By: Lucio S.B. No. 553

A BILL TO BE ENTITLED

AN ACT

relating to the disclosure of certain economic benefits provided by manufacturers or repackagers of prescription drugs; 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. PRESCRIPTION DRUG MARKETING

Sec. 431.451. DEFINITIONS. In this subchapter:

(1) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a manufacturer or repackager, engages in pharmaceutical detailing, promotional activity, or other marketing of prescription drugs in this state to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or other person authorized by law to dispense or prescribe prescription drugs in this state.

(2) "Repackager" has the meaning assigned by Section 431.401.

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

(b) Not later than February 1 of each year, a manufacturer or repackager that sells or repackages prescription drugs in this state shall submit to the department a report that discloses any gift, fee, payment, subsidy, or other economic benefit received by a physician, physician's office, hospital, nursing home, pharmacist, 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.

(c) The report required under Subsection (b) must cover the preceding calendar year and must be submitted on a form, including any electronic form, prescribed by the department. The report must include:

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

(2) the value and a description of the economic benefit; and

(3) the date of receipt of the economic benefit.

(d) The department shall make available to the public on request a report submitted under this section.

(e) Not later than March 1 of each year, the department shall make all reports submitted under this section available on the department's Internet website.

Sec. 431.453. EXEMPTIONS. The following economic benefits are exempt from disclosure under Section 431.452:

(1) a gift, fee, payment, subsidy, or other economic

benefit with a fair market value that is less than $75;

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

(3) 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;

(4) 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

(5) 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) The commissioner may, in accordance with the procedures applicable to administrative penalties assessed under Subchapter C, assess an administrative penalty against a person who does not 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).

SECTION 2. (a) Not later than January 1, 2010, 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 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.

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

(c) 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) Except as provided by Subsection (b) of this section, this Act takes effect September 1, 2009.

(b) Section 431.454, Health and Safety Code, as added by this Act, takes effect January 1, 2011.