

# House File 2315 - Introduced

HOUSE FILE \_\_\_\_\_  
BY SMITH

Passed House, Date \_\_\_\_\_ Passed Senate, 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, establishing a cancer clinical trial review board, and  
4 providing an applicability date.  
5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:  
6 TLSB 5684HH 82  
7 av/nh/8

PAG LIN

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

2 19 3. CRITERIA. Routine patient care costs for cancer  
2 20 treatment given pursuant to an approved cancer clinical trial  
2 21 shall be covered pursuant to this section if all of the  
2 22 following requirements are met:

2 23 a. The treatment is provided with therapeutic intent and  
2 24 is provided pursuant to an approved cancer clinical trial that  
2 25 has been authorized or approved by one of the following:

2 26 (1) The national institutes of health.  
2 27 (2) The United States food and drug administration.  
2 28 (3) The United States department of defense.  
2 29 (4) The United States department of veterans affairs.

2 30 b. The proposed treatment has been reviewed and approved  
2 31 by the applicable qualified institutional review board.

2 32 c. The available clinical or preclinical data indicate  
2 33 that the treatment that will be provided pursuant to the  
2 34 approved cancer clinical trial will be at least as effective  
2 35 as the standard therapy and is anticipated to constitute an  
3 1 improvement in therapeutic effectiveness for the treatment of  
3 2 the disease in question.

3 3 4. CANCER CLINICAL TRIAL REVIEW BOARD.

3 4 a. A cancer clinical trial review board is established in  
3 5 the department of public health.

3 6 b. The board shall consist of the director of public  
3 7 health or the director's designee, and the following  
3 8 additional members appointed by the governor and subject to  
3 9 confirmation by the senate:

3 10 (1) One member who is a physician licensed to practice  
3 11 medicine and surgery in this state and who specializes in  
3 12 oncology, is a member of a community medical oncology  
3 13 practice, and is not on the staff of a comprehensive or  
3 14 clinical cancer center designated by the national cancer  
3 15 institute.

3 16 (2) One member who is a physician licensed to practice  
3 17 medicine and surgery in this state who specializes in oncology  
3 18 and is on the staff of a comprehensive or clinical cancer  
3 19 center designated by the national cancer institute.

3 20 (3) One member who is a medical ethicist recognized for  
3 21 expertise in evaluating ethical implications of health care  
3 22 practices and procedures.

3 23 (4) One member who is a medical economist recognized for  
3 24 expertise in evaluating economic implications of health care  
3 25 practices and procedures.

3 26 (5) One member who is a physician licensed to practice  
3 27 medicine and surgery in this state who is employed by or  
3 28 represents an insurer.

3 29 (6) One member who is a physician licensed to practice  
3 30 medicine and surgery in this state who is employed by or  
3 31 represents a nonprofit health care service plan.

3 32 (7) One member who is a physician licensed to practice  
3 33 medicine and surgery in this state who is employed by or  
3 34 represents a health maintenance organization.

3 35 (8) One member who is a resident of this state who  
4 1 represents residents with health insurance who are consumers  
4 2 of oncology services.

4 3 c. The members of the board shall annually elect one  
4 4 member as chairperson and one as vice chairperson.

4 5 d. The board shall meet not less than four times per year  
4 6 at the call of the chairperson or at the request of a majority  
4 7 of the board's members.

4 8 e. The appointed members of the board shall be appointed  
4 9 for terms of four years beginning and ending as provided in  
4 10 section 69.19. A member of the board is eligible for  
4 11 reappointment. The governor shall fill a vacancy for the  
4 12 remainder of the unexpired term. An appointed member of the  
4 13 board may be removed by the governor for misfeasance,  
4 14 malfeasance, or willful neglect of duty or other cause after  
4 15 notice and a public hearing unless the notice and hearing are  
4 16 waived by the member in writing.

