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. Shadege) 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.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Dr. Sydney E. Salmon
- 5 Access to Cancer Clinical Trials Act of 1999".

1	SEC. 2. COVERAGE FOR INDIVIDUALS PARTICIPATING IN
2	APPROVED CANCER CLINICAL TRIALS.
3	(a) Group Health Plans.—
4	(1) Public Health Service act amend-
5	MENTS.—(A) Subpart 2 of part A of title XXVII of
6	the Public Health Service Act is amended by adding
7	at the end the following new section:
8	"SEC. 2707. COVERAGE FOR INDIVIDUALS PARTICIPATING
9	IN APPROVED CANCER CLINICAL TRIALS.
10	"(a) Coverage.—
11	"(1) In general.—If a group health plan (or
12	a health insurance issuer offering health insurance
13	coverage in connection with the plan) provides cov-
14	erage to a qualified individual (as defined in sub-
15	section (b)), the plan or issuer—
16	"(A) may not deny the individual partici-
17	pation in the clinical trial referred to in sub-
18	section $(b)(2)$;
19	"(B) subject to subsections (b), (c), and
20	(d) may not deny (or limit or impose additional
21	conditions on) the coverage of routine patient
22	costs for items and services furnished in con-
23	nection with participation in the trial; and
24	"(C) may not discriminate against the in-
25	dividual on the basis of the participant's or
26	beneficiaries participation in such trial.

- 1 "(2) EXCLUSION OF CERTAIN COSTS.—For pur-2 poses of paragraph (1)(B), routine patient costs do 3 not include the cost of the tests or measurements 4 conducted primarily for the purpose of the clinical 5 trial involved.
- 6 "(3) USE OF IN-NETWORK PROVIDERS.—If one 7 or more participating providers is participating in a 8 clinical trial, nothing in paragraph (1) shall be con-9 strued as preventing a plan from requiring that a 10 qualified individual participate in the trial through 11 such a participating provider if the provider will ac-12 cept the individual as a participant in the trial.
- "(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-14 poses of subsection (a), the term 'qualified individual' 15 means an individual who is a participant or beneficiary 16 in a group health plan and who meets the following condi-17 tions:
- 18 "(1)(A) The individual has been diagnosed with 19 cancer.
- 20 "(B) The individual is eligible to participate in 21 an approved clinical trial according to the trial pro-22 tocol 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.

23

24

1	"(2) Either—
2	"(A) the referring physician is a partici-
3	pating health care professional and has con-
4	cluded that the individual's participation in
5	such trial would be appropriate based upon the
6	individual meeting the conditions described in
7	paragraph (1); or
8	"(B) the participant or beneficiary pro-
9	vides medical and scientific information estab-
10	lishing that the individual's participation in
11	such trial would be appropriate based upon the
12	individual meeting the conditions described in
13	paragraph (1).
14	"(c) Payment.—
15	"(1) In general.—Under this section a group
16	health plan (or health insurance issuer offering
17	health insurance coverage in connection with the
18	plan) shall provide for payment for routine patient
19	costs described in subsection (a)(2) but is not re-
20	quired to pay for costs of items and services that are
21	reasonably expected to be paid for by the sponsors
22	of an approved clinical trial.
23	"(2) Routine patient care costs.—
24	"(A) IN GENERAL.—For purposes of this

Act, 'routine patient care costs' shall include

1	the costs associated with the provision of items
2	and services that—
3	"(i) would otherwise be covered under
4	the group health plan if such items and
5	services were not provided in connection
6	with an approved clinical trial program;
7	and
8	"(ii) are furnished according to the
9	protocol of an approved clinical trial pro-
10	gram.
11	"(B) Exclusion.—For purposes of this
12	Act, 'routine patient care costs' shall not in-
13	clude the costs associated with the provision
14	of—
15	"(i) an investigational drug or device,
16	unless the Secretary has authorized the
17	manufacturer of such drug or device to
18	charge for such drug or device; or
19	"(ii) any item or service supplied
20	without charge by the sponsor of the ap-
21	proved clinical trial program.
22	"(3) PAYMENT RATE.—In the case of covered
23	items and services provided by—
24	"(A) a participating provider, the payment
25	rate shall be at the agreed upon rate, or

