SENATE AMENDMENTS

2nd Printing

By: Oliverson, Blanco H.B. No. 2536

A BILL TO BE ENTITLED

1	AN ACT
2	relating to transparency related to drug costs.
3	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
4	SECTION 1. Subtitle A, Title 6, Health and Safety Code, is
5	amended by adding Chapter 441 to read as follows:
6	CHAPTER 441. DRUG COST TRANSPARENCY
7	SUBCHAPTER A. GENERAL PROVISIONS
8	Sec. 441.0001. DEFINITIONS. In this chapter:
9	(1) "Animal health product" means a medical product
LO	approved and licensed for use in animal or veterinary medicine,
L1	including a pharmaceutical, a biologic, an insecticide, and a
L2	parasiticide.
L3	(2) "Pharmaceutical drug manufacturer" means a person
L4	engaged in the business of producing, preparing, propagating,
L5	compounding, converting, processing, packaging, labeling, or
L6	distributing a drug. The term does not include a wholesale
L7	distributor or retailer of prescription drugs or a pharmacist
L8	licensed under Subtitle J, Title 3, Occupations Code.
L9	(3) "Prescription drug" and "drug" have the meanings
20	assigned by Section 551.003, Occupations Code, except that the term
21	"prescription drug" does not include a device or an animal health
22	product.
23	(4) "Wholesale acquisition cost" means, with respect
24	to a drug, the pharmaceutical drug manufacturer's list price for

- 1 the drug charged to wholesalers or direct purchasers in the United
- 2 States, as reported in wholesale price guides or other publications
- 3 of drug pricing data. The cost does not include any rebates, prompt
- 4 pay or other discounts, or other reductions in price.
- 5 Sec. 441.0002. DISCLOSURE OF DRUG PRICING INFORMATION. (a)
- 6 Not later than the 15th day of each calendar year, a pharmaceutical
- 7 drug manufacturer shall submit a report to the executive
- 8 commissioner stating the current wholesale acquisition cost
- 9 information for the United States Food and Drug
- 10 Administration-approved drugs sold in or into this state by that
- 11 manufacturer.
- 12 (b) The executive commissioner shall develop an Internet
- 13 website to provide to the general public drug price information
- 14 submitted under Subsection (a). The Internet website shall be made
- 15 available on the Health and Human Services Commission's Internet
- 16 website with a dedicated link that is prominently displayed on the
- 17 home page or by a separate easily identifiable Internet address.
- 18 (c) This subsection applies only to a drug with a wholesale
- 19 acquisition cost of at least \$100 for a 30-day supply before the
- 20 effective date of an increase described by this subsection. Not
- 21 later than the 30th day after the effective date of an increase of
- 22 40 percent or more over the preceding five calendar years or 10
- 23 percent or more in the preceding 12 months in the wholesale
- 24 acquisition cost of a drug to which this subsection applies, a
- 25 pharmaceutical drug manufacturer shall submit a report to the
- 26 executive commissioner. The report must include the following
- 27 information:

1 (1) the name of the drug; 2 whether the drug is a brand name or generic; 3 (3) the effective date of the change in wholesale 4 acquisition cost; 5 (4) aggregate, company-level research and development costs for the most recent year for which final audit data is 6 7 available; 8 (5) the name of each of the manufacturer's prescription drugs approved by the United States Food and Drug 9 10 Administration in the previous five calendar years; 11 (6) the name of each of the manufacturer's 12 prescription drugs that lost patent exclusivity in the United States in the previous five calendar years; 13 14 (7) all factors that caused the increase in the 15 wholesale acquisition cost; 16 (8) the percentage of the total increase in the 17 wholesale acquisition cost that is attributable to each factor listed in Subdivision (7); and 18 19 (9) an explanation of the role of each factor listed in Subdivision (7) in contributing to the increase in the wholesale 20 21 acquisition cost. (d) The quality and types of information and data that a 22 pharmaceutical drug manufacturer submits to the executive 23 24 commissioner under Subsection (c) must be consistent with the quality and types of information and data that the manufacturer 25 26 includes in the manufacturer's annual consolidated report on

