

**House File 802 - Introduced**

HOUSE FILE 802  
BY COMMITTEE ON HEALTH AND HUMAN  
SERVICES

(SUCCESSOR TO HF 320)

**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 exhausted all other United States food and drug  
28 administration-approved treatment options by contraindication,  
29 potential or previous treatment failure, or actual or potential  
30 adverse reaction.

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

1 metabolites.

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

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

6 3. "Individualized investigational treatment" means a drug,  
7 biological product, or device that is unique to, and produced  
8 exclusively for use by, an individual patient, based on the  
9 individual patient's own genetic profile, and is provided in a  
10 manner that is consistent with a federalwide assurance for the  
11 protection of human subjects. "Individualized investigational  
12 treatment" includes but is not limited to individualized  
13 gene therapy, antisense oligonucleotides, and individualized  
14 neoantigen vaccines.

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

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

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

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

35 (1) An explanation of the products and treatments approved by

1 the United States food and drug administration for the disease or  
2 condition from which the patient suffers.

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

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

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

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

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

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

1 drug, biological product, or device states 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  
15 outcomes 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 and that  
19 death could be hastened by use of the proposed individualized  
20 investigational treatment. The description shall be based on  
21 the treating physician's knowledge of the proposed individualized  
22 investigational treatment in conjunction with an awareness of the  
23 patient's condition.

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

1 of 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 2025, 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 144E.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 of  
20 an investigational drug, biological product, or device, or of an  
21 individualized investigational treatment to provide or otherwise  
22 make available the investigational drug, biological product, or  
23 device, or the individualized investigational treatment to an  
24 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 144E.1, subsection  
31 2, paragraph "a" or "b", without receiving compensation.

32 b. Require an eligible patient, as applicable under section  
33 144E.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 2025, 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 governmental  
8 agency may, but is not required to, provide coverage for the  
9 cost of an investigational drug, biological product, or device,  
10 or the cost of an individualized investigational treatment, the  
11 cost of services related to the use of an investigational drug,  
12 biological product, or device, or the cost of services related to  
13 the use of an individualized investigational treatment under this  
14 chapter.

15 3. This chapter does not require any governmental agency  
16 to pay costs associated with the use, care, or treatment of  
17 a 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 2025, 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 an  
28 individualized investigational treatment, the patient's heirs are  
29 not liable for any outstanding debt related to the treatment or  
30 lack of insurance due to the treatment, unless otherwise required  
31 by law.

32 Sec. 5. Section 144E.6, Code 2025, 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 to  
2 renew, suspend, or take any action against a physician's license  
3 based solely on the physician's recommendations to an eligible  
4 patient regarding access to or treatment with an investigational  
5 drug, biological product, or device, or an individualized  
6 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 2025, 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, or  
20 a recommendation consistent with medical standards of care from a  
21 licensed physician is not a violation of this section.

22 Sec. 7. Section 144E.8, Code 2025, 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  
29 other person or entity involved in the care of an eligible  
30 patient using the investigational drug, biological product,  
31 or device, or the individualized investigational treatment for  
32 any harm done to the eligible patient resulting from the  
33 investigational drug, biological product, or device, or the  
34 individualized investigational treatment, if the manufacturer,  
35 eligible facility, or other person or entity is complying in good

1 faith 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 an  
13 individual who has a life-threatening or severely debilitating  
14 illness, who has exhausted all other treatment options, who has  
15 received a recommendation from the individual's physician for  
16 individualized investigational treatment, who has given written  
17 informed consent, and who has documentation from the individual's  
18 physician that the individual meets these requirements.

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

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

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

26 The bill makes conforming changes in the Code chapter.