"(B) a nonparticipating provider, the pay-1 2 ment rate shall be at the rate the plan would 3 normally pay for comparable items or services 4 under subparagraph (A). 5 "(d) APPROVED CLINICAL TRIAL DEFINED.— "(1) IN GENERAL.—In this section, the term 6 7 'approved clinical trial' means a cancer clinical research study or cancer clinical investigation ap-8 9 proved by an Institutional Review Board. "(e) Construction.—Nothing in this section shall 10 be construed to limit a plan's coverage with respect to clinical trials. 12 13 "(f) Plan Satisfaction of Certain Require-14 MENTS; RESPONSIBILITIES OF FIDUCIARIES.— 15 "(1) In General.—For purposes of this sec-16 tion, insofar as a group health plan provides benefits 17 in the form of health insurance coverage through a 18 health insurance issuer, the plan shall be treated as 19 meeting the requirements of this section with respect 20 to such benefits and not be considered as failing to 21 meet such requirements because of a failure of the 22 issuer to meet such requirements so long as the plan 23 sponsor or its representatives did not cause such 24 failure by the issuer.

1	"(2) Construction.—Nothing in this section
2	shall be construed to affect or modify the respon-
3	sibilities of the fiduciaries of a group health plan
4	under part 4 of subtitle B.
5	"(g) Study and Report.—
6	"(1) Study.—The Secretary shall analyze can-
7	cer clinical research and its cost implications for
8	managed care, including differentiation in—
9	"(A) the cost of patient care in trials
10	versus standard care;
11	"(B) the cost effectiveness achieved in dif-
12	ferent sites of service;
13	"(C) research outcomes;
14	"(D) volume of research subjects available
15	in different sites of service;
16	"(E) access to research sites and clinical
17	trials by cancer patients;
18	"(F) patient cost sharing or copyament
19	costs realized in different sites of service;
20	"(G) health outcomes experienced in dif-
21	ferent sites of service;
22	"(H) long term health care services and
23	costs experienced in different sites of service;
24	"(I) morbidity and mortality experienced
25	in different sites of service; and

1	"(J) patient satisfaction and preference of
2	sites of service.
3	"(2) Report to congress.—Not later than
4	January 1, 2005, the Secretary shall submit a re-
5	port to Congress that contains—
6	"(A) an assessment of any incremental
7	cost to group health plans resulting from the
8	provisions of this section;
9	"(B) a projection of expenditures to such
10	plans resulting from this section;
11	"(C) an assessment of any impact on pre-
12	miums resulting from this section; and
13	"(D) recommendations regarding action on
14	other diseases.".
15	(2) ERISA AMENDMENTS.—(A) Subpart B of
16	part 7 of subtitle B of title I of the Employee Re-
17	tirement Income Security Act of 1974 is amended by
18	adding at the end the following new section:
19	"SEC. 714. COVERAGE FOR INDIVIDUALS PARTICIPATING IN
20	APPROVED CANCER CLINICAL TRIALS.
21	"(a) Coverage.—
22	"(1) IN GENERAL.—If a group health plan (or
23	a health insurance issuer offering health insurance
24	coverage in connection with the plan) provides cov-

1	erage to a qualified individual (as defined in sub-
2	section (b)), the plan or issuer—
3	"(A) may not deny the individual partici-
4	pation in the clinical trial referred to in sub-
5	section $(b)(2)$;
6	"(B) subject to subsections (b), (c), and
7	(d) may not deny (or limit or impose additional
8	conditions on) the coverage of routine patient
9	costs for items and services furnished in con-
10	nection with participation in the trial; and
11	"(C) may not discriminate against the in-
12	dividual on the basis of the participant's or
13	beneficiaries participation in such trial.
14	"(2) Exclusion of Certain Costs.—For pur-
15	poses of paragraph (1)(B), routine patient costs do
16	not include the cost of the tests or measurements
17	conducted primarily for the purpose of the clinical
18	trial involved.
19	"(3) Use of in-network providers.—If one
20	or more participating providers is participating in a
21	clinical trial, nothing in paragraph (1) shall be con-
22	strued as preventing a plan from requiring that a
23	qualified individual participate in the trial through
24	such a participating provider if the provider will ac-

cept the individual as a participant in the trial.

