

1
2
3
4
5
6
7
8
9
0
1
2
3
4
5
6
7
8
9
0
1
2
3
4

COMMITTEE SUBSTITUTE
FOR
SENATE BILL NO. 933

and

An Act relating to health care; creating the Right to Try for Individualized Treatments Act; providing short title; defining terms; authorizing individualized investigational treatments for eligible patients; making act voluntary for manufacturers; providing certain authorities to eligible facilities; limiting effect of act; making coverage voluntary for payors; granting certain immunities from civil liability; granting certain protections to health care providers; prohibiting certain acts by state entities; providing for codification; and providing an effective date.

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 3092.1 of Title 63, unless there is created a duplication in numbering, reads as follows:

This act shall be known and may be cited as the "Right to Try
for Individualized Treatments Act".

1 SECTION 2. NEW LAW A new section of law to be codified
2 in the Oklahoma Statutes as Section 3092.2 of Title 63, unless there
3 is created a duplication in numbering, reads as follows:

4 As used in this act:

5 1. "Eligible facility" means an institution that is operating
6 under a Federalwide Assurance (FWA) for the Protection of Human
7 Subjects under 42 U.S.C., Section 289(a) and 45 C.F.R., Part 46. An
8 eligible facility is subject to the FWA laws, regulations, policies,
9 and guidelines including renewals or updates;

10 2. "Eligible patient" means an individual who meets all of the
11 following conditions:

- 12 a. has a life-threatening or severely debilitating
13 illness, attested to by the patient's treating
14 physician,
- 15 b. has considered all other treatment options currently
16 approved by the United States Food and Drug
17 Administration,
- 18 c. has received a recommendation from his or her
19 physician for an individualized investigational
20 treatment, based on analysis of the patient's genomic
21 sequence, human chromosomes, deoxyribonucleic acid,
22 ribonucleic acid, genes, gene products such as enzymes
23 and other types of proteins, or metabolites,

- 1 d. has given written, informed consent for the use of the
2 individualized investigational treatment, and
3 e. has documentation from his or her physician that he or
4 she meets the requirements of this paragraph;

5 3. "Individualized investigational treatment" means drugs,
6 biological products, or devices that are unique to and produced
7 exclusively for use for an individual patient, based on the
8 patient's own genetic profile. Individualized investigational
9 treatment includes, but is not limited to, individualized gene
10 therapy antisense oligonucleotides (ASO) and individualized
11 neoantigen vaccines; and

12 4. "Written, informed consent" means a written document that is
13 signed by the patient; parent, if the patient is a minor; legal
14 guardian; or patient advocate designated by the patient, and
15 attested to by the patient's physician and a witness and that, at a
16 minimum, includes:

- 17 a. an explanation of the currently approved products and
18 treatments for the disease or condition from which the
19 patient suffers,
20 b. an attestation that the patient concurs with his or
21 her physician in believing that all currently approved
22 and conventionally recognized treatments are unlikely
23 to prolong the patient's life,
24

- 1 c. clear identification of the specific proposed
2 individualized investigational treatment that the
3 patient is seeking to use,
- 4 d. a description of the potentially best and worst
5 outcomes of using the individualized investigational
6 treatment and a realistic description of the most
7 likely outcome. The description shall include the
8 possibility that new, unanticipated, different, or
9 worse symptoms might result and that death could be
10 hastened by the proposed treatment. The description
11 shall be based on the physician's knowledge of the
12 proposed treatment in conjunction with an awareness of
13 the patient's condition,
- 14 e. a statement that the patient's health plan or third-
15 party administrator and provider are not obligated to
16 pay for any care or treatments consequent to the use
17 of the individualized investigational treatment,
18 unless specifically required by law or contract,
- 19 f. a statement that the patient's eligibility for hospice
20 care may be withdrawn if the patient begins curative
21 treatment with the individualized investigational
22 treatment and that care may be reinstated if this
23 treatment ends and the patient meets hospice
24 eligibility requirements, and

1 g. a statement that the patient understands that he or
2 she is liable for all expenses consequent to the use
3 of the individualized investigational treatment and
4 that this liability extends to the patient's estate,
5 unless a contract between the patient and the
6 manufacturer of the individualized investigational
7 treatment states otherwise.

