

111TH CONGRESS  
1ST SESSION

# H. R. 716

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.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 27, 2009

Mr. ISRAEL (for himself, Mrs. MYRICK, and Mrs. CAPPS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and Labor 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

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## 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,*

1 **SECTION 1. SHORT TITLE.**

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

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

6 (a) GROUP HEALTH PLANS.—

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

11 **“SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING**  
12 **IN APPROVED CANCER CLINICAL TRIALS.**

13 “(a) COVERAGE.—

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

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

22 “(B) subject to subsection (c), may not  
23 deny (or limit or impose additional conditions  
24 on) the coverage of routine patient costs for  
25 items and services furnished in connection with  
26 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) INCLUSIONS.—Such routine patient  
18           costs include costs for the following:

19                  “(i) CONVENTIONAL CARE.—Items or  
20                  services that are typically provided absent  
21                  a clinical trial.

22                  “(ii) ADMINISTRATIVE ITEMS.—Items  
23                  or services required solely for the provision  
24                  of the investigational item or service (such  
25                  as the administration of a noncovered

1           chemotherapeutic agent), the clinically ap-  
2           propriate monitoring of the effects of the  
3           item or service, or the prevention of com-  
4           plications.

5           “(iii) REASONABLE AND NECESSARY  
6           CARE.—Items or services needed for rea-  
7           sonable and necessary care arising from  
8           the provision of an investigational item or  
9           service, including the diagnosis or treat-  
10          ment of complications.

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

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

24                 “(1)(A) The individual has been diagnosed with  
25                 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  
13 treatment of cancer (including related symptoms)  
14 and is described in any of the following subpara-  
15 graphs:

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



1 **“SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**  
2 **APPROVED CANCER CLINICAL TRIALS.**

3 “(a) COVERAGE.—

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

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

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

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

20 “(2) EXCLUSION OF CERTAIN COSTS.—

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

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

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

7 “(B) EXCLUSION.—Such routine patient  
8 costs do include costs for the following:

9 “(i) CONVENTIONAL CARE.—Items or  
10 services that are typically provided absent  
11 a clinical trial.

12 “(ii) ADMINISTRATIVE ITEMS.—Items  
13 or services required solely for the provision  
14 of the investigational item or service (such  
15 as the administration of a noncovered  
16 chemotherapeutic agent), the clinically ap-  
17 propriate monitoring of the effects of the  
18 item or service, or the prevention of com-  
19 plications.

20 “(iii) REASONABLE AND NECESSARY  
21 CARE.—Items or services needed for rea-  
22 sonable and necessary care arising from  
23 the provision of an investigational item or  
24 service, including the diagnosis or treat-  
25 ment of complications.

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 individual who is a participant or beneficiary  
12 in a group health plan and who meets the following condi-  
13 tions:

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

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

19           “(2) Either—

20           “(A) the referring physician is a partici-  
21 pating health care professional and has con-  
22 cluded 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); 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 group  
9           health plan (or health insurance issuer offering  
10          health insurance coverage in connection with the  
11          plan) shall provide for payment for routine patient  
12          costs described in subsection (a)(2) but is not re-  
13          quired to pay for costs of items and services that are  
14          customarily provided by the research sponsors free  
15          of charge for individuals participating in the trial.

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

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

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

24          “(d) APPROVED CLINICAL TRIAL DEFINED.—

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

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

11                           “(i) NIH.—The National Institutes of  
12                           Health.

13                           “(ii) CDC.—The Centers for Disease  
14                           Control and Prevention.

15                           “(iii) AHRQ.—The Agency for Health  
16                           Care Research and Quality.

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

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

24                           “(vi) CENTER SUPPORT GRANTEEES.—  
25                           A qualified non-governmental research en-

1           tity identified in the guidelines issued by  
2           the National Institutes of Health for cen-  
3           ter support grants.

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

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

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

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

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

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

21           “(2) CONDITIONS FOR DEPARTMENTS.—The  
22           conditions described in this paragraph, for a study  
23           or investigation conducted by a Department, are  
24           that the study or investigation has been reviewed

1 and approved through a system of peer review that  
2 the Secretary determines—

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

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

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

13 (B) Section 732(a) of such Act (29 U.S.C.  
14 1191a(a)) is amended by striking “section 711” and  
15 inserting “sections 711 and 714”.

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

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

19 (3) INTERNAL REVENUE CODE AMEND-  
20 MENTS.—

21 (A) IN GENERAL.—Subchapter B of chap-  
22 ter 100 of the Internal Revenue Code of 1986  
23 is amended—

1 (i) in the table of sections, by insert-  
2 ing after the item relating to section 9812  
3 the following new item:

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

4 and

5 (ii) by inserting after section 9812 the  
6 following:

7 **“SEC. 9813. COVERAGE FOR INDIVIDUALS PARTICIPATING**  
8 **IN APPROVED CANCER CLINICAL TRIALS.**

9 “(a) COVERAGE.—

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

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

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

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

24 “(2) EXCLUSION OF CERTAIN COSTS.—



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

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

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

13           “(B) EXCLUSION.—Such routine patient  
14 costs do include costs for the following:

15           “(i) CONVENTIONAL CARE.—Items or  
16 services that are typically provided absent  
17 a clinical trial.

18           “(ii) ADMINISTRATIVE ITEMS.—Items  
19 or services required solely for the provision  
20 of the investigational item or service (such  
21 as the administration of a noncovered  
22 chemotherapeutic agent), the clinically ap-  
23 propriate monitoring of the effects of the  
24 item or service, or the prevention of com-  
25 plications.

1                   “(iii) REASONABLE AND NECESSARY  
2                   CARE.—Items or services needed for rea-  
3                   sonable and necessary care arising from  
4                   the provision of an investigational item or  
5                   service, including the diagnosis or treat-  
6                   ment of complications.

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

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

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

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

24                   “(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.

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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-  
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16                   “(III) The Department of En-  
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18           “(B) FDA DRUG TRIAL UNDER IND.—The  
19           study or investigation is conducted under an in-  
20           vestigational new drug application reviewed by  
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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, 2010.

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, 2010.

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, 2013, 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.

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