I

106TH CONGRESS
1ST SESSION

H. R. 3110

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 19, 1999

Mr. SALMON (for himself, Mr. KOLBE, and Mr. SHADEGG) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Ways and Means, and Education and the Workforce, 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 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 ''Dr. Sydney E. Salmon Access to Cancer Clinical Trials Act of 1999''.

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

(a) GROUP HEALTH PLANS.—

(1) PUBLIC HEALTH SERVICE ACT AMENDMENTS.—(A) 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 subsections (b), (c), and (d) 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 participant's or beneficiaries participation in such trial.

''(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

''(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.

''(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

''(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 reasonably expected to be paid for by the sponsors of an approved clinical trial.

''(2) ROUTINE PATIENT CARE COSTS.—

''(A) IN GENERAL.—For purposes of this Act, 'routine patient care costs' shall include

the costs associated with the provision of items and services that—

"(i) would otherwise be covered under the group health plan if such items and services were not provided in connection with an approved clinical trial program; and

"(ii) are furnished according to the protocol of an approved clinical trial program.

"(B) EXCLUSION.—For purposes of this Act, 'routine patient care costs' shall not include the costs associated with the provision of—

"(i) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

"(ii) any item or service supplied without charge by the sponsor of the approved clinical trial program.

"(3) 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 or services under subparagraph (A).

"(d) APPROVED CLINICAL TRIAL DEFINED.—

"(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a cancer clinical research study or cancer clinical investigation approved by an Institutional Review Board.

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

"(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

"(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

''(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

''(g) STUDY AND REPORT.—

''(1) STUDY.—The Secretary shall analyze cancer clinical research and its cost implications for managed care, including differentiation in—

''(A) the cost of patient care in trials versus standard care;

''(B) the cost effectiveness achieved in different sites of service;

''(C) research outcomes;

''(D) volume of research subjects available in different sites of service;

''(E) access to research sites and clinical trials by cancer patients;

''(F) patient cost sharing or copyament costs realized in different sites of service;

''(G) health outcomes experienced in different sites of service;

''(H) long term health care services and costs experienced in different sites of service;

''(I) morbidity and mortality experienced in different sites of service; and

''(J) patient satisfaction and preference of sites of service.

''(2) REPORT TO CONGRESS.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains—

''(A) an assessment of any incremental cost to group health plans resulting from the provisions of this section;

''(B) a projection of expenditures to such plans resulting from this section;

''(C) an assessment of any impact on premiums resulting from this section; and

''(D) recommendations regarding action on other diseases.''.

(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 cov-

erage 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 subsections (b), (c), and (d) 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 participant's or beneficiaries participation in such trial.

"(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

"(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.

''(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

''(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 reasonably expected to be paid for by the sponsors of an approved clinical trial.

''(2) ROUTINE PATIENT CARE COSTS.—

''(A) IN GENERAL.—For purposes of this Act, 'routine patient care costs' shall include the costs associated with the provision of items and services that—

''(i) would otherwise be covered under the group health plan if such items and services were not provided in connection with an approved clinical trial program; and

''(ii) are furnished according to the protocol of an approved clinical trial program.

"(B) EXCLUSION.—For purposes of this Act, 'routine patient care costs' shall not include the costs associated with the provision of—

"(i) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

"(ii) any item or service supplied without charge by the sponsor of the approved clinical trial program.

"(3) 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 or services under subparagraph (A).

"(d) APPROVED CLINICAL TRIAL DEFINED.—

"(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a cancer clinical research study or cancer clinical investigation approved by an Institutional Review Board.

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

''(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

''(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

''(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

''(g) STUDY AND REPORT.—

''(1) STUDY.—The Secretary shall analyze cancer clinical research and its cost implications for managed care, including differentiation in—

''(A) the cost of patient care in trials versus standard care;

"(B) the cost effectiveness achieved in different sites of service;

"(C) research outcomes;

"(D) volume of research subjects available in different sites of service;

"(E) access to research sites and clinical trials by cancer patients;

"(F) patient cost sharing or copyament costs realized in different sites of service;

"(G) health outcomes experienced in different sites of service;

"(H) long term health care services and costs experienced in different sites of service;

"(I) morbidity and mortality experienced in different sites of service; and

"(J) patient satisfaction and preference of sites of service.

"(2) REPORT TO CONGRESS.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains—

"(A) an assessment of any incremental cost to group health plans resulting from the provisions of this section;

"(B) a projection of expenditures to such plans resulting from this section;

''(C) an assessment of any impact on premiums resulting from this section; and

''(D) recommendations regarding action on other diseases.''.

(B) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 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 or issuer—

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

''(B) subject to subsections (b), (c), and (d) 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 participant's or beneficiaries participation in such trial.

''(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

''(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.

''(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

''(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 reasonably expected to be paid for by the sponsors of an approved clinical trial.

''(2) ROUTINE PATIENT CARE COSTS.—

''(A) IN GENERAL.—For purposes of this Act, 'routine patient care costs' shall include the costs associated with the provision of items and services that—

''(i) would otherwise be covered under the group health plan if such items and services were not provided in connection with an approved clinical trial program; and

''(ii) are furnished according to the protocol of an approved clinical trial program.

''(B) EXCLUSION.—For purposes of this Act, 'routine patient care costs' shall not in-

clude the costs associated with the provision of—

"(i) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

"(ii) any item or service supplied without charge by the sponsor of the approved clinical trial program.

"(3) 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 or services under subparagraph (A).

"(d) APPROVED CLINICAL TRIAL DEFINED.—

"(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a cancer clinical research study or cancer clinical investigation approved by an Institutional Review Board.

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

''(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

''(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

''(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

''(g) STUDY AND REPORT.—

''(1) STUDY.—The Secretary shall analyze cancer clinical research and its cost implications for managed care, including differentiation in—

''(A) the cost of patient care in trials versus standard care;

''(B) the cost effectiveness achieved in different sites of service;

''(C) research outcomes;

"(D) volume of research subjects available in different sites of service;

"(E) access to research sites and clinical trials by cancer patients;

"(F) patient cost sharing or copyament costs realized in different sites of service;

"(G) health outcomes experienced in different sites of service;

"(H) long term health care services and costs experienced in different sites of service;

"(I) morbidity and mortality experienced in different sites of service; and

"(J) patient satisfaction and preference of sites of service.

"(2) REPORT TO CONGRESS.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains—

"(A) an assessment of any incremental cost to group health plans resulting from the provisions of this section;

"(B) a projection of expenditures to such plans resulting from this section;

"(C) an assessment of any impact on premiums resulting from this section; and

''(D) recommendations regarding action on other diseases.''.

(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.—(1) Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2752 the following new section:

''SEC. 2753. STANDARD RELATING PATIENT FREEDOM OF CHOICE.

''(a) IN GENERAL.—The provisions of section 2707(a) 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.

''(b) NOTICE.—A health insurance issuer under this part shall comply with the notice requirement under section 714(b) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) as if such section applied to such issuer and such issuer were a group health plan.''.

(2) Section 2762(b)(2) of such Act (42 U.S.C. 300gg–62(b)(2)) is amended by striking ''section 2751'' and inserting ''sections 2751 and 2753''.

(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, 2000.

(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 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made 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 ex-

tension thereof agreed to after the date of enactment of this Act), or

(B) January 1, 2000.

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.

○