

By: Parker, Kacal

H.B. No. 2185

A BILL TO BE ENTITLED

AN ACT

relating to the promotion of off-label uses of certain drugs,
biological products, and devices.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle A, Title 6, Health and Safety Code, is
amended by adding Chapter 444 to read as follows:

CHAPTER 444. OFF-LABEL USE OF CERTAIN DRUGS, BIOLOGICAL PRODUCTS,
AND DEVICES

Sec. 444.001. DEFINITIONS. In this chapter:

(1) "Health care provider" means a person other than a
physician who is licensed, certified, or otherwise authorized by
the laws of this state to dispense or prescribe a prescription drug
in the ordinary course of business or practice of a profession.

(2) "Off-label use" means the use of a drug,
biological product, or device approved for use by the United States
Food and Drug Administration in a manner other than the use for
which it is approved by the United States Food and Drug
Administration.

(3) "Physician" means a person licensed to practice
medicine in this state.

(4) "Third-party payer" means an insurance company,
health benefit plan sponsor, or entity other than the patient or
healthcare provider that pays for medical services provided to a
patient.

1 Sec. 444.002. PROMOTION OF OFF-LABEL USE OF CERTAIN DRUGS,
2 BIOLOGICAL PRODUCTS, OR DEVICES. (a) Notwithstanding other law, a
3 pharmaceutical manufacturer or a representative of a
4 pharmaceutical manufacturer may promote, in the manufacturer's
5 advertising or marketing materials or directly to a physician,
6 health care provider, or third-party payer a medically truthful and
7 accurate off-label use of a drug, biological product, or device.

8 (b) A physician or health care provider may communicate or
9 otherwise promote to a patient an off-label use of a drug,
10 biological product, or device consistent with the off-label use
11 promoted for that drug, product, or device, as applicable, by a
12 pharmaceutical manufacturer under Subsection (a).

13 Sec. 444.003. DISCIPLINARY ACTION PROHIBITED FOR PROMOTION
14 OF OFF-LABEL USE. (a) A pharmaceutical manufacturer or a
15 representative of a pharmaceutical manufacturer may not be
16 prosecuted or be subject to disciplinary action, including a
17 revocation of or refusal to renew a license or certification, for
18 promoting an off-label use of a drug, biological product, or device
19 under Section 444.002.

20 (b) The state regulatory authority of a physician or health
21 care provider may not revoke or refuse to renew the license or
22 certificate of or otherwise impose a disciplinary action against a
23 physician or health care provider who communicates or otherwise
24 promotes an off-label use of a drug, biological product, or device
25 under Section 444.002.

26 Sec. 444.004. HEALTH BENEFIT PLAN COVERAGE FOR OFF-LABEL
27 USE NOT REQUIRED. This chapter does not require a health benefit

1 plan to provide health benefit coverage for an off-label use of a
2 drug, biological product, or device.

3 Sec. 444.005. USE OF STATE MONEY FOR CERTAIN PURPOSES
4 PROHIBITED. This state or a local governmental entity may not use
5 public money to enforce or to cooperate with the federal government
6 in enforcing 21 U.S.C. Sections 331 and 335 against a
7 pharmaceutical manufacturer or a representative of a
8 pharmaceutical manufacturer for promoting an off-label use under
9 Section 444.002.

10 SECTION 2. Section 444.003, Health and Safety Code, as
11 added by this Act, applies to a prosecution or disciplinary action
12 initiated or pending on or after the effective date of this Act.

13 SECTION 3. This Act takes effect September 1, 2021.