BILL ANALYSIS

Senate Research Center

C.S.S.B. 553
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Health & Human Services
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Pharmaceutical companies have access to data on how healthcare providers are prescribing medicines. As a result, pharmaceutical companies can strategically market their products to certain prescribers. However, patients do not have information about the relationships between their prescribers and prescription drug marketers and manufacturers. To increase transparency for all parties involved, information on the financial relationship between pharmaceutical companies and prescribers should be made available to the public.

C.S.S.B. 553 amends current law relating to the disclosure of certain economic benefits provided to health professionals in the marketing of prescription drugs, medical devices, and medical supplies and provides penalties.

[**Note:** While the statutory reference in this bill is to the Texas Department of Health (TDH), the following amendments affect the Department of State Health Services, as the successor agency to TDH.]

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 2 of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Chapter 431, Health and Safety Code, by adding Subchapter O, as follows:

SUBCHAPTER O. REPORTING REQUIREMENTS RELATED TO MARKETING OF PRESCRIPTION DRUGS, MEDICAL DEVICES, AND MEDICAL SUPPLIES

Sec. 431.451. DEFINITIONS. Defines "bona fide clinical trial," "distributor," "gift," "health professional," "manufacturer," "marketer," "medical device" or "device," "prescription drug" "repackage," "repackager," and "retailer."

Sec. 431.452. APPLICABILITY OF SUBCHAPTER. Provides that this subchapter applies only to a manufacturer, repackager, or retailer that exceeds $30 million in annual gross revenue and that manufactures, markets, sells, distributes, produces, prepares, compounds, converts, or processes a medical device, medical supply, or prescription drug 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. and 1397aa et seq.).

Sec. 431.453. ANNUAL DISCLOSURE OF CERTAIN ECONOMIC BENEFITS. (a) Requires a manufacturer or repackager that sells, repackages, or distributes prescription drugs, medical devices, or medical supplies in this state, and a retailer that sells medical devices or medical supplies in this state, to submit to the Texas Department of Health (TDH) a report that discloses any gift, fee, payment, subsidy, or other economic benefit given, paid, or provided by the manufacturer, repackager, or retailer to a physician, physician's office, hospital, nursing home, pharmacist, health benefit plan administrator, or other health professional in connection with detailing, promotional, or marketing

activities of the manufacturer, repackager, or retailer, directly or through a marketer, not later than March 31 of each year.

(b) Requires that the report required under Subsection (a) cover the preceding calendar year and be submitted on a form, including any electronic form, prescribed by TDH. Requires that the report, in connection with each gift, fee, payment, subsidy, or other economic benefit required to be disclosed under this subchapter, include certain information relating to the economic benefit.

(c) Requires TDH, not later than May 1 of each year, to make all reports submitted under this section on or before March 31 available on TDH's Internet website. Requires TDH to make reports submitted under this section after March 31 available on TDH's Internet website as soon as practicable.

(d) Provides that the reporting requirements described by Subsections (a) and (b) do not apply in an area of the state designated in an executive order or a proclamation by the governor under Chapter 418 (Emergency Management), Government Code, during the 30-day period after the executive order or proclamation is issued.

Sec. 431.454. EXEMPTIONS. (a) Provides that the following economic benefits are exempt from disclosure under Section 431.453 a gift, fee, payment, subsidy, or other economic benefit with a fair market value that is less than $50; free samples of prescription drugs intended for distribution to patients; any prescription drug rebate or discount; payment of reasonable compensation and reimbursement of expenses in connection with a bona fide clinical trial; a scholarship or other support for a medical student, resident, or fellow to attend a bona fide educational, scientific, or policy-making conference of an established professional association if the recipient of the scholarship or other support is selected by the association; a grant or other support for the development, production, or presentation of a bona fide educational, scientific, or policy-making program or conference of an established professional association if the professional association independently selects, develops, produces, or presents the educational, scientific, or policy-making program or conference; educational materials that directly benefit patients or are intended for patient use; in-kind items used for the provision of charity care; any transfer or payment of a benefit to treat a health condition of an individual described by Section 431.453(a), where the individual is a patient and is not acting in a professional capacity; a dividend or other profit distribution from, or an ownership or investment interest in, a mutual fund or publically-traded security; the loan of a device for a short-term trial period, not to exceed 90 days, to permit evaluation of the device by the recipient; and items or services provided under a contractual warranty, including the replacement of a device, where the terms for the warranty are set forth in the purchase or lease agreement for the covered device.

(b) Provides that, notwithstanding Subsection (a)(1) (relating to certain economic benefits having a fair market value of less than $50), any aggregate payment or transfer of a benefit to a single recipient during an annual reporting period that does not exceed $100 is exempt under this section. Authorizes that any value associated with free samples or with a dividend or other profit distribution be excluded from the calculation of aggregate value.

Sec. 431.455. PENALTIES; INJUNCTION. (a) Authorizes the commissioner of health (commissioner) to, in accordance with the procedures applicable to administrative penalties assessed under Subchapter C (Enforcement), assess an administrative penalty against a person who fails to file a report required under this subchapter.

(b) Authorizes the attorney general to bring an action for injunctive relief to compel a person to file a report required under this subchapter, and to impose a civil penalty of not more than $10,000 for a failure to file a report required under this subchapter.

(c) Provides that each failure to file a report required under this subchapter constitutes a separate violation.

(d) Authorizes the court to award to the attorney general reasonable court costs and attorney's fees in connection with an action brought under Subsection (b).

Sec. 431.456. PUBLIC RECORDS. Provides that the information required to be submitted to TDH under this subchapter and the data and reports compiled by TDH based on that information are public records under Chapter 552 (Public Information), Government Code. Provides that, notwithstanding any other provision of law, the identity of any recipient of a gift, fee, payment, subsidy, or other economic benefit required to be reported under this subchapter does not constitute confidential information or a trade secret.

Sec. 431.457. SUSPENSION OF STATE REPORTING REQUIREMENTS. Requires TDH, if a federal law provides for the disclosure of gifts to health professionals by manufacturers, repackagers, or retailers to whom this subchapter applies and the commissioner determines that the federal law substantially meets the purposes of provisions of this subchapter, to suspend the application of the state reporting requirements imposed under those provisions.

SECTION 2. (a) Requires the executive commissioner of the Health and Human Services Commission to adopt the rules and procedures necessary to implement Subchapter O, Chapter 431, Health and Safety Code, as added by this Act, including rules defining bona fide programs and conferences under Subdivisions (5) (relating to a scholarship or other support for a medical student, resident, or fellow) and (6) (relating to a grant or other support for the development, production, or presentation of a bona fide educational, scientific, or policy-making program or conference) , Section 431.454, Health and Safety Code, as added by this Act, not later than March 31, 2011.

(b) Requires the Department of State Health Services to develop the form required by Section 431.453, Health and Safety Code, as added by this Act, not later than March 31, 2011.

(c) Provides that, notwithstanding Section 431.453, Health and Safety Code, as added by this Act, a manufacturer, repackager, or retailer of prescription drugs, medical devices, or medical supplies is not required to submit the report required by that section before March 31, 2012.

SECTION 3. Effective date: January 1, 2011.