

Senate File 21

SENATE FILE _____
BY BOLKCOM

Passed Senate, Date _____ Passed House, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

1 An Act requiring health benefit coverage for certain cancer
2 treatment delivered pursuant to approved cancer clinical
3 trials and providing an applicability date.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
5 TLSB 1487XS 83
6 av/nh/8

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1 1 Section 1. NEW SECTION. 514C.24 APPROVED CANCER CLINICAL
1 2 TRIALS COVERAGE.
1 3 1. DEFINITIONS. For purposes of this section, unless the
1 4 context otherwise requires:
1 5 a. "Approved cancer clinical trial" means a scientific
1 6 study of a new therapy for the treatment of cancer in human
1 7 beings that meets the requirements set forth in subsection 3
1 8 and consists of a scientific plan of treatment that includes
1 9 specified goals, a rationale and background for the plan,
1 10 criteria for patient selection, specific directions for
1 11 administering therapy and monitoring patients, a definition of
1 12 quantitative measures for determining treatment response, and
1 13 methods for documenting and treating adverse reactions.
1 14 b. "Institutional review board" means a board, committee,
1 15 or other group formally designated by an institution and
1 16 approved by the national institutes of health, office for
1 17 protection from research risks, to review, approve the
1 18 initiation of, and conduct periodic review of biomedical
1 19 research involving human subjects. "Institutional review
1 20 board" means the same as "institutional review committee" as
1 21 used in section 520(g) of the federal Food, Drug, and Cosmetic
1 22 Act, as codified in 21 U.S.C. } 301 et seq.
1 23 c. "Routine patient care costs" means physician fees,
1 24 laboratory expenses, and expenses associated with the
1 25 hospitalization, administration of treatment, and evaluation
1 26 of a patient during the course of treatment which are
1 27 consistent with usual and customary patterns and standards of
1 28 care incurred whenever an enrollee, subscriber, or insured
1 29 receives medical care associated with an approved cancer
1 30 clinical trial, and which would be covered if such items and
1 31 services were provided other than in connection with an
1 32 approved cancer clinical trial.
1 33 d. "Therapeutic intent" means that a treatment is aimed at
1 34 improving a patient's health outcome relative to either
1 35 survival or quality of life.
2 1 2. COVERAGE REQUIRED. Notwithstanding the uniformity of
2 2 treatment requirements of section 514C.6, a policy or contract
2 3 providing for third-party payment or prepayment of health or
2 4 medical expenses shall provide coverage benefits for routine
2 5 patient care costs incurred for cancer treatment in an
2 6 approved cancer clinical trial to the same extent that such
2 7 policy or contract provides coverage for treating any other
2 8 sickness, injury, disease, or condition covered under the
2 9 policy or contract, if the insured has been referred for such
2 10 cancer treatment by two physicians who specialize in oncology
2 11 and the cancer treatment is given pursuant to an approved
2 12 cancer clinical trial that meets the criteria set forth in
2 13 subsection 3. Services that are furnished without charge to a
2 14 participant in the approved cancer clinical trial are not
2 15 required to be covered as routine patient care costs pursuant
2 16 to this section.
2 17 3. CRITERIA. Routine patient care costs for cancer

2 18 treatment given pursuant to an approved cancer clinical trial
2 19 shall be covered pursuant to this section if all of the
2 20 following requirements are met:
2 21 a. The treatment is provided with therapeutic intent and
2 22 is provided pursuant to an approved cancer clinical trial that
2 23 has been authorized or approved by one of the following:
2 24 (1) The national institutes of health.
2 25 (2) The United States food and drug administration.
2 26 (3) The United States department of defense.
2 27 (4) The United States department of veterans affairs.
2 28 b. The proposed treatment has been reviewed and approved
2 29 by the applicable qualified institutional review board.
2 30 c. The available clinical or preclinical data indicate
2 31 that the treatment that will be provided pursuant to the
2 32 approved cancer clinical trial will be at least as effective
2 33 as the standard therapy and is anticipated to constitute an
2 34 improvement in therapeutic effectiveness for the treatment of
2 35 the disease in question.

3 1 4. APPLICABILITY.

3 2 a. This section applies to the following classes of
3 3 third-party payment provider contracts or policies delivered,
3 4 issued for delivery, continued, or renewed in this state on or
3 5 after July 1, 2009:

- 3 6 (1) Individual or group accident and sickness insurance
3 7 providing coverage on an expense-incurred basis.
3 8 (2) An individual or group hospital or medical service
3 9 contract issued pursuant to chapter 509, 514, or 514A.
3 10 (3) An individual or group health maintenance organization
3 11 contract regulated under chapter 514B.
3 12 (4) Any other entity engaged in the business of insurance,
3 13 risk transfer, or risk retention, which is subject to the
3 14 jurisdiction of the commissioner.
3 15 (5) A plan established pursuant to chapter 509A for public
3 16 employees.
3 17 (6) An organized delivery system licensed by the director
3 18 of public health.

3 19 b. This section shall not apply to accident-only,
3 20 specified disease, short-term hospital or medical, hospital
3 21 confinement indemnity, credit, dental, vision, Medicare
3 22 supplement, long-term care, basic hospital and
3 23 medical-surgical expense coverage as defined by the
3 24 commissioner, disability income insurance coverage, coverage
3 25 issued as a supplement to liability insurance, workers'
3 26 compensation or similar insurance, or automobile medical
3 27 payment insurance.

3 28 EXPLANATION

3 29 This bill creates new Code section 514C.24 to require
3 30 health benefit coverage for cancer treatment delivered
3 31 pursuant to an approved cancer clinical trial. The bill
3 32 defines "approved cancer clinical trial" as a scientific study
3 33 of a new therapy for the treatment of cancer in human beings
3 34 that meets requirements specified in the bill and consists of
3 35 a scientific plan of treatment.

4 1 The bill requires that a policy or contract provide health
4 2 benefit coverage for routine patient care costs incurred for
4 3 cancer treatment in an approved cancer clinical trial to the
4 4 same extent that the policy or contract provides coverage for
4 5 treating any other sickness, injury, disease, or condition
4 6 covered under the policy or contract, if the insured has been
4 7 referred for such cancer treatment by two physicians who
4 8 specialize in oncology, and the cancer treatment is given
4 9 pursuant to an approved cancer clinical trial as set forth in
4 10 the bill.

4 11 The bill applies to specified classes of third-party
4 12 payment provider contracts or policies delivered, issued for
4 13 delivery, continued, or renewed in this state on or after July
4 14 1, 2009.