

SENATE BILL No. 250

By Committee on Public Health and Welfare

2-7

AN ACT concerning health and healthcare; relating to treatments for life-threatening illnesses; enacting the right to try for individualized treatments act to permit certain manufacturers to make individualized investigative treatments available to eligible requesting patients.

Be it enacted by the Legislature of the State of Kansas:

Section 1. (a) As used in this act, unless the context otherwise requires:

(1) "Eligible patient" means an individual who has:

(A) A life-threatening or severely debilitating illness, attested to by the patient's treating physician;

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

(C) received a recommendation from the patient's physician for an individualized investigational treatment, based on analysis of the patient's genomic sequence, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products, such as enzymes and other types of proteins, or metabolites;

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

(E) documentation from the patient's physician that such patient meets the requirements of this act.

(2) "Individualized investigational treatment" means drugs, biological products or devices that are unique to and produced exclusively for use on an individual patient, based on the patient's own genetic profile. "Individualized investigational treatment" includes, but is not limited to, individualized gene therapy antisense oligonucleotides (ASO) and individualized neoantigen vaccines.

(3) "Life-threatening or severely debilitating illness" means the same as currently defined in 21 C.F.R. § 312.81.

(4) "Physician" means an individual licensed by the state board of healing arts to practice medicine and surgery.

(5) "Written, informed consent" means a written document that is signed by the patient, a parent if the patient is a minor, the legal guardian or authorized representative as defined in K.S.A. 65-6836, and amendments thereto, and attested to by the patient's physician and a

1 witness, that includes all of the following:

2 (A) An explanation of the currently approved products and treatments
3 for the disease or condition from which the patient suffers;

4 (B) an attestation that the patient concurs with such patient's
5 physician that all currently approved and conventionally recognized
6 treatments are unlikely to prolong the patient's life;

7 (C) clear identification of the specific proposed individualized
8 investigational drug, biological product or device that the patient is
9 seeking to use;

10 (D) a description of the potentially best and worst outcomes of using
11 the individualized investigational drug, biological product or device and a
12 realistic description of the most likely outcome. The description shall
13 include the possibility that new, unanticipated, different or worse
14 symptoms might result and that death could be hastened by the proposed
15 treatment. Such description shall be based on the physician's knowledge of
16 the proposed treatment in conjunction with an awareness of the patient's
17 condition;

18 (E) a statement that the patient's health plan or third party
19 administrator and provider are not obligated to pay for any care or
20 treatments as a result of the use of the individualized investigational drug,
21 biological product or device, unless such provider is specifically required
22 to do so by law or contract;

23 (F) a statement that the patient's eligibility for hospice care may be
24 withdrawn if the patient begins curative treatment with the individualized
25 investigational drug, biological product or device and that such care may
26 be reinstated if such treatment ends and the patient meets hospice
27 eligibility requirements; and

28 (G) a statement that the patient understands that such patient is liable
29 for all expenses related to the use of the individualized investigational
30 drug, biological product or device and that this liability extends to the
31 patient's estate, unless a contract between the patient and the manufacturer
32 of the drug, biological product or device states otherwise.

33 (6) "Eligible facility" means an institution that is operating under a
34 federalwide assurance for the protection of human subjects under 42
35 U.S.C. § 289(a) and 45 C.F.R. part 46 and the "eligible facility" is subject
36 to the federalwide assurance laws, regulations, policies and guidelines
37 including renewals or updates.

38 (b) (1) A manufacturer operating within an eligible facility, pursuant
39 to all applicable federalwide assurance laws and regulations, may make
40 available an individualized investigative treatment and an eligible patient
41 may request an individualized investigational drug, biological product or
42 device from an eligible facility or manufacturer operating within an
43 eligible facility under this act. This act does not require that a

1 manufacturer make available an individualized investigational drug,
2 biological product or device to an eligible patient.

3 (2) An eligible facility or manufacturer operating within an eligible
4 facility may:

5 (A) Provide an individualized investigational drug, biological product
6 or device to an eligible patient without receiving compensation; or

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

10 (c) This act shall not expand the coverage required of an insurer
11 under the insurance code of the state of Kansas.

12 (d) A health plan, third party administrator or governmental agency
13 may provide coverage for the cost of an individualized investigational
14 drug, biological product or device or the cost of services related to the use
15 of an individualized investigational drug, biological product or device
16 under this act, except that, this act shall not require:

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

20 (2) a hospital or facility licensed under article 4 of chapter 65 of the
21 Kansas Statutes Annotated, and amendments thereto, to provide new or
22 additional services unless approved by the hospital or facility.

23 (e) If a patient dies while being treated by an individualized
24 investigational drug, biological product or device, the patient's heirs shall
25 not be liable for any outstanding debt related to the treatment or lack of
26 insurance due to the treatment.

27 (f) (1) A licensing board shall not revoke, fail to renew, suspend or
28 take any disciplinary action against a healthcare provider's license issued
29 under chapter 65 of the Kansas Statutes Annotated, and amendments
30 thereto, based solely on the healthcare provider's recommendations to an
31 eligible patient regarding access to or treatment with an individualized
32 investigational drug, biological product or device.

33 (2) Counseling, advice or a recommendation consistent with medical
34 standards of care from a licensed healthcare provider shall not be a
35 violation of this act.

36 (g) An entity responsible for medicare certification shall not take
37 action against a healthcare provider's medicare certification based solely
38 on the healthcare provider's recommendation that a patient have access to
39 an individualized investigational drug, biological product or device.

40 (h) An official, employee, or agent of this state shall not block or
41 attempt to block an eligible patient's access to an individualized
42 investigational drug, biological product or device.

43 (i) This act shall not create a private cause of action against a

1 manufacturer of an individualized investigational drug, biological product
2 or device or against any other person or entity involved in the care of an
3 eligible patient using the individualized investigational drug, biological
4 product or device for any harm done to the eligible patient resulting from
5 the individualized investigational drug, biological product or device if the
6 manufacturer or other person or entity is complying in good faith with the
7 terms of this act and has exercised reasonable care.

8 (j) This act shall not affect any mandatory healthcare coverage for
9 participation in clinical trials under the insurance code of the state of
10 Kansas.

11 (k) This section shall be known and may be cited as the right to try
12 for individualized treatments act.

13 Sec. 2. This act shall take effect and be in force from and after its
14 publication in the statute book.