Securities and Exchange Commission Form 10-K or any other public

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- 1 <u>disclosure</u>.
- 2 (e) Not later than the 60th day after receipt of the report
- 3 submitted under Subsection (c), the executive commissioner shall
- 4 publish the report on the Health and Human Services Commission's
- 5 Internet website described by Subsection (b).
- 6 (f) The executive commissioner may adopt rules to implement
- 7 this section.
- 8 SECTION 2. Chapter 1369, Insurance Code, is amended by
- 9 adding Subchapter K to read as follows:
- 10 SUBCHAPTER K. PRESCRIPTION DRUG COST TRANSPARENCY
- 11 Sec. 1369.501. DEFINITIONS. In this subchapter:
- 12 (1) "Animal health product" means a medical product
- 13 approved and licensed for use in animal or veterinary medicine,
- 14 including a pharmaceutical, a biologic, an insecticide, and a
- 15 parasiticide.
- 16 (2) "Health benefit plan" means an individual,
- 17 blanket, or group plan, policy, or contract for health care
- 18 services issued or delivered by a health benefit plan issuer in this
- 19 state.
- 20 (3) "Health benefit plan issuer" means an insurance
- 21 company, a health maintenance organization, or a hospital and
- 22 <u>medical service corporation.</u>
- 23 (4) "Pharmaceutical drug manufacturer" means a person
- 24 engaged in the business of producing, preparing, propagating,
- 25 compounding, converting, processing, packaging, labeling, or
- 26 distributing a prescription drug. The term does not include a
- 27 wholesale distributor or retailer of prescription drugs or a

- 1 pharmacist licensed under Subtitle J, Title 3, Occupations Code.
- 2 (5) "Pharmacy benefit manager" has the meaning
- 3 assigned by Section 4151.151.
- 4 (6) "Prescription drug" has the meaning assigned by
- 5 Section 551.003, Occupations Code, except that the term
- 6 "prescription drug" does not include a device or an animal health
- 7 product.
- 8 <u>(7) "Rebate" means a discount or concession that</u>
- 9 affects the price of a prescription drug to a pharmacy benefit
- 10 manager or health benefit plan issuer for a prescription drug
- 11 manufactured by the pharmaceutical drug manufacturer.
- 12 (8) "Specialty drug" means a prescription drug covered
- 13 under Medicare Part D that exceeds the specialty tier cost
- 14 threshold established by the Centers for Medicare and Medicaid
- 15 <u>Services.</u>
- 16 (9) "Utilization management" means a set of formal
- 17 techniques designed to monitor the use of, or evaluate the medical
- 18 necessity, appropriateness, efficacy, or efficiency of, health
- 19 care services, procedures, or settings.
- 20 <u>Sec. 1369.502. PHARMACY BENEF</u>IT MANAGER INFORMATION. (a)
- 21 Not later than February 1 of each year, each pharmacy benefit
- 22 manager shall file a report with the commissioner. The report must
- 23 state for the immediately preceding calendar year:
- 24 (1) the aggregated rebates, fees, price protection
- 25 payments, and any other payments collected from pharmaceutical drug
- 26 manufacturers; and
- 27 (2) the aggregated dollar amount of rebates, fees,

- 1 price protection payments, and any other payments collected from 2 pharmaceutical drug manufacturers that were: (A) passed to: 3 4 (i) health benefit plan issuers; or 5 (ii) enrollees at the point of sale of a 6 prescription drug; or 7 (B) retained as revenue by the pharmacy benefit 8 manager.
- 9 (b) A report submitted by a pharmacy benefit manager may not
 10 disclose the identity of a specific health benefit plan or
 11 enrollee, the price charged for a specific prescription drug or
 12 class of prescription drugs, or the amount of any rebate or fee
 13 provided for a specific prescription drug or class of prescription
 14 drugs.
- (c) Not later than the 60th day after receipt, the commissioner shall publish the report in an appropriate location on the department's Internet website.
- Not later than February 1 of each year, each health benefit plan issuer shall submit to the commissioner a report that states for the

Sec. 1369.503. HEALTH BENEFIT PLAN ISSUER INFORMATION. (a)

21 <u>immediately preceding calendar year:</u>

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- 22 (1) the names of the 25 most frequently prescribed 23 prescription drugs across all plans;
- 24 (2) the percent increase in annual net spending for
 25 prescription drugs across all plans;
- 26 (3) the percent increase in premiums that were 27 attributable to prescription drugs across all plans;

