Registration and Regulation Committee

Filed: 2/24/2005

AMENDMENT TO HOUSE BILL 656

AMENDMENT NO. _____. Amend House Bill 656 by replacing everything after the enacting clause with the following:

"Section 1. Short title. This Act may be cited as the Prescription Drug Ethical Marketing Act.

Section 5. Findings and purpose.

(a) The General Assembly finds that:

(1) Prescription drug spending is the fastest growing component of health care spending in the United States.

(2) Drug manufacturers' marketing to doctors, called "detailing", is affecting the way that doctors prescribe medications so that they too often prescribe the most expensive medicines when less expensive drugs are as effective or safer.

(3) Gifts from prescription drug detailers can influence the decisions of doctors in terms of the medicines that they prescribe.

(b) The purpose of this Act is to lower prescription drug costs for individuals, businesses, and the State and to protect the health of residents by deterring the practice of unethical gift-giving by drug manufacturers.

Section 10. Definitions. As used in this Act:

"Director" means the Director of Public Health.

"Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the Food and Drug Administration under 21 C.F. R. 207.20. "Labeler" does not include a retail pharmacy or pharmacist that labels a prescription vial.

"Manufacturer" means a manufacturer of prescription drugs as defined in 42 U.S.C. 1396r-8 (k)(5), including a subsidiary or affiliate of a manufacturer.

"Pharmaceutical marketer" means a person who, while employed by or under contract to represent a manufacturer or labeler, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this State to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe or dispense prescription drugs.

Section 15. Disclosure of marketing practices.

(a) On or before January 1 of each year, every manufacturer and labeler that sells prescription drugs in the State shall disclose to the Director the name and address of the individual responsible for the company's compliance with the provisions of this Section.

(b) On or before February 1 of each year, every manufacturer and labeler that sells prescription drugs in the State shall disclose to the Director the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing or promotional or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, health benefit plan administrator, or any other person in Illinois authorized to prescribe prescription drugs. Disclosure shall cover the prior year and it shall be made on a form and in a manner prescribed by the Director.

(c) On or before March 1 of each year, the Director shall report to the Governor and the General Assembly on the disclosures made under this Section.

(d) The following shall be exempt from disclosure:

(1) Any gift, fee, payment, subsidy or other economic benefit, the value of which is less than 25 dollars.

(2) Free samples of prescription drugs to be distributed to patients.

(3) The payment of reasonable compensation and reimbursement of expenses in connection with a bona fide clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments.

(4) Scholarship or other support for medical students, residents, and fellows 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.

Section 20. Administration and enforcement.

(a) This Act shall be enforced by the Director, who shall adopt any rules that are necessary to implement and administer compliance, including rules describing the bona fide clinical trials provided under paragraph (3) of subsection (d) of Section 15 and the bona fide conferences provided under paragraph (4) of subsection (d) of Section 15.

(b) If a manufacturer or labeler violates this Act, the Director may bring an action in court for injunctive relief, costs, attorney's fees, and a civil penalty of up to $10,000 per violation. Each unlawful failure to disclose shall constitute a separate violation.".