OHIO LEGISLATIVE SERVICE COMMISSION

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Office of Research and Drafting

Legislative Budget Office

S.B. 170
136th General Assembly

# Bill Analysis

**Version**: As Introduced

**Primary Sponsors**: Sens. Huffman and Roegner

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## SUMMARY


- Permits a treating physician to use an individualized investigational treatment to treat an eligible patient who is suffering from a life-threatening or severely debilitating illness or disease upon obtaining the patient's written, informed consent.
- Provides immunity to a physician who recommends or treats an eligible patient with an individualized investigational treatment.
- Authorizes, but does not require, the manufacturer to provide an individualized investigational treatment to an eligible patient and provides immunity to the manufacturer.
- Allows, but does not require, health plan issuers and governmental agencies to provide coverage for the cost of individualized investigational treatments or the cost of services related to the use of individualized investigational treatments.
- Relieves a patient's heirs from liability for any outstanding debt related to treatment if a patient dies while being treated by an individualized investigational treatment.
- Prohibits a state official, employee, or agent from preventing or attempting to prevent an eligible patient or treating physician from accessing an individualized investigational treatment.


## DETAILED ANALYSIS

### Use of individualized investigational treatments

The bill allows an eligible patient who is suffering from a life-threatening or severely debilitating illness to be treated with an individualized investigational treatment. For this purpose, an "individualized investigational treatment" is 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.[1] The bill expands upon existing law that allows an eligible patient to be treated with an investigational drug, product, or device for a terminal condition and establishes new requirements that apply to patients with life-threatening or severely debilitating illnesses seeking investigational treatments that are individualized to that patient.[2]

## Eligibility for treatment

### Life-threatening or severely debilitating disease

To be eligible for an individualized investigational treatment, a patient must have a life-threatening or severely debilitating illness, as attested to by the treating physician.[3] "Life-threatening or severely debilitating illness" means diseases or conditions that meet one or more of the following:

- The likelihood of death is high unless the course of the disease is interrupted.
- The outcome is potentially fatal and the end point of clinical trial analysis is survival.
- Cause major irreversible morbidity.[4]

### Other conditions for eligibility

In addition to having a life-threatening or severely debilitating disease, to be an eligible patient, the following conditions must be met:

1. **Treatment options and risks considered** – the individual has considered all treatment options for the illness that are approved by the U.S. Food and Drug Administration;
2. **Physician recommendation** – 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 (commonly known as "DNA"), ribonucleic acid (commonly known as "RNA"), genes, gene products (such as enzymes and other types of proteins), or metabolites;
3. **Written, informed consent** for the treatment has been executed (see "**Informed consent**," below); and
4. **Physician documentation** – The individual has documentation from the individual's treating physician that the individual meets all of these requirements.[5]

[1] R.C. 4731.971(C).

[2] R.C. 4731.97, not in the bill.

[3] R.C. 4731.972(A).

[4] R.C. 4731.971(D).

[5] R.C. 4731.971(A) and 4731.972(B) to (E).

## Informed consent

To treat an eligible patient, the bill requires the treating physician to secure the patient's informed consent in a document signed by the patient or patient's representative and others. If the patient is a minor, the document must be signed by a parent, legal custodian, or guardian. If the patient has designated an individual as the patient's attorney in fact under a durable power of attorney for health care, the document must be signed by the attorney in fact. If an individual has been appointed by a court to act as the patient's guardian, the guardian must sign the document. The treating physician also must sign the document. Both parties must sign the document in the presence of a witness, who signs the document as well.[6]

The written, informed consent must include all of the following:

1. An explanation of the currently approved products and treatments for the life-threatening or severely debilitating disease 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 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 above attestation.[7]

[6] R.C. 4731.973(A).

[7] R.C. 4731.973(B).

## Immunity for physicians

The bill prohibits the State Medical Board from taking any 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, including limiting, revoking, or suspending or refusing to grant, renew, or reinstate the license or certificate.[8]

The bill also specifies that, to the extent permitted under federal law, an entity responsible for Medicare certification cannot 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.[9]

## Manufacturer provision of individualized investigational treatments

The bill authorizes, but does not require, a manufacturer to make an individualized investigational drug available to an eligible patient. The manufacturer must operate within an eligible facility. The bill defines "eligible facility" as an institution that is operating under a federalwide assurance (FWA) for the protection of human subjects and is subject to the FWA laws, regulations, policies, and guidelines.[10] An FWA is an agreement between the Office for Human Research Protections within the U.S. Department of Health and Human Services and an institution regarding the oversight of medical ethics in the research being conducted. The FWA must provide for the establishment of an institutional review board to review the biomedical or behavioral research involving the human subjects being conducted to protect the human subject's rights.[11] Federal administrative regulations establish protections for all research subjects, as well as specific protections for pregnant women and fetuses, prisoners, and children.[12]

The bill also specifies that an eligible patient may request an individualized investigational, drug, biological product, or device from an eligible facility or manufacturer operating within an eligible facility. A manufacturer may do both of the following:

- Provide the individualized investigational treatment without receiving compensation;
- Require the eligible patient to pay the costs of, or associated with, the manufacture of the investigational drug, biological product, or device.[13]

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[8] R.C. 4731.977(A).

[9] R.C. 4731.977(B).

[10] R.C. 4729.891(A)(1) and (B).

[11] Federalwide Assurance (FWA) for the Protection of Human Subjects, Office for Human Research Protections, U.S. Department of Health and Human Services, accessible by searching "federalwide assurance" on the HHS website at hhs.gov.

[12] See 45 Code of Federal Regulation part 46.

[13] R.C. 4729.891(B) and (C).

## Qualified immunity for manufacturers

The bill specifies that nothing in the bill's provisions is to 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 treatment for any harm to the patient resulting from the treatment, if the manufacturer or other person or entity has complied in good faith with the bill's provisions and has exercised reasonable care.[14]

## Coverage for the cost of treatment

The bill allows, but does not require, health plan issuers and governmental agencies to provide coverage for the cost of individualized investigational treatments or the cost of services related to the use of individualized investigational treatments. The bill specifies that its requirements related to the individualized investigational treatments are not to be construed as doing any of the following:

- Expanding the coverage required under a health benefit plan;
- Requiring any governmental agency to pay costs associated with the use of an individualized investigational drug, biological product, or device, including any related treatment or care of that patient;
- Requiring a hospital or facility to provide new or additional services, unless approved by the hospital or facility;
- Authorizing 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;
- Negating, abrogating, or in any way affecting any mandatory coverage for participation in clinical trials, as otherwise required in law.[15]

## No liability for patient's heirs

The bill specifies that 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.[16]

## State interference prohibited

The bill prohibits an official, employee, or agent of the state from preventing or attempting 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 the bill. However, it is not considered a violation of this provision to provide counseling,

[14] R.C. 4731.979.

[15] R.C. 4731.975.

[16] R.C. 4731.976.

advice, or a recommendation consistent with medical standards of care from a treating physician.[17]

## Patient may elect which treatment to receive

The bill specifies that a patient who meets the requirements of an eligible patient under both the bill and existing law regarding treatment with investigational drugs, products, or devices for a patient who is suffering from a terminal condition, may elect to receive treatment in accordance with either the bill's provisions or existing law provisions regarding investigational drugs, products, or devices for terminal conditions, or both.[18]

# HISTORY

| Action | Date |
|---|---|
| Introduced | 04-08-25 |

ANSB0170IN-136/ts

[17] R.C. 4731.978.

[18] R.C. 4731.9710; R.C. 4731.97, not in the bill.