By: Oliverson H.B. No. 1033

A BILL TO BE ENTITLED

AN ACT

- 2 relating to prescription drug price disclosure; authorizing a fee;
- 3 providing an administrative penalty.
- 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
- 5 SECTION 1. Subchapter A, Chapter 441, Health and Safety
- 6 Code, is amended by adding Section 441.0003 to read as follows:
- 7 Sec. 441.0003. RULES. The executive commissioner may adopt
- 8 rules to implement this chapter.
- 9 SECTION 2. Chapter 441, Health and Safety Code, is amended
- 10 by adding Subchapter B, and a heading is added to that subchapter to
- 11 read as follows:

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- 12 SUBCHAPTER B. PRESCRIPTION DRUG PRICE DISCLOSURE
- 13 SECTION 3. Section 441.0002, Health and Safety Code, is
- 14 transferred to Subchapter B, Chapter 441, Health and Safety Code,
- 15 as added by this Act, redesignated as Sections 441.0051, 441.0052,
- 16 441.0053, and 441.0054, Health and Safety Code, and amended to read
- 17 as follows:
- 18 Sec. <u>441.0051</u> [<u>441.0002</u>]. <u>ANNUAL REPORT</u> [DISCLOSURE OF
- 19 DRUG PRICING INFORMATION]. [(a)] Not later than the 15th day of
- 20 each calendar year, a pharmaceutical drug manufacturer shall submit
- 21 a report to the department [executive commissioner] stating the
- 22 current wholesale acquisition cost information for the United
- 23 States Food and Drug Administration-approved prescription drugs
- 24 sold in or into this state by that manufacturer.

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1 Sec. 441.0052. PRESCRIPTION DRUG PRICE INFORMATION INTERNET WEBSITE. [(b)] The department [executive commissioner] 2 shall develop an Internet website to provide to the general public 3 prescription drug price information submitted under 4 441.0051 [Subsection (a)]. The Internet website shall be made 5 available on the <u>department's</u> [Health and Human Services 6 Commission's Internet website with a dedicated link that is 7 prominently displayed on the home page or by a separate easily 8 identifiable Internet address. 9 10 Sec. 441.0053. PRESCRIPTION DRUG COST INCREASE INFORMATION. (a) If during a calendar year [(c) This subsection 11 12 applies only to] a prescription drug with a wholesale acquisition cost of at least \$100 for a 30-day supply increases in price by 13 [before the effective date of an increase described by this 14 15 subsection. Not later than the 30th day after the effective date of 16 an increase of] 40 percent or more over the preceding three calendar 17 years or 15 percent or more in the preceding calendar year in the wholesale acquisition cost of the prescription [a] drug, the [to]18 19 which this subsection applies, a] pharmaceutical drug manufacturer must include in the annual [shall submit a report to the executive 20 21 commissioner. The] report submitted under Section 441.0051 [must include] the following information: 22 23 (1)the name of the prescription drug; 24 (2) whether the prescription drug is a brand name or 25 generic;

(3) the effective date of the change in wholesale

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acquisition cost;

- 1 (4) aggregate, company-level research and development
- 2 costs for the most recent year for which final audit data is
- 3 available;
- 4 (5) the name of each of the manufacturer's
- 5 prescription drugs approved by the United States Food and Drug
- 6 Administration in the previous three calendar years;
- 7 (6) the name of each of the manufacturer's
- 8 prescription drugs that lost patent exclusivity in the United
- 9 States in the previous three calendar years; and
- 10 (7) a statement regarding the factor or factors that
- 11 caused the increase in the wholesale acquisition cost and an
- 12 explanation of the role of each factor's impact on the cost.
- (b) $[\frac{d}{d}]$ The quality and types of information and data that
- 14 a pharmaceutical drug manufacturer submits to the <u>department</u>
- 15 [executive commissioner] under Subsection (a) [(c)] must be
- 16 consistent with the quality and types of information and data that
- 17 the manufacturer includes in the manufacturer's annual
- 18 consolidated report on Securities and Exchange Commission Form 10-K
- 19 or any other public disclosure.
- Sec. 441.0054. PUBLICATION OF COST INCREASE INFORMATION.
- 21 [(e)] Not later than the 60th day after receipt of the report
- 22 submitted under Section 441.0051 [Subsection (c)], the department
- 23 [executive commissioner] shall publish the cost increase
- 24 information required by Section 441.0053 [report] on the
- 25 department's prescription drug price information [Health and Human
- 26 Services Commission's Internet website [described by Subsection
- 27 $\frac{(b)}{(b)}$].

