SENATE AMENDMENTS

2nd Printing

By: Kacal, King of Hemphill, Rodriguez of Travis, Parker, Davis of Harris, et al. H.B. No. 21

A BILL TO BE ENTITLED

AN ACT

relating to authorizing patients with certain terminal illnesses to access certain investigational drugs, biological products, and devices that are in clinical trials.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. (a) This Act shall be known as the Right To Try Act.

(b) The legislature finds that:

(1) the process for the approval of investigational drugs, biological products, and devices in the United States takes many years;

(2) patients with a terminal illness do not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the United States Food and Drug Administration;

(3) the standards of the United States Food and Drug Administration for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-saving treatments to patients with a terminal illness;

(4) patients with a terminal illness have a fundamental right to attempt to pursue the preservation of their own lives by accessing available investigational drugs, biological products, and devices;

(5) the use of available investigational drugs, biological products, and devices is a decision that should be made

by the patient with a terminal illness in consultation with the patient's physician and is not a decision to be made by the government; and

(6) the decision to use an investigational drug, biological product, or device should be made with full awareness of the potential risks, benefits, and consequences to the patient with a terminal illness and the patient's family.

(c) It is the intent of the legislature to allow for patients with a terminal illness to use potentially life-saving investigational drugs, biological products, and devices.

SECTION 2. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 489 to read as follows:

CHAPTER 489. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS WITH TERMINAL ILLNESSES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 489.001. DEFINITIONS. In this chapter:

(1) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in the clinical trial.

(2) "Terminal illness" means an advanced stage of a disease with an unfavorable prognosis that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR PATIENTS WITH TERMINAL ILLNESSES

Sec. 489.051. PATIENT ELIGIBILITY. A patient is eligible to access and use an investigational drug, biological product, or device under this chapter if:

(1) the patient has a terminal illness, attested to by the patient's treating physician; and

(2) the patient's physician:

(A) in consultation with the patient, has considered all other treatment options currently approved by the United States Food and Drug Administration and determined that those treatment options are unavailable or unlikely to prolong the patient's life; and

(B) has recommended or prescribed in writing that the patient use a specific class of investigational drug, biological product, or device.

Sec. 489.052. INFORMED CONSENT. (a) Before receiving an investigational drug, biological product, or device, an eligible patient must sign a written informed consent described by this section that is attested to by the patient's physician and a witness.

(b) If the patient is a minor or lacks the mental capacity to provide informed consent, a parent, guardian, or conservator may provide informed consent on the patient's behalf.

(c) The executive commissioner of the Health and Human Services Commission, in collaboration with the Texas Medical Board, by rule shall adopt a form for the informed consent required under

this section.

Sec. 489.053. PROVISION OF INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER. (a) A manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients in accordance with this chapter if the patient provides to the manufacturer the informed consent required under Section 489.052.

(b) This chapter does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(c) 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.

Sec. 489.054. NO CAUSE OF ACTION CREATED. This chapter does not create a private or state cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device for any harm done to the eligible patient resulting from the investigational drug, biological product, or device.

Sec. 489.055. STATE MAY NOT INTERFERE WITH ACCESS TO

INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official, employee, or agent of this state may not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device under this chapter.

Sec. 489.056. CORRECTIONAL MANAGED CARE. A person covered by the correctional managed health care plan under Subchapter E, Chapter 501, Government Code, is an eligible patient for purposes of this chapter only to the extent that the correctional managed health care Offender Health Services Plan and federal law governing offender participation in biomedical research permit the offender's access to and use of the investigational drug, biological product, or device.

SUBCHAPTER C. HEALTH INSURANCE

Sec. 489.101. HEALTH BENEFIT PLANS. A health benefit plan may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device.

Sec. 489.102. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL TRIAL ENROLLEES. This chapter does not affect the coverage of enrollees in clinical trials under Chapter 1379, Insurance Code.

