access to Cancer Clin-
5 ical Trials Act of 2009”.

1 **§2. Coverage for individuals participating in ap-**
 2 **proved 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.—For pur-
 2 poses of paragraph (1)(B), routine patient costs in-
 3 clude all items and services provided in the clinical
 4 trial that are otherwise generally available to the
 5 qualified individual, except—

6 “(A) in the cases of items and services, the
 7 investigational item or service, itself; or

8 “(B) items and services that are provided
 9 solely to satisfy data collection and analysis
 10 needs and that are not used in the direct clin-
 11 ical management of the patient.

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

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

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

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

6 “(2) Either—

7 “(A) the referring physician is a partici-
8 pating health care professional and has con-
9 cluded 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); or

13 “(B) the participant or beneficiary pro-
14 vides medical and scientific information estab-
15 lishing that the individual’s participation in
16 such trial would be appropriate based upon the
17 individual meeting the conditions described in
18 paragraph (1).

19 “(c) PAYMENT.—

20 “(1) IN GENERAL.—Under this section a group
21 health plan (or health insurance issuer offering
22 health insurance coverage in connection with the
23 plan) shall provide for payment for routine patient
24 costs described in subsection (a)(2) but is not re-
25 quired to pay for costs of items and services that are

1 customarily provided by the research sponsors free
2 of charge for individuals participating in the trial.

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

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

7 “(B) a nonparticipating provider, the pay-
8 ment rate shall be at the rate the plan would
9 normally pay for comparable items and services
10 under subparagraph (A).

11 “(d) APPROVED CLINICAL TRIAL DEFINED.—

12 “(1) IN GENERAL.—In this section, the term
13 ‘approved clinical trial’ means a clinical research
14 study or clinical investigation that relates to the pre-
15 vention or treatment of cancer (including related
16 symptoms) and is described in any of the following
17 subparagraphs:

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

22 “(i) NIH.—The National Institutes of
23 Health.

24 “(ii) CDC.—The Centers for Disease
25 Control and Prevention.

1 “(iii) AHRQ.—The Agency for Health
2 Care Research and Quality.

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

5 “(v) COOPERATIVE CENTER.—A coop-
6 erative group or center of any of the enti-
7 ties described in clauses (i) through (iv) or
8 the Departments of Defense or Veterans
9 Affairs.

10 “(vi) CENTER SUPPORT GRANTEES.—
11 A qualified non-governmental research en-
12 tity identified in the guidelines issued by
13 the National Institutes of Health for cen-
14 ter support grants.

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

18 “(I) The Department of Veterans
19 Affairs.

20 “(II) The Department of De-
21 fense.

22 “(III) The Department of En-
23 ergy.

24 “(B) FDA DRUG TRIAL UNDER IND.—The
25 study or investigation is conducted under an in-

1 vestigational new drug application reviewed by
2 the Food and Drug Administration.

3 “(C) EXEMPT DRUG TRIAL.—The study or
4 investigation is a drug trial that is exempt from
5 having such an investigational new drug appli-
6 cation.

7 “(2) CONDITIONS FOR DEPARTMENTS.—The
8 conditions described in this paragraph, for a study
9 or investigation conducted by a Department, are
10 that the study or investigation has been reviewed
11 and approved through a system of peer review that
12 the Secretary determines—

13 “(A) to be comparable to the system of
14 peer review of studies and investigations used
15 by the National Institutes of Health, and

16 “(B) assures unbiased review of the high-
17 est scientific standards by qualified individuals
18 who have no interest in the outcome of the re-
19 view.

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

23 (2) ERISA AMENDMENTS.—(A) Subpart B of
24 part 7 of subtitle B of title I of the Employee Re-

1 tirement Income Security Act of 1974 is amended by
2 adding at the end the following new section:

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

5 “(a) COVERAGE.—

6 “(1) IN GENERAL.—If a group health plan (or
7 a health insurance issuer offering health insurance
8 coverage in connection with the plan) provides cov-
9 erage to a qualified individual (as defined in sub-
10 section (b)), the plan or issuer—

11 “(A) may not deny the individual partici-
12 pation in the clinical trial referred to in sub-
13 section (b)(2);

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

19 “(C) may not discriminate against the in-
20 dividual on the basis of the individual’s partici-
21 pation in such trial.

22 “(2) EXCLUSION OF CERTAIN COSTS.—For pur-
23 poses of paragraph (1)(B), routine patient costs in-
24 clude all items and services provided in the clinical

1 trial that are otherwise generally available to the
2 qualified individual, except—

3 “(A) in the cases of items and services, the
4 investigational item or service, itself; or

5 “(B) items and services that are provided
6 solely to satisfy data collection and analysis
7 needs and that are not used in the direct clin-
8 ical management of the patient.

