S-5472.1

SECOND SUBSTITUTE SENATE BILL 6302

State of Washington 60th Legislature 2008 Regular Session

By Senate Ways & Means (originally sponsored by Senators Kohl-Welles, Keiser, Fairley, Kline, Franklin, and Regala)

READ FIRST TIME 02/12/08.

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 regulate gifts, grants, and gratuities made by pharmaceutical manufacturing companies, directly or indirectly, to any person or entity authorized to prescribe, dispense, or purchase prescription drugs in 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) In 2004, the pharmaceutical industry spent twenty-seven billion dollars 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) Marketing programs are designed to increase sales, income, and profit. Frequently, progress toward these goals comes at the expense of evidence-based treatment and sometimes the health of individual patients;

(5) 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;

(6) 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;

(7) 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;

(8) 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;

(9) 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;

(10) 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;

(11) 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;

(12) 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) "Gift, fee, or payment" includes any subsidy or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company directly or through any other entity at the direction of or with the implied or express knowledge of the company, including:

(i) Food or entertainment;

(ii) Trips or travel;

(iii) Anything provided for less than market value;

(iv) Medical conferences, continuing medical education, or other educational or informational programs, materials, and seminars, and remuneration for promoting or participating in educational or informational sessions;

(v) Consulting fees or honoraria;

(vi) Product samples, including samples that will be distributed free of charge to patients; and

(vii) Clinical trials or research, including any compensation or reimbursement of expenses.

(b) "Gift, fee, or payment" does not include:

(i) Payments made in conjunction with returned merchandise and overpayments;

(ii) Publications and educational materials;

(iii) Salaries or other benefits paid to its employees;

(iv) Overpayments;

(v) Product rebates and discounts; and

(vi) Other normal course-of-business financial dealings unrelated to detailing, promotional, or other marketing activities.

(3) "Group purchasing organization" means any group of two or more hospitals, nursing homes, or other health care organizations that collectively purchase either directly from a pharmaceutical manufacturing company or by accessing contracts through another group.

(4) "Health benefit plan administrator" means any person or entity who manages or administers a private, self-insured health benefit plan or public employee health benefit plan and any person who manages or administers health benefit plans for another person, including health insuring corporations and sickness and accident insurers under contract to provide managerial and administrative services.

(5)(a) "Marketing" means any of the following activities undertaken or materials or products made available to prescribers or to their employees or agents 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.

(6) "Pharmaceutical detailing, promotional, or marketing activities" means promotional or educational activities by pharmaceutical marketers directed at physicians, their staff, or other health care professionals who prescribe, dispense, or administer prescription drugs.

(7)(a) "Pharmaceutical 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.

(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.

(8) "Pharmaceutical marketer" means a person, agent, or representative who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any entity or person authorized to prescribe, dispense, or purchase prescription drugs in this state.

(9) "Pharmacy benefit manager" means a person or business entity that administers or otherwise assists with prescription drug benefit services including formulary management, rebates, discounted pharmacy network, mail service pharmacies, and electronic claims processing. Such services may be provided on behalf of a health insurer, an employer-sponsored health benefit plan, or an agency of the state.

(10) "Recipient" means any:

(a) Health care professional licensed under Title 18 RCW who is authorized to prescribe or dispense prescription drugs or entity that employs such a professional;

(b) Hospital licensed under chapter 70.41 RCW;

(c) Health benefit plan administrator;

(d) Group purchasing organization or pharmacy benefit manager; or

(e) Other entity authorized to purchase prescription drugs in this state.

NEW SECTION. **Sec. 4.** Starting January 1, 2009, and annually thereafter, every pharmaceutical manufacturer shall:

(1) Disclose to the board information on each gift, fee, or payment made to recipients in the state;

(2) Submit information in a form and manner determined by the board, including for each expenditure:

(a) The value and nature;

(b) The purpose according to categories specified by the board; and

(c) The recipient, including the recipient's address, credentials, and institutional affiliation;

(3) Disclose to the board the name and address of the individual responsible for the company's compliance with the provisions of this section or, if this information has been previously reported, any changes to the name or address of the individual responsible for the company's compliance with the provisions of this section;

(4) Pay a fee, to be set by the board, to support the work of the board under this chapter.

Pharmaceutical manufacturers that comply with section 5 of this act are exempt from the reporting requirements under this section.

NEW SECTION. **Sec. 5.** A pharmaceutical manufacturer that provides the board with a written report documenting the manufacturer's compliance with the following requirements is exempt from section 4 of this act:

(1) A written marketing compliance code that establishes the practices and standards that govern the marketing and sale of the pharmaceutical manufacturer's products;

(2) A training program for employees that the pharmaceutical manufacturer undertakes regularly to train appropriate employees on the marketing compliance code;

(3) Regular audits to monitor compliance with the marketing compliance code;

(4) Policies and procedures for investigating instances of noncompliance with the marketing compliance code;

(5) Effective lines of communication for employees to report noncompliance, investigate reports of noncompliance, take corrective actions in response to noncompliance, and report instances of noncompliance to the department in an appropriate circumstance;

(6) The name and contact information for the pharmaceutical manufacturer's compliance officer responsible for developing, operating, and monitoring the marketing compliance code.

NEW SECTION. **Sec. 6.** The board shall:

(1) Report annually on disclosures made under this chapter to the legislature and the governor on or before March 1st of each year;

(2) Post specific and easily searchable data on its public internet site, including:

(a) Amount of each gift;

(b) Date given;

(c) Intended purpose of the gift;

(d) Pharmaceutical manufacturer; and

(e) Recipient identified by drug enforcement agency number or other unique identifier.

NEW SECTION. **Sec. 7.** 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. Each unlawful failure to disclose constitutes a separate violation.

NEW SECTION. **Sec. 8.** The board may adopt rules to implement the provisions of this chapter.

NEW SECTION. **Sec. 9.** This chapter may be known and cited as the prescription drug marketing and disclosure act.

NEW SECTION. **Sec. 10.** 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. 11.** Sections 1 through 10 of this act constitute a new chapter in Title 69 RCW.

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