1	[(f) The executive commissioner may adopt rules to
2	<pre>implement this section.</pre>
3	SECTION 4. Subchapter B, Chapter 441, Health and Safety
4	Code, as added by this Act, is amended by adding Section 441.0055 to
5	read as follows:
6	Sec. 441.0055. FEE. (a) A pharmaceutical drug
7	manufacturer shall submit a fee in the amount provided by
8	department rule with each report submitted under this subchapter.
9	(b) The executive commissioner by rule shall set the fee in
10	the amount necessary for the department to administer this chapter.
11	SECTION 5. Chapter 441, Health and Safety Code, is amended
12	by adding Subchapter C to read as follows:
13	SUBCHAPTER C. ENFORCEMENT
14	Sec. 441.0101. RIGHT TO CORRECT. (a) If the department
15	determines that a pharmaceutical drug manufacturer failed to submit
16	a report or fee required under Subchapter B and the rules adopted
17	under this chapter, the department shall provide written notice of
18	the failure to the manufacturer.
19	(b) On receipt of notice described by Subsection (a), a
20	<pre>pharmaceutical drug manufacturer shall submit, as applicable:</pre>
21	(1) a report that:
22	(A) complies with Subchapter B and rules adopted
23	under this chapter; and
24	(B) addresses the issues raised in the notice; or
25	(2) the fee required by Section 441.0055.
26	(c) The department may not assess an administrative penalty
27	under Section 441.0102 against a pharmaceutical drug manufacturer

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- 1 that submits to the department the required report or fee, as
- 2 applicable, on or before the 45th day after the date the
- 3 manufacturer receives notice under Subsection (a).
- 4 Sec. 441.0102. ADMINISTRATIVE PENALTY. (a) The department
- 5 may assess an administrative penalty against a person who violates
- 6 this chapter or a rule adopted under this chapter.
- 7 (b) In determining the amount of the penalty, the department
- 8 shall consider:
- 9 (1) the person's previous violations;
- 10 (2) the seriousness of the violation;
- 11 (3) the person's demonstrated good faith; and
- 12 (4) any other matters as justice may require.
- 13 (c) The penalty may not exceed \$1,000 a day for each
- 14 violation.
- 15 (d) Each day a violation continues may be considered a
- 16 separate violation.
- (e) The enforcement of the penalty may be stayed during the
- 18 time the order is under judicial review if the person pays the
- 19 penalty to the clerk of the court or files a supersedeas bond with
- 20 the court in the amount of the penalty. A person who cannot afford
- 21 to pay the penalty or file the bond may stay the enforcement by
- 22 filing an affidavit in the manner required by the Texas Rules of
- 23 Civil Procedure for a party who cannot afford to file security for
- 24 costs, subject to the right of the board to contest the affidavit as
- 25 provided by those rules.
- 26 (f) The attorney general may sue to collect the penalty.
- 27 Money collected under this section shall be deposited in the state

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- 1 treasury and may be appropriated only to the department for the
- 2 purposes of administrating this chapter.
- 3 Sec. 441.0103. ADMINISTRATIVE PROCEDURE. A proceeding to
- 4 impose an administrative penalty under Section 441.0102 is
- 5 considered to be a contested case under Chapter 2001, Government
- 6 Code.
- 7 SECTION 6. Subchapter C, Chapter 441, Health and Safety
- 8 Code, as added by this Act, applies only to a violation occurring on
- 9 or after the effective date of this Act.
- 10 SECTION 7. This Act takes effect September 1, 2021.