FIRST REGULAR SESSION

HOUSE BILL NO. 1206

103RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE STINNETT.

1791H.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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Require an eligible patient to pay the costs of, or the costs associated with, the 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 an insurer under chapter 376.

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

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

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

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

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

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

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

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

2. Counseling, advice, or a recommendation consistent with medical standards of 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 against a manufacturer of an individualized investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the individualized investigational drug, biological product, or device for any harm done to the eligible patient resulting from the individualized investigational drug, biological product, or device if the manufacturer or other person or entity has complied in good faith with the terms of sections 191.455 to 191.467 and has exercised reasonable care.

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

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