THE SENATE
TWENTY-FIFTH LEGISLATURE, 2009
STATE OF HAWAII

S.B. NO. 1092

JAN 26 2009

A BILL FOR AN ACT

RELATING TO PRESCRIPTION RECORDS PRIVACY.

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

SECTION 1. It is the intent of the legislature to safeguard the confidentiality of prescribing information, protect the integrity of the doctor-patient relationship, maintain the integrity and public trust in the medical profession, combat vexatious and harassing sales practices, restrain undue influence exerted by pharmaceutical industry marketing representatives over prescribing decisions, and further the public's interest in improving the quality and lowering the costs of health care in the State. The legislature intends to regulate the monitoring of prescribing practices only for commercial marketing purposes by companies selling prescribed products. It is not the legislature's intent to regulate monitoring for other uses, such as quality control, research unrelated to marketing, or use by governments or other entities not in the business of selling health care products.

SECTION 2. Chapter 328, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"PART . PRESCRIPTION RECORD PRIVACY

§328-A Definitions. As used in this part:

"Bona fide clinical trial" means any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome.

"Individual identifying information" means information that directly or indirectly identifies a prescriber or a patient, where the information is derived from or relates to a prescription for any prescribed product.

"Marketing" means any activity by a company making or selling prescribed products, or the company's agent, intended to influence prescribing or purchasing choices of its products, including but not limited to:

(1) Advertising, publicizing, promoting, or sharing information about a product;

(2) Identifying individuals to receive a message promoting use of a particular product, including but not limited to an advertisement, brochure, or contact by a sales representative;

(3) Planning the substance of a sales representative visit or communication or the substance of an advertisement or other promotional message or document;

(4) Evaluating or compensating sales representatives;

(5) Identifying individuals to receive any form of gift, product sample, consultancy, or any other item, service, compensation or employment of value; and

(6) Advertising or promoting prescribed products directly to patients.

"Person" means a business, individual, corporation, union, association, firm, partnership, committee, or other organization or group of persons.

"Pharmacy" has the meaning as defined in section 461-1.

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

"Regulated records" means information or documentation from a prescription written by a prescriber doing business in this State or a prescription dispensed in this State.

"State health care program" means a program for which the State purchases prescribed products, including but not limited to a state pharmaceutical assistance program, or a program for state employees and their dependents, individuals under the supervision of corrections, or state retirees and their dependents with the exception of the state medical assistance program (medicaid).

§328-B Prescription record privacy. (a) No person shall knowingly disclose or use regulated records that include prescription information containing individual identifying information for marketing a prescribed product.

(b) Regulated records containing individual identifying information may be disclosed, sold, transferred, exchanged, or used for non-marketing purposes.

(c) This section shall not prohibit conduct involving the collection, use, transfer, or sale of regulated records for marketing purposes if:

(1) The data is aggregated;

(2) The data does not contain individually identifying information; and

(3) There is no reasonable basis to believe that the data can be used to obtain individually identifying information.

(d) An authorized recipient of regulated records containing individual identifying information may resell, reuse, or redisclose the information only for a use permitted under subsection (b). Any authorized recipient that resells or rediscloses individual identifying information covered by this part shall keep records identifying each person or entity that receives the information and the permitted purpose for which the information will be used for a period of five years and shall make the records available to any person upon request.

(e) This section shall not prevent any person from disclosing individual identifying information to the identified individual as long as the information does not include protected information pertaining to any other person.

§328-C Rules. The department of health shall adopt rules in accordance with chapter 91 to carry out the purposes of this part.

§328-D Enforcement. Any person who knowingly fails to comply with the requirements of this part or rules adopted pursuant section 328-C by using or disclosing regulated records

in a manner not authorized by this part or by rules shall be subject to an administrative penalty of not more than $50,000 per violation, as assessed by the department of health. Each disclosure of a regulated record shall constitute a violation. The attorney general shall take necessary action to enforce payment of penalties assessed under this section.

§328-E Consumer fraud. In addition to any other remedy provided by law, a violation of this part is an unfair or deceptive act or practice within the meaning of section 480-2.

§328-F Non-medicaid state health care programs. (a) The intent of this section is to ensure the confidentiality of data held by a state agency or the agency's agent that may be used to directly or indirectly identify a patient or a health care professional licensed to prescribe drugs, biological products, or medical devices.

(b) Records held by an agency administering a state health care program that include prescription information containing individual identifying information shall only be disclosed for the purposes allowed in section 328-B.

(c) Any person who knowingly fails to comply with the requirements of this part or rules adopted pursuant to section 328-C by using or disclosing regulated records in a manner not

authorized by this part or by rules shall be subject to an administrative penalty of not more than $50,000 per violation, as assessed by the department of health. Each disclosure of a regulated record shall constitute a violation. The attorney general shall take necessary action to enforce payment of penalties assessed under this section.

§328-G Medicaid. (a) The intent of this section is to ensure compliance with federal medicaid law and regulations prohibiting the disclosure and use of medicaid data except to administer the medicaid program, and to ensure that data held by the department of human services or its agents that may directly or indirectly identify patients or health care professionals licensed to prescribe products be kept confidential.

(b) The department of human services, which administers the State's medical assistance program (medicaid) under 42 CFR chapter IV, subchapter C or a medicaid waiver approved by the Centers for Medicare and Medicaid Services shall disclose records that include prescription information only as provided for under 42 CFR section 431 and the Privacy Act of 1974. The department of human services shall ensure that any agent or contractor with the department of human services shall be informed of the limitations on redisclosure or use of the data

provided for under applicable federal regulations and shall have policies and procedures for insuring compliance with this part and federal regulations.

(c) Any person who knowingly fails to comply with the requirements of this part or rules adopted pursuant to section 328-C by using or disclosing regulated records in a manner not authorized by this part or by rules shall be subject to an administrative penalty of not more than $50,000 per violation, as assessed by the department of human services. Each disclosure of a regulated record shall constitute a violation. The attorney general shall take necessary action to enforce payment of penalties assessed under this section.

§328-H No extraterritorial effect. Nothing in this part shall be interpreted to regulate conduct that occurs entirely outside of the State.

§328-I No effect on truthful speech. Nothing in this part shall be interpreted to regulate the content, time, place, or manner of any discussion between a prescriber and a patient, or a prescriber and any person representing a prescription drug manufacturer."

SECTION 3. In codifying the new sections added by section 2 of this Act, the revisor of statutes shall substitute

S.B. NO. 1092

appropriate section numbers for the letters used in designating the new sections in this Act.

SECTION 4. This Act shall take effect on July 1, 2009.

INTRODUCED BY:

S.B. NO. 1092

Report Title:
Prescription Record Privacy

Description:
Protects the confidentiality of prescription records identifying a doctor or other health care professional licensed to prescribe medications by prohibiting the use of such information for marketing purposes. Ensures that the State comply with federal restrictions on the transfer and use of medicaid data.