THE SENATE
TWENTY-FIFTH LEGISLATURE, 2009
STATE OF HAWAII

S.B. NO. 449

JAN 2 3 2009

A BILL FOR AN ACT

RELATING TO PATIENT PRESCRIPTION INFORMATION.

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

SECTION 1. The legislature finds that in 2006, New Hampshire enacted a law that prohibits the sale of doctor-specific prescription drug data--data that is widely used in pharmaceutical marketing. The New Hampshire law is intended to reduce state health care costs by eliminating the tool used by drug sales representatives in targeting sales of brand name drugs. By purchasing the data describing which doctors prescribe what drugs, pharmaceutical sales agents can more readily identify doctors who might be likely to prescribe their products and thus be receptive to their sales proposals. Of greater concern, however, is that drug companies can also use the information to identify doctors who do not write many prescriptions for their products, in order to step up their marketing efforts.

On September 16, 2008, the United States First Circuit Court of Appeals upheld the New Hampshire statute against a challenge to its validity. In his ruling, United States Court

of Appeals Judge Bruce Marshall Selya wrote, "The record contains substantial evidence that, in several instances, detailers [pharmaceutical sales representatives] armed with prescribing histories encourage the overzealous prescription of more costly brand-name drugs regardless of both the public health consequences and the probable outcome of a sensible cost/benefit analysis."

The purpose of this Act is to enact a patient prescription information confidentiality law based on the New Hampshire statute that has recently withstood legal challenge.

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

"**§328- Prescription information; confidentiality; violation.** (a) Records relating to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of:

(1) Pharmacy reimbursement;

(2) Formulary compliance;

(3) Care management;

(4) Utilization review by a health care provider, the patient's insurance provider, or the agent of either;

(5) Health care research; or

(6) As otherwise provided by law.

(b) For the purpose of this section, "pharmacy benefit manager" means a third party administrator of prescription drug benefit programs primarily responsible for processing and paying prescription drug claims, developing and maintaining a drug formulary, contracting with pharmacies, and negotiating discounts and rebates with drug manufacturers. Commercial purposes include advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

(c) Nothing in this section shall prohibit:

(1) The dispensing of prescription medications to a patient or to the patient's authorized representative;

(2) The transmission of prescription information between an authorized prescriber and a licensed pharmacy;

(3) The transfer of prescription information between licensed pharmacies;

(4) The transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred;

(5) Care management educational communications provided to a patient about:

(A) The patient's health condition;

(B) Adherence to a prescribed course of therapy; or

(C) Other information about the drug being dispensed, treatment options, or clinical trials.

(d) Nothing in this section shall prohibit the collection, use, transfer, or sale of patient and prescriber data that are not identifiable by zip code, geographic region, or medical specialty for commercial purposes.

(e) In addition to other remedies, a violation of this section is an unfair or deceptive act or practice within the meaning of section 480-2."

SECTION 3. New statutory material is underscored.

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SECTION 4. This Act shall take effect upon its approval.

INTRODUCED BY:

S.B. NO. 449

Report Title:
Confidentiality of Prescription Information

Description:
Prohibits, except for certain limited purposes, the use, transfer, licensing, or sale of a patient's prescription information for any commercial purpose.

LINDA LINGLE
GOVERNOR OF HAWAII

CHIYOME LEINAALA FUKINO, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P.O. Box 3378
HONOLULU, HAWAII 96801-3378

In reply, please refer to:
File:

Senate Committee on Commerce and Consumer Protection

SB 449, RELATING TO PATIENT PRESCRIPTION INFORMATION

Testimony of Chiyome Leinaala Fukino, M.D.
Director of Health

February 13, 2009
8:30am

Department's Position: The Department appreciates the intent of this bill, but has concerns regarding this proposal; and therefore, respectfully opposes this bill.

Fiscal Implications: None

Purpose and Justification: This bill amends HRS Chapter 328 by prohibiting records containing patient prescription information to be licensed, transferred, used or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or internet pharmacies for any commercial purpose; except for certain limited purposes.