1	"(b) Qualified Individual Defined.—For pur-
2	poses of subsection (a), the term 'qualified individual'
3	means an individual who is a participant or beneficiary
4	in a group health plan and who meets the following condi-
5	tions:
6	"(1)(A) The individual has been diagnosed with
7	cancer.
8	"(B) The individual is eligible to participate in
9	an approved clinical trial according to the trial pro-
10	tocol with respect to treatment of such illness.
11	"(C) The individual's participation in the trial
12	offers meaningful potential for significant clinical
13	benefit for the individual.
14	"(2) Either—
15	"(A) the referring physician is a partici-
16	pating health care professional and has con-
17	cluded that the individual's participation in
18	such trial would be appropriate based upon the
19	individual meeting the conditions described in
20	paragraph (1); or
21	"(B) the participant or beneficiary pro-
22	vides medical and scientific information estab-
23	lishing that the individual's participation in
24	such trial would be appropriate based upon the

1	individual meeting the conditions described in
2	paragraph (1).
3	"(c) Payment.—
4	"(1) In general.—Under this section a group
5	health plan (or health insurance issuer offering
6	health insurance coverage in connection with the
7	plan) shall provide for payment for routine patient
8	costs described in subsection (a)(2) but is not re-
9	quired to pay for costs of items and services that are
10	reasonably expected to be paid for by the sponsors
11	of an approved clinical trial.
12	"(2) ROUTINE PATIENT CARE COSTS.—
13	"(A) In general.—For purposes of this
14	Act, 'routine patient care costs' shall include
15	the costs associated with the provision of items
16	and services that—
17	"(i) would otherwise be covered under
18	the group health plan if such items and
19	services were not provided in connection
20	with an approved clinical trial program;
21	and
22	"(ii) are furnished according to the
23	protocol of an approved clinical trial pro-
24	gram.

1	"(B) Exclusion.—For purposes of this
2	Act, 'routine patient care costs' shall not in-
3	clude the costs associated with the provision
4	of—
5	"(i) an investigational drug or device,
6	unless the Secretary has authorized the
7	manufacturer of such drug or device to
8	charge for such drug or device; or
9	"(ii) any item or service supplied
10	without charge by the sponsor of the ap-
11	proved clinical trial program.
12	"(3) Payment rate.—In the case of covered
13	items and services provided by—
14	"(A) a participating provider, the payment
15	rate shall be at the agreed upon rate, or
16	"(B) a nonparticipating provider, the pay-
17	ment rate shall be at the rate the plan would
18	normally pay for comparable items or services
19	under subparagraph (A).
20	"(d) APPROVED CLINICAL TRIAL DEFINED.—
21	"(1) In general.—In this section, the term
22	'approved clinical trial' means a cancer clinical re-
23	search study or cancer clinical investigation ap-
24	proved by an Institutional Review Board.

1	"(e) Construction.—Nothing in this section shall
2	be construed to limit a plan's coverage with respect to clin-
3	ical trials.
4	"(f) Plan Satisfaction of Certain Require-
5	MENTS; RESPONSIBILITIES OF FIDUCIARIES.—
6	"(1) In general.—For purposes of this sec-
7	tion, insofar as a group health plan provides benefits
8	in the form of health insurance coverage through a
9	health insurance issuer, the plan shall be treated as
10	meeting the requirements of this section with respect
11	to such benefits and not be considered as failing to
12	meet such requirements because of a failure of the
13	issuer to meet such requirements so long as the plan
14	sponsor or its representatives did not cause such
15	failure by the issuer.
16	"(2) Construction.—Nothing in this section
17	shall be construed to affect or modify the respon-
18	sibilities of the fiduciaries of a group health plan
19	under part 4 of subtitle B.
20	"(g) Study and Report.—
21	"(1) Study.—The Secretary shall analyze can-
22	cer clinical research and its cost implications for
23	managed care, including differentiation in—
24	"(A) the cost of patient care in trials
25	versus standard care:

