Second Regular Session
Sixty-seventh General Assembly
STATE OF COLORADO

PREAMENDED

This Unofficial Version Includes Committee Amendments Not Yet Adopted on Second Reading

LLS NO. 10-0027.01 Christy Chase **SENATE BILL 10-126**

SENATE SPONSORSHIP

Carroll M.,

HOUSE SPONSORSHIP

Tyler,

Senate Committees	**House Committees**
Health and Human Services	
Finance	
Appropriations	

A BILL FOR AN ACT

CONCERNING INCREASED TRANSPARENCY REPORTING REQUIREMENTS FOR CERTAIN PHARMACEUTICAL MANUFACTURERS.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://www.leg.state.co.us/billsummaries.)

The bill enacts the "Pharmaceutical Transparency Act" (act), to be administered by the secretary of state (secretary). The act, which is modeled on the federal "Physician Payments Sunshine Act of 2009" pending in the United States congress, requires manufacturers of a drug, medical device, biological product, or medical supply for which payment

is available under the state medicaid program or the children's basic health plan to submit an annual transparency report to the secretary. The transparency report, due March 31, 2011, and each March 31 thereafter, is to detail information regarding payments or other transfers of value made by the manufacturer to a health care practitioner during the immediately preceding calendar year. Specifically, the bill requires information as to the name, address, and other identifying information of the health care practitioner, and the value, dates, and description of the form and nature of the payment or transfer of value.

Like the pending federal legislation, the bill would also require manufacturers to disclose information pertaining to ownership or investment interests held by a health care practitioner in the manufacturer, detailing the dollar amount invested, the value and terms of the interest, and payments or other transfers of value provided to the health care practitioner.

The bill imposes an additional transparency requirement, not contained in the federal proposal, obligating a manufacturer to disclose whether or not it has adopted procedures to assure adherence to the code of interactions with healthcare professionals (code) adopted by the pharmaceuticals trade group known as "pharmaceutical research and manufacturers of America" (PhRMA). A manufacturer would also have to disclose whether it: Has publicly announced its commitment to abide by the code; completes an annual certification of its policies to ensure compliance; and is identified by PhRMA on a public web site as a manufacturer that has committed to abide by the code.

The bill authorizes the secretary to impose fines on a manufacturer for failure to comply with the reporting requirements of the act. The fines may be between $1,000 and $10,000 for each payment or transfer of value not reported, not to exceed an aggregate fine of $150,000 per calendar year, and in the case of knowing violations, between $10,000 and $100,000 for each payment or transfer of value not reported, not to exceed an aggregate fine of $1,000,000 in any calendar year.

The bill requires the secretary to adopt rules to establish reporting procedures and a method for making the reported information available to the public through a searchable web site. The secretary is also required, by rule, to establish fees to be imposed on reporting manufacturers to cover the secretary's direct and indirect costs to administer the act. The fees and any fines imposed on manufacturers are to be deposited in the department of state cash fund and are to be available, subject to appropriation by the general assembly, to the secretary for use in administering the act.

Finally, the act obligates the secretary to submit an annual report to the governor and the general assembly by May 1, 2011, and each May 1 thereafter, analyzing the data submitted by manufacturers that year.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. Part 1 of article 34 of title 24, Colorado Revised Statutes, is amended BY THE ADDITION OF A NEW SECTION to read:

24-34-110. Posting summary transparency reports required by federal law. UPON RECEIPT BY THE STATE FROM THE SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, THE DEPARTMENT OF REGULATORY AGENCIES SHALL POST ON ITS WEB SITE THE REPORT REQUIRED BY SECTION 6002 OF THE FEDERAL "PATIENT PROTECTION AND AFFORDABLE CARE ACT", H.R. 3590, PUB.L. 111-148, CONTAINING A SUMMARY OF INFORMATION SUBMITTED BY MANUFACTURERS AND GROUP PURCHASING ORGANIZATIONS TO THE SECRETARY PURSUANT TO SAID LAW. THE DEPARTMENT SHALL POST THE REPORT BY SEPTEMBER 30, 2013, AND BY JUNE 30 OF EACH CALENDAR YEAR THEREAFTER, OR AS SOON AS POSSIBLE AFTER THE STATE RECEIVES THE REPORT FROM THE SECRETARY, WHICHEVER OCCURS FIRST.

SECTION 2. Act subject to petition - effective date. This act shall take effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly (August 11, 2010, if adjournment sine die is on May 12, 2010); except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part shall not take effect unless approved by the people at the general election to be held in November 2010 and shall take effect on the date of the official declaration of the vote thereon by the governor.