I

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Access to Cancer Clinical Trials Act of 2009''.

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

(a) GROUP HEALTH PLANS.—

(1) PUBLIC HEALTH SERVICE ACT AMENDMENTS.—Subpart 2 of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

''SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

''(a) COVERAGE.—

''(1) IN GENERAL.—If a group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

''(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

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

''(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

''(2) EXCLUSION OF CERTAIN COSTS.—

''(A) IN GENERAL.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services provided in the clinical trial that are otherwise generally available to the qualified individual, except—

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

''(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient.

''(B) INCLUSIONS.—Such routine patient costs include costs for the following:

''(i) CONVENTIONAL CARE.—Items or services that are typically provided absent a clinical trial.

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

chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.

"(iii) REASONABLE AND NECESSARY CARE.—Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

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

"(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual' means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

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

''(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

''(2) Either—

''(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

''(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

''(c) PAYMENT.—

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

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

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

''(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable items and services under subparagraph (A).

''(d) APPROVED CLINICAL TRIAL DEFINED.—

''(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a clinical research study or clinical investigation that relates to the treatment of cancer (including related symptoms) and is described in any of the following subparagraphs:

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

''(i) NIH.—The National Institutes of Health.

''(ii) CDC.—The Centers for Disease Control and Prevention.

''(iii) AHRQ.—The Agency for Health Care Research and Quality.

''(iv) CMS.—The Centers for Medicare & Medicaid Services.

''(v) COOPERATIVE CENTER.—A cooperative group or center of any of the entities described in clauses (i) through (iv) or the Departments of Defense or Veterans Affairs.

''(vi) CENTER SUPPORT GRANTEES.—A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

''(vii) DOD; VA; DOE.—Any of the following if the conditions described in paragraph (2) are met:

''(I) The Department of Veterans Affairs.

''(II) The Department of Defense.

''(III) The Department of Energy.

''(B) FDA DRUG TRIAL UNDER IND.—The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

''(C) EXEMPT DRUG TRIAL.—The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

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

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

''(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

''(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.''.

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

"SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

''(a) COVERAGE.—

''(1) IN GENERAL.—If a group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

''(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

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

''(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

''(2) EXCLUSION OF CERTAIN COSTS.—

''(A) IN GENERAL.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services provided in the clinical trial that are otherwise generally available to the qualified individual, except—

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

''(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient.

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

''(i) CONVENTIONAL CARE.—Items or services that are typically provided absent a clinical trial.

''(ii) ADMINISTRATIVE ITEMS.—Items or services required solely for the provision of the investigational item or service (such as the administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.

''(iii) REASONABLE AND NECESSARY CARE.—Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

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

''(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual' means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

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

''(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

''(2) Either—

''(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

''(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

''(c) PAYMENT.—

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

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

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

''(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable items and services under subparagraph (A).

''(d) APPROVED CLINICAL TRIAL DEFINED.—

''(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a clinical research study or clinical investigation that relates to the treatment of cancer (including related symptoms) and is described in any of the following subparagraphs:

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

''(i) NIH.—The National Institutes of Health.

''(ii) CDC.—The Centers for Disease Control and Prevention.

''(iii) AHRQ.—The Agency for Health Care Research and Quality.

''(iv) CMS.—The Centers for Medicare & Medicaid Services.

''(v) COOPERATIVE CENTER.—A cooperative group or center of any of the entities described in clauses (i) through (iv) or the Departments of Defense or Veterans Affairs.

''(vi) CENTER SUPPORT GRANTEES.—A qualified non-governmental research en-

tity identified in the guidelines issued by the National Institutes of Health for center support grants.

''(vii) DOD; VA; DOE.—Any of the following if the conditions described in paragraph (2) are met:

''(I) The Department of Veterans Affairs.

''(II) The Department of Defense.

''(III) The Department of Energy.

''(B) FDA DRUG TRIAL UNDER IND.—The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

''(C) EXEMPT DRUG TRIAL.—The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

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

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

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

''(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

''(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.''.

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

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

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

(3) INTERNAL REVENUE CODE AMENDMENTS.—

(A) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(i) in the table of sections, by inserting after the item relating to section 9812 the following new item:

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

and

(ii) by inserting after section 9812 the following:

''SEC. 9813. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

''(a) COVERAGE.—

''(1) IN GENERAL.—If a group health plan provides coverage to a qualified individual (as defined in subsection (b)), the plan—

''(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

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

''(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

''(2) EXCLUSION OF CERTAIN COSTS.—

"(A) IN GENERAL.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services provided in the clinical trial that are otherwise generally available to the qualified individual, except—

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

"(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient.

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

"(i) CONVENTIONAL CARE.—Items or services that are typically provided absent a clinical trial.

"(ii) ADMINISTRATIVE ITEMS.—Items or services required solely for the provision of the investigational item or service (such as the administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.

''(iii) REASONABLE AND NECESSARY CARE.—Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

''(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

''(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual' means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

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

''(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

''(2) Either—

''(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

''(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

''(c) PAYMENT.—

''(1) IN GENERAL.—Under this section a group health plan shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are customarily provided by the research sponsors free of charge for individuals participating in the trial.

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

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

"(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable items and services under subparagraph (A).

"(d) APPROVED CLINICAL TRIAL DEFINED.—

"(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a clinical research study or clinical investigation that relates to the treatment of cancer (including related symptoms) and is described in any of the following subparagraphs:

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

"(i) NIH.—The National Institutes of Health.

"(ii) CDC.—The Centers for Disease Control and Prevention.

"(iii) AHRQ.—The Agency for Health Care Research and Quality.

"(iv) CMS.—The Centers for Medicare & Medicaid Services.

"(v) COOPERATIVE CENTER.—A cooperative group or center of any of the enti-

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

''(vi) CENTER SUPPORT GRANTEES.—A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

''(vii) DOD; VA; DOE.—Any of the following if the conditions described in paragraph (2) are met:

''(I) The Department of Veterans Affairs.

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''(III) The Department of Energy.

''(B) FDA DRUG TRIAL UNDER IND.—The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

''(C) EXEMPT DRUG TRIAL.—The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

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

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

''(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

''(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's coverage with respect to clinical trials.''.

(B) CONFORMING AMENDMENT.—Section 4980D(d)(1) of such Code is amended by striking ''section 9811'' and inserting ''sections 9811 and 9813''.

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

(1) by redesignating the first subpart 3 (relating to other requirements) as subpart 2; and

(2) by adding at the end of subpart 2 the following new section:

"SEC. 2753. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

''The provisions of section 2707 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.''.

(c) EFFECTIVE DATES.—

(1) GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.—Subject to paragraph (3), the amendments made by subsection (a) apply with respect to group health plans for plan years beginning on or after January 1, 2010.

(2) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The amendment made by subsection (b) applies with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after such date.

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

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

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

(B) January 1, 2010.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by subsection (a) shall not be treated as a termination of such collective bargaining agreement.

(d) COORDINATION OF ADMINISTRATION.—The Secretary of Labor, the Secretary of the Treasury, and the Secretary of Health and Human Services shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under the provisions of this Act (and the

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

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

(e) STUDY AND REPORT.—

(1) STUDY.—The Secretary of Health and Human Services, jointly with the Secretaries of Labor and the Treasury, shall study the impact on group health plans and health insurance issuers of requiring group health plans and health insurance coverage to cover routine patient care costs for individuals with serious and life threatening diseases other than cancer.

(2) REPORT TO CONGRESS.—Not later than January 1, 2013, such Secretary shall submit a report to Congress that contains an assessment of—

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

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

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

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