8 SECTION 3. NEW LAW A new section of law to be codified
9 in the Oklahoma Statutes as Section 3092.3 of Title 63, unless there
10 is created a duplication in numbering, reads as follows:

11 A. A manufacturer operating within an eligible facility and
12 pursuant to all applicable Federalwide Assurance (FWA) laws and
13 regulations may make available an individualized investigational
14 treatment and an eligible patient may request an individualized
15 investigational treatment from an eligible facility or manufacturer
16 operating within an eligible facility under this act. This act does
17 not require that a manufacturer make available an individualized
18 investigational treatment to an eligible patient.

19 B. An eligible facility or manufacturer operating within an
20 eligible facility may:

21 1. Provide an individualized investigational treatment to an
22 eligible patient without receiving compensation; and
23
24

1 2. Require an eligible patient to pay the costs of, or the
2 costs associated with, the manufacture of the individualized
3 investigational treatment.

4 SECTION 4. NEW LAW A new section of law to be codified
5 in the Oklahoma Statutes as Section 3092.4 of Title 63, unless there
6 is created a duplication in numbering, reads as follows:

7 A. This act does not:

8 1. Expand the coverage required of an insurer under the
9 Oklahoma Insurance Code;

10 2. Require any governmental agency to pay costs associated with
11 the use, care, or treatment of a patient with an individualized
12 investigational treatment;

13 3. Require a hospital or facility licensed by this state to
14 provide new or additional services, unless approved by the hospital
15 or facility; or

16 4. Affect any mandatory health care coverage for participation
17 in clinical trials under the Oklahoma Insurance Code.

18 B. A health plan, third-party administrator, or governmental
19 agency may, but is not required to, provide coverage for the cost of
20 an individualized investigational treatment, or the cost of services
21 related to the use of an individualized investigational treatment
22 under this act.

1 SECTION 5. NEW LAW A new section of law to be codified
2 in the Oklahoma Statutes as Section 3092.5 of Title 63, unless there
3 is created a duplication in numbering, reads as follows:

4 A. If a patient dies while being treated by an individualized
5 investigational treatment, the patient's heirs are not liable for
6 any outstanding debt related to the treatment or lack of insurance
7 due to the treatment.

8 B. This act does not create a private cause of action against a
9 manufacturer of an individualized investigational treatment or
10 against any other person or entity involved in the care of an
11 eligible patient using the individualized investigational treatment
12 for any harm done to the eligible patient resulting from the
13 individualized investigational treatment, if the manufacturer or
14 other person or entity is complying in good faith with the terms of
15 this act and has exercised reasonable care.

16 SECTION 6. NEW LAW A new section of law to be codified
17 in the Oklahoma Statutes as Section 3092.6 of Title 63, unless there
18 is created a duplication in numbering, reads as follows:

19 A. A licensing board shall not revoke, fail to renew, suspend,
20 or take any action against a health care provider's license based
21 solely on the health care provider's recommendations to an eligible
22 patient regarding access to or treatment with an individualized
23 investigational treatment. An entity responsible for Medicare
24 certification shall not take action against a health care provider's

1 Medicare certification based solely on the health care provider's
2 recommendation that a patient have access to an individualized
3 investigational treatment.

4 B. An official, employee, or agent of this state shall not
5 block or attempt to block an eligible patient's access to an
6 individualized investigational treatment. Counseling, advice, or a
7 recommendation consistent with medical standards of care from a
8 licensed health care provider is not a violation of this subsection.

9 SECTION 7. This act shall become effective November 1, 2026.

10 COMMITTEE REPORT BY: COMMITTEE ON HEALTH AND HUMAN SERVICES
11 March 2, 2026 - DO PASS AS AMENDED BY CS
12
13
14
15
16
17
18
19
20
21
22
23
24