

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

1 AN ACT

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

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

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

8 (b) The legislature finds that:

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

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

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

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

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

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

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

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

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

13 CHAPTER 489. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS

14 WITH TERMINAL ILLNESSES

15 SUBCHAPTER A. GENERAL PROVISIONS

16 Sec. 489.001. DEFINITIONS. In this chapter:

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

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

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

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

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

8 (2) the patient's physician:

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

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

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

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

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

1 this section.

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

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

12 (c) A manufacturer may:

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

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

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

27 Sec. 489.055. STATE MAY NOT INTERFERE WITH ACCESS TO

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

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

13 SUBCHAPTER C. HEALTH INSURANCE

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

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

20 SUBCHAPTER D. PHYSICIANS

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

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

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

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

ADOPTED

MAY 22 2015

Hatley Draw
Secretary of the Senate

By: *Paul Bellarosa*

H.B. No. 21

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

By: *C. Schwab*

C.S.H.B. No. 21

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11 many years;

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13 luxury of waiting until an investigational drug, biological
14 product, or device receives final approval from the United States
15 Food and Drug Administration;

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

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

24 (5) the use of available investigational drugs,

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

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

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

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13 amended by adding Chapter 489 to read as follows:

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22 Administration and remains under investigation in the clinical
23 trial.

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25 disease with an unfavorable prognosis that, without
26 life-sustaining procedures, will soon result in death or a state of
27 permanent unconsciousness from which recovery is unlikely.

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8 (2) the patient's physician:

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

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

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

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

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

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

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

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

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

22 Sec. 489.055. STATE MAY NOT INTERFERE WITH ACCESS TO
23 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official,
24 employee, or agent of this state may not block or attempt to block
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26 product, or device under this chapter.

1 SUBCHAPTER C. HEALTH INSURANCE

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

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10 Code, based solely on the physician's recommendations to an
11 eligible patient regarding access to or treatment with an
12 investigational drug, biological product, or device, provided that
13 the recommendations made to the patient meet the medical standard
14 of care.

15 SECTION 3. This Act takes effect immediately if it receives
16 a vote of two-thirds of all the members elected to each house, as
17 provided by Section 39, Article III, Texas Constitution. If this
18 Act does not receive the vote necessary for immediate effect, this
19 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.

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

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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No fiscal implication to units of local government is anticipated.

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