COMMITTEE REPORT

February 25, 2016

**H. 4542**

Introduced by Reps. McKnight, Clyburn, Cobb‑Hunter and Hill

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Read the first time January 12, 2016.

**THE COMMITTEE ON MEDICAL,**

**MILITARY, PUBLIC AND MUNICIPAL AFFAIRS**

To whom was referred a Bill (H. 4542) to amend the Code of Laws of South Carolina, 1976, by adding Chapter 65 to Title 44 to enact the “Experimental Health Care Treatment Law” so as to authorize, 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 2, page 4, by striking Section 44‑65‑60 and inserting:

/ Section 44‑65‑60. An official, employee, or agent of this State must not deny, or attempt to deny, an eligible patient lawful access to an investigational drug, biological product, or device. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section. /

Renumber sections to conform.

Amend title to conform.

LEON HOWARD for Committee.

**STATEMENT OF ESTIMATED FISCAL IMPACT**

**Fiscal Impact Summary**

This bill would have no expenditure impact on the general fund, federal funds, or other funds.

**Explanation of Fiscal Impact**

**State Expenditure**

This bill amends Title 44 by adding Chapter 65 relating to Experimental Health Care Treatment. The bill establishes definitions and procedures by which a patient with an advanced (terminal) illness, upon a doctor’s recommendation, may receive investigational drugs from a manufacturer. Insurers are not required to expand coverage to include such drugs and the cost of obtaining the drugs is solely the responsibility of the patient. However, manufacturers may provide the drug at no cost. The bill requires the patient to sign a consent form containing specified information and prohibits punitive actions against participants in these transactions.

The Department of Health and Environmental Control reports that this bill would have no expenditure impact on the general fund, federal funds, or other funds.

Frank A. Rainwater, Executive Director

Revenue and Fiscal Affairs Office

**A** **BILL**

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, BY ADDING CHAPTER 65 TO TITLE 44 TO ENACT THE “EXPERIMENTAL HEALTH CARE TREATMENT LAW” SO AS TO AUTHORIZE ACCESS TO EXPERIMENTAL TREATMENTS FOR PATIENTS WITH AN ADVANCED ILLNESS, TO ESTABLISH CONDITIONS FOR USE OF EXPERIMENTAL TREATMENTS, TO PROHIBIT PROFESSIONAL DISCIPLINE AND OTHER SANCTIONS OF HEALTH CARE PROVIDERS SOLELY FOR RECOMMENDING OR PROVIDING AN EXPERIMENTAL TREATMENT, TO CLARIFY DUTIES OF A HEALTH INSURER WITH REGARD TO EXPERIMENTAL TREATMENTS AUTHORIZED BY THIS CHAPTER, TO PROHIBIT CERTAIN ACTIONS BY STATE OFFICIALS, EMPLOYEES, AND AGENTS, TO RESTRICT CERTAIN CAUSES OF ACTION ARISING FROM THE USE OF EXPERIMENTAL TREATMENTS, AND FOR OTHER PURPOSES.

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

SECTION 1. This chapter may be cited as the “Experimental Health Care Treatment Law”.

SECTION 2. Title 44 of the 1976 Code is amended by adding:

“CHAPTER 65

Experimental Health Care Treatment

Section 44‑65‑10. As used in this chapter, and unless the context indicates otherwise:

(1) ‘Advanced illness’ means a progressive disease or medical or surgical condition which:

(a) causes significant functional impairment; and

(b) in the opinion of a treating physician, is not reversible, even with the administration of currently available FDA‑approved treatments, and which, without life‑sustaining measures, will likely result in death within six months.

(2) ‘Eligible patient’ means an individual who:

(a) has an advanced illness, attested to by the patient’s treating physician;

(b) has considered all other treatment options currently approved by the Food and Drug Administration;

(c) has received a recommendation from his treating physician for an investigational drug, biological product, or device;

(d) has given written, informed consent for the use of the investigational drug, biological product, or device; and

(e) has documentation provided by the treating physician that the individual meets the eligibility requirements of this item.

