THE SENATE
TWENTY-FIFTH LEGISLATURE, 2010
STATE OF HAWAII

JAN 2 2 2010

S.B. NO. 2506

A BILL FOR AN ACT

RELATING TO MEDICAL GIFTS.

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

SECTION 1. The legislature finds that pharmaceutical and medical equipment companies have historically given gifts to medical practitioners and have funded educational seminars and conferences. While these activities can serve important and beneficial functions, there has been a growing concern that gifts and expenditures may inappropriately influence doctors' prescribing decisions and may not be consistent with the principles of medical ethics.

Studies have shown that even the smallest gifts create what researchers call a "demand for reciprocity," and ninety-four per cent of America's prescribers have received such gifts. Doctors who attend talks sponsored by pharmaceutical companies often prescribe that company's drug more than a competitor's drug, and doctors are encouraged to prescribe newer, more expensive, and potentially more dangerous drugs instead of adhering to evidence-based treatment procedures.

The legislature further finds that the lack of transparency and limitations on gifts from pharmaceutical companies to doctors tends to undermine patient confidence in health care providers and increase health care costs by influencing prescribing patterns. Requirements are now needed to save money for consumers, businesses, and the State by reducing the promotion of expensive prescription drugs, biological products, and medical devices, and to protect public health by reducing sales-oriented information to prescribers.

The purpose of this Act is to increase transparency for consumers and reduce real or perceived conflicts of interest by providing limitations on gifts and by requiring disclosure of allowable expenditures and gifts to health care providers and facilities providing health care.

SECTION 2. The Hawaii Revised Statutes is amended by adding a new chapter to be appropriately designated and to read as follows:

"**CHAPTER**

GIFTS BY MANUFACTURERS OF PRESCRIBED PRODUCTS

§ -1 Definitions. (a) As used in this chapter:

"Allowable expenditures" means:

(1) Payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, provided:

(A) The payment is not made directly to a health care provider;

(B) Funding is used solely for bona fide educational purposes; and

(C) All program content is objective, free from industry control, and does not promote specific products;

(2) Honoraria and payment of the expenses of a health care professional who serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar, provided:

(A) There is an explicit contract with specific deliverables which are restricted to medical issues, not marketing activities; and

(B) The content of the presentation, including slides and written materials, is determined by the health care professional;

(3) For a bona fide clinical trial:

(A) Gross compensation for the location or locations in the State involved;

(B) Direct salary support per principal investigator and other health care professionals per year; and

(C) Expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial;

(4) For a research project that constitutes a systematic investigation, is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or health care professionals working in the particular field of inquiry:

(A) Gross compensation;

(B) Direct salary support per health care professional; and

(C) Expenses paid on behalf of each health care professional;

(5) Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a medical device if

the commitment to provide those expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer;

(6) Royalties and licensing fees paid to health care providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care provider holds an ownership right; and

(7) Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value.

"Bona fide clinical trial" means a Food and Drug Administration-reviewed clinical trial that constitutes "research" as that term is defined in 45 C.F.R. section 46.102 and reasonably can be considered to be of interest to scientists or health care professionals working in the particular field of inquiry.

"Clinical trial" means any study assessing the safety or efficacy of prescribed products administered alone or in combination with other prescribed products or other therapies, or assessing the relative safety or efficacy of prescribed

products in comparison with other prescribed products or other therapies.

"Gift" means:

(1) Anything of value provided to a health care provider for free; or

(2) Any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider, unless:

(A) It is an allowable expenditure; or

(B) The health care provider reimburses the cost at fair market value.

"Health care professional" means a person, a partnership or corporation made up of such a person, or an officer, employee, agent, or contractor of such a person, who is authorized to prescribe or to recommend prescribed products and who either is licensed by this State to provide or is otherwise lawfully providing health care in this State.

"Health care provider" means a health care professional, a hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to dispense or purchase for distribution prescribed products in this State.

"Manufacturer" means a pharmaceutical, biological product, or medical device manufacturer or any other person who is engaged in the production, preparation, propagation, compounding, processing, packaging, repacking, distributing, or labeling of prescribed products. The term "manufacturer" does not include a wholesale distributor of biological products or a pharmacist.

"Marketing" means promotion, detailing, or any activity that is intended to be used or is used to influence sales or market share or to evaluate the effectiveness of a professional sales force.

"Pharmaceutical manufacturer" means any entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, whether directly or indirectly by extraction from substances of natural origin, 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. The term "pharmaceutical manufacturer" does not include a wholesale distributor of prescription drugs or a pharmacist.

"Prescribed product" means a drug or device as defined in section 201 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. section 321, or a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. section 262.

"Significant educational, scientific, or policy-making conference or seminar" means an educational, scientific, or policy-making conference or seminar that:

(1) Is accredited by the Accreditation Council for Continuing Medical Education or a comparable organization; and

(2) Offers continuing medical education credit, features multiple presenters on scientific research, or is authorized by the sponsoring association to recommend or make policy.

§ -2 Gifts by manufacturers of prescribed products. (a) It is unlawful for any manufacturer of a prescribed product or any wholesale distributor of medical devices, or any agent thereof, to offer or give any gift to a health care provider.

