

SECOND REGULAR SESSION

HOUSE BILL NO. 2643

103RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE STINNETT.

6148H.01I

JOSEPH ENGLER, Chief Clerk

AN ACT

To amend chapter 191, RSMo, by adding thereto seven new sections relating to access to individualized investigational treatment.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Chapter 191, RSMo, is amended by adding thereto seven new sections, to be known as sections 191.455, 191.457, 191.459, 191.461, 191.463, 191.465, and 191.467, to read as follows:

191.455. 1. Sections 191.455 to 191.467 shall be known and may be cited as the "Hope for Missouri Patients Act".

2. As used in sections 191.455 to 191.467, unless the context otherwise requires, the following terms mean:

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

(2) "Eligible patient", an individual who meets the following conditions:

(a) Has considered all other treatment options currently approved by the United States Food and Drug Administration;

(b) Has received a recommendation from his or her physician for an individualized investigational treatment based on analysis of the patient's genomic sequence; human chromosomes; deoxyribonucleic acid; ribonucleic acid; genes; gene products, such as enzymes and other types of proteins; or metabolites;

EXPLANATION — Matter enclosed in bold-faced brackets **[thus]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

16 (c) Has a life-threatening or severely debilitating illness, or a serious disease or
17 condition associated with morbidity that has a substantial impact on day-to-day
18 functioning, as attested to by the patient's treating physician;

19 (d) Has given written, informed consent for the use of the individualized
20 investigational drug, biological product, or device; and

21 (e) Has documentation from his or her physician that he or she meets the
22 requirements of paragraphs (a) to (d) of this subdivision;

23 (3) "Individualized investigational drug, biological product, or device", any
24 drug, biological product, or device that is unique to and produced exclusively for use for
25 an individual patient based on the patient's own genetic profile. The term
26 "individualized investigational drug, biological product, or device":

27 (a) Shall include, but not be limited to, individualized gene therapy antisense
28 oligonucleotides and individualized neoantigen vaccines; and

29 (b) Shall not include any drug, biological product, or device derived from human
30 primary or secondary embryonic stem cells or cell lines, or tissues or cells derived from
31 abortion, but shall include any drug, biological product, or device derived from human
32 perinatal tissues, cells, and secreted factors not obtained from an abortion;

33 (4) "Individualized investigational treatment", treatment with an individualized
34 investigational drug, biological product, or device;

35 (5) "Life-threatening or severely debilitating illness", any disease or condition
36 that is life-threatening or severely debilitating, as such terms are defined in 21 CFR
37 312.81 or any successor law or regulation, as applicable;

38 (6) "Written, informed consent", a written document that:

39 (a) Is signed by the patient or, if the patient is a minor, signed by any person
40 authorized to consent under section 431.061;

41 (b) Is attested to by the patient's physician and a witness; and

42 (c) At a minimum, includes all of the following:

43 a. An explanation of the currently approved products and treatments for the
44 illness, disease, or condition from which the patient suffers;

45 b. An attestation that the patient concurs with his or her physician in believing
46 that all currently approved and conventionally recognized treatments are unlikely to
47 prolong the patient's life;

48 c. Clear identification of the specific proposed individualized investigational
49 drug, biological product, or device that the patient is seeking to use;

50 d. A description of the potentially best and worst outcomes of using the
51 individualized investigational drug, biological product, or device and a realistic
52 description of the most likely outcome. The description shall include the possibility

53 that new, unanticipated, different, or worse symptoms might result and that death could
54 be hastened by the proposed treatment. The description shall be based on the
55 physician's knowledge of the proposed treatment in conjunction with an awareness of
56 the patient's condition;

57 e. A statement that the patient's health plan or third-party administrator and
58 provider are not obligated to pay for any care or treatments consequent to the use of the
59 individualized investigational drug, biological product, or device unless they are
60 specifically required to do so by law or contract;

61 f. A statement that the patient's eligibility for hospice care may be withdrawn if
62 the patient begins curative treatment with the individualized investigational drug,
63 biological product, or device and that care may be reinstated if this treatment ends and
64 the patient meets hospice eligibility requirements; and

65 g. A statement that the patient understands that he or she is liable for all
66 expenses consequent to the use of the individualized investigational drug, biological
67 product, or device and that this liability extends to the patient's estate unless a contract
68 between the patient and the manufacturer of the individualized investigational drug,
69 biological product, or device states otherwise.

191.457. 1. A manufacturer operating within an eligible facility and in
2 accordance with all applicable Federalwide Assurance laws and regulations may make
3 available an individualized investigational drug, biological product, or device and an
4 eligible patient may request an individualized investigational drug, biological product,
5 or device from an eligible facility or manufacturer operating within an eligible facility
6 under sections 191.455 to 191.467. Sections 191.455 to 191.467 shall not require that a
7 manufacturer make available an individualized investigational drug, biological product,
8 or device to an eligible patient.

9 2. An eligible facility or manufacturer operating within an eligible facility may
10 do all of the following:

11 (1) Provide an individualized investigational drug, biological product, or device
12 to an eligible patient without receiving compensation; and

13 (2) Require an eligible patient to pay the costs of, or the costs associated with, the
14 manufacture of the individualized investigational drug, biological product, or device.

191.459. 1. Sections 191.455 to 191.467 shall not expand the coverage required of
2 an insurer under chapter 376.

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

6 investigational drug, biological product, or device in accordance with sections 191.455 to
7 191.467.

8 3. Sections 191.455 to 191.467 shall not require any governmental agency to pay
9 costs associated with the use of or care or treatment of a patient with an individualized
10 investigational drug, biological product, or device.

11 4. Sections 191.455 to 191.467 shall not require a hospital or facility licensed by
12 the department of health and senior services to provide new or additional services unless
13 approved by the hospital or facility.

191.461. If a patient's death is proximately caused by treatment with an
2 individualized investigational drug, biological product, or device, the patient's estate,
3 heirs, or devisees shall not be liable for any debt remaining after payment by insurance
4 for charges directly incurred for such treatment. However, this section shall not provide
5 an exemption to liability for charges for nonexperimental treatments provided to the
6 patient, including nonexperimental treatments rendered to the patient due to
7 complications or consequences of the experimental treatment.

191.463. 1. A licensing board or disciplinary subcommittee shall not revoke, fail
2 to renew, suspend, or take any action against a health care provider's license based
3 solely on the health care provider's recommendations to an eligible patient regarding
4 access to or treatment with an individualized investigational drug, biological product, or
5 device.

6 2. An entity responsible for Medicare certification shall not take action against a
7 health care provider's Medicare certification based solely on the health care provider's
8 recommendation that a patient have access to an individualized investigational drug,
9 biological product, or device.

191.465. 1. An official, employee, or agent of this state shall not block or attempt
2 to block an eligible patient's access to an individualized investigational drug, biological
3 product, or device.

4 2. Counseling, advice, or a recommendation consistent with medical standards of
5 care from a licensed health care provider shall not be a violation of this section.

191.467. 1. Sections 191.455 to 191.467 shall not create a private cause of action
2 against a manufacturer of an individualized investigational drug, biological product, or
3 device or against any other person or entity involved in the care of an eligible patient
4 using the individualized investigational drug, biological product, or device for any harm
5 done to the eligible patient resulting from the individualized investigational drug,
6 biological product, or device if the manufacturer or other person or entity has complied
7 in good faith with the terms of sections 191.455 to 191.467 and has exercised reasonable
8 care.

9 **2. Sections 191.455 to 191.467 shall not affect any health care coverage required**
10 **under section 376.429 for costs incurred due to participation in clinical trials.**

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