(3) ‘FDA’ or ‘Food and Drug Administration’ means the United States Food and Drug Administration.

(4) ‘Informed, written consent’ means a written document that is signed by the patient, the parent or legal guardian of the patient if the patient is a minor, an individual appointed by the probate court pursuant to Title 62 to serve as the guardian for an incapacitated person, or a person designated to make health care decisions for the patient pursuant to Chapter 66, Title 44 or Chapter 77, Title 44. The written consent must be attested to by the patient’s physician and one witness and must include, at a minimum:

(a) an explanation of the currently approved products and treatments for the disease or condition from which the patient suffers;

(b) an attestation that the patient concurs with his physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient’s life;

(c) a clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use;

(d) a description of the potential best and worst outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome. The description must:

(i) address the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment; and

(ii) be based on the physician’s knowledge of the proposed treatment in conjunction with an awareness of the patient’s condition;

(e) a statement that the patient’s health plan or third party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless specifically required to do so by law or contract;

(f) a statement that the patient may no longer qualify for hospice care if the patient begins curative treatment with the investigational drug, biological product, or device and that the patient may qualify for hospice care if the treatment ends and the patient meets hospice eligibility requirements; and

(g) a statement that the patient understands that he is financially liable for all expenses of using the investigational drug, biological product, or device and that this liability extends to the patient’s estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

(5) ‘Investigational drug, biological product, or device’ means a drug, biological product, or device that has completed phase one of a FDA‑approved clinical trial successfully but has not yet been approved for general use by the Food and Drug Administration and remains under investigation as part of a FDA‑approved clinical trial.

Section 44‑65‑20. (A) A manufacturer of an investigational drug, biological product, or device may make available, and an eligible patient may request treatment by, the manufacturer’s investigational drug, biological product, or device pursuant to this chapter. This chapter does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(B) A manufacturer may:

(1) provide an investigational drug, biological product, or device to an eligible patient without receiving compensation; or

(2) require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

Section 44‑65‑30. (A) This chapter does not expand coverage an insurer must provide pursuant to Title 38.

(B) This chapter does not require:

(1) a governmental agency to pay costs associated with the use, care, or treatment of a patient with an investigational drug, biological product, or device; or

(2) a hospital or other health care facility licensed pursuant to Chapter 7, Title 44 to provide new or additional services, unless approved or required by the hospital or facility.

(C) A health plan, third party administrator, or governmental agency is not required to, but may, provide coverage for the cost of an investigational drug, biological product, or device, or the cost of services related to the use of an investigational drug, biological product, or device under this chapter.

Section 44‑65‑40. If a patient dies while being treated with an investigational drug, biological product, or device, the patient’s heirs are not liable for any outstanding debt related to the treatment or the lack of insurance for the treatment.

Section 44‑65‑50. A licensing board or disciplinary subcommittee must not revoke, fail to renew, suspend, or take any action against a health care provider’s license or other certification issued pursuant to state law, based solely on the health care provider’s recommendations to an eligible patient about access to or treatment with an investigational drug, biological product, or device. An entity responsible for Medicare certification must not take action against a health care provider’s Medicare certification based solely on the health care provider’s recommendation that a patient have access to an investigational drug, biological product, or device.

Section 44‑65‑60. An official, employee, or agent of this State must not deny, or attempt to deny, an eligible patient access to an investigational drug, biological product, or device. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

Section 44‑65‑70. (A) This chapter does not create a private cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person or entity providing care to an eligible patient using the investigational drug, biological product, or device for any injury, illness, or other damage to the eligible patient resulting from the investigational drug, biological product, or device, if the manufacturer or other person or entity is complying in good faith with the terms of this chapter and has exercised reasonable care.

(B) This chapter does not affect any mandatory health care coverage for participation in clinical trials under Title 38.”

SECTION 3. This act takes effect upon approval by the Governor.

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