

House File 2290 - Introduced

HOUSE FILE 2290

BY BODEN

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:

1 Section 1. Section 144E.2, Code 2024, 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
12 "b":

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 otherwise.

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

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

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

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

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

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

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

34 (7) A statement that the patient understands that the
35 patient is liable for all expenses consequent to the use of

1 the individualized investigational treatment and that this
2 liability extends to the patient's estate, unless a contract
3 between the patient and the manufacturer of the individualized
4 investigational treatment states otherwise.

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

7 **144E.3 Manufacturer and eligible facility rights.**

8 1. A manufacturer of an investigational drug, biological
9 product, or device or a manufacturer operating within, and in
10 compliance with all requirements applicable to, an eligible
11 facility may make available, and an eligible patient, as
12 applicable under section 144.1, subsection 2, paragraph "a"
13 or "b", may request from a manufacturer of an investigational
14 drug, biological product, or device, or a manufacturer
15 operating within, and in compliance with all requirements
16 applicable to, an eligible facility, the manufacturer's
17 investigational drug, biological product, or device, or the
18 manufacturer's individualized investigational treatment under
19 this chapter. This chapter does not require a manufacturer
20 of an investigational drug, biological product, or device, or
21 of an individualized investigational treatment to provide or
22 otherwise make available the investigational drug, biological
23 product, or device, or the individualized investigational
24 treatment to an eligible patient.

25 2. A An eligible facility, or a manufacturer described
26 in [subsection 1](#), that is in compliance with all applicable
27 requirements, may do any of the following:

28 a. Provide an investigational drug, biological product, or
29 device, or an individualized investigational treatment to an
30 eligible patient, as applicable under section 144.1, subsection
31 2, paragraph "a" or "b", without receiving compensation.

32 b. Require an eligible patient, as applicable under section
33 144.1, subsection 2, paragraph "a" or "b", to pay the costs
34 of, or the costs associated with, the manufacture of the
35 investigational drug, biological product, or device, or the

1 individualized investigational treatment.

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

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

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

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

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

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

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

25 **144E.5 Heirs not liable for treatment debts.**

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

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

34 **144E.6 Provider recourse.**

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

1 medicine created under [chapter 147](#) shall not revoke, fail
2 to renew, suspend, or take any action against a physician's
3 license based solely on the physician's recommendations to
4 an eligible patient regarding access to or treatment with an
5 investigational drug, biological product, or device, or an
6 individualized investigational treatment.

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

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

15 **144E.7 State interference.**

16 An official, employee, or agent of this state shall not
17 block or attempt to block an eligible patient's access to an
18 investigational drug, biological product, or device, or to an
19 individualized investigational treatment. Counseling, advice,
20 or a recommendation consistent with medical standards of care
21 from a licensed physician is not a violation of [this section](#).

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

24 **144E.8 Private cause of action.**

25 1. [This chapter](#) shall not create a private cause of action
26 against a manufacturer of an investigational drug, biological
27 product, or device or an individualized investigational
28 treatment, against an eligible facility, or against any other
29 person or entity involved in the care of an eligible patient
30 using the investigational drug, biological product, or device,
31 or the individualized investigational treatment for any harm
32 done to the eligible patient resulting from the investigational
33 drug, biological product, or device, or the individualized
34 investigational treatment, if the manufacturer, eligible
35 facility, or other person or entity is complying in good faith

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

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

6 EXPLANATION

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

9 This bill relates to Code chapter 144E, the right to try Act.
10 Under current law, an "eligible patient" under the Code
11 chapter is, in part, a person who has a terminal illness.
12 Under the bill, an "eligible patient" also includes, in part,
13 a person who has a life-threatening or severely debilitating
14 illness.

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

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

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

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

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

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