## Right to Try for Individualized Treatments Act; SB 250

**SB 250** creates the Right to Try for Individualized Treatments Act (Act). The bill authorizes a manufacturer operating in an eligible facility to make available individualized investigative treatments and allows individuals with life-threatening or severely debilitating illnesses to request an individualized investigational drug, biologic product, or device (investigational treatment product) from such manufacturers. The bill defines terms used in the Act; defines and establishes a procedure for use of a patient's biospecimen; addresses requirements for informed consent for investigational treatments, manufacturer requirements, and liability exemptions; and clarifies insurance and health coverage pursuant to the Act. The bill also makes conforming amendments.

### *Definitions*

The bill defines several terms applicable to the Act:

- "Biospecimen" means biological materials obtained from living or deceased human subjects;

- "Eligible patient" means an individual who has:

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

    - Considered all other treatment options currently approved by the U.S. Food and Drug Administration;

    - 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 (DNA); ribonucleic acid (RNA); genes; gene products, such as enzymes and other types of proteins; or metabolites;

    - Given written, informed consent for the use of the investigational treatment product; and

    - Documentation from the patient's physician that such patient meets the requirements of the Act;

- "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. The term includes, but is not limited to, individualized gene therapy antisense oligonucleotides (ASO), and individualized neoantigen vaccines;

- "Life-threatening or severely debilitating illness" has the meaning as contained in federal law. [*Note:* 21 CFR § 312.81 defines "life-threatening" to mean diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and with potentially fatal outcomes, where the end point of

clinical trial analysis is survival. "Severely debilitating" means diseases or conditions that cause major irreversible morbidity.];

- "Physician" means an individual licensed by the State Board of Healing Arts to practice medicine and surgery;

- "Written, informed consent" (consent) means a written document that is signed by a patient, a parent if the patient is a minor, the legal guardian or authorized representative (defined in KSA 65-6836 to mean the person designated in writing by the patient to obtain the health care records of the patient or the person otherwise authorized by law to obtain the health care records of the patient), and attested to by the patient's physician and a witness who is unaffiliated with the patient's physician or the physician's place of business, that includes specific consent document requirements detailed below; and

- "Eligible facility" means an institution that is operating under a federal-wide assurance for the protection of human subjects under federal law and that is subject to the federal-wide assurance laws, regulations, policies, and guidelines, including renewals and updates.

***Consent Document Requirements***

The bill requires written, informed consent to include the following:

- An explanation of the currently approved products and treatments for the patient's disease or condition;

- Clear identification of the specific proposed investigational treatment product the patient is seeking to use;

- A description of potential best and worst outcomes of using the investigational treatment product and a realistic description of the most likely outcome. The bill requires the description to:

    - Include the possibility that new, unanticipated, different, or worse symptoms might result and death could be hastened by the proposed treatment; and

    - Be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

- A statement that the patient's health plan or third-party administrator is not required to pay for any care or treatment as a result of the use of the investigational treatment product, unless such provider is required to do so by law or contract;

- A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with an investigational treatment product, and

that such care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements; and

- A statement that the patient understands the patient is liable for all expenses related to the use of the investigational treatment product and the liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational treatment states otherwise.

### *Eligible Facilities or Manufacturers Operating within an Eligible Facility*

*Use of Patient's Biospecimen*

The bill requires notification to the patient or the patient's estate and their consent to such intended use if the patient's biospecimen will be used or has been requested to be used by an eligible facility for a purpose other than the individualized investigative treatment of the patient.

The bill requires that an eligible facility disclose to a patient or a patient's estate each potential commercial application on any product developed from a patient's biospecimen prior to a profit being realized. The bill requires the patient or patient's estate to consent to each commercial application of the patient's biospecimen, including profit sharing or other contractual obligations.

*Availability of Investigational Treatment or Product*

The bill authorizes a manufacturer operating within an eligible facility, according to all applicable federal-wide assurance laws and regulations, to make available an individualized investigative treatment, and allows an eligible patient to request an investigative treatment product from an eligible facility or manufacturer operating within an eligible facility under this Act. The Act does not require a manufacturer to make an investigational treatment product available to an eligible patient.

The bill provides that an eligible facility or a manufacturer within an eligible facility could:

- Provide an investigational treatment product to an eligible patient without receiving compensation; or

- Require an eligible patient to pay the costs of, or costs associated with the manufacture of, the investigational treatment product.

### *Insurance Coverage and Payment of Costs*

The bill does not expand the coverage required of an insurer under the Insurance Code of the State of Kansas (Insurance Code).

The bill provides that a health plan, third-party administrator, or governmental agency could provide coverage for the cost of an investigative treatment product or the cost of services related to the use of such product under the Act. However, the Act will not require:

- Any governmental agency to pay costs associated with the use, care, or treatment of a patient with an investigational treatment product; or

- A hospital or facility licensed under Article 4 of Chapter 65 of the *Kansas Statutes Annotated* to provide new or additional services unless approved by the hospital or facility. [*Note*: KSA 65-411 defines "medical facility" to include public health centers; psychiatric hospitals; health maintenance organizations as defined in KSA 40-3202; medical care facilities as defined in KSA 65-425; adult care homes, which are limited to nursing facilities and intermediate personal care homes as these terms are defined in KSA 39-923; kidney disease treatment centers, including centers not located in a medical care facility; and other facilities as may be designated by the Secretary of Health, Education, and Welfare for the provision of health care. {*Note:* The U.S. Department of Health, Education and Welfare was divided into the Department of Health and Human Services and the Department of Education in 1979-1980.} KSA 65-424a defines "medical facilities" as diagnostic and treatment centers, rehabilitation facilities and nursing homes as those terms are defined in Title VI of the U.S. Public Health Service Act, and such other medical facilities for which aid may be authorized under such federal act.]

*Liability of Patient's Heirs*

The bill provides, if a patient dies while being treated by an investigational treatment product, the patient's heirs would 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.

### *Disciplinary Action Against Health Care Provider Licensure or Certification*

The bill prohibits a licensing board from revoking, failing to renew, suspending, or taking any disciplinary action against a health care provider's license issued under Kansas Public Health statutes (Chapter 65 of *Kansas Statutes Annotated*) based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational treatment product.

The bill states that counseling, advice, or recommendations consistent with medical standards of care from a licensed health care provider would not be a violation of the Act.

The bill prohibits an entity responsible for Medicare certification from taking action against a health care provider's Medicare certification based solely on such provider's recommendation that a patient have access to investigational treatment products.

### *Blocking Access to Investigational Treatment Products Prohibited*

The bill prohibits an official, employee, or agent of the State from blocking or attempting to block an eligible patient's access to investigational treatment products.

### *Private Cause of Action Prohibited*

The bill provides, if a manufacturer of an investigational treatment product or any other person or entity involved in the care of an eligible patient using an investigational treatment product complies in good faith with the terms of the Act and exercises reasonable care, the Act does not create a private cause of action against such manufacturer or against any other person or entity for any harm done to the eligible patient resulting from the product. However, the bill does allow for a patient's estate to be held liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

### *Participation in Clinical Trials*

The bill provides that the Act would not affect any mandatory health care coverage for participation in clinical trials under the Insurance Code.