SB 72

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 Health

Senate Committee on Commerce and Consumer Protection

SB 72, RELATING TO PRESCRIPTIONS

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

February 18, 2009
9:00am

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 consider this measure unnecessary as HRS Chapter 328, section 328-16 and the federal Health Insurance Portability and Accountability Act (HIPAA) already addresses the confidentiality of information contained in a prescription order for entities under its jurisdictional authority. Entities not covered by HRS Chapter 328 and HIPAA are beyond the scope and jurisdiction of the Department.

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

Thank you for the opportunity to testify.

LINDA LINGLE
GOVERNOR

STATE OF HAWAII
DEPARTMENT OF PUBLIC SAFETY
919 Ala Moana Blvd. 4th Floor
Honolulu, Hawaii 96813

CLAYTON A. FRANK
DIRECTOR

DAVID F. FESTERLING
Deputy Director of
Administration

TOMMY JOHNSON
Deputy Director
Corrections

JAMES L. PROPOTNICK
Deputy Director
Law Enforcement

No. _____

TESTIMONY ON SENATE BILL 72
A BILL FOR AN ACT RELATING TO PRESCRIPTIONS

Clayton A. Frank, Director
Department of Public Safety

Committee on Health
Senator David Y. Ige, Chair
Senator Josh Green, M. D., Vice Chair

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

Tuesday, February 18, 2009, 9:00 am
State Capitol, Room 229

Senator Ige, Senator Baker, and Members of the Committee:

The Department of Public Safety (PSD) does not support Senate Bill 72 because if passed, it would adversely affect a pharmacy's ability to refill or transfer a refill to another pharmacy for any controlled substance prescribed by a physician. The Department's electronic prescription monitoring program under Chapter 329, Part VIII, Hawaii Revised Statutes, (HRS) collects the data from all dispensed schedule II through V controlled substance prescriptions. Presently section 329-104(d) HRS already makes it a class C felony for any person to disclose or attempt to disclose any controlled substance prescription information provided by the department utilizing its electronic prescription monitoring program.

PSD does not support this measure as written, however, if passed PSD would then request that Section 2 of Senate Bill 72 be deleted.

Thank you for the opportunity to testify on this matter.

LINDA LINGLE
GOVERNOR

LILLIAN B. KOLLER, ESQ.
DIRECTOR

HENRY OLIVA
DEPUTY DIRECTOR

STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES
P. O. Box 339
Honolulu, Hawaii 96809-0339

February 18, 2009

MEMORANDUM

TO: Honorable David Y. Ige, Chair
Senate Committee on Health

Honorable Rosalyn H. Baker, Chair
Senate Committee on Commerce and Consumer Protection

FROM: Lillian B. Koller, Director

SUBJECT: **S.B. 72 – RELATING TO PRESCRIPTIONS**

Hearing: Wednesday, February 18 2009, 9:00 AM.
Conference Room 229, State Capitol

PURPOSE: The purpose of this bill is to prohibit, except for certain limited purposes, the use, transfer, licensing, or sale of a patient's prescription information for any commercial purpose.

DEPARTMENT'S POSITION: The Department of Human Services (DHS) appreciates the intent of this bill but is cognizant of its impact on the Hawaii RX Plus program.

Hawaii Rx Plus is not part of Medicaid and consists of two phases. The first phase involves discounts for prescriptions for non-Medicaid clients and is being funded by participating pharmacies. Through phase 1 last year, over 100,000 people were enrolled in Hawaii Rx

Plus, and nearly 2,500 persons used the program's benefits to fill 17,500 prescriptions at a total savings of $224,000 (26%).

The second phase of Hawaii Rx Plus is obtaining potential "rebates" which would require the sale of prescription information compliant with the Federal Health Insurance Accountability and Portability Act (HIPAA). Through phase 2, Hawaii Rx Plus will receive $1,765.98 in "rebates" from July 1, 2006 to June 30, 2007 and $428.88 from July 1, 2007 to February 28, 2008. The proposed bill would prevent the pursuit of phase 2.

Medicaid is regulated under 42 C.F.R. chapter IV, subchapter C, or under a Medicaid waiver as approved by the Centers for Medicare & Medicaid Services (CMS), and Med-QUEST programs comply with federal Medicaid laws and regulations to protect disclosure and use of prescription data. In addition, DHS has policies and procedures in place for the HIPAA compliance.

In an effort to better serve Hawaii Medicaid population and improve quality, DHS does share aggregated and/or de-identified information to track larger health trends related to Hawaii's Medicaid population. DHS responds to CMS-related program development requests, CMS tracking of federal programs, survey requests, and other government/non-government requests on a case by case basis.

Protection of prescribing information from marketing purposes is important to avoid undue influence by the pharmaceutical industry over provider prescribing decisions.

Thank you for this opportunity to testify.

February 18, 2009, 9:00 a.m. in Room 229

To: Senate Committee on Health
Senator David Y. Ige, Chair
Senator Josh Green, MD, Vice Chair

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

By: Hawaii Medical Association
Gary A. Okamoto, MD, President
Philip Hellreich, MD, Legislative Co-Chair
Linda Rasmussen, MD, Legislative Co-Chair
April Donahue, Executive Director
Richard C. Botti, Government Affairs
Lauren Zirbel, Government Affairs

Re: SB72 RELATING TO PRESCRIPTIONS.

Chairs & Committee Members:

Hawaii Medical Association would like to provide comments on this measure.

We support the intent to restrict the commercial use of prescription information to protect patient privacy and limit pharmaceutical companies' influence on physician prescription patterns. However, this bill may be superfluous because the American Medical Association has a program that addresses this issue, The AMA Physician Data Restriction Program (PDRP).

The AMA conducted a Gallup survey of physician attitudes regarding the use of physician prescribing data by pharmaceutical companies. The survey found that the majority (84%) of physicians said either they were not concerned about the release of prescribing data or that the ability to "opt-out" of the release of their data to pharmaceutical sales representatives would alleviate their concerns. In response to these findings, the AMA created the PDRP.

PDRP gives physicians the option to withhold their prescribing data from pharmaceutical sales representatives while still making it available for medical research purposes. Physicians can register online, by phone or by fax. The restriction is permanent unless reversed by the physician. The PDRP is offered and promoted to all physicians, both AMA members and non-members.

Through licensing agreements with health care information organizations (HIOs) that collect and compile physician prescribing data and sell it to pharmaceutical companies, the AMA can exert influence over how the HIOs and their pharmaceutical clients use prescribing data. These licensing contracts require the pharmaceutical companies to honor PDRP physician opt-outs.

More information is available at www.ama-assn.org/go/prescribingdata.

Hawaii Medical Association
1360 S. Beretania St.
Suite 200
Honolulu, HI 96814
(808) 536-7702
(808) 528-2376 fax
www.hmaonline.net

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 HEALTH
Senator David Y. Ige
Senator Josh Green, M.D., Vice Chair

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

Wednesday, February 18, 2009
9:00 a.m.

SB 72

Chair Ige, Chair Baker and members of the Committees, 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. 72 **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 8 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.

Statement PhRMA

In Opposition to Hawaii Senate Bill 72

Position: PhRMA respectfully opposes prohibitions on the commercial use of physician prescribing data as proposed in Senate Bill 72.

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.