

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.

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

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.

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, 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.

○