By: McGee H.B. No. 1260

A BILL TO BE ENTITLED

AN ACT

relating to the disclosure of financial interests by and the regulation of advertising by health care practitioners who promote or facilitate the sale of drugs to consumers; providing administrative and civil penalties.

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

SECTION 1. SHORT TITLE. This Act may be cited as the Practitioner Drug Promotion Transparency Act.

SECTION 2. Subtitle A, Title 3, Occupations Code, is amended by adding Chapter 118 to read as follows:

CHAPTER 118. PROMOTION AND SALE OF DRUGS BY HEALTH CARE PRACTITIONERS

Sec. 118.001. DEFINITIONS. In this chapter:

(1) "Advertising" means any communication made to the public or to a consumer, in any medium, that promotes the purchase or use of a drug, including a statement made on an Internet website, a social media platform, a newsletter, a subscription publication, a podcast, a broadcast, a video, a livestream, an e-mail, or a text message, and including a link, discount code, or other means of directing a consumer to a point of sale.

(2) "Affiliated entity" means a person in which a health care practitioner or a member of the practitioner's immediate family holds a financial interest, including a pharmacy, telemedicine platform, distributor, wholesaler, or online

retailer.

(3) "Covered sale" means a sale or dispensing of a drug to a consumer in this state in which a health care practitioner has a financial interest, whether the drug is dispensed under a prescription drug order, under a statewide standing order or protocol, or without a prescription.

(4) "Drug" has the meaning assigned by Section 431.002, Health and Safety Code, and includes a compounded drug.

(5) "Financial interest" means any direct or indirect interest in, or expectation of, remuneration that varies with or is contingent on the sale of a drug, including:

(A) an ownership or investment interest in an affiliated entity;

(B) a commission, affiliate fee, referral fee, royalty, or share of revenue or profit;

(C) compensation attributable to a discount code, tracking link, or similar referral mechanism; and

(D) a consulting, speaking, sponsorship, or licensing fee paid by a person that manufactures, compounds, distributes, or dispenses the drug.

The term does not include ownership of less than one percent of the outstanding securities of a publicly traded company, or a reasonable fee for professional services lawfully billed to a patient that does not vary with the patient's purchase of a particular drug.

(6) "Health care practitioner" means an individual licensed, certified, or registered under this title who is

authorized to prescribe or order a drug.

(7) "Licensing authority" means the state agency that issued the health care practitioner's license, certification, or registration.

(8) "Unapproved use" means the use of a drug for a disease, condition, or purpose that is not included in the drug's labeling approved by the United States Food and Drug Administration.

Sec. 118.002. APPLICABILITY. This chapter applies to a health care practitioner who, directly or through an affiliated entity or agent, advertises a drug in which the practitioner has a financial interest or facilitates a covered sale, regardless of whether the practitioner has a practitioner-patient relationship with the consumer.

Sec. 118.003. REQUIRED DISCLOSURES IN ADVERTISING AND AT POINT OF SALE. (a) A health care practitioner who advertises a drug in which the practitioner has a financial interest shall include in the advertising a clear and conspicuous statement that:

(1) the practitioner has a financial interest in the sale of the drug;

(2) describes the nature of the financial interest, including whether the practitioner owns or is compensated by the seller; and

(3) if the advertising promotes an unapproved use, states: "This drug has not been approved by the U.S. Food and Drug Administration for the use described. Talk to a licensed health care provider who does not profit from this sale before taking it."

(b) Before a covered sale is completed through an Internet website or other remote ordering system, the seller and the health care practitioner shall ensure the consumer is shown, on a page the consumer must view before payment:

(1) the disclosures required by Subsection (a);

(2) the name, address, and license number of each health care practitioner who has a financial interest in the sale;

(3) the name, license number, and physical address of the pharmacy or other person that will dispense the drug;

(4) a statement that the consumer may obtain the drug, if lawfully available, from any pharmacy of the consumer's choosing; and

(5) the address of an Internet website maintained by the licensing authority where the consumer may file a complaint.

