By: Lucio, et al. S.B. No. 553

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COMMITTEE SUBSTITUTE FOR S.B. No. 553 By: Deuell

A BILL TO BE ENTITLED
AN ACT

relating to the disclosure of certain economic benefits provided to health professionals in the marketing of prescription drugs, medical devices, and medical supplies; providing penalties.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Chapter 431, Health and Safety Code, is amended by adding Subchapter O to read as follows:

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

Sec. 431.451. DEFINITIONS. In this subchapter:

(1) "Bona fide clinical trial" means any study assessing the safety or efficacy of:

(A) drugs administered alone or in combination with other drugs or other therapies or assessing the relative safety or efficacy of drugs in comparison with other drugs or other therapies; or

(B) a medical device.

(2) "Distributor" means a person who furthers the marketing of a prescription drug, medical device, or medical supply from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

(3) "Gift" means a payment, food, entertainment, travel, honorarium, subscription, advance, service, product sample, or anything of value, unless consideration of equal or greater value is received, and includes anything of value provided for less than market value.

(4) "Health professional" means:

(A) a physician;

(B) a physician medical practice; and

(C) a physician group practice.

(5) "Manufacturer" means a person who manufactures, fabricates, distributes, or repackages a prescription drug, medical device, or medical supply.

(6) "Marketer" means a person who, while employed by or under contract to represent a manufacturer, repackager, or retailer, engages in detailing, promotional activity, or other marketing of a prescription drug, medical device, or medical supply in this state to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or other health professional.

(7) "Medical device" or "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(A) recognized in the official National Formulary or the United States Pharmacopia, or any supplement thereto;

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans; or

(C) intended to affect the structure or any function of the human body, and which does not achieve its primary intended purposes through chemical action within or on the human body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(8) "Prescription drug" has the meaning assigned by 21

C.F.R. Section 203.3.

(9) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling of a prescription drug, medical device, or medical supply to further the distribution of the drug, device, or supply. The term does not include repackaging by a pharmacist to dispense a drug, device, or supply to a patient.

(10) "Repackager" means a person who engages in repackaging.

(11) "Retailer" means a person who is engaged in the business of buying for resale, selling, or exchanging a medical device or medical supply or offering a device or supply for sale, exchange, or lease-purchase to a consumer or user.

Sec. 431.452. APPLICABILITY OF SUBCHAPTER. 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, 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) Not later than March 31 of each year, 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, shall submit to the department 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.

(b) A report required under Subsection (a) must cover the preceding calendar year and must be submitted on a form, including any electronic form, prescribed by the department. In connection with each gift, fee, payment, subsidy, or other economic benefit required to be disclosed under this subchapter, the report must include:

(1) the name and business address of each recipient of the benefit;

(2) the value of each benefit;

(3) the date of payment or transfer of each benefit;

(4) a categorized description of the form of each benefit, including:

(A) cash or cash equivalent;

(B) an in-kind item or service;

(C) an ownership interest or other return on investment, including securities, stock options, dividends, or profit-sharing arrangement; and

(D) any other category the commissioner deems appropriate;

(5) a categorized description of the nature of each benefit, including:

(A) a consulting fee;

(B) compensation for a service other than consulting;

(C) honoraria;

(D) a gift;

(E) entertainment;

(F) food;

(G) travel;

(H) education;

(I) research;

(J) a charitable contribution;

(K) a royalty or license;

(L) current or prospective ownership of an

investment interest;

(M) compensation for serving as faculty or as a speaker for a continuing medical education program;

(N) a grant; and

(O) any other category the commissioner determines appropriate;

(6) if the payment or transfer of the benefit is related to marketing, education, or research specific to a particular prescription drug, medical device, or medical supply the name of the drug, device, or supply; and

(7) any other category of information regarding the payment or transfer of a benefit the commissioner determines appropriate.

(c) Not later than May 1 of each year, the department shall make all reports submitted under this section on or before March 31 available on the department's Internet website. The department shall make reports submitted under this section after March 31 available on the department's Internet website as soon as practicable.

(d) 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, Government Code, during the 30-day period after the executive order or proclamation is issued.

Sec. 431.454. EXEMPTIONS. (a) The following economic benefits are exempt from disclosure under Section 431.453:

(1) a gift, fee, payment, subsidy, or other economic benefit with a fair market value that is less than $50;

(2) free samples of prescription drugs intended for distribution to patients;

(3) any prescription drug rebate or discount;

(4) payment of reasonable compensation and reimbursement of expenses in connection with a bona fide clinical trial;

(5) 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;

(6) 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;

(7) educational materials that directly benefit patients or are intended for patient use;

(8) in-kind items used for the provision of charity care;

(9) 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;

(10) a dividend or other profit distribution from, or an ownership or investment interest in, a mutual fund or publically-traded security;

(11) 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

(12) 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) Notwithstanding Subsection (a)(1), 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. Any value associated with free samples or with a dividend or other profit distribution may be excluded from the calculation of aggregate value.

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

(b) The attorney general may bring an action:

(1) for injunctive relief to compel a person to file a report required under this subchapter; and

(2) to impose a civil penalty of not more than $10,000 for a failure to file a report required under this subchapter.

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

(d) The court may 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. The information required to be submitted to the department under this subchapter and the data and reports compiled by the department based on that information are public records under Chapter 552, Government Code. 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. 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, the department shall suspend the application of the state reporting requirements imposed under those provisions.

SECTION 2. (a) Not later than March 31, 2011, the executive commissioner of the Health and Human Services Commission shall 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) and (6), Section 431.454, Health and Safety Code, as added by this Act.

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

(c) 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. This Act takes effect January 1, 2011.

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