House Study Bill 530 - Introduced

HOUSE FILE _____ BY (PROPOSED COMMITTEE ON COMMERCE BILL BY CHAIRPERSON PETERSEN)

A BILL FOR

- An Act requiring health benefit coverage for certain cancer
 treatment delivered pursuant to approved cancer clinical
 trials and providing an applicability date.
- 4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. <u>NEW SECTION</u>. 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.

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

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

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.

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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 The treatment is provided with therapeutic intent and is a. 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. (3) The United States department of defense. 25 26 (4) The United States department of veterans affairs. 27 The proposed treatment has been reviewed and approved by b. 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.

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

5 (1) Individual or group accident and sickness insurance6 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.

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

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

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

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LSB 5238HC (8) 83 av/nh 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.

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