SECOND REGULAR SESSION

[PERFECTED]

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 1685

97TH GENERAL ASSEMBLY

5556H.04P D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To amend chapter 191, RSMo, by adding thereto one new section relating to the use of investigational drugs, with a penalty provision.

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

Section A. Chapter 191, RSMo, is amended by adding thereto one new section, to be known as section 191.480, 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 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 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 drug, biological product, or device", a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains

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.

under investigation in a clinical trial. The term does not include Schedule I controlled substances;

(3) "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 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 a manufacturer make available an investigational drug, biological product, or device to an eligible patient. A 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. 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.

5. 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.

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.

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