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

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

22 “(1)(A) The individual has been diagnosed with
23 cancer.

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

4 “(2) Either—

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

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

17 “(c) PAYMENT.—

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

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

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

5 “(B) a nonparticipating provider, the pay-
6 ment rate shall be at the rate the plan would
7 normally pay for comparable items and services
8 under subparagraph (A).

9 “(d) APPROVED CLINICAL TRIAL DEFINED.—

10 “(1) IN GENERAL.—In this section, the term
11 ‘approved clinical trial’ means a clinical research
12 study or clinical investigation that relates to the pre-
13 vention or treatment of cancer (including related
14 symptoms) and is described in any of the following
15 subparagraphs:

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

20 “(i) NIH.—The National Institutes of
21 Health.

22 “(ii) CDC.—The Centers for Disease
23 Control and Prevention.

24 “(iii) AHRQ.—The Agency for Health
25 Care Research and Quality.

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

3 “(v) COOPERATIVE CENTER.—A coop-
4 erative group or center of any of the enti-
5 ties described in clauses (i) through (iv) or
6 the Departments of Defense or Veterans
7 Affairs.

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

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

16 “(I) The Department of Veterans
17 Affairs.

18 “(II) The Department of De-
19 fense.

20 “(III) The Department of En-
21 ergy.

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

1 “(C) EXEMPT DRUG TRIAL.—The study or
2 investigation is a drug trial that is exempt from
3 having such an investigational new drug appli-
4 cation.

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

11 “(A) to be comparable to the system of
12 peer review of studies and investigations used
13 by the National Institutes of Health, and

14 “(B) assures unbiased review of the high-
15 est scientific standards by qualified individuals
16 who have no interest in the outcome of the re-
17 view.

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

21 (B) Section 732(a) of such Act (29 U.S.C.
22 1191a(a)) is amended by striking “section 711” and
23 inserting “sections 711 and 714”.

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

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

4 (3) INTERNAL REVENUE CODE AMEND-
5 MENTS.—

6 (A) IN GENERAL.—Subchapter B of chap-
7 ter 100 of the Internal Revenue Code of 1986
8 is amended—

9 (i) in the table of sections, by insert-
10 ing after the item relating to section 9812
11 the following new item:

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

12 and

13 (ii) by inserting after section 9812 the
14 following:

15 **“SEC. 9813. COVERAGE FOR INDIVIDUALS PARTICIPATING**
16 **IN APPROVED CANCER CLINICAL TRIALS.**

17 “(a) COVERAGE.—

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

21 “(A) may not deny the individual partici-
22 pation in the clinical trial referred to in sub-
23 section (b)(2);

1 “(B) subject to subsection (c), may not
2 deny (or limit or impose additional conditions
3 on) the coverage of routine patient costs for
4 items and services furnished in connection with
5 participation in the trial; and

6 “(C) may not discriminate against the in-
7 dividual on the basis of the individual’s partici-
8 pation in such trial.

9 “(2) EXCLUSION OF CERTAIN COSTS.—For pur-
10 poses of paragraph (1)(B), routine patient costs in-
11 clude all items and services provided in the clinical
12 trial that are otherwise generally available to the
13 qualified individual, except—

14 “(A) in the cases of items and services, the
15 investigational item or service, itself; or

16 “(B) items and services that are provided
17 solely to satisfy data collection and analysis
18 needs and that are not used in the direct clin-
19 ical management of the patient.

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 from requiring that a
24 qualified individual participate in the trial through

1 such a participating provider if the provider will ac-
2 cept the individual as a participant in the 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 shall provide for payment for routine pa-
4 tient costs described in subsection (a)(2) but is not
5 required to pay for costs of items and services that
6 are customarily provided by the research sponsors
7 free of charge for individuals participating in the
8 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 pre-
21 vention or treatment of cancer (including related
22 symptoms) and is described in any of the following
23 subparagraphs:

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 coverage with respect to clin-
3 ical trials.”.

4 (B) CONFORMING AMENDMENT.—Section
5 4980D(d)(1) of such Code is amended by strik-
6 ing “section 9811” and inserting “sections
7 9811 and 9813”.

8 (b) INDIVIDUAL HEALTH INSURANCE.—Subpart 2 of
9 part B of title XXVII of the Public Health Service Act
10 is amended by adding at the end the following:

11 **“SEC. 2754. COVERAGE FOR INDIVIDUALS PARTICIPATING**
12 **IN APPROVED CANCER CLINICAL TRIALS.**

13 “The provisions of section 2707 shall apply to health
14 insurance coverage offered by a health insurance issuer
15 in the individual market in the same manner as they apply
16 to health insurance coverage offered by a health insurance
17 issuer in connection with a group health plan in the small
18 or large group market.”.

