H-5150.1

SUBSTITUTE HOUSE BILL 2680

State of Washington 60th Legislature 2008 Regular Session

By House Health Care & Wellness (originally sponsored by Representatives Green, Hasegawa, Morrell, Conway, and Simpson)

READ FIRST TIME 02/04/08.

AN ACT Relating to reporting of gifts, fees, or payments by pharmaceutical marketers; adding a new chapter to Title 69 RCW; and prescribing penalties.

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

NEW SECTION. **Sec. 1.** The purpose of this chapter is to provide for the adoption of minimum standards related to pharmaceutical manufacturer marketing activities within the state of Washington.

NEW SECTION. **Sec. 2.** The legislature finds that:

(1) The state of Washington has an interest in maximizing the well-being of its residents and containing health care costs;

(2) There is a strong link between pharmaceutical marketing activities, health care spending, and the health of Washingtonians;

(3) It is estimated that the pharmaceutical industry spends between thirty billion and fifty-four billion dollars annually on marketing pharmaceuticals in the United States. Over eighty-five percent of these marketing expenditures are directed at the small percentage of the population that practice medicine. Pharmaceutical manufacturers spend twice as much on marketing as on research and development;

(4) There is considerable evidence that pharmaceutical marketing campaigns lead doctors to prescribe drugs based on incomplete and biased information, particularly for prescribers who lack the time to perform substantive research assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate;

(5) A significant portion of prescriber time is spent meeting with pharmaceutical representatives. According to a survey published in the New England Journal of Medicine, family practitioners reported the highest frequency of meetings with representatives, an average of sixteen times per month. To the extent that this meeting time comes at the expense of time spent with patients, quality of care is negatively affected;

(6) The federal food and drug administration requires marketing and advertising to be fair and balanced; however, the federal food and drug administration has limited legal ability to enforce this requirement;

(7) Newer drugs on the market do not necessarily provide evidence-based benefits over older drugs but do add costs and as yet unknown side effects;

(8) Between 1975 and 2000, fifty percent of all drug withdrawals from the market and "black box warnings" were within the first two years of the release of the drug. One-fifth of all drugs are subject to "black box warnings" or withdrawal from the market because of serious public health concerns. Marketing that results in prescribers using the newest drugs also results in prescribing drugs that are more likely to be subject to these warnings and withdrawal;

(9) Nearly one third of the five-fold increase in spending in the United States on drugs over the last decade can be attributed to marketing-induced shifts in doctors' prescribing from existing, effective, and lower cost, often generic, therapies to new and more expensive treatments, which often have little or no evidence-based therapeutic value;

(10) Several studies suggest that drug samples clearly affect prescribing behavior in favor of the sample, and that the presence of drug samples may influence physicians to dispense or prescribe drugs that differ from their preferred drug source;

(11) The pharmaceutical industry increased its spending on direct marketing to doctors by over two hundred seventy-five percent and

doubled its sales force to over ninety thousand drug representatives. It is estimated that there is a pharmaceutical sales representative for every five office-based physicians.

NEW SECTION. **Sec. 3.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Board" means the board of pharmacy.

(2)(a) "Marketing" means any of the following activities undertaken or materials or products made available to prescribers or to their employees or agents by any person, agent, or representative employed by or under contract to represent a pharmaceutical manufacturer that is related to the transfer of prescription drugs from the producer or seller to the consumer or buyer:

(i) Advertising, publicizing, promoting, or selling a prescription drug;

(ii) Activities undertaken for the purpose of influencing the market share of a prescription drug or the prescribing patterns of a prescriber, a detailing visit, or a personal appearance;

(iii) Activities undertaken to evaluate or improve the effectiveness of a professional detailing sales force; or

(iv) A brochure, media advertisement or announcement, poster, or free sample of a prescription drug.

(b) "Marketing" does not include pharmacy reimbursement, formulary compliance, pharmacy file transfers in response to a patient request or as a result of the sale or purchase of a pharmacy, patient care management, utilization review by a health care provider or agent of a health care provider or the patient's health plan or an agent of the patient's health plan, and health care research.

