

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:

House Committee on Health

HB 2086, Relating to Health Care Data

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

January 26, 2010

1 **Department's Position:** The Department of Health has concerns and respectfully opposes the bill as
2 written.

3 **Fiscal Implications:** Uncertain but substantial costs for departmental and private information
4 technology (IT). For the department, we will need employees or vendors to develop, test and maintain
5 an electronic data transmission system in compliance with the bill. Such costs are not covered by the
6 executive supplemental budget and would cause financial hardship to the department.

7 **Purpose and Justification:** The measure requires that laboratory test results be provided to health care
8 providers or their designees, and HIPAA entities and business associates as defined by 45 CFR Parts
9 160-164.

10 The department understands the need for health care entities to share electronic information to expedite
11 patient care, including access to and payment of necessary laboratory testing, and the department urges
12 that such information sharing be done carefully, with consideration of relevant issues, such as privacy
13 under the law, business needs, information technology, and costs.

14 The bill appears over-broad. It requires providing personal health information to "authorized persons"
15 to the extent of the definition of such persons whether those persons request the information or not. The

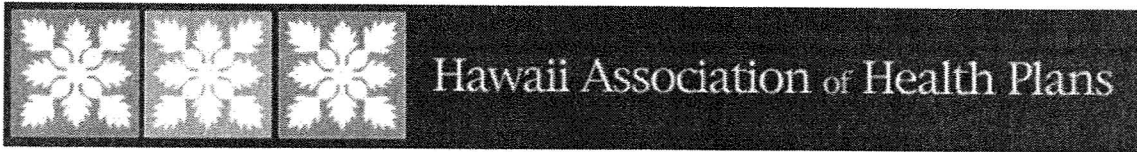
1 bill also provides any HIPAA-defined entity or business associate, such as insurance companies, broad
2 and unrestricted access to all patient laboratory information without the current provider-patient
3 permissions, or even health plan membership.

4 We have already noted the costs of IT development, but we also have a major concern with the time
5 needed to develop a good IT system even when resources are available, and the bill takes effect upon
6 approval.

7 Designing and operating a good IT system also requires teamwork by the affected parties, especially if a
8 new system is to be integrated with or connected to existing systems or coordinated with other proposed
9 systems. The bill does not recognize this need.

10 For these reasons we respectfully oppose the measure as written.

11 Thank you for the opportunity to testify.



January 26, 2010

The Honorable Ryan Yamane, Chair
The Honorable Scott Nishimoto, Vice Chair
House Committee on Health

Re: HB 2086 – Relating to Health Care Data

Dear Chair Yamane, Vice Chair Nishimoto and Members of the Committee:

My name is Howard Lee and I am President of the Hawaii Association of Health Plans (“HAHP”). HAHP is a non-profit organization consisting of seven (7) member organizations:

AlohaCare
Hawaii Medical Assurance Association
HMSA
Hawaii-Western Management Group, Inc.

MDX Hawai‘i
University Health Alliance
UnitedHealthcare

Our mission is to promote initiatives aimed at improving the overall health of Hawaii. We are also active participants in the legislative process. Before providing any testimony at a Legislative hearing, all HAHP member organizations must be in unanimous agreement of the statement or position.

HAHP appreciates the opportunity to testify in support of HB 2086 which would amend the state’s regulatory framework regarding the sharing of clinical laboratory data to more closely comply with the federal Health Insurance Portability and Accountability Act (HIPAA.)

Health information technology is rapidly expanding and the state is expecting an influx of federal funding through the American Recovery and Reinvestment Act (ARRA). These monies will be used to create a statewide health information exchange which will ultimately connect the entire state and provide a framework to allow all types of health care providers to access clinical data.

One of the initial goals of ARRA is for states to examine local statutes in relation to data sharing to determine if changes need to be made in order to meet aggressive federal implementation timeframes. An examination of Hawaii regulations reveals that there is opportunity for change.

Clinical laboratories are overseen through federal regulation know as the Clinical Laboratories Improvement Amendments (CLIA). CLIA gives states leeway to define who may receive clinical laboratory results. In Hawaii, per Hawaii Administrative Rules (HAR), the only person who may receive laboratory results is the ordering physician or their "designee."