19 (c) FEDERAL EMPLOYEES.—Chapter 89 of title 5,
20 United States Code, is amended by inserting after section
21 8904 the following:

22 **“§ 8904A. Coverage for individuals participating in**
23 **approved cancer clinical trials**

24 “(a) COVERAGE.—

1 “(1) IN GENERAL.—If a plan described in sec-
2 tion 8903 provides coverage to a qualified individual
3 (as defined in subsection (b)), the plan—

4 “(A) may not deny the individual partici-
5 pation in the clinical trial referred to in sub-
6 section (b)(2);

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

12 “(C) may not discriminate against the in-
13 dividual on the basis of the individual’s partici-
14 pation in such trial.

15 “(2) EXCLUSION OF CERTAIN COSTS.—For pur-
16 poses of paragraph (1)(B), routine patient costs in-
17 clude all items and services provided in the clinical
18 trial that are otherwise generally available to the
19 qualified individual, except—

20 “(A) in the cases of items and services, the
21 investigational item or service, itself; or

22 “(B) items and services that are provided
23 solely to satisfy data collection and analysis
24 needs and that are not used in the direct clin-
25 ical management of the patient.

1 “(3) USE OF IN-NETWORK PROVIDERS.—If one
2 or more participating providers is participating in a
3 clinical trial, nothing in paragraph (1) shall be con-
4 strued as preventing a plan or issuer from requiring
5 that a qualified individual participate in the trial
6 through such a participating provider if the provider
7 will accept the individual as a participant in the
8 trial.

9 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
10 poses of subsection (a), the term ‘qualified individual’
11 means an enrolled individual who meets the following con-
12 ditions:

13 “(1)(A) The individual has been diagnosed with
14 cancer.

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

18 “(2) Either—

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

1 “(B) the participant or beneficiary pro-
2 vides medical and scientific information estab-
3 lishing 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).

7 “(c) PAYMENT.—

8 “(1) IN GENERAL.—Under this section a plan
9 described in section 8903 shall provide for payment
10 for routine patient costs described in subsection
11 (a)(2) but is not required to pay for costs of items
12 and services that are customarily provided by the re-
13 search sponsors free of charge for individuals par-
14 ticipating in the trial.

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

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

19 “(B) a nonparticipating provider, the pay-
20 ment rate shall be at the rate the plan would
21 normally pay for comparable items and services
22 under subparagraph (A).

23 “(d) APPROVED CLINICAL TRIAL DEFINED.—

24 “(1) IN GENERAL.—In this section, the term
25 ‘approved clinical trial’ means a clinical research

1 study or clinical investigation that relates to the pre-
2 vention or treatment of cancer (including related
3 symptoms) and is described in any of the following
4 subparagraphs:

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

9 “(i) NIH.—The National Institutes of
10 Health.

11 “(ii) CDC.—The Centers for Disease
12 Control and Prevention.

13 “(iii) AHRQ.—The Agency for Health
14 Care Research and Quality.

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

17 “(v) COOPERATIVE CENTER.—A coop-
18 erative group or center of any of the enti-
19 ties described in clauses (i) through (iv) or
20 the Departments of Defense or Veterans
21 Affairs.

22 “(vi) CENTER SUPPORT GRANTEEES.—
23 A qualified non-governmental research en-
24 tity identified in the guidelines issued by

1 the National Institutes of Health for cen-
2 ter support grants.

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

6 “(I) The Department of Veterans
7 Affairs.

8 “(II) The Department of De-
9 fense.

10 “(III) The Department of En-
11 ergy.

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

16 “(C) EXEMPT DRUG TRIAL.—The study or
17 investigation is a drug trial that is exempt from
18 having such an investigational new drug appli-
19 cation.

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

1 “(A) to be comparable to the system of
2 peer review of studies and investigations used
3 by the National Institutes of Health, and

4 “(B) assures unbiased review of the high-
5 est scientific standards by qualified individuals
6 who have no interest in the outcome of the re-
7 view.

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

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

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

1 sponsibility under the provisions of this Act (and the
2 amendments made thereby) are administered so as
3 to have the same effect at all times; and

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

9 (f) STUDY AND REPORT.—

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

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

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

24 (B) a projection of expenditures of such
25 plans and issuers if coverage of routine patient

1 care costs in an approved clinical trial program
2 were extended to individuals entitled to benefits
3 under such plans or health insurance coverage
4 who have a diagnosis other than cancer.

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