

By Senator Lee

23-745A-00

1 A bill to be entitled
2 An act relating to health insurance; creating
3 s. 627.4296, F.S.; providing definitions;
4 prohibiting certain health insurers and health
5 maintenance organizations from denying
6 qualified individuals from participating in
7 approved clinical trials; requiring certain
8 health insurers and health maintenance
9 organizations to provide coverage to qualified
10 individuals for certain costs relating to
11 approved clinical trials; providing for
12 reimbursement of patient costs; amending s.
13 627.6515, F.S.; requiring out-of-state group
14 policies to provide coverage for certain costs
15 relating to approved clinical trials; providing
16 a legislative finding that the act fulfills an
17 important state interest; providing an
18 effective date.

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

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22 Section 1. Section 627.4296, Florida Statutes, is
23 created to read:

24 627.4296 Health insurance coverage for approved
25 clinical trials.--

26 (1) DEFINITIONS.--As used in this section, the term:

27 (a) "Approved clinical trial" means a clinical
28 research study or clinical investigation treatment program
29 approved by the federal Food and Drug Administration or the
30 National Institute of Health in cooperation with the National
31 Cancer Institute.

1 (b) "Qualified individual" means an individual who is
2 a participant or beneficiary in a health plan or an enrollee
3 under health insurance coverage, whose participation in an
4 approved clinical trial has been approved by a participating
5 health care professional and who:

6 1. Has a life-threatening illness for which no
7 standard treatment is effective;

8 2. Is eligible to participate in an approved clinical
9 trial according to the approved clinical trial protocol with
10 respect to treatment of such illness; and

11 3. Could receive potentially significant clinical
12 benefit from participation in the approved clinical trial.

13 (c) "Routine patient cost" means the cost of a
14 medically necessary health care service which is incurred as a
15 result of the treatment being provided to a qualified
16 individual in an approved clinical trial.

17 (2) COVERAGE FOR APPROVED CLINICAL TRIALS.--

18 (a) Any health insurer or health maintenance
19 organization that issues major medical insurance coverage in
20 this state may not:

21 1. Deny a qualified individual participation in an
22 approved clinical trial;

23 2. Deny, limit, or impose additional conditions on the
24 coverage of routine patient costs for items and services
25 furnished in connection with participation in an approved
26 clinical trial; or

27 3. Discriminate against a qualified individual on the
28 basis of that individual's participation in such an approved
29 clinical trial.

30 (b) A health insurer or health maintenance
31 organization that issues major medical insurance coverage in

1 this state shall provide for payment of routine patient costs.

2 Routine patient costs do not include the following items;

3 1. Cost of nonhealth care services that a patient
4 could be required to receive as a result of the treatment
5 being provided pursuant to an approved clinical trial;

6 2. Costs not otherwise covered under the insured's,
7 subscriber's, or enrollee's policy, plan, or contract of
8 coverage for noninvestigational treatments;

9 3. Cost of tests or measurements conducted primarily
10 for the purpose of evaluating the approved clinical trial;

11 4. Costs associated with managing the research
12 associated with the approved clinical trial; and

13 5. Costs for treatments or services prescribed for the
14 convenience of the insured, subscriber, enrollee, or
15 physician.

16 (c) A health insurer or health maintenance
17 organization that issues major medical insurance coverage in
18 this state is not required to pay for costs of items and
19 services that are reasonably expected to be paid for by the
20 sponsors of an approved clinical trial, including the cost of
21 an investigational drug or device.

22 (d) The reimbursement for routine patient costs
23 incurred during participation in an approved clinical trial
24 for treatment must be determined in the same manner as
25 reimbursement is determined for other medical and surgical
26 procedures. Such coverage must have durational limits, dollar
27 limits, deductibles, copayments, and coinsurance factors that
28 are no less favorable to the insured, subscriber, or enrollee
29 than for physical illness generally.

30 Section 2. Subsection (2) of section 627.6515, Florida
31 Statutes, is amended to read:

1 627.6515 Out-of-state groups.--

2 (2) This part does not apply to a group health
3 insurance policy issued or delivered outside this state under
4 which a resident of this state is provided coverage if:

5 (a) The policy is issued to an employee group the
6 composition of which is substantially as described in s.
7 627.653; a labor union group or association group the
8 composition of which is substantially as described in s.
9 627.654; an additional group the composition of which is
10 substantially as described in s. 627.656; a group insured
11 under a blanket health policy when the composition of the
12 group is substantially in compliance with s. 627.659; a group
13 insured under a franchise health policy when the composition
14 of the group is substantially in compliance with s. 627.663;
15 an association group to cover persons associated in any other
16 common group, which common group is formed primarily for
17 purposes other than providing insurance; a group that is
18 established primarily for the purpose of providing group
19 insurance, provided the benefits are reasonable in relation to
20 the premiums charged thereunder and the issuance of the group
21 policy has resulted, or will result, in economies of
22 administration; or a group of insurance agents of an insurer,
23 which insurer is the policyholder;

24 (b) Certificates evidencing coverage under the policy
25 are issued to residents of this state and contain in
26 contrasting color and not less than 10-point type the
27 following statement: "The benefits of the policy providing
28 your coverage are governed primarily by the law of a state
29 other than Florida"; and

30 (c) The policy provides the benefits specified in ss.
31 627.419, 627.4296, 627.6574, 627.6575, 627.6579, 627.6612,

1 627.66121, 627.66122, 627.6613, 627.667, 627.6675, 627.6691,
2 and 627.66911.

3 Section 3. The Legislature finds that the provisions
4 of this act fulfill an important state interest.

5 Section 4. This act shall take effect January 1, 2001
6 and shall apply to policies issued or renewed on or after that
7 date.

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SENATE SUMMARY

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Requires health insurers and health maintenance organizations that issue major medical insurance coverage in this state to provide to qualified individuals coverage of the routine patient costs for participation in a clinical research study or investigation treatment program (an approved clinical trial) approved by the Federal Food and Drug Administration or the National Institute of Health in cooperation with the National Cancer Institute. Prohibits such organizations from denying qualified individuals the right to participate in such an approved clinical trial. Provides that certain specified costs are not routine patient costs. Provides that reimbursement for routine patient costs incurred during participation in an approved clinical trial for treatment must be determined in the same manner as reimbursement is determined for other medical and surgical procedures. Requires out-of-state group policies to provide coverage for certain costs relating to approved clinical trials.