

SECOND REGULAR SESSION

SENATE BILL NO. 993

100TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR BURLISON.

Read 1st time February 11, 2020, and ordered printed.

ADRIANE D. CROUSE, Secretary.

5357S.011

AN ACT

To amend chapter 191, RSMo, by adding thereto one new section relating to off-label uses of drugs, biological products, or medical devices.

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 191.482, to read as follows:

191.482. 1. This section shall be known and may be cited as the "Free Speech in Medicine Act".

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

(1) "Biological product", the same meaning as in 42 U.S.C. Section 262;

(2) "Health carrier", the same meaning as in section 376.1350;

(3) "Misbranding", the same meaning as in 21 U.S.C. Section 352;

(4) "Off-label", the use of a U.S. Food and Drug Administration-approved drug, biological product, or medical device other than the use approved by the U.S. Food and Drug Administration.

3. No official, employee, or agent of the state shall enforce or apply any state law against, or otherwise prosecute, a pharmaceutical manufacturer, or its representatives, for engaging in truthful promotion of an off-label use of a drug, biological product, or medical device.

4. No state regulatory board shall revoke, fail to renew, or take any other action against the license or registry of any pharmaceutical manufacturer, or its representatives, or health care provider solely for engaging in truthful promotion of an off-label use of a drug, biological product, or medical device.

5. The state and any political subdivision of the state shall be

22 prohibited from using any personnel or financial resources to enforce
23 or cooperate with federal attempts to enforce or apply 21 U.S.C. Section
24 331 or 21 U.S.C. Section 352 against, or otherwise prosecute, a
25 pharmaceutical manufacturer, or its representatives, solely for
26 engaging in truthful promotion of an off-label use of a drug, biological
27 product, or medical device.

28 6. The provisions of this section shall not require a health
29 carrier, other third-party payer, or other health plan sponsor to
30 provide coverage for the cost of any off-label treatment. A health
31 carrier, other third-party payer, or other health plan sponsor may
32 provide coverage for an off-label use of a drug, biological product, or
33 medical device.

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