(b) The prohibition set forth in subsection (a) shall not apply to any of the following:

(1) Samples of a prescribed product provided to a health care provider for free distribution to patients;

(2) The loan of a medical device for a short-term trial period, not to exceed ninety days, to permit evaluation of a medical device by a health care provider or patient;

(3) The provision of reasonable quantities of medical device demonstration or evaluation units to a health care provider to assess the appropriate use and function of the product and determine whether and when to use or recommend the product in the future;

(4) The provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical articles or journals and other items that serve a genuine educational function provided to a health care provider for the benefit of patients;

(5) Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference or seminar of a national, regional, or specialty medical or other professional association if the

recipient of the scholarship or other support is selected by the association;

(6) Rebates and discounts for prescribed products provided in the normal course of business; or

(7) Labels approved by the federal Food and Drug Administration for prescribed products.

(c) The director of commerce and consumer affairs may bring a civil action for injunctive relief, costs, and attorney's fees and may impose on a manufacturer that violates this section a civil penalty of not more than $10,000 per violation. Each unlawful gift shall constitute a separate violation.

§ -3 Disclosure of allowable expenditures and gifts by manufacturers of prescribed products. (a) Annually, on or before October 1, every manufacturer of prescribed products shall disclose to the director of commerce and consumer affairs for the fiscal year ending the previous June 30, the value, nature, and purpose, and recipient information of:

(1) Any allowable expenditure or gift permitted under section -2(b) to any health care provider, except:

(A) Royalties and licensing fees;

(B) Rebates and discounts for prescribed products provided in the normal course of business;

(C) Payments for clinical trials which shall be disclosed after the earlier of the date of the approval or clearance of the prescribed product by the Food and Drug Administration or two calendar years after the date the payment was made. For a clinical trial for which disclosure is delayed under this subparagraph, the manufacturer shall identify to the director of commerce and consumer affairs the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry; and

(D) Samples of a prescription drug provided to a health care professional for free distribution to patients;

(2) Any allowable expenditure or gift permitted under section -2(b) to an academic institution or to a professional, educational, or patient organization representing or serving health care providers or consumers, except:

(A) Royalties and licensing fees;

(B) Rebates and discounts for prescribed products provided in the normal course of business;

(C) Payments for clinical trials which shall be disclosed after the earlier of the date of the approval or clearance of the prescribed product by the Food and Drug Administration or two calendar years after the date the payment was made. For a clinical trial for which disclosure is delayed under this subparagraph, the manufacturer shall identify to the director of commerce and consumer affairs the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry; and

(D) Samples of a prescription drug provided to a health care professional for free distribution to patients.

(b) Annually, on or before July 1, each manufacturer of prescribed products also shall disclose to the director of commerce and consumer affairs, the name and address of the

individual responsible for the manufacturer's compliance with this section.

(c) Disclosure under this section shall be made on a form and in a manner prescribed by the director of commerce and consumer affairs and shall require manufacturers of prescribed products to report each allowable expenditure or gift permitted under section -2(b) including:

(1) Except as otherwise provided in this section, the value, nature, and purpose of each allowable expenditure, and gift permitted under section -2(b) according to specific categories identified by the director of commerce and consumer affairs;

(2) The name of the recipient;

(3) The recipient's address;

(4) The recipient's institutional affiliation; and

(5) Prescribed product or products being marketed, if any.

(d) The director of commerce and consumer affairs shall report annually on the disclosures made under this section to the legislature and the governor on or before April 1. The report shall include:

(1) Information on allowable expenditures and gifts required to be disclosed under this section, which

shall be presented in both aggregate form and by selected types of health care providers or individual health care providers, as prioritized each year by the director;

(2) Information on violations and enforcement actions brought pursuant to this section and section -2.

(e) After issuance of the report required by this section, the director of commerce and consumer affairs shall make all disclosed data used for the report publicly available and searchable through an internet website.

(f) The department of health shall examine the data available from the director of commerce and consumer affairs for relevant expenditures and determine whether and to what extent prescribing patterns by health care providers of prescribed products reimbursed by Medicaid and other third party payors may reflect manufacturer influence. The department of health may select the data most relevant to its analysis. The department of health shall report its analysis annually to the legislature and the governor on or before October 1.

(g) Annually, on or before July 1, the director of commerce and consumer affairs shall collect a $500 fee from each manufacturer of prescribed products filing annual disclosures of

expenditures for deposit into the compliance resolution fund established under section 26-9(o).

(h) The director of commerce and consumer affairs may bring a civil action for injunctive relief, costs, and attorney's fees, and to impose on a manufacturer of prescribed products that fails to make the required disclosures a civil penalty of not more than $10,000 per violation. Each unlawful failure to disclose shall constitute a separate violation."

SECTION 3. This Act shall take effect upon its approval.

INTRODUCED BY: _____

S.B. NO. 2506

Report Title:
Gifts; Drug or Device Manufacturers; Health Care Providers

Description:
Bans drug or device manufacturers or any wholesale distributor of medical devices from offering gifts to health care providers, unless excepted. Requires disclosure of permissible gifts to the director of commerce and consumer affairs. Makes disclosures publicly available.

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