SUBCHAPTER D. PHYSICIANS

Sec. 489.151. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED. Notwithstanding any other law, the Texas Medical Board may not revoke, fail to renew, suspend, or take any action against a physician's license under Subchapter B, Chapter 164, Occupations Code, based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device, provided that

the care provided or recommendations made to the patient meet the standard of care and the requirements of this chapter.

SECTION 3. The executive commissioner of the Health and Human Services Commission by rule shall adopt the form for informed consent as required by Section 489.052(c), Health and Safety Code, as added by this Act, not later than the 30th day after the effective date of this Act.

SECTION 4. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2015.

ADOPTED

MAY 22 2015

Secretary of the Senate

By: Paul Bettencourt H.B. No. 21

Substitute the following for H.B. No. 21:

By: C. C. Schwertner C.S.H.B. No. 21

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(3) the standards of the United States Food and Drug Administration for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-saving treatments to terminally ill patients;

(4) patients with a terminal illness have a fundamental right to attempt to pursue the preservation of their own lives by accessing available investigational drugs, biological products, and devices;

(5) the use of available investigational drugs,

biological products, and devices is a decision that should be made by the patient with a terminal illness in consultation with the patient's physician to pursue the preservation of the patient's own life and is not a decision to be made by the government; and

(6) the decision to use an investigational drug, biological product, or device should be made with full awareness of the potential risks, benefits, and consequences to the patient with a terminal illness and the patient's family.

(c) It is the intent of the legislature to allow for patients with a terminal illness to use potentially life-saving investigational drugs, biological products, and devices.

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(2) "Terminal illness" means an advanced stage of a disease with an unfavorable prognosis that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

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(1) the patient has a terminal illness, attested to by the patient's treating physician; and

(2) the patient's physician:

(A) in consultation with the patient, has considered all other treatment options currently approved by the United States Food and Drug Administration and determined that those treatment options are unavailable or unlikely to prolong the patient's life; and

(B) has recommended or prescribed in writing that the patient use a specific class of investigational drug, biological product, or device.

Sec. 489.052. INFORMED CONSENT. (a) Before receiving an investigational drug, biological product, or device, an eligible patient must sign a written informed consent. If the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian may provide informed consent on the patient's behalf.

(b) The executive commissioner of the Health and Human Services Commission by rule may adopt a form for the informed consent under this section.

Sec. 489.053. PROVISION OF INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE BY MANUFACTURER. (a) A manufacturer

of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients in accordance with this chapter if the patient provides to the manufacturer the informed consent required under Section 489.052.

(b) This chapter does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(c) If a manufacturer makes available an investigational drug, biological product, or device to an eligible patient under this subchapter, the manufacturer must provide the investigational drug, biological product, or device to the eligible patient without receiving compensation.

Sec. 489.054. NO CAUSE OF ACTION CREATED. This chapter does not create a private or state cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device for any harm done to the eligible patient resulting from the investigational drug, biological product, or device.

Sec. 489.055. STATE MAY NOT INTERFERE WITH ACCESS TO INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official, employee, or agent of this state may not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device under this chapter.

SUBCHAPTER C. HEALTH INSURANCE

Sec. 489.101. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL TRIAL ENROLLEES. This chapter does not affect the coverage of enrollees in clinical trials under Chapter 1379, Insurance Code.

SUBCHAPTER D. PHYSICIANS

Sec. 489.151. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED. Notwithstanding any other law, the Texas Medical Board may not revoke, fail to renew, suspend, or take any action against a physician's license under Subchapter B, Chapter 164, Occupations Code, based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device, provided that the recommendations made to the patient meet the medical standard of care.

SECTION 3. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2015.

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION

May 22, 2015

TO: Honorable Joe Straus, Speaker of the House, House of Representatives

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: **HB21** by Kacal (Relating to authorizing patients with certain terminal illnesses to access certain investigational drugs, biological products, and devices that are in clinical trials.), **As Passed 2nd House**

No significant fiscal implication to the State is anticipated.