4 17 f. A majority of the members of the board constitutes a  
4 18 quorum. The affirmative vote of a majority of the members is  
4 19 necessary for any action taken by the board. The majority  
4 20 shall not include a member who has a conflict of interest and  
4 21 a statement by a member of a conflict of interest is  
4 22 conclusive for this purpose. A vacancy in the membership of  
4 23 the board does not impair the right of a quorum to exercise  
4 24 the rights and perform the duties of the board.

4 25 g. The board has the power and duty to hold hearings and  
4 26 issue adjudications of disputes referred to the board by the  
4 27 commissioner of insurance involving third-party reimbursement  
4 28 for routine patient care costs incurred in association with  
4 29 approved cancer clinical trials, subject to review and appeal,

4 30 pursuant to chapter 17A.

4 31 h. Members of the board shall not receive compensation for  
4 32 the performance of their duties as members but each member  
4 33 shall be paid necessary expenses incurred while engaged in the  
4 34 performance of the duties of the board.

4 35 5. APPLICABILITY.

5 1 a. This section applies to the following classes of  
5 2 third-party payment provider contracts or policies delivered,  
5 3 issued for delivery, continued, or renewed in this state on or  
5 4 after July 1, 2008:

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

5 7 (2) An individual or group hospital or medical service  
5 8 contract issued pursuant to chapter 509, 514, or 514A.

5 9 (3) An individual or group health maintenance organization  
5 10 contract regulated under chapter 514B.

5 11 (4) Any other entity engaged in the business of insurance,  
5 12 risk transfer, or risk retention, which is subject to the  
5 13 jurisdiction of the commissioner.

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

5 16 (6) An organized delivery system licensed by the director  
5 17 of public health.

5 18 b. This section shall not apply to accident-only,  
5 19 specified disease, short-term hospital or medical, hospital  
5 20 confinement indemnity, credit, dental, vision, Medicare  
5 21 supplement, long-term care, basic hospital and  
5 22 medical-surgical expense coverage as defined by the  
5 23 commissioner, disability income insurance coverage, coverage  
5 24 issued as a supplement to liability insurance, workers'  
5 25 compensation or similar insurance, or automobile medical  
5 26 payment insurance.

5 27 EXPLANATION

5 28 This bill requires health benefit coverage for cancer  
5 29 treatment delivered pursuant to an approved cancer clinical  
5 30 trial. The bill defines "approved cancer clinical trial" as a  
5 31 scientific study of a new therapy for the treatment of cancer  
5 32 in human beings that meets requirements specified in the bill  
5 33 and consists of a scientific plan of treatment.

5 34 The bill requires that a policy or contract provide health  
5 35 benefit coverage for routine patient care costs incurred for  
6 1 cancer treatment in an approved cancer clinical trial to the  
6 2 same extent that the policy or contract provides coverage for  
6 3 treating any other sickness, injury, disease, or condition  
6 4 covered under the policy or contract, if the insured has been  
6 5 referred for such cancer treatment by two physicians who  
6 6 specialize in oncology, and the cancer treatment is given  
6 7 pursuant to an approved cancer clinical trial as set forth in  
6 8 the bill.

6 9 The bill also establishes the cancer clinical trial review  
6 10 board in the department of public health, consisting of the  
6 11 director of public health and eight additional members with  
6 12 specified expertise, appointed by the governor and subject to  
6 13 confirmation by the senate. The purpose of the board is to  
6 14 hold hearings and issue adjudications of disputes referred to  
6 15 the board by the commissioner of insurance involving  
6 16 third-party reimbursement for routine patient care costs for  
6 17 cancer treatment incurred in association with approved cancer  
6 18 clinical trials, subject to review and appeal, pursuant to  
6 19 Code chapter 17A.

6 20 The bill applies to specified classes of third-party  
6 21 payment provider contracts or policies delivered, issued for  
6 22 delivery, continued, or renewed in this state on or after July  
6 23 1, 2008.

6 24 LSB 5684HH 82

6 25 av/nh/8