

House Study Bill 510 - Introduced

HOUSE FILE _____

BY (PROPOSED COMMITTEE ON
HUMAN RESOURCES BILL BY
CHAIRPERSON SMITH)

A BILL FOR

1 An Act relating to the provision of health benefit coverage
2 for certain cancer treatment delivered pursuant to
3 approved cancer clinical trials and including applicability
4 provisions.

5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 514C.26 **Approved cancer clinical**
2 **trials coverage.**

3 1. *Definitions.* For purposes of this section, unless the
4 context otherwise requires:

5 a. "*Approved cancer clinical trial*" means a scientific
6 study of a new therapy for the treatment of cancer in human
7 beings that meets the requirements set forth in subsection 3
8 and consists of a scientific plan of treatment that includes
9 specified goals, a rationale and background for the plan,
10 criteria for patient selection, specific directions for
11 administering therapy and monitoring patients, a definition of
12 quantitative measures for determining treatment response, and
13 methods for documenting and treating adverse reactions.

14 b. "*Institutional review board*" means a board, committee, or
15 other group formally designated by an institution and approved
16 by the national institutes of health, office for protection
17 from research risks, to review, approve the initiation of,
18 and conduct periodic review of biomedical research involving
19 human subjects. "*Institutional review board*" means the same as
20 "*institutional review committee*" as used in section 520(g) of
21 the federal Food, Drug, and Cosmetic Act, as codified in 21
22 U.S.C. § 301 et seq.

23 c. "*Routine patient care costs*" means physician fees,
24 laboratory expenses, and expenses associated with the
25 hospitalization, administration of treatment, and evaluation of
26 a patient during the course of treatment which are consistent
27 with usual and customary patterns and standards of care
28 incurred whenever an enrollee, subscriber, or insured receives
29 medical care associated with an approved cancer clinical trial,
30 and which would be covered if such items and services were
31 provided other than in connection with an approved cancer
32 clinical trial.

33 d. "*Therapeutic intent*" means that a treatment is aimed
34 at improving a patient's health outcome relative to either
35 survival or quality of life.

1 2. *Coverage required.* Notwithstanding the uniformity of
2 treatment requirements of section 514C.6, a policy or contract
3 providing for third-party payment or prepayment of health or
4 medical expenses shall provide coverage benefits for routine
5 patient care costs incurred for cancer treatment in an approved
6 cancer clinical trial to the same extent that such policy or
7 contract provides coverage for treating any other sickness,
8 injury, disease, or condition covered under the policy or
9 contract, if the insured has been referred for such cancer
10 treatment by two physicians who specialize in oncology and
11 the cancer treatment is given pursuant to an approved cancer
12 clinical trial that meets the criteria set forth in subsection
13 3. Services that are furnished without charge to a participant
14 in the approved cancer clinical trial are not required to be
15 covered as routine patient care costs pursuant to this section.

16 3. *Criteria.* Routine patient care costs for cancer
17 treatment given pursuant to an approved cancer clinical
18 trial shall be covered pursuant to this section if all of the
19 following requirements are met:

20 a. The treatment is provided with therapeutic intent and is
21 provided pursuant to an approved cancer clinical trial that has
22 been authorized or approved by one of the following:

- 23 (1) The national institutes of health.
- 24 (2) The United States food and drug administration.
- 25 (3) The United States department of defense.
- 26 (4) The United States department of veterans affairs.

27 b. The proposed treatment has been reviewed and approved by
28 the applicable qualified institutional review board.

29 c. The available clinical or preclinical data indicate
30 that the treatment that will be provided pursuant to the
31 approved cancer clinical trial will be at least as effective
32 as the standard therapy and is anticipated to constitute an
33 improvement in therapeutic effectiveness for the treatment of
34 the disease in question.

35 4. *Applicability.*

1 a. This section applies to the following classes of
2 third-party payment provider contracts or policies delivered,
3 issued for delivery, continued, or renewed in this state on or
4 after July 1, 2010:

5 (1) Individual or group accident and sickness insurance
6 providing coverage on an expense-incurred basis.

7 (2) An individual or group hospital or medical service
8 contract issued pursuant to chapter 509, 514, or 514A.

9 (3) An individual or group health maintenance organization
10 contract regulated under chapter 514B.

11 (4) Any other entity engaged in the business of insurance,
12 risk transfer, or risk retention, which is subject to the
13 jurisdiction of the commissioner.

14 (5) A plan established pursuant to chapter 509A for public
15 employees.

16 (6) An organized delivery system licensed by the director
17 of public health.

18 b. This section shall not apply to accident-only,
19 specified disease, short-term hospital or medical, hospital
20 confinement indemnity, credit, dental, vision, Medicare
21 supplement, long-term care, basic hospital and medical-surgical
22 expense coverage as defined by the commissioner, disability
23 income insurance coverage, coverage issued as a supplement
24 to liability insurance, workers' compensation or similar
25 insurance, or automobile medical payment insurance.

26 EXPLANATION

27 This bill creates new Code section 514C.26 to require health
28 benefit coverage for cancer treatment delivered pursuant to an
29 approved cancer clinical trial. The bill defines "approved
30 cancer clinical trial" as a scientific study of a new therapy
31 for the treatment of cancer in human beings that meets
32 requirements specified in the bill and consists of a scientific
33 plan of treatment.

34 The bill requires that a policy or contract provide health
35 benefit coverage for routine patient care costs incurred for

1 cancer treatment in an approved cancer clinical trial to the
2 same extent that the policy or contract provides coverage for
3 treating any other sickness, injury, disease, or condition
4 covered under the policy or contract, if the insured has been
5 referred for such cancer treatment by two physicians who
6 specialize in oncology, and the cancer treatment is given
7 pursuant to an approved cancer clinical trial as set forth in
8 the bill.

9 The bill applies to specified classes of third-party payment
10 provider contracts or policies delivered, issued for delivery,
11 continued, or renewed in this state on or after July 1, 2010.