



## Bill Summary

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# HF 2075 Cancer Clinical Trials Insurance Coverage of Routine Patient Care

Status of Bill: House Calendar  
Committee: Commerce  
Subcommittee: Tyler Olson-Chair, Donovan Olson, and Doug Struyk  
Floor Manager: Tyler Olson  
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### BACKGROUND

House File 2075 does not require health insurance policies to cover the costs of cancer clinical trials. It merely requires them to continue to pay for routine care of cancer patients while they participate in such trials.

Health insurers say they already cover these costs, but policies differ, disputes happen, and coverage is still denied. This leaves cancer patients confused and fearful that if they join a clinical trial their insurer may stop paying for routine care. This makes cancer patients reluctant to join clinical trials, which hurts all Iowans who ultimately stand to benefit from cancer research.

The intent of HF 2075 is to codify exactly how this situation should be dealt with so: (1) it will be clear to cancer patients what types of routine care will continue to be covered so that they will not be reluctant to join a cancer clinical trial; and (2) it will be clear to insurance companies what types of routine care will continue to be covered so that disputes regarding their liability will be limited.

### SUMMARY OF HF 2075

**Continued Payment of Routine Care:** HF 2075 requires insurers to continue to cover routine patient care costs, incurred for cancer treatment in an approved cancer clinical trial, to the same extent coverage is provided for treating any other, injury, disease, or condition under that policy.

- **Patient Referral:** Two physicians who specialize in oncology must refer the patient to the clinical trial.
- **“Routine patient care costs”** are defined as medically necessary services or treatments that are a benefit under a contract or policy providing for third-party payment or prepayment of health or medical expenses that would be covered if the patient were receiving standard cancer treatment.
- **“Routine patient care costs” do not include:**
  1. Any treatments, procedures, drugs, devices, services, or items that are the subject of the approved cancer clinical trial or any other investigational treatments, procedures, drugs, devices, services, or items.
  2. Nonhealth care services that the patient is required to receive as a result of participation in clinical trial.
  3. Costs associated with managing the research associated with the approved cancer clinical trial.
  4. Costs that would not be covered by insurer if noninvestigational treatments were provided.
  5. Any services, procedures, or tests provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient participating in the clinical trial.
  6. Costs paid for, or not charged for, by the clinical trial providers.
  7. Transportation, lodging, food, or other expenses for the patient, a family member, or patient companion that are associated with travel to or from a facility where a clinical trial is conducted.
  8. Services, items, or drugs that are eligible for reimbursement from a source other than a patient's contract or policy, including the sponsor of the clinical trial.
  9. Costs associated with trials designed exclusively to test toxicity or disease pathophysiology.

**Insurer Immunity:** HF 2075 states that the insurer is not liable for any damages to a patient who participates in a clinical trial arising out of participation in the clinical trial.

**"Approved cancer clinical trial"** is a scientific study of a new therapy for the treatment of cancer in human beings and 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. It must also meet all of the following requirements:

1. The treatment is provided with therapeutic intent pursuant to a cancer clinical trial that has been authorized or approved by one of the following:
  - The National Institutes of Health.
  - The U. S. Food and Drug Administration.
  - The U. S. Department of Defense.
  - The U. S. Department of Veterans Affairs.
  - "Therapeutic intent" means that a treatment is aimed at improving a patient's health outcome relative to either survival or quality of life.
2. The proposed cancer treatment has been reviewed and approved by the applicable Qualified Institutional Review Board.
3. The available clinical or preclinical data indicate that the treatment that will be provided pursuant to the clinical trial 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.

**Notice of Participation to Insurer:** As soon as practical after the patient provides written consent to participate in the cancer clinical trial, the physician shall notify the insurer of the patient's intent to participate. Failure to provide notice is not basis for denying the required coverage.

**Applicability:** HF 2075 applies to individual or group third-party provider contracts or policies delivered, issued for delivery, continued, or renewed in this state on or after July 1, 2010.

1. Does Not Apply to ERISA Plans: This will not apply to employer self-insured health coverage plans, because the federal Employee Retirement Income Security Act (ERISA) preempts state insurance regulation of such plans. As an employer's size approaches or exceeds 100 employees, the more feasible it is to self-insure.
  - 2,240 of Iowa's 93,555 employers have 100 or more employees – representing 43.2% of all Iowa employees. (Department of Workforce Development's 2008 Quarterly Census of Employment and wages).
2. Does Not Apply to Medicaid/Medicare/Veterans Administration: Although these are federal programs with their own regulations, **Medicaid, Medicare and the Veterans Administration provide similar coverage.**
3. Applies to Non-ERISA Plans: Currently, this is about 22% or 23% of the market; the rest are either covered by exempt self-insured employer plans, government programs, or have no insurance.

## Amendment Summaries

**H-8025 by T. Olson (D-Linn) and Struyk (R-Pottawattamie) – Routine Care / Immunity:** The amendment does the following:

1. Items that are not "routine patient care costs": Changes the nine items from being designated "1" through "9" to being designated "a" through "i" and adds the following new tenth item "h": "*Costs of extras treatments, services, procedures, tests, or drugs that would not be performed or administered except for participation in the cancer clinical trial. Nothing in this subparagraph subdivision shall limit payment for treatments, services, procedures, tests, or drugs that are otherwise a covered benefit under subparagraph (1).*"
2. Strikes the insurer immunity provision.