

**HOUSE BILL No. 2022**

By Representative Kiegerl

1-10

1 AN ACT concerning health and healthcare; enacting the Kansas right to  
2 try act.

3  
4 *Be it enacted by the Legislature of the State of Kansas:*

5 Section 1. The provisions of sections 1 through 7, and amendments  
6 thereto, shall be known and may be cited as the Kansas right to try act.

7 Sec. 2. (a) The legislature hereby finds and declares that:

8 (1) The process of approval for investigational drugs, biological  
9 products and devices in the United States protects future patients from  
10 premature, ineffective and unsafe medications and treatments over the long  
11 run, but the process often takes many years;

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

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

18 (4) the use of available investigational drugs, biological products and  
19 devices is a decision that should be made by the patient with a terminal  
20 illness in consultation with the patient's healthcare provider and the  
21 patient's healthcare team, if applicable; and

22 (5) the decision to use an investigational drug, biological product or  
23 device should be made with full awareness of the potential risks, benefits  
24 and consequences to the patient and the patient's family.

25 (b) It is the intent of the legislature to allow for terminally ill patients  
26 to use potentially life-saving investigational drugs, biological products and  
27 devices.

28 Sec. 3. As used in sections 1 through 7, and amendments thereto,  
29 unless the context requires otherwise:

30 (a) (1) "Eligible patient" means a person who has:

31 (A) A terminal illness, attested to by the patient's treating physician;

32 (B) carefully considered all other treatment options approved by the  
33 United States food and drug administration;

34 (C) been unable to participate in a clinical trial for the terminal illness  
35 within 100 miles of the patient's home address, or has not been accepted to  
36 the clinical trial within one week of completion of the clinical trial

1 application process;

2 (D) received a recommendation from such patient's treating physician  
3 for an investigational drug, biological product or device;

4 (E) given written, informed consent for the use of the investigational  
5 drug, biological product or device, or, if the patient is a minor or lacks the  
6 mental capacity to provide informed consent, a parent or legal guardian  
7 has given written, informed consent on the patient's behalf; and

8 (F) documentation from such patient's treating physician that such  
9 patient meets the requirements of this paragraph.

10 (2) "Eligible patient" does not include a person being treated as an  
11 inpatient in any hospital or recuperation center, as those terms are defined  
12 in K.S.A. 65-425, and amendments thereto.

13 (b) "Investigational drug, biological product or device" means a drug,  
14 biological product or device that has successfully completed phase one of  
15 a clinical trial but has not yet been approved for general use by the United  
16 States food and drug administration and remains under investigation in a  
17 clinical trial approved by the United States food and drug administration.

18 (c) "Terminal illness" means a condition that, without life-sustaining  
19 procedures, will result in death or a state of permanent unconsciousness  
20 from which recovery is unlikely.

21 (d) "Written, informed consent" means a written document signed by  
22 the patient and attested to by the patient's treating physician and a witness  
23 that, at a minimum:

24 (1) Explains the currently approved products and treatments for the  
25 disease or condition from which the patient suffers;

26 (2) attests to the fact that the patient concurs with the patient's  
27 treating physician in believing that all currently approved and  
28 conventionally recognized treatments are unlikely to prolong the patient's  
29 life;

30 (3) clearly identifies the specific proposed investigational drug,  
31 biological product or device that the patient is seeking to use;

32 (4) describes the potentially best and worst outcomes of using the  
33 investigational drug, biological product or device with a realistic  
34 description of the most likely outcome, including the possibility that new,  
35 unanticipated, different or worse symptoms might result, and that death  
36 could be hastened by the proposed treatment, based on the physician's  
37 knowledge of the proposed treatment in conjunction with an awareness of  
38 the patient's condition;

39 (5) makes clear that the patient's health insurer and provider are not  
40 obligated to pay for any care or treatments consequent to the use of the  
41 investigational drug, biological product or device;

42 (6) makes clear that the patient's eligibility for hospice care may be  
43 withdrawn if the patient begins curative treatment, and care may be

1 reinstated if the curative treatment ends and the patient meets hospice  
2 eligibility requirements;

3 (7) makes clear that in-home healthcare may be denied if treatment  
4 begins; and

5 (8) states that the patient understands that the patient is liable for all  
6 expenses consequent to the use of the investigational drug, biological  
7 product or device, and that this liability extends to the patient's estate,  
8 unless a contract between the patient and the manufacturer of the  
9 investigational drug, biological product or device states otherwise.

10 (e) "Physician" means a person licensed to practice medicine and  
11 surgery by the board of healing arts.

12 Sec. 4. (a) A manufacturer of an investigational drug, biological  
13 product or device may make available the manufacturer's investigational  
14 drug, biological product or device to eligible patients pursuant to sections  
15 1 through 7, and amendments thereto. Nothing in sections 1 through 7, and  
16 amendments thereto, shall be construed to require that a manufacturer  
17 make available an investigational drug, biological product or device to an  
18 eligible patient.

19 (b) (1) A health insurance carrier may, but shall not be required to,  
20 provide coverage for the cost of an investigational drug, biological product  
21 or device.

22 (2) An insurer may deny coverage to an eligible patient from the time  
23 the eligible patient begins use of the investigational drug, biological  
24 product or device through a period not to exceed six months from the time  
25 the investigational drug, biological product or device is no longer used by  
26 the eligible patient, except coverage may not be denied for a pre-existing  
27 condition and for coverage for benefits which commenced prior to the time  
28 the eligible patient begins use of such investigational drug, biological  
29 product or device.

30 (c) If a patient dies while being treated with an investigational drug,  
31 biological product or device, the patient's heirs shall not be liable for any  
32 outstanding debt related to such treatment or lack of insurance due to such  
33 treatment.

34 Sec. 5. (a) No physician, who, in good faith, recommends or  
35 participates in the use of an investigational drug, biological product or  
36 device pursuant to sections 1 through 7, and amendments thereto, shall be  
37 subject to any criminal or civil liability, nor shall such physician be found  
38 to have committed an act of unprofessional conduct pursuant to K.S.A. 65-  
39 2837, and amendments thereto.

40 (b) Notwithstanding any other law to the contrary, the board of  
41 healing arts shall not revoke, suspend or otherwise take any action against  
42 any individual holding a license issued pursuant to the Kansas healing arts  
43 act, K.S.A. 65-2801 et seq., and amendments thereto, based solely on such

1 provider's recommendations to an eligible patient regarding access to or  
2 treatment with an investigational drug, biological product or device. Any  
3 action against an individual or entity's medicare certification based solely  
4 on recommendations that a patient have access to an investigational drug,  
5 biological product or device is prohibited.

6 Sec. 6. No state officer, employee or agent thereof shall block or  
7 attempt to block an eligible patient's access to an investigational drug,  
8 biological product or device. Counseling, advice or a recommendation  
9 from a licensed healthcare provider is not a violation of this section.

10 Sec. 7. Nothing in sections 1 through 7, and amendments thereto,  
11 shall be construed as creating a private cause of action against a  
12 manufacturer of an investigational drug, biological product or device, or  
13 against any other person or entity involved in the care of an eligible patient  
14 using an investigational drug, biological product or device for any injury  
15 suffered by the eligible patient resulting from the investigational drug,  
16 biological product or device, so long as the manufacturer or other person  
17 or entity acted in accordance with the provisions of sections 1 through 7,  
18 and amendments thereto.

19 Sec. 8. This act shall take effect and be in force from and after its  
20 publication in the statute book.