5 .B. NO. 2729

JAN 25 2010

A BILL FOR AN ACT

RELATING TO IMMUNIZATION.

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

- 1 SECTION 1. Chapter 325, Hawaii Revised Statutes, is
- 2 amended by adding a new part to be appropriately designated and
- 3 to read as follows:
- 4 "PART . IMMUNIZATION REGISTRY
- 5 §325-A Definitions. As used in this part:
- 6 "Health care provider" means a program, agency, clinic,
- 7 health care center, physician licensed under the provisions of
- 8 chapter 453 or 460, advanced practice registered nurse
- 9 recognized under the provisions of chapter 457, pharmacist
- 10 licensed under the provisions of chapter 461, physician's
- 11 assistant licensed under the provisions of chapter 453, or
- 12 person authorized to practice medicine as a physician or
- 13 physician's assistant, or nursing as an advanced practice
- 14 registered nurse, in federal facilities located in the State,
- 15 that administers immunizations in Hawaii;

22

S.B. NO. 2729

"Post-secondary school" means any adult education school, 1 business school, trade school, community college, college, or 2 university enrolling or registering students above the age of 3 compulsory attendance; 4 "Registry" means the Hawaii immunization registry; 5 "School" means any child care center, preschool, day care 6 center, day nursery, Head Start program, group child care home, 7 kindergarten, elementary, intermediate, middle, or secondary 8 school, that is responsible for ensuring student compliance with 9 mandatory school immunization entrance requirements; 10 "Student" means any child or adult enrolled in any school or 11 post-secondary school in the State. 12 §325-B Hawaii immunization registry; establishment and 13 14 purposes. The department of health may establish and maintain an immunization information system to be designated as the 15 "Hawaii Immunization Registry." The purposes of the registry 16 shall be to maintain a single statewide repository of 17 immunization records to aid, coordinate, and help promote 18 efficient and cost-effective screening, prevention, and control 19 of vaccine preventable diseases, including pandemic influenza. 20 §325-C Confidentiality and content of registry records. 21

(a) All immunization records and reports made for the purposes

shall be	kept confidential and shall not be disclosed by any
person ex	cept so far as:
(1)	The person identified, the person's legal guardian, or
	in the case of a minor, the parent or guardian,
	consents;
(2)	Disclosure may be deemed necessary by the director of
	health to carry out this chapter;
(3)	A court may direct upon its determination that
	disclosure is necessary for the conduct of proceedings
N.	before it;
(4)	Disclosures are made between the person's health care
	provider and payor to obtain reimbursement for
	services rendered to the person; provided that
	disclosure shall be made only if the provider informs
	the person that a reimbursement claim will be made to
	the person's payor, the person is afforded an
	opportunity to pay the reimbursement directly, and the
	person does not pay; or
(5)	The department of health may release aggregate
	immunization information that does not disclose any
	person ex (1) (2) (3)

of this part and directly or indirectly identifying a person

1	identifying information of persons whose information			
2	is maintained in the registry.			
3	(b) Registry information shall be limited to patient name,			
4	demographic, and contact information; information specific to			
5	immunizations or medications received, including types,			
6	manufacturers, lot numbers, expiration dates, anatomical sites			
7	of administration, routes of administration, vaccine information			
8	statement publication dates, doses, dates administered, and			
9	adverse reactions to immunizations or medications; and the name			
10	and contact information of the vaccination administrator or			
11	medication provider, and the patient's health care provider.			
12	(c) The department of health shall adopt measures to			
13	assure the security of the registry to prevent unauthorized			
14	access to registry information.			
15	§325-D Purposes for access to registry information; access			
16	not a disclosure. (a) Notwithstanding section 325-C, it shall			
17	not be a disclosure for the persons listed below to have limited			
18	access to registry information for the purposes specified in			
19	this section.			
20	(b) Registry information regarding specific individuals in			
21	the registry may be accessed by health care providers who are			
22	treating, have treated, or have been assigned to treat those			

individuals; by employees of these health care providers; and by 2 authorized department of health personnel assigned to monitor the immunization or health status of these individuals for the 3 4 purposes of: 5 (1)Recording the administration of any vaccination, including pandemic influenza vaccine; 6 (2)Determining the immunization history of a patient to 7 8 deliver health care treatment accordingly; 9 (3) Notifying individuals or parents or legal quardians of the need to schedule a visit for an immunization; 10 (4)Generating official immunization records; 11 Ensuring compliance with mandatory immunization 12 (5) 13 requirements; or (6) Recording the distribution of prophylactic and 14 treatment medications administered or dispensed in 15 preparation for and response to a potentially 16 17 catastrophic disease threat. Registry information regarding specific individuals in 18 19 the registry may be accessed by school and post-secondary school personnel authorized by the director of health, the 20 superintendent of education, or the administrator of a private 21 22 or post-secondary school for the purpose of ensuring compliance 23 with mandatory student immunization requirements.

