BILL ANALYSIS

Senate Research Center

S.B. 553
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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.

As proposed, S.B. 553 requires pharmaceutical companies and marketers to report the cost and nature of gifts valued over $75 on an annual basis to the Department of State Health Services (DSHS), and requires DSHS to post all reports online.

[**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. PRESCRIPTION DRUG MARKETING

Sec. 431.451. DEFINITIONS. Defines "pharmaceutical marketer" and "repackager."

Sec. 431.452. ANNUAL REPORT; DISCLOSURE OF CERTAIN ECONOMIC BENEFITS. (a) Requires a manufacturer or repackager that sells or repackages prescription drugs in this state to submit to the Texas Department of Health (TDH) the name and address of the individual responsible for the manufacturer's or repackager's compliance with this section not later than January 1 of each year.

(b) Requires a manufacturer or repackager that sells or repackages prescription drugs in this state to submit to TDH a report that discloses any gift, fee, payment, subsidy, or other economic benefit received by a physician, health benefit plan administrator, or other person authorized by law to dispense or prescribe prescription drugs in this state in connection with detailing, promotional, or marketing activities of the manufacturer or repackager, directly or through its pharmaceutical marketers, not later than February 1 of each year.

(c) Requires that the report required under Subsection (b) cover the preceding calendar year and be submitted on a form, including any electronic form, prescribed by TDH. Requires that the report include certain information relating to the economic benefit.

(d) Requires TDH to make available to the public on request a report submitted under this section.

(e) Requires TDH to make all reports submitted under this section available on TDH's Internet website not later than March 1 of each year.

Sec. 431.453. EXEMPTIONS. Provides that the following economic benefits are exempt from disclosure under Section 431.452: a gift, fee, payment, subsidy, or other economic benefit with a fair market value that is less than $75; free samples of prescription drugs intended for distribution to patients; payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials conducted in relation to a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments; 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; and 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.

Sec. 431.454. 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 does not 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).

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 clinical trials and bona fide programs and conferences under Subdivisions (3), (4), and (5), Section 431.453, Health and Safety Code, as added by this Act, not later than January 1, 2010.

(b) Requires the Department of State Health Services to develop the form required by Section 431.452, Health and Safety Code, as added by this Act, not later than January 1, 2010.

(c) Provides that, notwithstanding Section 431.452, Health and Safety Code, as added by this Act, a manufacturer or repackager of prescription drugs is not required to submit the report required by that section before February 1, 2011.

SECTION 3. (a) Effective date, except as provided by Subsection (b) of this section: September 1, 2009.

(b) Effective date, Section 431.454, Health and Safety Code, as added by this Act: January 1, 2011.