Since the HAR does not include other HIPAA covered entities, laboratories would be unable to provide clinical data to a health information exchange or for a physician to populate a field in an electronic medical record with this data. HAHP believes that making the statutory change included in HB 2086 to include HIPAA covered entities within the scope of those permitted to share laboratory data would be an easy step as we forge ahead to incorporate health care technology in a more comprehensive way.

Thank you for the opportunity to offer comments today.

Sincerely,



Howard Lee
President

HMSA



An Independent Licensee of the Blue Cross and Blue Shield Association

January 26, 2010

The Honorable Ryan Yamane, Chair
The Honorable Scott Nishimoto, Vice Chair
House Committee on Health

Re: HB 2086 – Relating to Health Care Data

Dear Chair Yamane, Vice Chair Nishimoto and Members of the Committee:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify in support of HB 2086 which would allow clinical laboratories to provide access to lab data to HIPAA entities and business associates.

On the state level, Hawaii Revised Statutes do not directly oversee clinical laboratories and instead the Hawaii Department of Health regulates these entities under the Hawaii Administrative Rules (HAR). Current HAR only permit clinical laboratories to disclose lab results to “authorized persons” and their “designees.” Under the HAR definition, “authorized person” only includes medical providers licensed in the state. This current definition hinders the ability to meaningfully share clinical laboratory data to improve Hawaii’s health care system.

This issue is especially pressing since the state is on the cutting edge of health information technology implementation. This includes efforts of the Hawaii Health Information Exchange to draw down American Recovery and Reinvestment Act (ARRA) funding to create a statewide information exchange and HMSA’s own Online Care, the first of its kind in the nation. Unless HIPAA covered entities, such as health plans, are able to share this type of information, it is virtually impossible to utilize technology to promote a more efficient and higher quality health care system.

As such, we respectfully request the Committee’s support of this important measure and hope you see fit to pass HB 2086. Thank you for the opportunity to testify today.

Sincerely,

A handwritten signature in black ink, appearing to read "JD", written over a white background.

Jennifer Diesman
Vice President
Government Relations

Hawai'i Health Information Exchange

Health information, when and where you need it.

To: The House Committee on Health
Representative Ryan Yamane, Chair
Representative Scott Nishimoto, Vice Chair

Testimony in General Support of House Bill 2086 Relating to Health Care Data

**Submitted by: Christine Maii Sakuda, Executive Director
Hawaii Health Information Exchange
January 26, 2010, 9:00 p.m. Agenda, Room 329**

Dear Honorable Chairs, Vice Chairs and committee members,

I am submitting testimony on House Bill 2086 to you today on behalf of the Hawaii Health Information Exchange (HHIE); a 501(c)(3) non-profit established in 2006 by leading healthcare stakeholders in Hawaii and designated by the State to develop and implement a statewide health information exchange.

The HHIE agrees with the premise of this bill: that appropriate sharing of health data in this case clinical laboratory test results is an important step to improving the quality and coordination of care patients receive across the continuum of care.

Within the next 6 months, HHIE will facilitate the development of a statewide health information exchange plan to include:

- development of the technical infrastructure for HIE to include hardware, software, applications and network configuration
- identification of the legal and policy barriers and enablers to HIE that include privacy and security requirements that need to support data sharing agreements
- Identification and agreement on the data elements themselves; what is the purpose of sharing the patient's health data, to whom, and who authorizes the exchange
- Development of a sustainable business model

The Hawaii HIE has set up working committees to include Finance, Governance, Data Access & Management, Technical Infrastructure & Standards, and Legal Policy. Establishing interdependencies among these key pillars of an HIE will assure its long term success.

Therefore HHIE supports the intent of HB2086 and looks forward to sharing its view with the legislature in the future.

Thank you for the opportunity to testify on this bill.

**PART 160 – GENERAL
ADMINISTRATIVE REQUIREMENTS**

Subpart A – General Provisions

- 160.101 Statutory basis and purpose.
- 160.102 Applicability.
- 160.103 Definitions.
- 160.104 Modifications.

Subpart B – Preemption of State Law

- 160.201 Applicability.
- 160.202 Definitions.
- 160.203 General rule and exceptions.
- 160.204 Process for requesting exception determinations.
- 160.205 Duration of effectiveness of exception determinations.