We appreciate the intent to protect personal medical information from the potential abuse by unauthorized entities. However, the focus of HRS Chapter 328, with respect to prescription drugs, is to prevent the adulteration and the misbranding of drugs and ensuring the validity of a prescription drug order. As the enforcer of HRS Chapter 328, the Department currently has no jurisdictional authority over pharmacy benefits managers or insurance companies since they do not sell, distribute or manufacture prescription drugs. In addition, while HRS Chapter 328 does apply to licensed pharmacies

operating in Hawaii, it has no jurisdiction over retail, mail order and internet pharmacies operating in other states.

We also consider this measure unnecessary as HRS Chapter 328, section 328-16 already addresses the confidentiality of information contained in a prescription order. The confidentiality issue is also addressed by the federal Health Insurance Portability and Accountability Act (HIPAA).

For these reasons, the Department recommends this measure be deferred.

Thank you for the opportunity to testify.

HAWAII INSURERS COUNCIL
A trade association of property and casualty insurance companies

Pauahi Tower, Suite 2010
1003 Bishop Street
Honolulu, Hawaii 96813
Telephone (808) 525-5877
Facsimile (808) 525-5879

Alison Powers
Executive Director

TESTIMONY OF ALISON POWERS

SENATE COMMITTEE ON COMMERCE AND CONSUMER PROTECTION
Senator Rosalyn H. Baker, Chair
Senator David Y. Ige, Vice Chair

Friday, February 13, 2009
8:30 a.m.

SB 449

Chair Baker, Vice Chair Ige and members of the Committee, my name is Alison Powers, Executive Director of Hawaii Insurers Council. Hawaii Insurers Council is a non-profit trade association of property and casualty insurance companies licensed to do business in Hawaii. Member companies underwrite approximately 60% of all property and casualty insurance premiums in the state.

Hawaii Insurers Council **supports** S.B. 449 **with clarifying amendments**. We offer amended language to section 328 - ____(a) (4) so that utilization review can also be done by a third party insurance provider. For example, in the case of a tort claim resulting from a motor vehicle insurance accident, the bodily injury insurer would be the third party insurance provider and medical records including prescription information may be requested.

"Section 328-_____ (a)(4) Utilization review by a health care provider, the patient's insurance provider, ***third party insurance provider,*** or the agent of either;"

We also request that the words, “or evaluate” be deleted from Page 3, line 15 of the bill because insurers would like to be able to evaluate prescription information in the event certain patterns are revealed, for instance, consistent overprescribing of pain medication.

Thank you for the opportunity to testify.

February 11, 2009

TO: Chair Rosalyn H. Baker and Members of the Committee on Commerce and Consumer Protection

FROM: Pharmaceutical Research and Manufacturers of America (William L. Goo/Norman H. Suzuki)

RE: **SB 449** - Relating to Patient Prescription Information

Hearing Date: Friday, February 13, 2009 at 8:30 a.m.

We represent Pharmaceutical Research and Manufacturers of America (PhRMA).

PhRMA respectfully opposes passage of **SB 449** for the reasons set forth in the attached statement.

Thank you for considering this testimony. It is respectfully requested that the Committee hold this measure.

Statement PhRMA

In Opposition to Hawaii Senate Bill 449

Position: PhRMA respectfully opposes prohibitions on the commercial use of physician prescribing data as proposed in Senate Bill 449.

Restricting the use of prescribing data could result in significant unintended consequences that could adversely impact patient care and safety and hamper manufacturers' ability to alert physicians to important new drug information. This data is critical to the efficient, timely, and targeted dissemination of information to doctors and patients. The data used by manufacturers does not contain patient identifiable information and allows prescription drug manufacturers to carry out federally required drug programs that help safeguard patients, helps companies address other patient safety concerns, and can help reduce the cost of prescription drug marketing.

Patient Identifiable Information Is Protected

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) bars any unauthorized use of patient identifiable information. Therefore, under federal law, prescriber data cannot include individual patient identifiable information.

Critical Value of Prescriber Data Reinforced by US Congress

The federal regulatory system increasingly depends on pharmaceutical companies to communicate directly with health care providers about how to use medicines safely and effectively. This communication allows drugs with significant benefits, but serious safety risks, to be made available to patients. Without prescriber data, such communication will be less efficient.

