
HOUSE BILL 2498

State of Washington 60th Legislature 2008 Regular Session

By Representatives Green, Pedersen, Appleton, Hasegawa, Conway, Hudgins, Morrell, and Chase

Prefiled 01/03/08. Read first time 01/14/08. Referred to Committee on Health Care & Wellness.

1 AN ACT Relating to prescription drug marketing and disclosure;
2 adding a new chapter to Title 69 RCW; and prescribing penalties.

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

4 NEW SECTION. **Sec. 1.** The purpose of this chapter is to regulate
5 gifts, grants, and gratuities made by pharmaceutical manufacturing
6 companies, directly or indirectly, to any person or entity authorized
7 to prescribe, dispense, or purchase prescription drugs in Washington.

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

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

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

13 (3) In 2004, the pharmaceutical industry spent twenty-seven billion
14 dollars marketing pharmaceuticals in the United States. Over
15 eighty-five percent of these marketing expenditures are directed at the
16 small percentage of the population that practice medicine.
17 Pharmaceutical manufacturers spend twice as much on marketing as on
18 research and development;

1 (4) Marketing programs are designed to increase sales, income, and
2 profit. Frequently, progress toward these goals comes at the expense
3 of evidence-based treatment and sometimes the health of individual
4 patients;

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

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

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

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

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

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

36 (11) Several studies suggest that drug samples clearly affect
37 prescribing behavior in favor of the sample, and that the presence of

1 drug samples may influence physicians to dispense or prescribe drugs
2 that differ from their preferred drug source;

3 (12) The pharmaceutical industry increased its spending on direct
4 marketing to doctors by over two hundred seventy-five percent and
5 doubled its sales force to over ninety thousand drug representatives.
6 It is estimated that there is a pharmaceutical sales representative for
7 every five office-based physicians.

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

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

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

- 16 (i) Food or entertainment;
- 17 (ii) Trips or travel;
- 18 (iii) Anything provided for less than market value;
- 19 (iv) Medical conferences, continuing medical education, or other
20 educational or informational programs, materials, and seminars, and
21 remuneration for promoting or participating in educational or
22 informational sessions;
- 23 (v) Consulting fees or honoraria;
- 24 (vi) Product samples, including samples that will be distributed
25 free of charge to patients;
- 26 (vii) Clinical trials or research, including any compensation or
27 reimbursement of expenses.

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

- 29 (i) Payments made in conjunction with returned merchandise and
30 overpayments;
- 31 (ii) Publications and educational materials;
- 32 (iii) Salaries or other benefits paid to its employees;
- 33 (iv) Overpayments;
- 34 (v) Product rebates and discounts; and
- 35 (vi) Other normal course-of-business financial dealings unrelated
36 to detailing, promotional, or other marketing activities.

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

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

11 (5)(a) "Marketing" means any of the following activities undertaken
12 or materials or products made available to prescribers or to their
13 employees or agents related to the transfer of prescription drugs from
14 the producer or seller to the consumer or buyer:

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

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

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

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

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

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

35 (7)(a) "Pharmaceutical manufacturer" means an entity that is
36 engaged in the production, preparation, propagation, compounding,
37 conversion, or processing of prescription drugs, either directly or
38 indirectly by extraction from substances of natural origin, or

1 independently by means of chemical synthesis, or by a combination of
2 extraction and chemical synthesis, or any entity engaged in the
3 packaging, repackaging, labeling, relabeling, or distribution of
4 prescription drugs, biologics, or medical devices.

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

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

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

21 (10) "Recipient" means any:

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

25 (b) Hospital licensed under chapter 70.41 RCW;

26 (c) Health benefit plan administrator;

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

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

30 NEW SECTION. **Sec. 4.** Starting January 1, 2010, and annually
31 thereafter, every pharmaceutical manufacturer shall:

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

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

36 (a) The value and nature;

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

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

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

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

10 NEW SECTION. **Sec. 5.** The board shall:

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

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

15 (a) Amount of each gift;

16 (b) Date given;

17 (c) Intended purpose of the gift;

18 (d) Pharmaceutical manufacturer; and

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

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

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

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

31 NEW SECTION. **Sec. 9.** If any provision of this act or its
32 application to any person or circumstance is held invalid, the

1 remainder of the act or the application of the provision to other
2 persons or circumstances is not affected.

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

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