

By Senator Clary

7-1295-01

See HB

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A bill to be entitled
An act relating to insurance coverage for
investigational cancer treatments; requiring
coverage for investigational cancer treatments
under certain circumstances; specifying covered
costs; providing exceptions; providing criteria
for certain cancer trials; providing an
effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Coverage for investigational cancer
treatments.--

(1) An insurer that issues, delivers, amends, or
renews an individual or group policy of accident and health
insurance in this state shall offer to the applicant or
policyholder coverage for routine patient care of insureds for
participation in an approved cancer research trial, when
medically appropriate and when the insured has a terminal
condition related to cancer that, according to the diagnosis
of the treating physician licensed to practice medicine in all
its branches, is considered life-threatening, and shall
provide coverage for the patient care provided pursuant to
investigational cancer treatments as provided in subsection
(2). Coverage under this act may have an annual benefit limit
of \$10,000.

(2) Coverage shall include routine patient care costs,
including, but not limited to, costs for blood tests, X rays,
bone scans, magnetic resonance images, patient visits, or
hospital stays, or other similar costs generally incurred by
the insured party in standard cancer treatment. Routine

1 patient care costs specifically shall not include the cost of
2 any clinical trial therapies, regimens, or combinations
3 thereof; the cost of any drugs or pharmaceuticals in
4 connection with an approved clinical trial; any costs
5 associated with the provision of any goods, services, or
6 benefits that are generally furnished without charge in
7 connection with an approved clinical trial program for
8 treatment of cancer; any additional costs associated with the
9 provision of any goods, services, or benefits that previously
10 have been provided, paid for, or reimbursed; or any other
11 similar costs. Routine patient care costs shall specifically
12 not include costs for treatments or services prescribed for
13 the convenience of the insured, enrollee, or physician. It is
14 specifically the intent of this act not to relieve the sponsor
15 of a clinical trial program of financial responsibility for
16 accepted costs of the program.

17 (3) For purposes of this act, coverage is provided
18 only for cancer trials that meet the following criteria:

19 (a) The effectiveness of the treatment has not been
20 determined relative to established therapies.

21 (b) The trial is under clinical investigation as part
22 of an approved cancer research trial in Phase II, Phase III,
23 or Phase IV of investigation.

24 (c) The trial is approved by the United States
25 Secretary of Health and Human Services, the Director of the
26 National Institutes of Health, the Commissioner of the United
27 States Food and Drug Administration, through an
28 investigational new drug exemption under s. 505(1) of the
29 Federal Food, Drug, and Cosmetic Act or an investigational
30 device exemption under s. 520(g) of that act, or a qualified
31 nongovernmental cancer research entity as defined in

1 guidelines of the National Institutes of Health or a
2 peer-reviewed and approved cancer research program, as defined
3 by the United States Secretary of Health and Human Services,
4 conducted for the primary purpose of determining whether a
5 cancer treatment is safe or efficacious or has any other
6 characteristic of a cancer treatment that must be demonstrated
7 in order for the cancer treatment to be medically necessary or
8 appropriate.

9 (d) The trial is being conducted at multiple sites
10 throughout the state.

11 (e) The patient's primary care physician, if any, is
12 involved in the coordination of care.

13 (f) The results of the investigational trial will be
14 submitted for publication in peer-reviewed scientific studies,
15 research, or literature published in or accepted for
16 publication by medical journals that meet nationally
17 recognized requirements for scientific manuscripts and that
18 submit most of their published articles for review by experts
19 who are not part of the editorial staff. These studies may
20 include those conducted by or under the auspices of the
21 Federal Government's Agency for Health Care Policy and
22 Research, National Institutes of Health, National Cancer
23 Institute, National Academy of Sciences, Health Care Financing
24 Administration, and any national board recognized by the
25 National Institutes of Health for the purpose of evaluating
26 the medical value of health services.

27 Section 2. This act shall take effect October 1, 2001.
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HOUSE SUMMARY

Requires individual or group health insurance policies to cover investigational cancer treatments. Specifies covered costs. Provides criteria for acceptable cancer trials. See bill for details.