1	"(B) the cost effectiveness achieved in dif-
2	ferent sites of service;
3	"(C) research outcomes;
4	"(D) volume of research subjects available
5	in different sites of service;
6	"(E) access to research sites and clinical
7	trials by cancer patients;
8	"(F) patient cost sharing or copyament
9	costs realized in different sites of service;
10	"(G) health outcomes experienced in dif-
11	ferent sites of service;
12	"(H) long term health care services and
13	costs experienced in different sites of service;
14	"(I) morbidity and mortality experienced
15	in different sites of service; and
16	"(J) patient satisfaction and preference of
17	sites of service.
18	"(2) Report to congress.—Not later than
19	January 1, 2005, the Secretary shall submit a re-
20	port to Congress that contains—
21	"(A) an assessment of any incremental
22	cost to group health plans resulting from the
23	provisions of this section;
24	"(B) a projection of expenditures to such
25	plans resulting from this section:

1	"(C) an assessment of any impact on pre-
2	miums resulting from this section; and
3	"(D) recommendations regarding action on
4	other diseases.".
5	(B) CLERICAL AMENDMENT.—The table of con-
6	tents in section 1 of the Employee Retirement In-
7	come Security Act of 1974 is amended by inserting
8	after the item relating to section 713 the following
9	new item:
	"Sec. 714. Coverage for individuals participating in approved cancer clinical trials.".
10	(3) Internal revenue code amend-
11	MENTS.—
12	(A) IN GENERAL.—Subchapter B of chap-
13	ter 100 of the Internal Revenue Code of 1986
14	is amended—
15	(i) in the table of sections, by insert-
16	ing after the item relating to section 9812
17	the following new item:
	"Sec. 9813. Coverage for individuals participating in approved cancer clinical trials."; and
18	(ii) by inserting after section 9812 the
19	following:
20	"SEC. 9813. COVERAGE FOR INDIVIDUALS PARTICIPATING
21	IN APPROVED CANCER CLINICAL TRIALS.
22	"(a) Coverage.—

1	"(1) IN GENERAL.—If a group health plan pro-
2	vides coverage to a qualified individual (as defined in
3	subsection (b)), the plan or issuer—
4	"(A) may not deny the individual partici-
5	pation in the clinical trial referred to in sub-
6	section (b)(2);
7	"(B) subject to subsections (b), (c), and
8	(d) may not deny (or limit or impose additional
9	conditions on) the coverage of routine patient
10	costs for items and services furnished in con-
11	nection with participation in the trial; and
12	"(C) may not discriminate against the in-
13	dividual on the basis of the participant's or
14	beneficiaries participation in such trial.
15	"(2) Exclusion of Certain Costs.—For pur-
16	poses of paragraph (1)(B), routine patient costs do
17	not include the cost of the tests or measurements
18	conducted primarily for the purpose of the clinical
19	trial involved.
20	"(3) Use of in-network providers.—If one
21	or more participating providers is participating in a
22	clinical trial, nothing in paragraph (1) shall be con-
23	strued as preventing a plan from requiring that a
24	qualified individual participate in the trial through

1	such a participating provider if the provider will ac-
2	cept the individual as a participant in the trial.
3	"(b) Qualified Individual Defined.—For pur-
4	poses of subsection (a), the term 'qualified individual
5	means an individual who is a participant or beneficiary
6	in a group health plan and who meets the following condi-
7	tions:
8	"(1)(A) The individual has been diagnosed with
9	cancer.
10	"(B) The individual is eligible to participate in
11	an approved clinical trial according to the trial pro-
12	tocol with respect to treatment of such illness.
13	"(C) The individual's participation in the trial
14	offers meaningful potential for significant clinical
15	benefit for the individual.
16	"(2) Either—
17	"(A) the referring physician is a partici-
18	pating health care professional and has con-
19	cluded that the individual's participation in
20	such trial would be appropriate based upon the
21	individual meeting the conditions described in
22	paragraph (1); or
23	"(B) the participant or beneficiary pro-
24	vides medical and scientific information estab-
25	lishing that the individual's participation in

