

House Bill 2536
Senate Amendments
Section-by-Section Analysis

HOUSE VERSION

SECTION 1. Subtitle A, Title 6, Health and Safety Code, is amended by adding Chapter 441 to read as follows:

CHAPTER 441. DRUG COST TRANSPARENCY

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 441.0001. DEFINITIONS. In this chapter:

(1) "Animal health product" means a medical product approved and licensed for use in animal or veterinary medicine, including a pharmaceutical, a biologic, an insecticide, and a parasiticide.

(2) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, labeling, or distributing a drug. The term does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed under Subtitle J, Title 3, Occupations Code.

(3) "Prescription drug" and "drug" have the meanings assigned by Section 551.003, Occupations Code, except that the term "prescription drug" does not include a device or an animal health product.

(4) "Wholesale acquisition cost" means, with respect to a drug, the pharmaceutical drug manufacturer's list price for the drug charged to wholesalers or direct purchasers in the United States, as reported in wholesale price guides or other publications of drug pricing data. The cost does not include any rebates, prompt pay or other discounts, or other reductions in price.

Sec. 441.0002. DISCLOSURE OF DRUG PRICING INFORMATION. (a) Not later than the 15th day of each calendar year, a pharmaceutical drug manufacturer shall submit a report to the executive commissioner stating the current wholesale acquisition cost information for the United States Food and Drug Administration-approved drugs sold in

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or into this state by that manufacturer.

(b) The executive commissioner shall develop an Internet website to provide to the general public drug price information submitted under Subsection (a). The Internet website shall be made available on the Health and Human Services Commission's Internet website with a dedicated link that is prominently displayed on the home page or by a separate easily identifiable Internet address.

(c) This subsection applies only to a drug with a wholesale acquisition cost of at least \$100 for a 30-day supply before the effective date of an increase described by this subsection. Not later than the 30th day after the effective date of an increase of 40 percent or more over the preceding five calendar years or 10 percent or more in the preceding 12 months in the wholesale acquisition cost of a drug to which this subsection applies, a pharmaceutical drug manufacturer shall submit a report to the executive commissioner. The report must include the following information:

(1) the name of the drug;

(2) whether the drug is a brand name or generic;

(3) the effective date of the change in wholesale acquisition cost;

(4) aggregate, company-level research and development costs for the most recent year for which final audit data is available;

(5) the name of each of the manufacturer's prescription drugs approved by the United States Food and Drug Administration in the previous five calendar years;

(6) the name of each of the manufacturer's prescription drugs that lost patent exclusivity in the United States in the previous five calendar years;

(7) all factors that caused the increase in the wholesale acquisition cost;

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or into this state by that manufacturer.

(b) The executive commissioner shall develop an Internet website to provide to the general public drug price information submitted under Subsection (a). The Internet website shall be made available on the Health and Human Services Commission's Internet website with a dedicated link that is prominently displayed on the home page or by a separate easily identifiable Internet address.

(c) This subsection applies only to a drug with a wholesale acquisition cost of at least \$100 for a 30-day supply before the effective date of an increase described by this subsection. Not later than the 30th day after the effective date of an increase of 40 percent or more over the preceding three calendar years or 15 percent or more in the preceding calendar year in the wholesale acquisition cost of a drug to which this subsection applies, a pharmaceutical drug manufacturer shall submit a report to the executive commissioner. The report must include the following information: [FA1(1)-(2)]

(1) the name of the drug;

(2) whether the drug is a brand name or generic;

(3) the effective date of the change in wholesale acquisition cost;

(4) aggregate, company-level research and development costs for the most recent year for which final audit data is available;

(5) the name of each of the manufacturer's prescription drugs approved by the United States Food and Drug Administration in the previous three calendar years; [FA1(3)]

(6) the name of each of the manufacturer's prescription drugs that lost patent exclusivity in the United States in the previous three calendar years; and [FA1(4)-(5)]

(7) a statement regarding the factor or factors that caused the increase in the wholesale acquisition cost and an explanation

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(8) the percentage of the total increase in the wholesale acquisition cost that is attributable to each factor listed in Subdivision (7); and

(9) an explanation of the role of each factor listed in Subdivision (7) in contributing to the increase in the wholesale acquisition cost.

(d) The quality and types of information and data that a pharmaceutical drug manufacturer submits to the executive commissioner under Subsection (c) must be consistent with the quality and types of information and data that the manufacturer includes in the manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K or any other public disclosure.

(e) Not later than the 60th day after receipt of the report submitted under Subsection (c), the executive commissioner shall publish the report on the Health and Human Services Commission's Internet website described by Subsection (b).

(f) The executive commissioner may adopt rules to implement this section.

SECTION 2. Chapter 1369, Insurance Code, is amended by adding Subchapter K to read as follows:

SUBCHAPTER K. PRESCRIPTION DRUG COST TRANSPARENCY

Sec. 1369.501. DEFINITIONS. In this subchapter:

(1) "Animal health product" means a medical product approved and licensed for use in animal or veterinary medicine, including a pharmaceutical, a biologic, an insecticide, and a parasiticide.

(2) "Health benefit plan" means an individual, blanket, or group plan, policy, or contract for health care services issued

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of the role of each factor's impact on the cost. [FA1(6)]

(8) [Deleted by FA1(6)]

(9) [Deleted by FA1(6)]

(d) The quality and types of information and data that a pharmaceutical drug manufacturer submits to the executive commissioner under Subsection (c) must be consistent with the quality and types of information and data that the manufacturer includes in the manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K or any other public disclosure.

(e) Not later than the 60th day after receipt of the report submitted under Subsection (c), the executive commissioner shall publish the report on the Health and Human Services Commission's Internet website described by Subsection (b).

