Senate File 2323 - Introduced

SENATE FILE 2323
BY COMMITTEE ON TECHNOLOGY

(SUCCESSOR TO SSB 3170)

(COMPANION TO HF 2290)

A BILL FOR

An Act relating to the right to try Act.

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

TLSB 5892SV (1) 90
pf/ko

Section 1. Section 144E.2, Code 2024, is amended to read as follows:

144E.2 Definitions.

As used in this chapter:

1. *"Eligible facility"* means an institution operating under a federalwide assurance for the protection of human subjects pursuant to 42 U.S.C. §289(a) and 45 C.F.R. pt. 46, and subject to the federalwide assurance laws, rules, policies, and guidelines including renewals and updates.

~~1.~~ 2. *"Eligible patient"* means an individual who meets all of the ~~following~~ conditions specified under paragraph *"a"* or *"b"*:

a. (1) Has a terminal illness, attested to by the patient's treating physician.

~~*b.*~~ (2) Has considered and rejected or has tried and failed to respond to all other treatment options approved by the United States food and drug administration.

~~*c.*~~ (3) Has received a recommendation from the individual's physician for an investigational drug, biological product, or device.

~~*d.*~~ (4) Has given written informed consent for the use of the investigational drug, biological product, or device.

~~*e.*~~ (5) Has documentation from the individual's physician that the individual meets the requirements of this ~~subsection~~ paragraph *"a"*.

b. (1) Has a life-threatening or severely debilitating illness, attested to by the patient's treating physician.

(2) Has considered all other treatment options currently approved by the United States food and drug administration.

(3) Has received a recommendation from the individual's physician for an individualized investigational treatment, based on an 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.

(4) Has given written informed consent for the use of the individualized investigational treatment.

(5) Has documentation from the individual's physician that the individual meets the requirements of this paragraph "*b*".

3. "*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 individual patient's own genetic profile. "*Individualized investigational treatment*" includes but is not limited to individualized gene therapy, antisense oligonucleotides, and individualized neoantigen vaccines.

~~2.~~ 4. "*Investigational drug, biological product, or device*" means a drug, biological product, or device that has successfully completed phase 1 of a United States food and drug administration-approved clinical trial but has not yet been approved for general use by the United States food and drug administration and remains under investigation in a United States food and drug administration-approved clinical trial.

~~3.~~ 5. "*Terminal illness*" means a progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating physician to be reversible even with administration of treatments approved by the United States food and drug administration, and that, without life-sustaining procedures, will result in death.

~~4.~~ 6. "*Written informed consent*" means a written document that is signed by the patient, a parent of a minor patient, or a legal guardian or other legal representative of the patient and attested to by the patient's treating physician and a witness and that includes, at a minimum, all of the following:

a. If the patient is an eligible patient as specified in subsection 2, paragraph "*a*":

(1) An explanation of the products and treatments approved by the United States food and drug administration for the disease or condition from which the patient suffers.

~~b.~~ (2) An attestation that the patient concurs with the patient's treating physician in believing that all products and treatments approved by the United States food and drug administration are unlikely to prolong the patient's life.

~~c.~~ (3) Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use.

~~d.~~ (4) A description of the best and worst potential outcomes of using the 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 use of the proposed investigational drug, biological product, or device. The description shall be based on the treating physician's knowledge of the proposed investigational drug, biological product, or device in conjunction with an awareness of the patient's condition.

~~e.~~ (5) A statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless they are specifically required to do so by law or contract.

~~f.~~ (6) A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements.

~~g.~~ (7) A statement that the patient understands that the patient is liable for all expenses consequent to the use of the 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 investigational drug, biological product, or device states

otherwise.

b. If the patient is an eligible patient as specified in subsection 2, paragraph "*b*":

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

(2) An attestation that the patient concurs with the patient's treating physician in believing that all currently approved and conventionally recognized products and treatments are unlikely to prolong the patient's life.

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

(4) A description of the best and worst potential outcomes of using the individualized investigational treatment 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 use of the proposed individualized investigational treatment. The description shall be based on the treating physician's knowledge of the proposed individualized investigational treatment in conjunction with an awareness of the patient's condition.

(5) A statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the individualized investigational treatment, unless they are specifically required to do so by law or contract.

(6) 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.

(7) A statement that the patient understands that the patient is liable for all expenses consequent 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 individualized investigational treatment states otherwise.

Sec. 2. Section 144E.3, Code 2024, is amended to read as follows:

144E.3 Manufacturer and eligible facility rights.

1. A manufacturer of an investigational drug, biological product, or device or a manufacturer operating within, and in compliance with all requirements applicable to, an eligible facility may make available, and an eligible patient, as applicable under section 144.1, subsection 2, paragraph "*a*" or "*b*", may request from a manufacturer of an investigational drug, biological product, or device, or a manufacturer operating within, and in compliance with all requirements applicable to, an eligible facility, the manufacturer's investigational drug, biological product, or device, or the manufacturer's individualized investigational treatment under this chapter. This chapter does not require a manufacturer of an investigational drug, biological product, or device, or of an individualized investigational treatment to provide or otherwise make available the investigational drug, biological product, or device, or the individualized investigational treatment to an eligible patient.