1	such trial would be appropriate based upon the
2	individual meeting the conditions described in
3	paragraph (1).
4	"(c) Payment.—
5	"(1) In general.—Under this section a group
6	health plan shall provide for payment for routine pa-
7	tient costs described in subsection (a)(2) but is not
8	required to pay for costs of items and services that
9	are reasonably expected to be paid for by the spon-
10	sors of an approved clinical trial.
11	"(2) ROUTINE PATIENT CARE COSTS.—
12	"(A) In general.—For purposes of this
13	Act, 'routine patient care costs' shall include
14	the costs associated with the provision of items
15	and services that—
16	"(i) would otherwise be covered under
17	the group health plan if such items and
18	services were not provided in connection
19	with an approved clinical trial program;
20	and
21	"(ii) are furnished according to the
22	protocol of an approved clinical trial pro-
23	gram.
24	"(B) Exclusion.—For purposes of this
25	Act. 'routine patient care costs' shall not in-

1	clude the costs associated with the provision
2	of—
3	"(i) an investigational drug or device,
4	unless the Secretary has authorized the
5	manufacturer of such drug or device to
6	charge for such drug or device; or
7	"(ii) any item or service supplied
8	without charge by the sponsor of the ap-
9	proved clinical trial program.
10	"(3) PAYMENT RATE.—In the case of covered
11	items and services provided by—
12	"(A) a participating provider, the payment
13	rate shall be at the agreed upon rate, or
14	"(B) a nonparticipating provider, the pay-
15	ment rate shall be at the rate the plan would
16	normally pay for comparable items or services
17	under subparagraph (A).
18	"(d) Approved Clinical Trial Defined.—
19	"(1) In general.—In this section, the term
20	'approved clinical trial' means a cancer clinical re-
21	search study or cancer clinical investigation ap-
22	proved by an Institutional Review Board.
23	"(e) Construction.—Nothing in this section shall
24	be construed to limit a plan's coverage with respect to clin-
25	ical trials.

1	"(f) Plan Satisfaction of Certain Require-
2	MENTS; RESPONSIBILITIES OF FIDUCIARIES.—
3	"(1) In general.—For purposes of this sec-
4	tion, insofar as a group health plan provides benefits
5	in the form of health insurance coverage through a
6	health insurance issuer, the plan shall be treated as
7	meeting the requirements of this section with respect
8	to such benefits and not be considered as failing to
9	meet such requirements because of a failure of the
10	issuer to meet such requirements so long as the plan
11	sponsor or its representatives did not cause such
12	failure by the issuer.
13	"(2) Construction.—Nothing in this section
14	shall be construed to affect or modify the respon-
15	sibilities of the fiduciaries of a group health plan
16	under part 4 of subtitle B.
17	"(g) Study and Report.—
18	"(1) Study.—The Secretary shall analyze can-
19	cer clinical research and its cost implications for
20	managed care, including differentiation in—
21	"(A) the cost of patient care in trials
22	versus standard care;
23	"(B) the cost effectiveness achieved in dif-
24	ferent sites of service;
25	"(C) research outcomes;

1	"(D) volume of research subjects available
2	in different sites of service;
3	"(E) access to research sites and clinical
4	trials by cancer patients;
5	"(F) patient cost sharing or copyament
6	costs realized in different sites of service;
7	"(G) health outcomes experienced in dif-
8	ferent sites of service;
9	"(H) long term health care services and
10	costs experienced in different sites of service;
11	"(I) morbidity and mortality experienced
12	in different sites of service; and
13	"(J) patient satisfaction and preference of
14	sites of service.
15	"(2) Report to congress.—Not later than
16	January 1, 2005, the Secretary shall submit a re-
17	port to Congress that contains—
18	"(A) an assessment of any incremental
19	cost to group health plans resulting from the
20	provisions of this section;
21	"(B) a projection of expenditures to such
22	plans resulting from this section;
23	"(C) an assessment of any impact on pre-
24	miums resulting from this section; and

