

House File 320 - Introduced

HOUSE FILE 320
BY BRADLEY

A BILL FOR

1 An Act relating to the right to try Act.

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

unofficial

1 Section 1. Section 144E.2, Code 2025, is amended to read as
2 follows:

3 **144E.2 Definitions.**

4 As used in this chapter:

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

10 ~~1.~~ 2. "Eligible patient" means an individual who meets all
11 of the following conditions specified under paragraph "a" or "b":

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

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

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

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

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

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

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

29 (3) Has received a recommendation from the individual's
30 physician for an individualized investigational treatment, based
31 on an analysis of the patient's genomic sequence, human
32 chromosomes, deoxyribonucleic acid, ribonucleic acid, genes,
33 gene products such as enzymes and other types of proteins, or
34 metabolites.

35 (4) Has given written informed consent for the use of the

1 individualized investigational treatment.

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

4 3. "Individualized investigational treatment" means a drug,
5 biological product, or device that is unique to, and produced
6 exclusively for use by, an individual patient, based on the
7 individual patient's own genetic profile. "Individualized
8 investigational treatment" includes but is not limited to
9 individualized gene therapy, antisense oligonucleotides, and
10 individualized neoantigen vaccines.

11 ~~2.~~ 4. "Investigational drug, biological product, or
12 device" means a drug, biological product, or device that has
13 successfully completed phase 1 of a United States food and
14 drug administration-approved clinical trial but has not yet been
15 approved for general use by the United States food and drug
16 administration and remains under investigation in a United States
17 food and drug administration-approved clinical trial.

18 ~~3.~~ 5. "Terminal illness" means a progressive disease or
19 medical or surgical condition that entails significant functional
20 impairment, that is not considered by a treating physician to
21 be reversible even with administration of treatments approved by
22 the United States food and drug administration, and that, without
23 life-sustaining procedures, will result in death.

24 ~~4.~~ 6. "Written informed consent" means a written document
25 that is signed by the patient, a parent of a minor patient, or a
26 legal guardian or other legal representative of the patient and
27 attested to by the patient's treating physician and a witness and
28 that includes, at a minimum, all of the following:

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

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

34 ~~b.~~ (2) An attestation that the patient concurs with the
35 patient's treating physician in believing that all products

1 and treatments approved by the United States food and drug
2 administration are unlikely to prolong the patient's life.

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

6 ~~d.~~ (4) A description of the best and worst potential
7 outcomes of using the investigational drug, biological product,
8 or device and a realistic description of the most likely
9 outcome. The description shall include the possibility that
10 new, unanticipated, different, or worse symptoms might result
11 and that death could be hastened by use of the proposed
12 investigational drug, biological product, or device. The
13 description shall be based on the treating physician's knowledge
14 of the proposed investigational drug, biological product, or
15 device in conjunction with an awareness of the patient's
16 condition.

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

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

27 ~~g.~~ (7) A statement that the patient understands that the
28 patient is liable for all expenses consequent to the use of
29 the investigational drug, biological product, or device and that
30 this liability extends to the patient's estate unless a contract
31 between the patient and the manufacturer of the investigational
32 drug, biological product, or device states otherwise.

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

35 (1) An explanation of the currently approved products and

1 treatments for the disease or condition from which the patient
2 suffers.

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

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

10 (4) A description of the best and worst potential
11 outcomes of using the individualized investigational treatment
12 and a realistic description of the most likely outcome.
13 The description shall include the possibility that new,
14 unanticipated, different, or worse symptoms might result and that
15 death could be hastened by use of the proposed individualized
16 investigational treatment. The description shall be based on
17 the treating physician's knowledge of the proposed individualized
18 investigational treatment in conjunction with an awareness of the
19 patient's condition.

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

25 (6) A statement that the patient's eligibility for hospice
26 care may be withdrawn if the patient begins curative treatment
27 with the individualized investigational treatment and that
28 hospice care may be reinstated if this treatment ends and the
29 patient meets hospice eligibility requirements.

30 (7) A statement that the patient understands that the
31 patient is liable for all expenses consequent to the use
32 of the individualized investigational treatment and that this
33 liability extends to the patient's estate, unless a contract
34 between the patient and the manufacturer of the individualized
35 investigational treatment states otherwise.

