House File 768 - Introduced

HOUSE FILE _____
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO HSB 85)

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

A BILL FOR

An Act providing for an expedited review of denials of health benefit coverage for certain cancer treatments.
BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
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Section 1. Section 514F.5, Code 2009, is amended by adding the following new subsection:
NEW SUBSECTION. 3. a. A person covered under a plan or contract who is participating in an approved cancer clinical trial and has been denied coverage for routine patient care costs because the proposed treatment is experimental may file a written request for an expedited review of the denial by the commissioner of insurance. The commissioner shall conduct a review of the denial of such coverage and submit its external review decision within three working days of receiving such a request for expedited review.
b. For the purposes of this subsection:
(1) "Approved cancer clinical trial" means a scientific study of a new therapy for the treatment of cancer in human beings to which an enrollee has been referred for cancer treatment by two physicians who specialize in oncology and the cancer treatment is to be given pursuant to a cancer clinical trial that consists of a scientific plan of treatment that includes specified goals, a rationale and background for the plan, criteria for patient selection, specific directions for administering therapy and monitoring patients, a definition of quantitative measures for determining treatment response, and methods for documenting and treating adverse reactions. In addition, the cancer treatment that is to be provided pursuant to the clinical trial meets all of the following criteria:
(a) The treatment is provided with therapeutic intent and is provided pursuant to a cancer clinical trial that has been authorized or approved by one of the following:
(i) The national institutes of health.
(ii) The United States food and drug administration.
(iii) The United States department of defense.
(iv) The United States department of veterans affairs.
(b) The proposed cancer treatment has been reviewed and approved by the applicable qualified institutional review board.
(c) The available clinical or preclinical data indicate that the cancer treatment will be at least as effective as the standard therapy and is anticipated to constitute an improvement in therapeutic effectiveness for the treatment of the disease in question.
(2) "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.
(3) "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 receives medical care, that are 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 clinical trial.

(4) "Therapeutic intent" means that a treatment is aimed at improving a patient's health outcome relative to either survival or quality of life.

EXPLANATION

This bill provides for an expedited review by the commissioner of insurance of denials of health benefit coverage for routine patient care costs for cancer treatment delivered pursuant to an approved cancer clinical trial because the proposed treatment is experimental.

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 plan of treatment. "Routine patient care costs" is defined to mean physician fees, laboratory expenses, and other expenses associated with treatment administered pursuant to an approved cancer clinical trial that are consistent with usual and customary standards of care and would be covered if provided in connection with other types of medical treatments.