The critical nature of prescriber data was recently recognized by Congress in the Food and Drug Administration Amendments Act of 2007 (FDAAA). The FDAAA authorizes the FDA to require Risk Evaluation and Mitigation Strategies (REMS) for certain high risk medicines. These structured, required programs are intended to increase safeguards for patients when FDA believes that extra vigilance is needed.

A REMS can require manufacturers to: ensure that prescribers have specific training, experience or certification; disseminate information about the REMS to health care providers; ensure that a drug is dispensed to patients only "with evidence or other documentation of safe-use conditions, such as laboratory test results" or if "each patient using the drug [is] subject to certain monitoring;" and monitor, evaluate, and improve the implementation of REMS.

Complete access to prescriber data is necessary to train providers and monitor REMS. This is because, most importantly, one cannot predict in advance which drugs will be the subject of a REMS (e.g., a safety issue can be identified after FDA approval). Drug manufacturers will need access to prescriber data for compliance so it is important that access to prescriber data is not limited to only when required by federal law.

The importance of REMS is further emphasized by the penalties for non-compliance. Manufacturers will be subject to $250,000 per violation; $1 million for all violations adjudicated in a single proceeding; and $10 million for all violations adjudicated in a single proceeding if the violations continue after written notice from FDA for failing to comply with REMS requirements.

Other Patient Safety Concerns

Because pharmaceutical companies generally sell their medicines to wholesalers (who in turn sell to pharmacies), without prescriber data manufacturers do not have direct knowledge of which health care professionals prescribe their medicines. For example, without access to prescriber data, it becomes extremely difficult for pharmaceutical companies to conduct targeted and effective drug recalls; identify and report to FDA any adverse events associated with a medicine; and efficiently distribute new drug labeling information such as drug-drug interactions and black box warnings.

Additionally, prescriber data contributes significantly to the acceleration of clinical trials by identifying physicians most likely to have pools of patients eligible for enrollment. Analysis of prescriber data also helps efforts to identify: physicians from whom to solicit information on unmet medical needs (for use in the development of new medicines or new formulations of existing medicines); specific patient populations for targeted sales and marketing of pharmaceuticals; prescribers who are not treating patients optimally (e.g. under-prescribing for high cholesterol); and physicians whose patients could use samples.

Access to Prescriber Data Allows Manufacturers to Focus Outreach Efforts on Providers and Patients

Continued access to prescriber data can help pharmaceutical manufacturers reduce the cost of marketing by preventing expensive, blanketed marketing of prescription medicines. Banning the commercial use of this data may hinder the ability of prescription drug manufacturers to effectively target the dissemination of necessary clinical information and drug samples to those physicians most likely to need education on certain prescription and require specific drug samples for their patient populations.

The AMA PDRP Allows Physicians to Restrict the Use of Their Prescribing Data

The AMA's PDRP provides physicians with an opt-out mechanism to prohibit the release of their prescribing data to pharmaceutical sales representatives for a period of three years. Physicians can also register complaints against companies or individuals who have used prescriber data inappropriately through the PDRP. Physicians may easily opt-out by logging on to **www.ama-assn.org/go/prescribingdata** or by requesting the restriction via phone, fax, email, or standard mail. Pharmaceutical companies must ensure compliance with the PDRP by processing restriction requests within 90 days.

Prescriber data does not contain patient identifiable information, allows prescription drug manufacturers to carry out federally required drug programs that help safeguard patients, helps manufacturers address other patient safety concerns, and can help reduce the cost of prescription drug marketing.

For these reasons, PhRMA urges Hawaii senators to oppose efforts to ban the use of physician prescribing data.

Senate Committee on Commerce and Consumer Protection
Senator Rosalyn H Baker, Chair
Senator David Y Ige, Vice Chair

SB449- Prohibits, except for certain limited purposes, the use, transfer, licensing, or sale of a patient's prescription information for any commercial purpose.

My name is Nathan Say, a citizen of the City and County of Honolulu. I am writing today in support of SB449. Protecting our prescription information is important. Receiving unsolicited information and offers by companies that provide similar drugs to people with the same conditions as the ones we are being treated for may prove to be dangerous, especially when tempted with a less expensive drug that could be unknowingly harmful to consumers.

Thank you for your time.