1 Sec. 2. Section 144E.3, Code 2025, is amended to read as
2 follows:

3 **144E.3 Manufacturer and eligible facility rights.**

4 1. A manufacturer of an investigational drug, biological
5 product, or device or a manufacturer operating within, and in
6 compliance with all requirements applicable to, an eligible
7 facility may make available, and an eligible patient, as
8 applicable under section 144E.1, subsection 2, paragraph "a"
9 or "b", may request from a manufacturer of an investigational
10 drug, biological product, or device, or a manufacturer
11 operating within, and in compliance with all requirements
12 applicable to, an eligible facility, the manufacturer's
13 investigational drug, biological product, or device, or the
14 manufacturer's individualized investigational treatment under
15 this chapter. This chapter does not require a manufacturer of
16 an investigational drug, biological product, or device, or of an
17 individualized investigational treatment to provide or otherwise
18 make available the investigational drug, biological product, or
19 device, or the individualized investigational treatment to an
20 eligible patient.

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

24 a. Provide an investigational drug, biological product, or
25 device, or an individualized investigational treatment to an
26 eligible patient, as applicable under section 144E.1, subsection
27 2, paragraph "a" or "b", without receiving compensation.

28 b. Require an eligible patient, as applicable under section
29 144E.1, subsection 2, paragraph "a" or "b", to pay the costs
30 of, or the costs associated with, the manufacture of the
31 investigational drug, biological product, or device, or the
32 individualized investigational treatment.

33 Sec. 3. Section 144E.4, Code 2025, is amended to read as
34 follows:

35 **144E.4 Treatment coverage.**

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

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

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

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

19 Sec. 4. Section 144E.5, Code 2025, is amended to read as
20 follows:

21 **144E.5 Heirs not liable for treatment debts.**

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

28 Sec. 5. Section 144E.6, Code 2025, is amended to read as
29 follows:

30 **144E.6 Provider recourse.**

31 1. To the extent consistent with state law, the board of
32 medicine created under chapter 147 shall not revoke, fail to
33 renew, suspend, or take any action against a physician's license
34 based solely on the physician's recommendations to an eligible
35 patient regarding access to or treatment with an investigational

1 drug, biological product, or device, or an individualized
2 investigational treatment.

3 2. To the extent consistent with federal law, an entity
4 responsible for Medicare certification shall not take action
5 against a physician's Medicare certification based solely on
6 the physician's recommendation that a patient have access to
7 an investigational drug, biological product, or device, or an
8 individualized investigational treatment.

9 Sec. 6. Section 144E.7, Code 2025, is amended to read as
10 follows:

11 **144E.7 State interference.**

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

18 Sec. 7. Section 144E.8, Code 2025, is amended to read as
19 follows:

20 **144E.8 Private cause of action.**

21 1. This chapter shall not create a private cause of action
22 against a manufacturer of an investigational drug, biological
23 product, or device, or an individualized investigational
24 treatment, against an eligible facility, or against any
25 other person or entity involved in the care of an eligible
26 patient using the investigational drug, biological product,
27 or device, or the individualized investigational treatment for
28 any harm done to the eligible patient resulting from the
29 investigational drug, biological product, or device, or the
30 individualized investigational treatment, if the manufacturer,
31 eligible facility, or other person or entity is complying in good
32 faith with the terms of this chapter and has exercised reasonable
33 care.

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

1 subtitle 1.

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EXPLANATION

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The inclusion of this explanation does not constitute agreement with

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the explanation's substance by the members of the general assembly.

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

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

"Eligible facility" is defined as 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

1 may request from a manufacturer of an investigational drug,
2 biological product, or device, or a manufacturer operating
3 within, and in compliance with all requirements applicable
4 to, an eligible facility, the manufacturer's investigational
5 drug, biological product, or device, or the manufacturer's
6 individualized investigational treatment. However, the Code
7 chapter does not require a manufacturer of an individualized
8 investigational treatment to provide or otherwise make available
9 the individualized investigational treatment to an eligible
10 patient. The bill provides that an eligible facility or
11 a manufacturer that is in compliance with all applicable
12 requirements may provide an individualized investigational
13 treatment to an eligible patient without receiving compensation,
14 or require an eligible patient to pay the costs of, or the
15 costs associated with, the manufacture of the individualized
16 investigational treatment.

17 The bill makes conforming changes in the Code chapter.