As Introduced

136th General Assembly
Regular Session
2025-2026

S. B. No. 170

Senators Huffman, Roegner

A BILL

To enact sections 4729.891, 4731.971, 4731.972, 4731.973, 4731.975, 4731.976, 4731.977, 4731.978, 4731.979, and 4731.9710 of the Revised Code regarding individualized investigational treatments for life-threatening or severely debilitating illnesses.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 4729.891, 4731.971, 4731.972, 4731.973, 4731.975, 4731.976, 4731.977, 4731.978, 4731.979, and 4731.9710 of the Revised Code be enacted to read as follows:

Sec. 4729.891. (A) As used in this section:

(1) "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 is subject to the federalwide assurance laws, regulations, policies, and guidelines.

(2) "Eligible patient" and "individualized investigational treatment" have the same meanings as in section 4731.971 of the Revised Code.

(B) A manufacturer operating within an eligible facility and pursuant to all applicable federalwide assurance laws and regulations may make available an individualized investigational 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. Nothing in this section requires a manufacturer to make available an individualized investigational treatment to an eligible patient.

(C) An eligible facility or a manufacturer operating within an eligible facility may do both of the following:

(1) Provide an individualized investigational treatment to an eligible patient without receiving compensation;

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

Sec. 4731.971. As used in sections 4731.971 to 4731.9710 of the Revised Code:

(A) "Eligible patient" means an individual who meets all of the requirements of section 4731.972 of the Revised Code.

(B) "Health benefit plan" and "health plan issuer" have the same meanings as in section 3922.01 of the Revised Code.

(C) "Individualized investigational treatment" means a drug, biological product, or device that is unique to and produced exclusively for use by an individual patient, based on the patient's own genetic profile, including individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines.

(D) "Life-threatening or severely debilitating illness" means diseases or conditions that meet one or more of the following:

(1) The likelihood of death is high unless the course of the disease is interrupted.

(2) The outcome is potentially fatal and the end point of clinical trial analysis is survival.

(3) Cause major irreversible morbidity.

Sec. 4731.972. An individual is an eligible patient for purposes of sections 4731.971 to 4731.9710 and section 4729.891 of the Revised Code if the individual meets all of the following:

(A) The individual has a life-threatening or severely debilitating illness, as attested to by the individual's treating physician.

(B) The individual has considered all treatment options for the illness that are approved by the United States food and drug administration.

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

(D) Written, informed consent has been executed in accordance with section 4731.973 of the Revised Code for the use of the individualized investigational treatment.

(E) The individual has documentation from the individual's

treating physician that the individual meets the requirements of divisions (A) to (D) of this section.

Sec. 4731.973. (A) A treating physician may treat an eligible patient with an individualized investigational treatment after securing the patient's written, informed consent in a signed document that includes all of the provisions described in division (B) of this section. The document shall be signed by the patient's treating physician and one of the following, in the presence of a witness who must also sign the document:

(1) The patient;

(2) If the patient is a minor, the patient's parent, legal custodian, or guardian;

(3) If the patient has designated an individual as the patient's attorney in fact under a durable power of attorney for health care in accordance with section 1337.12 of the Revised Code, by the attorney in fact;

(4) If an individual has been appointed by a court to act as the patient's guardian, by the guardian.

(B) Written, informed consent shall include all of the following:

(1) An explanation of the currently approved products and treatments for the life-threatening or severely debilitating illness from which the patient suffers;

(2) Clear identification of the specific proposed individualized investigational treatment that the patient is seeking to use;

(3) A description, based on the treating physician's

knowledge of the proposed treatment in conjunction with an awareness of the patient's condition, of the potentially best and worst outcomes of using the individualized investigational treatment and a realistic description of the most likely outcome, including the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment;

(4) A statement that the patient's health plan issuer and provider are not obligated to pay for any care or treatment directly related to the use of the individualized investigational treatment, unless the entity is specifically required to do so by law or contract;

(5) A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the individualized investigational treatment and that hospice care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements;

(6) A statement that the patient understands that the patient is liable for all expenses directly related to the use of the individualized investigational treatment 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) An attestation that the patient has a life-threatening or severely debilitating illness and the physician believes that all approved and conventionally recognized products and treatments are unlikely to prolong the patient's life.

(8) An attestation that the patient, or the patient's representative, agrees with the physician's attestation under

division (B)(7) of this section.

Sec. 4731.975. (A) A health benefit plan or governmental agency may provide coverage for the cost of an individualized investigational treatment or the cost of services related to the use of an individualized investigational treatment.

(B) Nothing in section 4729.891 or sections 4731.971 to 4731.9710 of the Revised Code shall not be construed to do any of the following:

(1) Expand the coverage required under a health benefit plan;

(2) Require any governmental agency to pay costs associated with the use by an eligible patient of an individualized investigational drug, biological product, or device, including any related care or treatment of that patient;

(3) Require a hospital or facility to provide new or additional services, unless approved by the hospital or facility;

(4) Authorize a health benefit plan or governmental agency to exclude coverage for a covered person receiving an individual investigational treatment for health services that are not related to an individual investigational treatment and that are otherwise covered by the health benefit plan or governmental agency;

(5) Negate, abrogate, or in any way affect any mandatory coverage for participation in clinical trials required in sections 1739.05, 1751.01, and 3923.80 of the Revised Code.

Sec. 4731.976. If a patient dies while being treated by an individualized investigational treatment, the patient's heirs

are not liable for any outstanding debt related to the treatment or lack of coverage due to the treatment.

Sec. 4731.977. (A) The state medical board shall not limit, revoke, or suspend; refuse to grant, renew, or reinstate; or take any other action against a physician's license or certificate to practice based solely on the physician's recommendations to an eligible patient regarding an individualized investigational treatment.

(B) To the extent permitted under federal law, an entity responsible for medicare certification shall not take action against a physician's medicare certification based solely on the physician's recommendation that an eligible patient have access to an individualized investigational treatment.

Sec. 4731.978. (A) An official, employee, or agent of this state shall not prevent or attempt to prevent access by an eligible patient or eligible patient's treating physician to an individualized investigational treatment that is being provided or is to be provided in accordance with sections 4731.971 to 4731.977 and section 4729.891 of the Revised Code.

(B) Counseling, advice, or a recommendation consistent with medical standards of care from a treating physician shall not be considered a violation of this section.

Sec. 4731.979. Nothing in sections 4731.971 to 4731.978 and section 4729.891 of the Revised Code shall be construed to create a private cause of action against a manufacturer of an individualized investigational treatment or against any other person or entity involved in the care of an eligible patient using the individualized investigational treatment for any harm to the patient resulting from the individualized investigational

treatment, if the manufacturer or other person or entity has complied in good faith with sections 4731.971 to 4731.978 and section 4729.891 of the Revised Code and has exercised reasonable care.

Sec. 4731.9710. A patient who is an eligible patient under section 4731.97 and sections 4731.971 to 4731.979 of the Revised Code may elect to receive treatment in accordance with either or both section 4731.97 and sections 4731.971 to 4731.979 of the Revised Code.