FIRST REGULAR SESSION

HOUSE BILL NO. 1020

98TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE NEELY.

2258H.01I D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To amend chapter 192, RSMo, by adding thereto one new section relating to the cancer information reporting system, with penalty provisions.

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

Section A. Chapter 192, RSMo, is amended by adding thereto one new section, to be known as section 192.654, to read as follows:

192.654. 1. As used in this section, the following terms shall mean:

(1) "Investigator", the same meaning as under 21 CFR 50.3;

(2) "Off-label usage", when a Food and Drug Administration-approved drug is used for the practice of medicine in a manner that differs from the approved drug label including, but not limited to:

(a) Used for a different disease or medical condition;

(b) Administered in a different manner; or

(c) Administered in a different dose;

(3) "Placebo-controlled clinical drug trial research project", part of an investigation conducted as part of an investigational new drug application for the Food and Drug Administration as defined by 21 CFR 314.126;

(4) "Sponsor", the same meaning as under 21 CFR 50.3;

(5) "Terminally ill", a medical state for which no adequate treatment exists and which will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

2. Oncologists and other health care providers may notify the department of health and senior services if they are engaged in the treatment of cancer or terminally ill patients

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.

in this state through the off-label usage of drugs for treatment, as well as notify the department as to which drugs they use and for what purposes.

3. (1) The department shall maintain, as part of the cancer information reporting system, a database of oncologists and other health care providers who have notified the department of their practice of off-label usage of drugs for treatment. The database shall include the names, addresses, and specified off-label usage of a drug for treatment for each oncologist or health care provider who provided the department with such information.

(2) The sponsor or investigator shall notify the department of his or her intent to run a placebo-controlled clinical drug trial research project in the state, as well as notify the department as to which drug or drugs are being investigated and for what purpose. The department shall do the following:

(a) Provide notice to all licensed oncologists and other health care providers in the state, as well as appropriate nationally recognized cancer research institutions within and outside of the state, of the placebo-controlled clinical drug trial research project, the drug or drugs being investigated, and for what purpose;

(b) Accompany this notice with a request for voluntary notification to the department by oncologists and other health care providers in the state, as well as appropriate nationally recognized cancer research institutions within and outside of the state, if they are engaged in the treatment of cancer or terminally ill patients through the off-label usage of drugs for treatment, as well as which drugs they use and for what purposes;

(c) Compile a list of the provided names and addresses of the oncologists and other health care providers within and outside of the state who are engaged in the treatment of cancer and terminally ill patients with medical conditions the same as or similar to the prospective trial participants's medical conditions through the off-label usage of drugs for treatment; and

(d) Provide the sponsor or investigator with this list for use under subsection 4 of this section in exchange for a fee to cover the cost of processing the data.

4. Any sponsor or investigator of a placebo-controlled clinical drug trial research project of a treatment drug for patients with cancer or terminal illness conducted in the state shall provide prospective trial participants, as part of the informed consent proceedings conducted under 21 CFR 50.25, with a list of oncologists and other health care providers in the state who are engaged in the treatment of patients with medical conditions the same as or similar to the prospective trial participant's medical condition through the off-label usage of drugs for treatment.

5. Any sponsor of a placebo-controlled clinical drug trial research project who willfully fails to obtain a trial participant's informed consent under subsection 4 of this section shall be subject to a fine of fifty thousand dollars.

6. The department shall promulgate rules to implement the provisions 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, 2015, shall be invalid and void.

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