BILL ANALYSIS

Senate Research Center 80R4633 YDB-D

S.B. 414 By: Lucio Health and Human Services 3/9/2007 As Filed

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Currently, pharmaceutical marketers have access to a significant amount of data relating to how healthcare providers are prescribing medicines. As a result, pharmaceutical companies can be extremely strategic about their marketing campaigns. Direct marketing of prescription drugs to healthcare providers causes providers to change their prescribing habits, even if other remedies are cheaper, more effective, or safer. The ability of pharmaceutical companies to monitor prescribing practices and target key healthcare providers with gifts may compromise the interest of the patient. Patients should be informed about this relationship.

As proposed, S.B. 414 requires pharmaceutical companies and marketers to report gifts valued over a certain amount on an annual basis to the Department of State Health Services (DSHS), and requires DSHS to post all reports online.

RULEMAKING AUTHORITY

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

SECTION BY SECTION ANALYSIS

[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 (DSHS), as the successor agency to TDH.]

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 "p harmaceutical 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 the State of Texas 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 to submit to TDH a report that discloses certain benefits 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 the State of Texas 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 the report to cover the previous calendar year and to be submitted on a form prescribed by TDH. Requires the report to include the name and address of each recipient, the value and a description, and the date of receipt of an economic benefit.

- (d) Requires TDH to make a report available to the public upon request.
- (e) Requires TDH to make all reports available on its internet Website not later than March 1 of each year.
- Sec. 431.453. EXEMPTIONS. Provides that certain economic benefits are exempt from disclosure.
- Sec. 431.454. PENALTIES; INJUNCTION. (a) Authorizes the commissioner of health (commissioner) to charge 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 require a person to file a report required under this subchapter, and to impose a civil penalty for a failure to file a report required under this subchapter of not more than \$10,000.
 - (c) Provides that each failure to file a report 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 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 conferences under Sections 431.453(3) and (4), Health and Safety Code, as added by this Act, not later than January 1, 2008.
 - (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 then January 1, 2009
 - (c) Provides that a manufacturer or repackager of prescription drugs is not required to submit the report required by that section before February 1, 2009, notwithstanding Section 431.452, Health and Safety Code, as added by this Act.
- SECTION 3. (a) Effective date: September 1, 2007, except as provided by Subsection (b).
 - (b) Effective date, Section 431.454, Health and Safety Code: January 1, 2009.