(3)(a) "Pharmaceutical manufacturer" or "manufacturer" means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs, biologics, or medical devices. For purposes of this act, "pharmaceutical manufacturer" includes any person, agent, or

representative employed by or under contract to represent a pharmaceutical manufacturer or engage in activities to market prescription drugs sold by a manufacturer.

(b) "Pharmaceutical manufacturer" does not include pharmacists or pharmacies licensed under chapter 18.64 RCW or pharmacy operations of any integrated delivery system undertaken for the benefit of patients obtaining care through that system.

NEW SECTION. **Sec. 4.** Starting January 1, 2010, and annually thereafter, every pharmaceutical manufacturer shall submit an attestation with a written report documenting that the manufacturer, for purposes of its operations in the state of Washington, has:

(1) Adopted a comprehensive compliance program that is at least as stringent as the April 2003 publication "compliance program guidance for pharmaceutical manufacturers," which was developed by the United States department of health and human services office of inspector general. A pharmaceutical manufacturer shall make conforming changes to its comprehensive compliance program within six months of any update or revision to the "compliance program guidance for pharmaceutical manufacturers," to the extent that making a conforming change would not have the effect of weakening the guidelines related to marketing activities provided in the April 2003 version of the compliance program guidance;

(2) Included in its comprehensive compliance program policies that are at least as stringent as the pharmaceutical research and manufacturers of America "code on interactions with health care professionals," dated July 1, 2002. The pharmaceutical manufacturer shall make conforming changes to its comprehensive compliance program within six months of any update or revision of the "code on interactions with health care professionals," to the extent that making a conforming change would not have the effect of expanding the scope of allowable marketing activities beyond those provided in the July 2002 version of the code;

(3)Included in its comprehensive compliance program limits on gifts or incentives provided to medical or health professionals, in accordance with this section.

(a) Each pharmaceutical manufacturer shall establish explicitly in its comprehensive compliance program a specific annual dollar limit on

gifts, promotional materials, or items or activities that the manufacturer may give or otherwise provide to an individual medical or health care professional in accordance with the "compliance program guidance for pharmaceutical manufacturers" and with the "code on interactions with health care professionals." Drug samples given to physicians and health care professionals intended for free distribution to patients, financial support for continuing medical education forums sponsored by entities other than the manufacturer, and financial support for health educational scholarships are exempt from any limits if that support is provided in a manner that conforms to the "compliance program guidance for pharmaceutical manufacturers" and the "code on interactions with health care professionals."

(b) Payments made for legitimate professional services provided by a health care or medical professional including, but not limited to, consulting are exempt from any limits, provided that the payment does not exceed the fair market value of the services rendered, and those payments are provided in a manner that conforms to the "compliance program guidance for pharmaceutical manufacturers" and with the "code on interactions with health care professionals."

The attestation must include the name and contact information for the manufacturer's compliance officer responsible for developing, operating, and monitoring the compliance program.

NEW SECTION. **Sec. 5.** The board shall report annually, on or before March 1st of each year, to the legislature and the governor on attestations and reports made under this chapter. The report shall include a list of manufacturers who have filed attestations, and any enforcement actions taken by the attorney general related to the attestations. The report must be posted on the board's public internet site.

NEW SECTION. **Sec. 6.** The attorney general may bring an action in Thurston county superior court for injunctive relief, costs, and attorneys' fees, and to impose on a pharmaceutical manufacturing company that fails to comply with this chapter a civil penalty of not more than ten thousand dollars per violation.

NEW SECTION. **Sec. 7.** The board may adopt rules to implement the provisions of this chapter.

NEW SECTION. **Sec. 8.** This chapter may be known and cited as the prescription drug marketing integrity act.

NEW SECTION. **Sec. 9.** If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

NEW SECTION. **Sec. 10.** Sections 1 through 9 of this act constitute a new chapter in Title 69 RCW.

--- END ---