Subpart C – Compliance and Enforcement

- 160.300 Applicability.
- 160.302 Definitions.
- 160.304 Principles for achieving compliance.
- 160.306 Complaints to the Secretary.
- 160.308 Compliance reviews.
- 160.310 Responsibilities of covered entities.
- 160.312 Secretarial action regarding complaints and compliance reviews.

Authority: Sec. 1171 through 1179 of the Social Security Act, (42 U.S.C. 1320d-1329d-8) as added by sec. 262 of Pub. L. No. 104-191, 110 Stat. 2021-2031 and sec. 264 of Pub. L. No. 104-191 (42 U.S.C. 1320d-2(note)).

Subpart A - General Provisions

§ 160.101 Statutory basis and purpose.
The requirements of this subchapter implement sections 1171 through 1179 of the Social Security Act (the Act), as added by section 262 of Public Law 104-191, and section 264 of Public Law 104-191.

§ 160.102 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) To the extent required under the Social Security Act, 42 U.S.C. 1320a-7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as

amended (5 U.S.C. App.).

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.
ANSI stands for the American National Standards Institute.

Business associate.

(1) Except as provided in paragraph (2) of this definition, *business associate* means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in § 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.

(3) A covered entity may be a business

associate of another covered entity.

Compliance date means the date by which a covered entity must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

Covered entity means:

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

EIN stands for the employer identification number assigned by the Internal Revenue Service, U.S. Department of the Treasury. The EIN is the taxpayer identifying number of an individual or other entity (whether or not an employer) assigned under one or the following:

(1) 26 U.S.C. 6011(b), which is the portion of the Internal Revenue Code dealing with identifying the taxpayer in tax returns and statements, or corresponding provisions of prior law.

(2) 26 U.S.C. 6109, which is the portion of the Internal Revenue Code dealing with identifying numbers in tax returns, statements, and other required documents.

Employer is defined as it is in 26 U.S.C. 3401(d).

Group health plan (also see definition of *health plan* in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HCFA stands for Health Care Financing Administration within the Department of Health and Human Services.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies related to the health of an individual. *Health care* includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care,

individually identifiable health information.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, *State* has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, *State* means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

- (1) Health care claims or equivalent encounter information.
- (2) Health care payment and remittance advice.
- (3) Coordination of benefits.
- (4) Health care claim status.
- (5) Enrollment and disenrollment in a health plan.
- (6) Eligibility for a health plan.
- (7) Health plan premium payments.
- (8) Referral certification and authorization.
- (9) First report of injury.
- (10) Health claims attachments.
- (11) Other transactions that the Secretary may prescribe by regulation.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.

§ 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification.

(c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section.

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

Subpart B - Preemption of State Law

§ 160.201 Applicability.

The provisions of this subpart implement section 1178 of the Act, as added by section 262 of Public Law 104-191.

§ 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings:

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

(1) A covered entity would find it impossible to comply with both the State and federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act or section 264 of Pub. L. 104-191, as applicable.

More stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria:

(1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:

(i) Required by the Secretary in connection with determining whether a covered entity is in compliance with this subchapter; or

(ii) To the individual who is the subject of the individually identifiable health information.

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information.

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration.

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information.

Relates to the privacy of individually identifiable health information means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

State law means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

§ 160.203 General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under § 160.204 that the provision of State law:

(1) Is necessary;

(i) To prevent fraud and abuse related to the provision of or payment for health care;

HMSA



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January 26, 2010

The Honorable Ryan Yamane, Chair
The Honorable Scott Nishimoto, Vice Chair
House Committee on Health

Re: HB 2206 – Relating to Health Savings Accounts

Dear Chair Yamane, Vice Chair Nishimoto and Members of the Committee:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on HB 2206 which would create a task force to examine the current state of Health Savings Accounts (HSAs) in Hawaii and determine ways to expand their use.

HMSA supports the effort outlined in HB 2206 to research the possibilities HSAs could offer to those seeking coverage in Hawaii. We believe that it is worth examining how HSAs could play an expanded role in our health care system. HMSA currently administers an HSA qualified plan limited to individuals but it has not generated as much interest as originally conceived. We welcome the opportunity to participate in a task force and look forward to working together with other stakeholders on this issue.

Thank you for the opportunity to testify today.

Sincerely,

Jennifer Diesman
Vice President
Government Relations