

By: Harrison

H.B. No. 4341

A BILL TO BE ENTITLED

AN ACT

relating to promoting, prescribing, administering, or dispensing prescription drugs for off-label use.

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 PRESCRIPTION DRUGS

Sec. 444.001. DEFINITIONS. In this chapter:

(1) "Off-label use" means the use of a prescription drug approved for use by the United States Food and Drug Administration in a manner other than the approved use.

(2) "Pharmacist" means a person licensed by the Texas State Board of Pharmacy to practice pharmacy.

(3) "Physician" means an individual licensed by the Texas Medical Board to practice medicine in this state.

Sec. 444.002. APPLICABILITY. This chapter applies only to the promoting, prescribing, administering, and dispensing of a prescription drug the United States Food and Drug Administration has approved for human use.

Sec. 444.003. PROHIBITED DISCIPLINARY ACTION AGAINST PHYSICIAN'S OR PHARMACIST'S LICENSE. The state agency with licensing or regulatory authority over a physician or pharmacist may not revoke, fail to renew, suspend, or take any other adverse action against a physician's or pharmacist's license based solely

1 on the physician or pharmacist:

2 (1) prescribing, administering, or dispensing a
3 prescription drug for off-label use to treat a patient, unless such
4 authorities prove beyond a reasonable doubt that the prescribing,
5 administering, or dispensing led to the direct physical harm of a
6 person who was a patient within the 3 years immediately preceding
7 the physical harm; or

8 (2) communicating or otherwise promoting to a patient
9 an off-label use of a prescription drug, unless such authorities
10 prove beyond a reasonable doubt that the speech led to the direct
11 physical harm of a person who was a patient within the 3 years
12 immediately preceding the physical harm.

13 SECTION 2. The changes in law made by this Act apply only to
14 a prescription issued or a prescription drug promoted,
15 administered, or dispensed on or after the effective date of this
16 Act.

17 SECTION 3. This Act takes effect September 1, 2023.