(c) A statement required by this section is clear and conspicuous only if it is:

(1) in written advertising, displayed in the body of the advertising itself, and not only in a linked page, profile, or caption that requires the consumer to expand or click, in a type size at least as large as the largest type used to describe the drug's benefits;

(2) in audio or video advertising, spoken at the beginning of the communication and, for video, also displayed on screen for not less than five seconds; and

(3) in a livestream or recurring broadcast, repeated at least once every 15 minutes during which the drug is promoted.

(d) The licensing authorities, in consultation with the

Health Professions Council, may adopt rules prescribing additional format requirements for disclosures on specific media platforms.

Sec. 118.004. PUBLIC REPORTING OF FINANCIAL INTERESTS. (a) Not later than March 1 of each year, a health care practitioner who had a financial interest in a covered sale or who advertised a drug in which the practitioner had a financial interest during the preceding calendar year shall file a report with the practitioner's licensing authority that includes:

(1) the name and address of each affiliated entity and each person from whom the practitioner received remuneration described by Section 118.001(5);

(2) each drug advertised or sold, and each disease or condition for which the practitioner promoted the drug;

(3) the total remuneration received, reported in ranges prescribed by rule of the licensing authority; and

(4) the approximate number of covered sales.

(b) The licensing authority shall make the information described by Subsections (a)(1), (2), and (3) available to the public on its Internet website, including in any public profile of the practitioner maintained by the licensing authority.

(c) Information described by Subsection (a)(4) is confidential, except that it may be disclosed in a disciplinary proceeding or an enforcement action under this chapter.

Sec. 118.005. UNSUPPORTED CLAIMS PROHIBITED. (a) A health care practitioner may not, in advertising for a drug in which the practitioner has a financial interest, represent that the drug prevents, treats, mitigates, or cures a disease or condition

unless:

(1) that use is included in the drug's labeling approved by the United States Food and Drug Administration; or

(2) at the time the representation is made, the representation is substantiated by competent and reliable scientific evidence, which must include at least one adequate and well-controlled clinical study in humans, published in a peer-reviewed scientific or medical journal, that demonstrates the claimed effect for that disease or condition.

(b) A representation is not substantiated under Subsection (a)(2) if it is based solely on laboratory or in vitro data, animal studies, the drug's mechanism of action, anecdotal reports, or the practitioner's personal clinical experience.

(c) The health care practitioner bears the burden of producing the substantiation required by Subsection (a)(2) in a disciplinary proceeding or enforcement action under this chapter.

Sec. 118.006. NONPRESCRIPTION AND REMOTE SALES. (a) A health care practitioner may not hold a financial interest in, or accept remuneration from any person in connection with, the dispensing of a drug by a pharmacist under a statewide standing order or protocol that authorizes dispensing without a patient-specific prescription drug order, including dispensing under Chapter 446, Health and Safety Code.

(b) A health care practitioner who has a financial interest in a covered sale may not issue a prescription drug order for that sale unless the practitioner has established a practitioner-patient relationship that meets the standard of care,

as provided by Chapter 111. A practitioner-patient relationship is not established for purposes of this subsection solely by the consumer's completion of an online questionnaire or by the consumer's purchase of the drug.

(c) Before issuing a prescription drug order for a covered sale, the health care practitioner shall provide the patient the written disclosures required by Section 118.003(b) and obtain the patient's acknowledgment, which may be electronic, and shall retain the acknowledgment in the patient's medical record.

Sec. 118.007. EXCEPTIONS. This chapter does not apply to:

(1) a statement, opinion, publication, testimony, or other communication by a health care practitioner who does not have a financial interest in the sale of the drug that is the subject of the communication;

(2) a communication made solely to another health care practitioner in a professional or scientific context, including a peer-reviewed publication or a presentation at a professional conference, that does not include a point of sale or referral mechanism;

(3) a drug sample provided without charge in compliance with federal law;

(4) the provision or dispensing of a drug by a physician in compliance with Chapter 158, other than through advertising to the public; or

(5) a drug administered to a patient in a hospital, ambulatory surgical center, or the practitioner's office as part of a course of treatment.

