FIRST REGULAR SESSION

HOUSE BILL NO. 1218

100TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE NEELY.

2415H.01I DANA RADEMAN MILLER, Chief Clerk

AN ACT

To repeal section 191.480, RSMo, and to enact in lieu thereof two new sections relating to investigational access organizations, with a penalty clause.

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

Section A. Section 191.480, RSMo, is repealed and two new sections enacted in lieu thereof, to be known as sections 191.480 and 191.481, to read as follows:

191.480. 1. For purposes of this section, the following terms shall mean:

(1) "Eligible patient", a person who meets all of the following:

(a) Has a terminal illness;

(b) Has considered all other treatment options currently approved by the **[**~~United States~~**]** **federal** Food and Drug Administration and all relevant clinical trials conducted in this state;

(c) Has received a prescription or recommendation from the person's physician for an investigational drug, biological product, or device;

(d) Has given written informed consent which shall be at least as comprehensive as the consent used in clinical trials for the use of the investigational drug, biological product, or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written informed consent on the patient's behalf; and

(e) Has documentation from the person's physician that the person has met the requirements of this subdivision;

(2) **"Investigational access organization", an entity licensed under section 191.481 to manufacture, produce, and distribute investigational drugs, biological products, or devices;**

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.

(3) "Investigational drug, biological product, or device", a drug, biological product, or device**[**~~, any of which are used to treat the patient's terminal illness,~~**]** that has successfully completed phase one of a clinical trial but has not been approved for general use by the **[**~~United States~~**]** **federal** Food and Drug Administration and remains under investigation in a clinical trial. The term shall not include **state or federal** Schedule I controlled substances;

[~~(3)~~**]** **(4)** "Terminal illness", a disease that without life-sustaining procedures will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

2. **[**~~A~~**]** **An investigational access organization or** manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to eligible patients under this section. This section does not require that **an investigational access organization or** a manufacturer make available an investigational drug, biological product, or device to an eligible patient. **[**~~A~~**]** **An investigational access organization or** manufacturer may:

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

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

3. This section does not require a health care insurer to provide coverage for the cost of any investigational drug, biological product, or device. A health care insurer may provide coverage for an investigational drug, biological product, or device.

4. This section does not require the department of corrections to provide coverage for the cost of any investigational drug, biological product, or device.

5. Notwithstanding any other provision of law to the contrary, no state agency or regulatory board shall revoke, fail to renew, or take any other action against a physician's license issued under chapter 334 based solely on the physician's recommendation to an eligible patient regarding prescription for or treatment with an investigational drug, biological product, or device. 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 investigational drug, biological product, or device is prohibited.

6. **[**~~If a provision of this section or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this section that can be given effect without the invalid provision or application, and to this end the provisions of this section are severable~~**]** **Notwithstanding any other provision of law to the contrary, no state agency or regulatory board shall revoke, fail to renew, or take any other action against an investigational access organization's license issued under section 191.491 based solely on**

the investigational access organization's sale of an investigational drug, biological product, or device to an eligible patient under this section.

7. If the clinical trial is closed due to lack of efficacy or toxicity, the drug shall not be offered. If notice is given on a drug, product, or device taken by a patient outside of a clinical trial, the pharmaceutical company or patient's physician shall notify the patient of the information from the safety committee of the clinical trial.

8. Except in the case of gross negligence or willful misconduct, any person who manufactures, imports, distributes, prescribes, **recommends,** dispenses, or administers an investigational drug or device to an eligible patient with a terminal illness in accordance with this section shall not be liable in any action under state law for any loss, damage, or injury arising out of, relating to, or resulting from:

(1) The design, development, clinical testing and investigation, manufacturing, labeling, distribution, sale, purchase, donation, dispensing, prescription, administration, or use of the drug or device; or

(2) The safety or effectiveness of the drug or device.

9. Any official, employee, or agent of this state who blocks or attempts to block access of an eligible patient to an investigational drug, biological product, or device is guilty of a class A misdemeanor.

10. If any provision of this section or its application to any person or circumstance is held invalid, such determination shall not affect the provisions or applications of this section which may be given effect without the invalid provision or application, and to that end, the provisions of this section are severable.

191.481. 1. Any sponsor of a placebo-controlled clinical trial for patients with terminal illnesses conducted in the state shall provide prospective trial participants, as part of the informed consent proceedings conducted under 21 C.F.R. 50.25, with a list of licensed physicians or investigational access organizations which may provide the patient with the trial drug, biological product, or device outside of the sponsor's trial.

2. If a manufacturer does not provide an investigational drug, biological product, or device to an eligible patient under section 191.480 outside of a clinical trial, a licensed investigational access organization may manufacture, produce, and distribute the manufacturer's investigational drug, biological product, or device.

3. The department of health and senior services shall issue an investigational access organization license to an entity to manufacture, produce, and distribute investigational drugs, biological products, or devices, if the entity, which is operated by at least one licensed physician and at least one licensed pharmacist, has submitted to the department

an application as required by this subsection, and the entity meets all requirements of this section and the rules promulgated by the department.

4. A licensed investigational access organization may manufacture, produce, and distribute investigational drugs, biological products, or devices for the treatment of persons suffering from a terminal illness consistent with state regulations regarding the production, manufacture, or distribution of such investigational products.

5. Any company or health benefit plan that provides coverage or benefits for assisted-suicide drugs or procedures in any state shall provide coverage and benefits for investigational drugs, biological products, and devices on a basis no less favorable than assisted-suicide drugs or procedures.

6. Coverage of investigational drugs, biological products, and devices shall be subject to any prior authorization, dollar limit, co-payment, deductible, or other out-of-pocket expense that does not apply to assisted-suicide drugs or procedures, regardless of benefit category determination by the company administering the health benefit plan.

7. For a health benefit plan that meets the definition of "high deductible health plan" as defined by 26 U.S.C. Section 223(c)(2), the provisions of subsection 6 of this section shall only apply after a covered person's deductible has been satisfied for the year.

8. The director of the department of health and senior services may promulgate all necessary rules and regulations for the administration of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable, and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2019, shall be invalid and void.

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