SENATE BILL No. 250

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) "Biospecimen" means biological materials obtained from living or deceased human subjects.

(2) "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.

(3) "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.

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

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

(6) "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 witness who is unaffiliated with such patient's physician or the physician's place of business and that includes all of the following:

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

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

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

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

(E) a statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the

individualized investigational drug, biological product or device and that such care may be reinstated if such treatment ends and the patient meets hospice eligibility requirements; and

(F) a statement that the patient understands that such patient is liable for all expenses related to the use of the individualized 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.

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

(b) (1) If a patient's biospecimen is used or requested for use by an eligible facility for a purpose other than the individualized investigative treatment of such patient, the patient or the patient's estate shall be notified of the intended use and asked to consent to such intended use of such biospecimen.

(2) Prior to a profit being realized on any product developed from a patient's biospecimen, an eligible facility shall disclose to the patient or the patient's estate each potential commercial application. The patient or the patient's estate must consent to each commercial application of the patient's biospecimen, which shall include a profit-sharing agreement or other contractual obligations benefiting the patient or such patient's estate for the commercial application of such patient's biospecimen.

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

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

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

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

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

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

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

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

(f) If a patient dies while being treated by an individualized investigational drug, biological product or device, the patient's heirs shall not be liable for any outstanding debt related to the treatment or

lack of insurance due to the treatment, except that, a patient's estate may be held liable for any outstanding debt related to the treatment or lack of insurance due to such treatment.

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

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

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

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

(j) This act shall not create a private cause of action against a manufacturer of an individualized investigational drug, biological product or device or against any other person or entity involved in the care of an eligible patient using the individualized investigational drug, biological product or device for any harm done to the eligible patient resulting from the individualized investigational drug, biological product or device if the manufacturer or other person or entity is complying in good faith with the terms of this act and has exercised reasonable care.

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

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

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

I hereby certify that the above BILL originated in the SENATE, and passed that body

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SENATE adopted
Conference Committee Report _____

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President of the Senate.

_____
Secretary of the Senate.

Passed the HOUSE
as amended _____

HOUSE adopted
Conference Committee Report _____

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Speaker of the House.

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Chief Clerk of the House.

APPROVED _____

_____
Governor.