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S.L.C.

AMENDMENT NO. _____ Calendar No. _____

Purpose: To require all health insurance products to cover the routine costs associated with participation in certain clinical trials.

IN THE SENATE OF THE UNITED STATES—111th Cong., 1st Sess.

H. R. 3590

To amend the title of the bill, **AMENDMENT NO. 2871** by *Brown-Hutchison*

To: *Amdt 2786*

Referred _____
8
Page(s)

GPO: 2008-45-608 (msc)

AMENDMENT intended to be proposed by *Mr. Brown (with Ms. Hutchison)* to the amendment (No. 2786) proposed by Mr. REID

Viz:

1 On page 97, between lines 6 and 7, insert the following:
2

3 **“SEC. 2710. COVERAGE FOR INDIVIDUALS PARTICIPATING**
4 **IN APPROVED CLINICAL TRIALS.**

5 **“(a) COVERAGE.—**

6 **“(1) IN GENERAL.—**If a group health plan or
7 a health insurance issuer offering group or indi-

1 vidual health insurance coverage provides coverage
2 to a qualified individual, then such 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 subsection (c), may not
7 deny (or limit or impose additional conditions
8 on) the coverage of routine patient costs; and

9 “(C) may not discriminate against the in-
10 dividual on the basis of the individual’s partici-
11 pation in such trial.

12 “(2) ROUTINE PATIENT COSTS.—

13 “(A) INCLUSION.—For purposes of para-
14 graph (1)(B), subject to subparagraph (B), rou-
15 tine patient costs include all items and services
16 consistent with the coverage provided in the
17 plan (or coverage) that is typically covered for
18 a qualified individual who is not enrolled in a
19 clinical trial.

20 “(B) EXCLUSION.—For purposes of para-
21 graph (1)(B), routine patient costs does not in-
22 clude—

23 “(i) the investigational item, device, or
24 service, itself;

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

6 “(iii) a service that is clearly incon-
7 sistent with widely accepted and estab-
8 lished standards of care for a particular di-
9 agnosis.

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

18 “(4) USE OF OUT-OF-NETWORK.—Notwith-
19 standing paragraph (3), paragraph (1) shall apply to
20 a qualified individual participating in an approved
21 clinical trial that is conducted outside the State in
22 which the qualified individual resides.

23 “(b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
24 poses of subsection (a), the term ‘qualified individual’
25 means an individual who is a participant or beneficiary

1 in a health plan or with coverage described in subsection
2 (a)(1) and who meets the following conditions:

3 “(1) The individual is eligible to participate in
4 an approved clinical trial according to the trial pro-
5 tocol with respect to treatment of cancer or other
6 life-threatening disease or condition.

7 “(2) Either—

8 “(A) the referring health care professional
9 is a participating health care provider and has
10 concluded 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); or

14 “(B) the participant or beneficiary pro-
15 vides medical and scientific information estab-
16 lishing that the individual’s participation in
17 such trial would be appropriate based upon the
18 individual meeting the conditions described in
19 paragraph (1).

20 “(c) LIMITATIONS ON COVERAGE.—This section shall
21 not be construed to require a group health plan, or a
22 health insurance issuer offering group or individual health
23 insurance coverage, to provide benefits for routine patient
24 care services provided outside of the plan’s (or coverage’s)

1 health care provider network unless out-of-network bene-
2 fits are otherwise provided under the plan (or coverage).

3 “(d) APPROVED CLINICAL TRIAL DEFINED.—

4 “(1) IN GENERAL.—In this section, the term
5 ‘approved clinical trial’ means a clinical trial (includ-
6 ing a phase I, phase II, phase III, or phase IV trial)
7 that is conducted in relation to the treatment of can-
8 cer or other life-threatening disease or condition and
9 is described in any of the following subparagraphs:

10 “(A) The study or investigation is ap-
11 proved or funded (which may include funding
12 through in-kind contributions) by one or more
13 of the following:

14 “(i) The National Institutes of
15 Health.

16 “(ii) The Centers for Disease Control
17 and Prevention.

18 “(iii) The Agency for Health Care Re-
19 search and Quality.

20 “(iv) The Centers for Medicare &
21 Medicaid Services.

22 “(v) A cooperative group or center of
23 any of the entities described in clauses (i)
24 through (iv) or the Department of Defense
25 or the Department of Veterans Affairs.

1 “(vi) A qualified non-governmental re-
2 search entity identified in the guidelines
3 issued by the National Institutes of Health
4 for center support grants.

5 “(vii) Any of the following if the con-
6 ditions described in paragraph (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) The study or investigation is con-
14 ducted in accordance with the requirements for
15 investigational new drugs or investigational de-
16 vices under the Federal Food, Drug, and Cos-
17 metic Act.

18 “(C) The study or investigation is a clin-
19 ical trial of a drug or device that is exempt
20 from the requirements described under subpara-
21 graph (B).

22 “(2) CONDITIONS FOR DEPARTMENTS.—The
23 conditions described in this paragraph, for a study
24 or investigation conducted by a Department, are
25 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) LIFE-THREATENING CONDITION DEFINED.—In
11 this section, the term ‘life-threatening condition’ means
12 any disease or condition from which the likelihood of death
13 is probable unless the course of the disease or condition
14 is interrupted.

15 “(f) CONSTRUCTION.—Nothing in this section shall
16 be construed to limit a plan’s or issuer’s coverage with
17 respect to clinical trials.

18 “(g) APPLICATION TO FEHBP.—Notwithstanding
19 any provision of chapter 89 of title 5, United States Code,
20 this section shall apply to health plans offered under the
21 program under such chapter.

22 “(h) PREEMPTION.—Notwithstanding any other pro-
23 vision of this Act, nothing in this section shall preempt
24 State laws that require a clinical trials policy for State

- 1 regulated health insurance plans that is in addition to the
- 2 policy required under this section.”.