Sec. 118.008. ENFORCEMENT; PENALTIES. (a) A violation of this chapter by a health care practitioner is:

(1) unprofessional conduct and a ground for disciplinary action by the practitioner's licensing authority under the law governing the practitioner's license, including Section 164.051 for a physician; and

(2) a false, misleading, or deceptive act or practice under Section 17.46, Business & Commerce Code, and is actionable under Subchapter E, Chapter 17, Business & Commerce Code.

(b) A person who violates this chapter is liable to the state for a civil penalty of not more than $10,000 for each violation. Each advertisement disseminated and each covered sale made in violation of this chapter constitutes a separate violation.

(c) The maximum civil penalty under Subsection (b) is doubled for a violation of Section 118.005 that relates to a disease or condition that is the subject of a public health disaster declared under Section 81.003, Health and Safety Code, or a state of disaster declared under Chapter 418, Government Code, if the violation occurs while the declaration is in effect.

(d) The attorney general, or the district attorney or county attorney of a county in which a consumer who received the advertising or purchased the drug resides, may bring an action to recover a civil penalty, obtain restitution for affected consumers, or obtain injunctive relief under this chapter. A prosecuting attorney who prevails in an action under this subsection may recover reasonable attorney's fees and investigative costs.

(e) A licensing authority shall refer a complaint alleging a

violation of this chapter to the attorney general and to the appropriate local prosecuting attorney not later than the 30th day after the date the licensing authority determines the complaint is not frivolous.

(f) The remedies provided by this chapter are cumulative of any other remedy provided by law.

Sec. 118.009. RULES. Each licensing authority shall adopt rules as necessary to implement this chapter. The Health Professions Council shall coordinate the rules to ensure consistent disclosure standards across licensing authorities.

SECTION 3. Chapter 446, Health and Safety Code, is amended by adding Sections 446.003 and 446.004 to read as follows:

Sec. 446.003. REFERRAL PAYMENTS PROHIBITED; DISCLOSURE. (a) A pharmacist or pharmacy may not pay or offer remuneration of any kind to a health care practitioner, as defined by Section 118.001, Occupations Code, or to any other person in exchange for referring, directing, or recruiting a consumer to purchase ivermectin dispensed under Section 446.001.

(b) A pharmacist who dispenses ivermectin under Section 446.001 shall provide the consumer a written notice stating: "Ivermectin has not been approved by the U.S. Food and Drug Administration to prevent or treat COVID-19, hantavirus, or other viral infections. Taking more than the recommended dose can cause serious harm."

(c) A violation of Subsection (a) is grounds for disciplinary action by the Texas State Board of Pharmacy and constitutes a violation of Chapter 102, Occupations Code.

Sec. 446.004. ANNUAL REPORT. Not later than March 1 of each year, each pharmacy that dispensed ivermectin under Section 446.001 during the preceding calendar year shall report to the Texas State Board of Pharmacy, in the form prescribed by the board, the number of doses dispensed and any adverse event reported to the pharmacy. The board shall publish an aggregate summary of the reports on its Internet website.

SECTION 4. Section 154.006(a), Occupations Code, is amended by adding Subdivision (__) to read as follows:

(__) the information required to be made public under Section 118.004, as reported by the physician;

SECTION 5. Not later than December 1, 2027, each licensing authority shall adopt the rules required by Section 118.009, Occupations Code, as added by this Act.

SECTION 6. (a) Sections 118.003, 118.005, and 118.006, Occupations Code, as added by this Act, apply only to advertising disseminated or a sale made on or after January 1, 2028.

(b) A health care practitioner is not required to file a report under Section 118.004, Occupations Code, as added by this Act, before March 1, 2029.

(c) Section 446.003, Health and Safety Code, as added by this Act, applies only to remuneration paid or offered on or after January 1, 2028.

SECTION 7. SEVERABILITY. If any provision of this Act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this Act that can be given effect without the invalid provision or

application, and to this end the provisions of this Act are severable.

SECTION 8. This Act takes effect September 1, 2027.