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(2) "Health benefit plan" means an individual, blanket, or group plan, policy, or contract for health care services issued

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or delivered by a health benefit plan issuer in this state.

(3) "Health benefit plan issuer" means an insurance company, a health maintenance organization, or a hospital and medical service corporation.

(4) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, labeling, or distributing a prescription drug. The term does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed under Subtitle J, Title 3, Occupations Code.

(5) "Pharmacy benefit manager" has the meaning assigned by Section 4151.151.

(6) "Prescription drug" has the meaning assigned by Section 551.003, Occupations Code, except that the term "prescription drug" does not include a device or an animal health product.

(7) "Rebate" means a discount or concession that affects the price of a prescription drug to a pharmacy benefit manager or health benefit plan issuer for a prescription drug manufactured by the pharmaceutical drug manufacturer.

(8) "Specialty drug" means a prescription drug covered under Medicare Part D that exceeds the specialty tier cost threshold established by the Centers for Medicare and Medicaid Services.

(9) "Utilization management" means a set of formal techniques designed to monitor the use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings.

Sec. 1369.502. PHARMACY BENEFIT MANAGER INFORMATION. (a) Not later than February 1 of each year, each pharmacy benefit manager shall file a report with the commissioner. The report must state for the immediately

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or delivered by a health benefit plan issuer in this state.

(3) "Health benefit plan issuer" means an insurance company, a health maintenance organization, or a hospital and medical service corporation.

(4) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, labeling, or distributing a prescription drug. The term does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed under Subtitle J, Title 3, Occupations Code.

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preceding calendar year:

(1) the aggregated rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers; and

(2) the aggregated dollar amount of rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers that were:

(A) passed to:

(i) health benefit plan issuers; or

(ii) enrollees at the point of sale of a prescription drug; or

(B) retained as revenue by the pharmacy benefit manager.

(b) A report submitted by a pharmacy benefit manager may not disclose the identity of a specific health benefit plan or enrollee, the price charged for a specific prescription drug or class of prescription drugs, or the amount of any rebate or fee provided for a specific prescription drug or class of prescription 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.

Sec. 1369.503. HEALTH BENEFIT PLAN ISSUER INFORMATION. (a) Not later than February 1 of each year,

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preceding calendar year:

(1) the aggregated rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers; and

(2) the aggregated dollar amount of rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers that were:

(A) passed to:

(i) health benefit plan issuers; or

(ii) enrollees at the point of sale of a prescription drug; or

(B) retained as revenue by the pharmacy benefit manager.

(a-1) Notwithstanding Subsection (a), the report due not later than February 1, 2020, under that subsection must state the required information for the immediately preceding three calendar years in addition to stating the required information for the preceding calendar year. This subsection expires September 1, 2021. [FA1(7)]

(b) A report submitted by a pharmacy benefit manager may not disclose the identity of a specific health benefit plan or enrollee, the price charged for a specific prescription drug or class of prescription drugs, or the amount of any rebate or fee provided for a specific prescription drug or class of prescription drugs.

(c) Not later than May 1 of each year, the commissioner shall publish the aggregated data from all reports for that year required by this section in an appropriate location on the department's Internet website. The combined aggregated data from the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager. [FA1(8)]

Sec. 1369.503. HEALTH BENEFIT PLAN ISSUER INFORMATION. (a) Not later than February 1 of each year,

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each health benefit plan issuer shall submit to the commissioner a report that states for the immediately preceding calendar year:

(1) the names of the 25 most frequently prescribed prescription drugs across all plans;

(2) the percent increase in annual net spending for prescription drugs across all plans;

(3) the percent increase in premiums that were attributable to prescription drugs across all plans;

(4) the percentage of specialty drugs with utilization management requirements across all plans; and

(5) the premium reductions that were attributable to specialty drug utilization management.

(b) A report submitted by a health benefit plan issuer may not disclose the identity of a specific health benefit plan or the price charged for a specific prescription drug or class of prescription 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.

Sec. 1369.504. RULES. The commissioner may adopt rules to implement this subchapter.

SECTION 3. Notwithstanding Chapter 441, Health and Safety Code, as added by this Act, and Subchapter K, Chapter 1369, Insurance Code, as added by this Act, a pharmaceutical drug manufacturer, pharmacy benefit manager, or health

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each health benefit plan issuer shall submit to the commissioner a report that states for the immediately preceding calendar year:

(1) the names of the 25 most frequently prescribed prescription drugs across all plans;

(2) the percent increase in annual net spending for prescription drugs across all plans;

(3) the percent increase in premiums that were attributable to prescription drugs across all plans;

(4) the percentage of specialty drugs with utilization management requirements across all plans; and

(5) the premium reductions that were attributable to specialty drug utilization management.

(b) A report submitted by a health benefit plan issuer may not disclose the identity of a specific health benefit plan or the price charged for a specific prescription drug or class of prescription drugs.

(c) Not later than May 1 of each year, the commissioner shall publish the aggregated data from all reports for that year required by this section in an appropriate location on the department's Internet website. The combined aggregated data from the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any health benefit plan issuer. [FA1(9)]

Sec. 1369.504. RULES. The commissioner may adopt rules to implement this subchapter.

SECTION 3. Same as House version.

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benefit plan issuer is not required to submit a summary report as required by Chapter 441, Health and Safety Code, as added by this Act, or Subchapter K, Chapter 1369, Insurance Code, as added by this Act, as applicable, before January 1, 2020.

SECTION 4. This Act takes effect September 1, 2019.

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SECTION 4. Same as House version.

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