- 1 "(D) recommendations regarding action on 2 other diseases.".
- 3 (B) CONFORMING AMENDMENT.—Section 4 4980D(d)(1) of such Code is amended by strik-5 ing "section 9811" and inserting "sections 6 9811 and 9813".
- 7 (b) Individual Health Insurance.—(1) Part B 8 of title XXVII of the Public Health Service Act is amend-9 ed by inserting after section 2752 the following new sec-
- 10 tion:
- 11 "SEC. 2753. STANDARD RELATING PATIENT FREEDOM OF
- 12 CHOICE.
- 13 "(a) In General.—The provisions of section
- 14 2707(a) shall apply to health insurance coverage offered
- 15 by a health insurance issuer in the individual market in
- 16 the same manner as they apply to health insurance cov-
- 17 erage offered by a health insurance issuer in connection
- 18 with a group health plan in the small or large group mar-
- 19 ket.
- 20 "(b) Notice.—A health insurance issuer under this
- 21 part shall comply with the notice requirement under sec-
- 22 tion 714(b) of the Employee Retirement Income Security
- 23 Act of 1974 with respect to the requirements referred to
- 24 in subsection (a) as if such section applied to such issuer
- 25 and such issuer were a group health plan.".

1 (2) Section 2762(b)(2) of such Act (42 U.S.C. 2 300gg-62(b)(2)) is amended by striking "section 2751" and inserting "sections 2751 and 2753". 3 4 (c) Effective Dates.— 5 (1)GROUP HEALTH PLANS AND **GROUP** 6 HEALTH INSURANCE COVERAGE.—Subject to para-7 graph (3), the amendments made by subsection (a) 8 apply with respect to group health plans for plan 9 years beginning on or after January 1, 2000. 10 (2)Individual health insurance cov-11 ERAGE.—The amendment made by subsection (b) 12 applies with respect to health insurance coverage of-13 fered, sold, issued, renewed, in effect, or operated in 14 the individual market on or after such date. (3) Collective Bargaining Exception.—In 15 16 the case of a group health plan maintained pursuant 17 to 1 or more collective bargaining agreements be-18 tween employee representatives and 1 or more em-19 ployers ratified before the date of enactment of this 20 Act, the amendments made subsection (a) shall not 21 apply to plan years beginning before the later of— 22 (A) the date on which the last collective 23 bargaining agreements relating to the plan ter-

minates (determined without regard to any ex-

1	tension thereof agreed to after the date of en-
2	actment of this Act), or
3	(B) January 1, 2000.
4	For purposes of subparagraph (A), any plan amend-
5	ment made pursuant to a collective bargaining
6	agreement relating to the plan which amends the
7	plan solely to conform to any requirement added by
8	subsection (a) shall not be treated as a termination
9	of such collective bargaining agreement.
10	(d) COORDINATION OF ADMINISTRATION.—The Sec-
11	retary of Labor, the Secretary of the Treasury, and the
12	Secretary of Health and Human Services shall ensure,
13	through the execution of an interagency memorandum of
14	understanding among such Secretaries, that—
15	(1) regulations, rulings, and interpretations
16	issued by such Secretaries relating to the same mat-
17	ter over which two or more such Secretaries have re-
18	sponsibility under the provisions of this Act (and the
19	amendments made thereby) are administered so as
20	to have the same effect at all times; and
21	(2) coordination of policies relating to enforcing
22	the same requirements through such Secretaries in
23	order to have a coordinated enforcement strategy

- 1 that avoids duplication of enforcement efforts and
- 2 assigns priorities in enforcement.

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