- 1 (4) the percentage of specialty drugs with utilization
- 2 management requirements across all plans; and
- 3 (5) the premium reductions that were attributable to
- 4 specialty drug utilization management.
- 5 (b) A report submitted by a health benefit plan issuer may
- 6 not disclose the identity of a specific health benefit plan or the
- 7 price charged for a specific prescription drug or class of
- 8 prescription drugs.
- 9 (c) Not later than the 60th day after receipt, the
- 10 commissioner shall publish the report in an appropriate location on
- 11 the department's Internet website.
- 12 Sec. 1369.504. RULES. The commissioner may adopt rules to
- 13 implement this subchapter.
- 14 SECTION 3. Notwithstanding Chapter 441, Health and Safety
- 15 Code, as added by this Act, and Subchapter K, Chapter 1369,
- 16 Insurance Code, as added by this Act, a pharmaceutical drug
- 17 manufacturer, pharmacy benefit manager, or health benefit plan
- 18 issuer is not required to submit a summary report as required by
- 19 Chapter 441, Health and Safety Code, as added by this Act, or
- 20 Subchapter K, Chapter 1369, Insurance Code, as added by this Act, as
- 21 applicable, before January 1, 2020.
- 22 SECTION 4. This Act takes effect September 1, 2019.



MAY 2 2 2019

Secretary of the Sense

FLOOR AMENDMENT NO.

BY: Killy Harmon

- Amend H.B. No. 2536 (senate committee report) as follows:
- 2 (1) In SECTION 1 of the bill, in added Section 441.0002(c),
- 3 Health and Safety Code (page 1, line 63), strike "five calendar
- 4 years or 10" and substitute "three calendar years or 15".
- 5 (2) In SECTION 1 of the bill, in added Section 441.0002(c),
- 6 Health and Safety Code (page 2, line 1), strike "12 months" and
- 7 substitute "calendar year".
- 8 (3) In SECTION 1 of the bill, in added Section
- 9 441.0002(c)(5), Health and Safety Code (page 2, line 15), strike
- 10 "five" and substitute "three".
- 11 (4) In SECTION 1 of the bill, in added Section
- 12 441.0002(c)(6), Health and Safety Code (page 2, line 18), strike
- 13 "five" and substitute "three".
- 14 (5) In SECTION 1 of the bill, in added Section
- 15 441.0002(c)(6), Health and Safety Code (page 2, line 18),
- 16 immediately following "calendar years;", insert "and".
- 17 (6) In SECTION 1 of the bill, in added Section 441.0002(c),
- 18 Health and Safety Code, strike Subdivisions (7), (8), and (9) (page
- 19 2, lines 19-26) and substitute the following:
- 20 (7) a statement regarding the factor or factors that
- 21 caused the increase in the wholesale acquisition cost and an
- 22 explanation of the role of each factor's impact on the cost.
- 23 (7) In SECTION 2 of the bill, in added Section 1369.502,
- 24 Insurance Code (page 3, between lines 23 and 24), between
- 25 Subsections (a) and (b), insert the following:
- 26 (a-1) Notwithstanding Subsection (a), the report due not
- 27 later than February 1, 2020, under that subsection must state the
- 28 required information for the immediately preceding three calendar
- 29 years in addition to stating the required information for the

- 1 preceding calendar year. This subsection expires September 1,
- 2 2021.
- 3 (8) In SECTION 2 of the bill, in added Section 1369.502,
- 4 Insurance Code, strike Subsection (c) (page 3, lines 30-32) and
- 5 substitute the following:
- 6 (c) Not later than May 1 of each year, the commissioner
- 7 shall publish the aggregated data from all reports for that year
- 8 required by this section in an appropriate location on the
- 9 department's Internet website. The combined aggregated data from
- 10 the reports must be published in a manner that does not disclose or
- 11 tend to disclose proprietary or confidential information of any
- 12 pharmacy benefit manager.
- 13 (9) In SECTION 2 of the bill, in added Section 1369.503,
- 14 Insurance Code, strike Subsection (c) (page 3, lines 51-53) and
- 15 substitute the following:
- 16 (c) Not later than May 1 of each year, the commissioner
- 17 shall publish the aggregated data from all reports for that year
- 18 required by this section in an appropriate location on the
- 19 department's Internet website. The combined aggregated data from
- 20 the reports must be published in a manner that does not disclose or
- 21 tend to disclose proprietary or confidential information of any
- 22 health benefit plan issuer.

FISCAL NOTE, 86TH LEGISLATIVE REGULAR SESSION

May 22, 2019

TO: Honorable Dennis Bonnen, Speaker of the House, House of Representatives

FROM: John McGeady, Assistant Director Sarah Keyton, Assistant Director

Legislative Budget Board

IN RE: HB2536 by Oliverson (Relating to transparency related to drug costs.), As Passed 2nd

House

No significant fiscal implication to the State is anticipated.

The bill would require pharmaceutical drug manufacturers (PDMs) to annually report to the Health and Human Services Commission (HHSC) on the current wholesale acquisition costs of certain FDA-approved drugs sold in the state. HHSC would be required to develop a website to provide this information to the public. The bill would also require PDMs to report information on certain drug price increases. HHSC would be required to publish these reports online.

