

By: Harrison

H.B. No. 855

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 446 to read as follows:

CHAPTER 446. OFF-LABEL USE OF PRESCRIPTION DRUGS

Sec. 446.001. 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. 446.002. 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. 446.003. PROHIBITED DISCIPLINARY ACTION AGAINST PHYSICIAN'S OR PHARMACIST'S LICENSE. (a) Except as provided by Subsection (b), 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

1 physician's or pharmacist's license based solely on the physician
2 or pharmacist:

3 (1) prescribing, administering, or dispensing a
4 prescription drug for off-label use to treat a patient; or

5 (2) communicating or otherwise promoting to a patient
6 an off-label use of a prescription drug.

7 (b) The state agency with licensing or regulatory authority
8 over a physician or pharmacist may revoke, fail to renew, suspend,
9 or take any other adverse action against a physician's or
10 pharmacist's license based on conduct described by Subsection
11 (a)(1) or (2) if, after notice and hearing, the agency proves beyond
12 a reasonable doubt that:

13 (1) the conduct caused the physician's or pharmacist's
14 patient to suffer physical harm; and

15 (2) the initial onset of the patient's physical harm
16 occurred not later than three years after the date of the
17 physician's or pharmacist's conduct.

18 SECTION 2. The changes in law made by this Act apply only to
19 a prescription issued or a prescription drug promoted,
20 administered, or dispensed on or after the effective date of this
21 Act.

22 SECTION 3. This Act takes effect September 1, 2025.