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## A BILL FOR AN ACT

RELATING TO PRESCRIPTION RECORDS PRIVACY.

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

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

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



1                   **"PART . PRESCRIPTION RECORD PRIVACY**

2           **§328-A Definitions.** As used in this part:

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

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

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

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

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



- 1 (3) Planning the substance of a sales representative visit
- 2 or communication or the substance of an advertisement
- 3 or other promotional message or document;
- 4 (4) Evaluating or compensating sales representatives;
- 5 (5) Identifying individuals to receive any form of gift,
- 6 product sample, consultancy, or any other item,
- 7 service, compensation or employment of value; and
- 8 (6) Advertising or promoting prescribed products directly
- 9 to patients.

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

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

14 "Prescribed product" includes a biological product as  
15 defined in section 351 of the Public Health Service Act, 42  
16 U.S.C. section 262 and a device or a drug as defined in section  
17 201 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.  
18 section 321.

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



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

8 **§328-B Prescription record privacy.** (a) No person shall  
9 knowingly disclose or use regulated records that include  
10 prescription information containing individual identifying  
11 information for marketing a prescribed product.

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

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

- 18 (1) The data is aggregated;  
19 (2) The data does not contain individually identifying  
20 information; and



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

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

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

17           **§328-C Rules.** The department of health shall adopt rules  
18 in accordance with chapter 91 to carry out the purposes of this  
19 part.

20           **§328-D Enforcement.** Any person who knowingly fails to  
21 comply with the requirements of this part or rules adopted  
22 pursuant section 328-C by using or disclosing regulated records



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

7       **§328-E Consumer fraud.** In addition to any other remedy  
8 provided by law, a violation of this part is an unfair or  
9 deceptive act or practice within the meaning of section 480-2.

10       **§328-F Non-medicaid state health care programs.** (a) The  
11 intent of this section is to ensure the confidentiality of data  
12 held by a state agency or the agency's agent that may be used to  
13 directly or indirectly identify a patient or a health care  
14 professional licensed to prescribe drugs, biological products,  
15 or medical devices.

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

20       (c) Any person who knowingly fails to comply with the  
21 requirements of this part or rules adopted pursuant to section  
22 328-C by using or disclosing regulated records in a manner not



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

7       **§328-G Medicaid.** (a) The intent of this section is to  
8 ensure compliance with federal medicaid law and regulations  
9 prohibiting the disclosure and use of medicaid data except to  
10 administer the medicaid program, and to ensure that data held by  
11 the department of human services or its agents that may directly  
12 or indirectly identify patients or health care professionals  
13 licensed to prescribe products be kept confidential.

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



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

4 (c) Any person who knowingly fails to comply with the  
5 requirements of this part or rules adopted pursuant to section  
6 328-C by using or disclosing regulated records in a manner not  
7 authorized by this part or by rules shall be subject to an  
8 administrative penalty of not more than \$50,000 per violation,  
9 as assessed by the department of human services. Each  
10 disclosure of a regulated record shall constitute a violation.  
11 The attorney general shall take necessary action to enforce  
12 payment of penalties assessed under this section.

13 **§328-H No extraterritorial effect.** Nothing in this part  
14 shall be interpreted to regulate conduct that occurs entirely  
15 outside of the State.

16 **§328-I No effect on truthful speech.** Nothing in this part  
17 shall be interpreted to regulate the content, time, place, or  
18 manner of any discussion between a prescriber and a patient, or  
19 a prescriber and any person representing a prescription drug  
20 manufacturer."

21 SECTION 3. In codifying the new sections added by section  
22 2 of this Act, the revisor of statutes shall substitute





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

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

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INTRODUCED BY:

*Beal*

*Guthrie Thelen*

JAN 28 2009



**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.