The bill would amend the Health and Safety Code to allow eligible patients access to investigational drugs, biological products, or devices if certain conditions are met. The bill would authorize certain actions by manufacturers and physicians to ensure access to such products. It is anticipated that the duties and responsibilities of implementing agencies would be accomplished through existing resources.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 323 Teacher Retirement System, 327 Employees Retirement System, 454 Department of Insurance, 529 Health and Human Services Commission

LBB Staff: UP, SD, ADe, ER, NB, WP, VJC, EMo, PFe

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION

May 20, 2015

TO: Honorable Charles Schwertner, Chair, Senate Committee on Health & Human Services

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: **HB21** by Kacal (Relating to authorizing patients with certain terminal illnesses to access certain investigational drugs, biological products, and devices that are in clinical trials.), **Committee Report 2nd House, Substituted**

No significant fiscal implication to the State is anticipated.

The bill would amend the Health and Safety Code to allow eligible patients access to investigational drugs, biological products, or devices if certain conditions are met. The bill would authorize certain actions by manufacturers and physicians to ensure access to such products. It is anticipated that the duties and responsibilities of implementing agencies would be accomplished through existing resources.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 323 Teacher Retirement System, 327 Employees Retirement System, 454 Department of Insurance, 529 Health and Human Services Commission

LBB Staff: UP, ADe, ER, NB, WP, VJC, EMo, PFe

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION

May 15, 2015

TO: Honorable Charles Schwertner, Chair, Senate Committee on Health & Human Services

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: **HB21** by Kacal (Relating to authorizing patients with certain terminal illnesses to access certain investigational drugs, biological products, and devices that are in clinical trials.), **As Engrossed**

No significant fiscal implication to the State is anticipated.

The bill would amend the Health and Safety Code to allow eligible patients access to investigational drugs, biological products, or devices if certain conditions are met. The bill would authorize certain actions by manufacturers, health insurers, and physicians to ensure access to such products. It is anticipated that the duties and responsibilities of implementing agencies would be accomplished through existing resources.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 696 Department of Criminal Justice, 323 Teacher Retirement System, 327 Employees Retirement System, 454 Department of Insurance, 529 Health and Human Services Commission

LBB Staff: UP, ADe, ER, NB, WP, VJC, EMo, PFe

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION

April 9, 2015

TO: Honorable Myra Crownover, Chair, House Committee on Public Health

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: **HB21** by Kacal (relating to authorizing patients with certain terminal illnesses to access certain investigational drugs, biological products, and devices that are in clinical trials.), **Committee Report 1st House, Substituted**

No significant fiscal implication to the State is anticipated.

The bill would amend the Health and Safety Code to allow eligible patients access to investigational drugs, biological products, or devices if certain conditions are met. The bill would authorize certain actions by manufacturers, health insurers, and physicians to ensure access to such products. It is anticipated that the duties and responsibilities of implementing agencies would be accomplished through existing resources.

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No fiscal implication to units of local government is anticipated.

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LBB Staff: UP, ADe, ER, NB, WP, VJC, EMo, PFe

LEGISLATIVE BUDGET BOARD
Austin, Texas

FISCAL NOTE, 84TH LEGISLATIVE REGULAR SESSION

March 21, 2015

TO: Honorable Myra Crownover, Chair, House Committee on Public Health

FROM: Ursula Parks, Director, Legislative Budget Board

IN RE: **HB21** by Kacal (Relating to authorizing patients with certain terminal illnesses to access certain investigational drugs, biological products, and devices that are in clinical trials.), **As Introduced**

No significant fiscal implication to the State is anticipated.

The bill would amend the Health and Safety Code to allow eligible patients access to investigational drugs, biological products, or devices if certain conditions are met. The bill would authorize certain actions by manufacturers, health insurers, and physicians to ensure access to such products. It is anticipated that the duties and responsibilities of implementing agencies would be accomplished through existing resources.

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