2. ~~A~~ An eligible facility, or a manufacturer described in subsection 1, that is in compliance with all applicable requirements, may do any of the following:

a. Provide an investigational drug, biological product, or device, or an individualized investigational treatment to an eligible patient, as applicable under section 144.1, subsection 2, paragraph "*a*" or "*b*", without receiving compensation.

b. Require an eligible patient, as applicable under section 144.1, subsection 2, paragraph "*a*" or "*b*", to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device, or the

individualized investigational treatment.

Sec. 3. Section 144E.4, Code 2024, is amended to read as follows:

144E.4 Treatment coverage.

1. This chapter does not expand the coverage required of an insurer under Title XIII, subtitle 1.

2. A health plan, third-party administrator, or governmental agency may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device, the cost of an individualized investigational treatment, or the cost of services related to the use of an investigational drug, biological product, or device, or an individualized investigational treatment under this chapter.

3. This chapter does not require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an investigational drug, biological product, or device, or an individualized investigational treatment.

4. This chapter does not require a hospital licensed under chapter 135B or other health care facility to provide new or additional services, unless approved by the hospital or other health care facility.

Sec. 4. Section 144E.5, Code 2024, is amended to read as follows:

144E.5 Heirs not liable for treatment debts.

If a patient dies while being treated ~~by~~ with an investigational drug, biological product, or device, or an individualized investigational treatment, the patient's heirs are not liable for any outstanding debt related to the treatment or lack of insurance due to the treatment~~, unless otherwise required by law~~.

Sec. 5. Section 144E.6, Code 2024, is amended to read as follows:

144E.6 Provider recourse.

1. To the extent consistent with state law, the board of

medicine created under chapter 147 shall not revoke, fail to renew, suspend, or take any action against a physician's license based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device, or an individualized investigational treatment.

2. To the extent consistent with 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 a patient have access to an investigational drug, biological product, or device, or an individualized investigational treatment.

Sec. 6. Section 144E.7, Code 2024, is amended to read as follows:

144E.7 State interference.

An official, employee, or agent of this state shall not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device, or to an individualized investigational treatment. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed physician is not a violation of this section.

Sec. 7. Section 144E.8, Code 2024, is amended to read as follows:

144E.8 Private cause of action.

1. This chapter shall not create a private cause of action against a manufacturer of an investigational drug, biological product, or device or an individualized investigational treatment, against an eligible facility, or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device, or the individualized investigational treatment for any harm done to the eligible patient resulting from the investigational drug, biological product, or device, or the individualized investigational treatment, if the manufacturer, eligible facility, or other person or entity is complying in good faith

with the terms of this chapter and has exercised reasonable care.

2. This chapter shall not affect any mandatory health care coverage for participation in clinical trials under Title XIII, subtitle 1.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to Code chapter 144E, the right to try Act.

Under current law, an "eligible patient" under the Code chapter is, in part, a person who has a terminal illness. Under the bill, an "eligible patient" also includes, in part, a person who has a life-threatening or severely debilitating illness.

Under current law, the Code chapter applies to an "investigational drug, biological product, or device", meaning a drug, biological product, or device that has successfully completed phase I of a United States food and drug administration (FDA)-approved clinical trial but has not yet been approved for general use by the FDA and that remains under investigation in an FDA-approved clinical trial. Under the bill, the Code chapter also applies to an "individualized investigational treatment", meaning a drug, biological product, or device that is unique to and produced exclusively for use by an individual patient based on the individual patient's own genetic profile and includes individualized gene therapy, antisense oligonucleotides, and individualized neoantigen vaccines.

The bill amends the definition under the Code chapter for "written informed consent" to reflect the changes made to "eligible patient" and the application of the Code chapter to individualized investigational treatments.

The bill provides a definition of "eligible facility" to mean an institution that is operating under a federalwide assurance for the protection of human subjects pursuant

to federal law. The bill amends provisions relating to a manufacturer's rights under the Code chapter to also apply to eligible facilities. The bill provides that a manufacturer of an investigational drug, biological product, or device or a manufacturer operating within, and in compliance with all requirements applicable to, an eligible facility may make available, and an eligible patient may request from a manufacturer of an investigational drug, biological product, or device, or a manufacturer operating within, and in compliance with all requirements applicable to, an eligible facility, the manufacturer's investigational drug, biological product, or device, or the manufacturer's individualized investigational treatment. However, the Code chapter does not require a manufacturer of an individualized investigational treatment to provide or otherwise make available the individualized investigational treatment to an eligible patient. The bill provides that an eligible facility or a manufacturer that is in compliance with all applicable requirements may provide an individualized investigational treatment to an eligible patient without receiving compensation, or require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the individualized investigational treatment.

The bill makes conforming changes in the Code chapter to reflect the bill's provisions.

The bill does not amend Code section 144E.9, which provides that the Code chapter shall not be construed to allow a patient's treating physician to assist the patient in committing or attempting to commit suicide.