

BILL ANALYSIS

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S.B. 296
By: West et al.
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AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

A perception exists that drug companies and other medical industries unduly influence the prescription and other practices of physicians through various gifts, meals, and speaking fees. This can be a significant cost to the state if, for example, a more expensive drug is prescribed through the state's Medicaid preferred drug list than is necessary, as has recently been alleged in a fraud lawsuit filed by the state against a pharmaceutical company.

As proposed, S.B. 296 requires drug, medical device, and medical supply manufacturers with more than \$1 million in gross annual revenue to disclose payments or transfers of value to doctors and related professional entities. Such disclosures will take the form of quarterly and annual reports to the Office of the Attorney General. Gifts and payments of less than \$25 are exempt from the quarterly reporting requirement, as are free drug samples intended for distribution to patients, transfers of value to physicians who are patients, and compensation paid by a manufacturer to a physician who is directly and solely employed by the manufacturer. The bill also establishes civil penalties for a failure to report and authorizes the attorney general to sue to collect such penalties.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the attorney general in SECTION 1 (Section 174.002, Health and Safety Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subtitle H, Title 2, Health and Safety Code, by adding Chapter 174, as follows:

CHAPTER 174. REPORTING REQUIREMENTS FOR MANUFACTURERS OF PRESCRIPTION DRUGS, MEDICAL DEVICES, AND MEDICAL SUPPLIES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 174.001. **APPLICABILITY.** Provides that this chapter applies to a manufacturer that exceeds \$1 million in annual gross revenue and produces, prepares, compounds, converts, or processes a prescription drug, medical device, or medical supply for which payment is available through the medical assistance program under Chapter 32 (Medical Assistance Program), Human Resources Code, or under Title XVIII, XIX, or XXI of the Social Security Act (42 U.S.C. Sections 1395 et seq., 1396 et seq., and 1397aa et seq.).

Sec. 174.002. **RULES.** Requires the attorney general to adopt rules necessary to implement this chapter.

[Reserves Sections 174.003-174.050 for expansion.]

SUBCHAPTER B. REPORTING REQUIREMENTS

Sec. 174.051. **QUARTERLY REPORT.** (a) Requires a manufacturer doing business in this state to submit a report for each fiscal quarter to the attorney general that discloses any payment or other transfer of valued provided directly, indirectly, or through an agent, subsidiary, or other third party to a physician; an entity that a physician is employed by,

has tenure with, or has a significant ownership interest in; or an organization involved in health care financing, organization, or delivery and in which a physician is a voluntary paying member or through which a physician receives professional certification.

(b) Requires that for each payment or other transfer of value reported, the quarterly report list certain information regarding the physician and the payment or other transfer of value.

(c) Exempts certain payments or other transfers of value are exempt from the quarterly reporting requirement.

(d) Requires a manufacturer to submit each quarterly report electronically in the manner prescribed by the attorney general not later than the 30th day after the date the state fiscal year quarter ends.

Sec. 174.052. ANNUAL SUMMARY REPORT. (a) Requires each manufacturer that is required to submit quarterly reports under Section 174.051 to submit, not later than October 15 of each year, an annual summary report to the attorney general that summarizes each submission of information under Section 174.051 made by the manufacturer during the previous fiscal year and includes the aggregate amount of all transfers of anything of value less than \$25 for the previous fiscal year.

(b) Requires the manufacturer to submit the annual summary report electronically in the manner prescribed by the attorney general.

(c) Authorizes the attorney general to assess a fee for filing the annual summary report in an amount sufficient to recover the cost of administering this chapter.

Sec. 174.053. PUBLICATION OF REPORTS. (a) Requires the attorney general to review and make available to the public information reported under Sections 174.051 and 174.052.

(b) Requires the attorney general to publish the quarterly and annual summary reports on the attorney general's website and make printed copies of the reports available on request.

Sec. 174.054. REPORT TO THE LEGISLATURE. Requires the attorney general to submit, not later than December 1 of each year, a report to the legislature that includes information collected under Sections 174.051 and 174.052 for the preceding fiscal year and a description of any action taken to enforce this chapter during the preceding fiscal year.

Sec. 174.055. CIVIL PENALTY. (a) Provides that a manufacturer that fails to report a payment or other transfer of value is liable to the state for a civil penalty of not less than \$500 but not more than \$2,500 for each violation, not to exceed \$50,000 in one fiscal year.

(b) Provides that a manufacturer that fails to file a quarterly or annual summary report required under this subchapter is liable to the state for a civil penalty of not less than \$5,000 but not more than \$25,000, not to exceed \$250,000 in one fiscal year.

(c) Provides that each failure to report a payment or other transfer of value or failure to file a quarterly or annual summary report constitutes a separate violation.

(d) Authorizes the attorney general to sue to collect a penalty under this section.

SECTION 2. (a) Requires the attorney general to require the first quarterly report under Section 174.051, Health and Safety Code, as added by this Act, to be submitted not later than December 30, 2009.

(b) Requires the attorney general to require the first annual report under Section 174.052, Health and Safety Code, as added by this Act, to be submitted not later than October 15, 2010.

(c) Requires the attorney general to submit the first report to the legislature required by Section 174.054, Health and Safety Code, as added by this Act, not later than December 1, 2010.

(d) Requires the attorney general to adopt rules required by Section 174.002, as added by this Act, as soon as practicable after the effective date of this Act.

SECTION 3. Effective date: upon passage or September 1, 2009.