Senate File 404 - Introduced

SENATE FILE 404
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO SSB 1115)

A BILL FOR

An Act relating to the use of experimental treatments for patients with a terminal illness.

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

TLSB 1882SV (1) 87
tr/nh

Section 1. NEW SECTION. **144E.1 Title.**

This chapter shall be known and may be cited as the *"Right to Try Act"*.

Sec. 2. NEW SECTION. **144E.2 Definitions.**

As used in this chapter:

1. *"Eligible patient"* means an individual who meets all of the following conditions:

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

b. 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. Has received a recommendation from the individual's physician for an investigational drug, biological product, or device.

d. Has given written informed consent for the use of the investigational drug, biological product, or device.

e. Has documentation from the individual's physician that the individual meets the requirements of this subsection.

2. *"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. *"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. *"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 all of the following:

a. 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. 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. Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use.

d. 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. 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. 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 care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements.

g. 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.

Sec. 3. NEW SECTION. **144E.3 Manufacturer rights.**

1. A manufacturer of an investigational drug, biological product, or device may make available and an eligible patient may request the manufacturer's investigational drug, biological product, or device under this chapter. This chapter does not require a manufacturer of an investigational drug, biological product, or device to provide or otherwise make available the investigational drug, biological product, or device to an eligible patient.

2. A manufacturer described in subsection 1 may do any of the following:

a. Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

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

Sec. 4. NEW SECTION. **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 provide coverage for the cost of an investigational drug, biological product, or device, or the cost of services related to the use of an investigational drug, biological product, or device 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.

4. This chapter does not require a hospital licensed under chapter 135B or other health care facility to provide new or

additional services.

Sec. 5. NEW SECTION. **144E.5 Heirs not liable for treatment debts.**

If a patient dies while being treated by an investigational drug, biological product, or device, 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. 6. NEW SECTION. **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.

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.

Sec. 7. NEW SECTION. **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. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed physician is not a violation of this section.

Sec. 8. NEW SECTION. **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 against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device for any harm done to the eligible patient resulting from the investigational drug, biological product, or device, if

the manufacturer 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, titled the "Right to Try Act", permits manufacturers of investigational drugs, biological products, or devices to make available, and eligible patients with terminal illnesses to attempt treatment with, an investigational drug, biological product, or device as long as they provided written informed consent. The bill defines the terms "eligible patient", "terminal illness", "investigational drug, biological product, or device", and "written informed consent".

Under the bill, an eligible patient's physician must acknowledge that the patient's illness is terminal and recommend the patient try an investigational drug, biological product, or device. The patient's written informed consent must acknowledge that treatments currently approved by the United Stated food and drug administration are unlikely to prolong the patient's life. It must identify the specific treatment sought and the potential best, worst, and expected results from the treatment. It must acknowledge that the patient's insurance is not required to pay for the treatment and that any hospice service may refuse to accept the patient after receiving the treatment. It must also acknowledge that expenses will be credited to the patient, including the patient's estate, unless an agreement with the manufacturer of an investigational drug, biological product, or device states otherwise. If the patient dies during treatment, the patient's heirs are not liable for any remaining debts unless otherwise required by law.

The manufacturer of an investigational drug, biological product, or device may charge an eligible patient or provide the treatment free of charge. Governmental entities are not required to pay costs associated with the use, care, or treatment of a patient with an investigational drug, biological product, or device. The bill does not require hospitals licensed under Code chapter 135B or other health care facilities to provide new or additional services.

Consistent with existing law, the board of medicine shall not take an adverse action against a physician's license solely for recommending an investigational drug, biological product, or device for the physician's eligible patient. The bill does not create a new private cause of action against any person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device for any harm done to the patient resulting from the treatment if the person or entity is complying in good faith with the terms of the bill and has exercised reasonable care.