The bill would require Pharmacy Benefit Managers and Health Benefit Plan Issuers to submit reports to the Insurance Commissioner, who would be required to publish the combined aggregated data from those reports online.

The Employee Retirement System, Department of Insurance, The University of Texas System Administration, Texas A&M University System Administrative and General Office, and HHSC indicate that the provisions of the bill could be absorbed using existing resources.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 327 Employees Retirement System, 454 Department of Insurance, 529

Health and Human Services Commission, 710 Texas A&M University System Administrative and General Offices, 720 The University of Texas

System Administration

LBB Staff: WP, CLo, JQ, BH, CMa

FISCAL NOTE, 86TH LEGISLATIVE REGULAR SESSION

May 15, 2019

TO: Honorable Kelly Hancock, Chair, Senate Committee on Business & Commerce

FROM: John McGeady, Assistant Director Sarah Keyton, Assistant Director

Legislative Budget Board

IN RE: HB2536 by Oliverson (Relating to transparency related to drug costs.), As Engrossed

No significant fiscal implication to the State is anticipated.

The bill would require pharmaceutical drug manufacturers (PDMs) to annually report to the Health and Human Services Commission (HHSC) on the current wholesale acquisition costs of certain FDA-approved drugs sold in the state. HHSC would be required to develop a website to provide this information to the public. The bill would also require PDMs to report, and HHSC to publish, information on certain drug price increases.

The bill would also require Pharmacy Benefit Managers and Health Benefit Plan Issuers to submit reports to HHSC, and require HHSC to publish those reports online.

The Employee Retirement System, Department of Insurance, The University of Texas System Administration, Texas A&M University System Administrative and General Office, and HHSC indicate that the provisions of the bill could be absorbed using existing resources.

Local Government Impact

No fiscal implication to units of local government is anticipated.

Source Agencies: 327 Employees Retirement System, 454 Department of Insurance, 529

Health and Human Services Commission, 710 Texas A&M University System Administrative and General Offices, 720 The University of Texas

System Administration

LBB Staff: WP, CLo, JQ, BH, CMa

FISCAL NOTE, 86TH LEGISLATIVE REGULAR SESSION

April 18, 2019

TO: Honorable Eddie Lucio III, Chair, House Committee on Insurance

FROM: John McGeady, Assistant Director Sarah Keyton, Assistant Director

Legislative Budget Board

IN RE: HB2536 by Oliverson (relating to transparency related to drug costs.), Committee Report 1st House, Substituted

No significant fiscal implication to the State is anticipated.

The bill would require pharmaceutical drug manufacturers (PDMs) to annually report to the Health and Human Services Commission (HHSC) on the current wholesale acquisition costs of FDA-approved drugs sold in the state. HHSC would be required to develop a website to provide this information to the public. The bill would also require PDMs to report, and HHSC to publish, information on certain drug price increases.

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The Employee Retirement System, Department of Insurance, The University of Texas System Administration, Texas A&M University System Administrative and General Office, and HHSC indicate that the provisions of the bill could be absorbed using existing resources.

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Health and Human Services Commission, 710 Texas A&M University System Administrative and General Offices, 720 The University of Texas

System Administration

LBB Staff: WP, CMa, JQ, BH

FISCAL NOTE, 86TH LEGISLATIVE REGULAR SESSION

April 8, 2019

TO: Honorable Eddie Lucio III, Chair, House Committee on Insurance

FROM: John McGeady, Assistant Director Sarah Keyton, Assistant Director

Legislative Budget Board

IN RE: HB2536 by Oliverson (Relating to transparency related to drug costs.), As Introduced

No significant fiscal implication to the State is anticipated.

The bill would require pharmaceutical drug manufacturers (PDMs) to annually report to the Health and Human Services Commission (HHSC) on the current wholesale acquisition costs of FDA-approved drugs sold in the state. HHSC would be required to develop a website to provide this information to the public. The bill would also require PDMs to report, and HHSC to publish, information on certain drug price increases.

The bill would also require Pharmacy Benefit Managers and Health Benefit Plan Issuers to submit reports to HHSC, and require HHSC to publish those reports online.

The Employee Retirement System, Department of Insurance, The University of Texas System Administration, Texas A&M University System Administrative and General Office, and HHSC indicate that the provisions of the bill could be absorbed using existing resources.

Local Government Impact

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Health and Human Services Commission, 710 Texas A&M University System Administrative and General Offices, 720 The University of Texas

System Administration

LBB Staff: WP, CMa, JQ, BH