COMMITTEE REPORT

February 25, 2010

**S. 613**

Introduced by Senator Hayes

S. Printed 2/25/10--S.

Read the first time March 25, 2009.

**THE COMMITTEE ON BANKING AND INSURANCE**

To whom was referred a Bill (S. 613) to amend the Code of Laws of South Carolina, 1976, by adding Section 38‑71‑732 so as to require health insurance coverage, including coverage under the State Health Plan, etc., respectfully

**REPORT:**

That they have duly and carefully considered the same and recommend that the same do pass with amendment:

Amend the bill, as and if amended, Section 38‑71‑732(A)(2), as contained in SECTION 1, page 1, line 36, by inserting / and Section 38‑71‑840(14) / after / 38‑71‑670(6) /.

Amend the bill further, SECTION 1, by deleting Section 38‑71‑732(A)(4) in its entirety and inserting:

/ (4) ‘Health insurance plan’ means an individual health plan, a group health plan, or a health benefit plan, including the State Health Plan, that is delivered, issued for delivery, or renewed in this State and provides health insurance coverage. /

Amend the bill further, Section 38‑71‑732(A), as contained in SECTION 1, page 2, line 7, by inserting an appropriately numbered item to read:

/ (\_) ‘Routine patient care costs’ means a physician fee, laboratory expense, or other expense associated with the hospitalization, administration of treatment, and evaluation of a patient during the course of treatment that are consistent with usual and customary patterns and standards of care incurred when an enrollee, subscriber, or insured receives medical care associated with an approved cancer clinical trial, and that would be covered if these items and services were provided other than in connection with an approved cancer clinical trial. /

Amend the bill further, Section 38‑71‑732(B)(1), page 2, lines 9‑10 by deleting / an insured / and inserting / a covered person / and on line 11 by deleting / insured / and inserting / covered person /.

Amend the bill further, Section 38‑71‑732(B)(2), page 2, by deleting line 18 in its entirety and inserting / restrict coverage on a covered person solely because he has /.

Amend the bill further, Section 38‑71‑732(C), page 2, line 22, by deleting / an insured / and inserting / a covered person /.

Amend the bill further, SECTION 2, page 3, line 4, by deleting / July 1, 2010 / and inserting / December 31, 2010 /.

Renumber sections to conform.

Amend title to conform.

DAVID L. THOMAS for Committee.

**STATEMENT OF ESTIMATED FISCAL IMPACT**

ESTIMATED FISCAL IMPACT ON GENERAL FUND EXPENDITURES:

See Below

ESTIMATED FISCAL IMPACT ON FEDERAL & OTHER FUND EXPENDITURES:

See Below

**EXPLANATION OF IMPACT:**

Budget and Control Board

The State Health Plan currently covers medically necessary care for patients in Phase 3 and 4 trials so any impact is negligible for these patients. Both Phase 1 and 2 trials fall under the State Health Plan’s exclusion for investigational services and are not covered. Phase 1 trials are the first stage of testing in humans, and are to evaluate the safety and tolerability of the study drug. Phase 2 trials are designed to evaluate if the study drug has any effect on the disease process, and to further evaluate tolerability. The State Health Plan has not been able to model any cost impact based on coverage for phase 1 and 2 trials. Therefore, the impact on health insurance premiums is not quantifiable at this time. Premiums are paid by state agencies with a combination of state, federal and other funds.

Department of Insurance

The department indicates that this bill would generate additional filings that would need to be reviewed. Any additional costs are anticipated to be minimal and would be absorbed within existing resources.

*Approved By:*

Harry Bell

Office of State Budget

**A** **BILL**

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, BY ADDING SECTION 38‑71‑732 SO AS TO REQUIRE HEALTH INSURANCE COVERAGE, INCLUDING COVERAGE UNDER THE STATE HEALTH PLAN, FOR AN INSURED WHO PARTICIPATES IN AN APPROVED CANCER CLINICAL TRIAL.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. Subarticle 1, Article 5, Chapter 71, Title 38 of the 1976 Code is amended by adding:

“Section 38‑71‑732. (A) As used in this section:

(1) ‘Approved cancer clinical trial’ means a scientific study of a new therapy for the treatment of cancer in human beings that meets the requirements set forth in subsection (D) 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.

(2) ‘Insurer’ means an insurance company, a health maintenance organization, and any other entity providing health insurance coverage, as defined in Section 38‑71‑670(6), which is licensed to engage in the business of insurance in this State and which is subject to state insurance regulation.

(3) ‘Health maintenance organization’ means an organization as defined in Section 38‑33‑20(8).

(4) ‘Health insurance plan’ means a group health insurance policy or group health benefit plan offered by an insurer. It includes the State Health Plan, but does not otherwise include any health insurance plan offered in the individual market as defined in Section 38‑71‑670(11), any health insurance plan that is individually underwritten, or any health insurance plan provided to a small employer, as defined by Section 38‑71‑1330(17) of the 1976 Code.

(5) ‘State Health Plan’ means the employee and retiree insurance program provided for in Article 5, Chapter 11, Title 1.

(B)(1) A health insurance plan must provide coverage for an insured who has had coverage under the plan for routine patient care costs incurred for cancer treatment and the insured is referred for participation in an approved cancer clinical trial. The referral must be made by two physicians who specialize in oncology and the cancer treatment must be given pursuant to an approved cancer clinical trial that meets the criteria set forth in subsection (D).

(2) With regards to a health insurance plan, an insurer may not refuse to renew or refuse to reissue or otherwise terminate or restrict coverage on an individual solely because the insured has entered an approved cancer clinical trial.

(C) The coverage required pursuant to subsection (B) must not be subject to dollar limits, deductibles, or coinsurance provisions that are less favorable to an insured than the dollar limits, deductibles, or coinsurance provisions that apply to routine patient care costs incurred for cancer treatment generally under the health insurance plan. However, the coverage required pursuant to subsection (B) may be subject to other general exclusions and limitations of the health insurance plan.

(D) Routine patient care costs for cancer treatment given pursuant to an approved cancer clinical trial must be covered pursuant to this section if all of the following requirements are met:

(1) The treatment is provided with therapeutic intent and is provided pursuant to an approved cancer clinical trial that has been authorized or approved by one of the following:

(a) the National Institutes of Health;

(b) the United States Food and Drug Administration;

(c) the United States Department of Defense; or

(d) the United States Department of Veterans Affairs.

(2) The proposed 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 approved cancer 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.”

SECTION 2. This act takes effect July 1, 2010, and applies to health insurance plans, as defined in Section 38‑71‑732 of the 1976 Code, as added by Section 1 of this act, issued, renewed, delivered, or entered into on or after this act’s effective date.

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