SESSION OF 2025

CONFERENCE COMMITTEE REPORT BRIEF
SENATE BILL NO. 250

As Agreed to March 25, 2025

Brief*

SB 250 would create the Right to Try for Individualized Treatments Act (Act). The bill would authorize a manufacturer operating in an eligible facility to make available individualized investigative treatments and allow individuals with life-threatening or severely debilitating illnesses to request an individualized investigational drug, biologic product, or device from such manufacturers (referred to herein as "investigational treatment products"). The bill would define terms used in the Act; define and establish a procedure for use of a patient's biospecimen; address requirements for informed consent for investigational treatments, manufacturer requirements, and liability exemptions; and clarify insurance and health coverage pursuant to the Act. The bill would also make technical and conforming amendments.

Definitions

The bill would define several terms applicable to the Act:

- "Biospecimen" would mean biological materials obtained from living or deceased human subjects;
- "Eligible patient" would mean 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 (FDA);
    - 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

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

- "Individualized investigational treatment" would mean 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 would include, but not be limited to, individualized gene therapy antisense oligonucleotides (ASO), and individualized neoantigen vaccines;

- "Life-threatening or severely debilitating illness" would have 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" would mean an individual licensed by the State Board of Healing Arts (Board) to practice medicine and surgery;

- "Written, informed consent" (referred to herein as "consent") would mean 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" would mean 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 would require 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 description would be required 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 would require notification to the patient or the patient's estate and their consent to such intended use if the patient's biospecimen would be used or requested to be used by an eligible facility for a purpose other than the individualized investigative treatment of the patient.

The bill would require 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 would require 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 would authorize 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 an eligible patient would be allowed to request an investigative treatment product from an eligible facility or manufacturer operating within an eligible facility under this Act. The Act would not require a manufacturer to make an investigational treatment product available to an eligible patient.

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

The bill would provide 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 would 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 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. 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 would provide, 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.

Disciplinary Action Against Health Care Provider Licensure or Certification

The bill would prohibit 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) 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 would provide 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 would prohibit 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.

Access to Investigational Treatment Products Prohibited

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

Conference Committee Action

The Conference Committee agreed to the House version of the bill, and further amended the bill to define and establish a procedure for the use of a patient's biospecimen.

Background

The bill was introduced by the Senate Committee on Public Health and Welfare at the request of Senator Gossage.

Senate Committee on Public Health and Welfare

In the Senate Committee hearing, **proponent** testimony was provided by a representative of the Goldwater Institute and two private citizens. The representative of the Goldwater Institute stated the bill would create a physician-directed pathway for patients with ultra-rare, life-threatening, or debilitating illnesses for whom no treatment options are available and who could possibly benefit from an individualized treatment based on their unique genetic profile. The representative stated the Act would provide an option for treatment without requiring the current clinical trial evaluation system designed for evaluating drugs that would be used to treat large populations. The representative noted the Act is law in six states and similar legislation is being considered in numerous other states. The private citizens shared their personal experiences in seeking individualized treatment for their children with rare diseases, including the need to travel abroad for treatments not available in the United States and physicians' hesitation to prescribe a medication that was in various stages of clinical trials for off-label use.

Written-only proponent testimony was provided by representatives of Americans for Prosperity-Kansas, Destroy Duchenne, and the Myositis Association.

Written-only neutral testimony was provided by a representative of the Board of Healing Arts.

House Committee on Health and Human Services

In the House Committee hearing, a representative of the Goldwater Institute provided **proponent** testimony substantially similar to that provided in the Senate Committee.

Written-only proponent testimony was provided by a representative of Americans for Prosperity-Kansas.

Neutral testimony was provided by the Executive Director of the Board of Healing Arts (Board), who noted some concerns of the Board with the bill, highlighting the vulnerability of patients looking for hope. The Executive Director suggested amendments to clarify the witness to the patient's written, informed consent be unaffiliated with the treating physician or the physician's office; to remove the required attestation of the patient; and to clarify the patient's estate could be held liable for remaining debt were the patient to pass away during treatment.

The House Committee amended the bill to:

- Clarify that the witness to the patient's written, informed consent must be an individual who is unaffiliated with the patient's physician or the physician's place of business;
- Remove the attestation that the patient concurs with the patient's physician that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life in the definition of "written, informed consent"; and
- Clarify that a patient's estate may be held liable for any outstanding debt related to the treatment or lack of insurance due to the treatment if the patient dies during treatment.

[*Note:* The Conference Committee retained the amendments.]

Fiscal Information

According to the fiscal note prepared by the Division of the Budget on the bill, as introduced, the Board indicates enactment of the bill could lead to some actionable complaints, but the Board anticipates any resulting effect could be managed within existing resources.

Health; Right to Try for Individualized Treatment Act; treatments; life-threatening illness; severely debilitating illness; written, informed consent; eligible patient; physician; manufacturer; liability exemptions; eligible facility; State Board of Healing Arts; Insurance Code of the State of Kansas; biospecimen

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