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<u>J</u>.B. NO. 2119

1	(α)	Registry intormation regarding specific individuals in
2	the regist	try may be accessed by the department of health or
3.	agents of	the department of health for the purposes of:
4	(1)	Ensuring compliance with mandatory immunization
5		requirements;
6	(2)	Performing immunization-related quality improvement or
7		quality assessment activities;
8	(3)	Complying with Hawaii vaccines for children/teen vax
9		program vaccine accountability policies and procedures
10	(4)	Producing aggregate immunization assessment reports to
11		monitor and improve public health;
12	(5)	Supporting efforts to prevent and manage outbreaks of
13		vaccine preventable diseases, including pandemic
14		influenza;
15	(6)	Assisting the department of health in the event of a
16		public health emergency; or
17	(7)	Managing and maintaining the Hawaii immunization
18		registry system.
19	(e)	The use of registry information accessed pursuant to
20	this sect	ion shall be limited to the purposes for which access
21	is granted	d.
22	§325	-E Registry record requirements; duration of

The establishment of an individual's record in

- 1 the registry shall not require the prior consent of a patient,
- 2 or in the case of a minor or dependent, the consent of a parent
- 3 or guardian. The department of health shall make available to
- 4 the patient, or in the case of a minor or dependent, the
- 5 patient's parent or legal guardian, via the patient's health care
- 6 provider or birthing hospital, a written description of the
- 7 purpose and benefits of the registry as well as the procedure
- 8 for refusing inclusion in the registry. No registry information
- 9 shall be established in the registry for any individual who
- 10 refuses, or in the case of a minor or dependent, whose parent or
- 11 legal guardian refuses, in writing, their or their child's,
- 12 dependent's, or ward's inclusion in the registry. Each health
- 13 care provider or birthing hospital shall maintain the records of
- 14 refusal of inclusion and shall report any refusal to the
- 15 department of health in a manner specified by rule.
- 16 (b) Registry information for any individual included
- 17 within the registry shall be retained as a part of the registry
- 18 for twenty-five years after the last entry, except in the case
- 19 of minors, whose records shall be retained during the period of
- 20 minority plus twenty-five years after the minor reaches the age
- 21 of majority. At the conclusion of the retention period, the

- 1 data stored in the registry for that individual shall be
- 2 archived.
- 3 §325-F Civil and criminal liability. (a) Authorized
- 4 users of the registry shall not be subject to civil liability
- for damages by reason of:
- 6 (1) Providing information to the registry in good faith; or
- 7 (2) Accessing and using information from the registry in
- 8 good faith for the purposes specified in section 325-D.
- 9 (b) Any person who intentionally or knowingly discloses
- 10 registry information contrary to the confidentiality provisions
- of this part shall be quilty of a misdemeanor."
- 12 SECTION 2. Section 325-13, Hawaii Revised Statutes, is
- 13 amended to read as follows:
- 14 "§325-13 [Regulations.] Rules. (a) For the purposes of
- 15 carrying out this chapter, the director of health, with the
- 16 approval of the governor, may [make-such regulations] adopt,
- 17 amend, or repeal such rules as the director deems necessary
- 18 which, when adopted in accordance with [section 321-10,] chapter
- 19 91, shall have the force and effect of law.
- 20 (b) The rules shall be designed to;
- 21 (1) Protect the health and safety of the public;

1	(2)	Establish appropriate levels of access to Hawaii
2		immunization registry information by authorized users;
3	(3)	Establish data entry and reporting requirements for
4		health care providers; and
5	(4)	Establish penalties for the failure to comply with any
6		rule."
7	SECT	ION 3. In codifying the new sections in the new part
8	added to	chapter 325, Hawaii Revised Statutes, by section 1 of
9	this Act,	the revisor of statutes shall substitute appropriate
10	section n	umbers for the letters used in designating and referring
11	to the ne	w sections in this Act.
12	SECT	ION 4. Statutory material to be repealed is bracketed
13	and stric	ken. New statutory material is underscored.
14	SECT	ION 5. This Act shall take effect upon its approval.
15		
16		INTRODUCED BY:
17		BY REQUEST

Report Title:

Immunization

Description:

Authorizes the Department of Health to establish and maintain a single repository of immunization records to be designated as the "Hawaii Immunization Registry" in order to aid, coordinate, and help promote efficient and cost-effective screening, prevention, and control of vaccine preventable diseases, including pandemic influenza.

JUSTIFICATION SHEET

DEPARTMENT:

Health

TITLE:

A BILL FOR AN ACT RELATING TO IMMUNIZATION.

PURPOSE:

Authorizes the Department of Health (department) to establish and maintain a single repository of immunization records to be designated as the "Hawaii Immunization Registry" in order to aid, coordinate, and help promote efficient and cost-effective screening, prevention, and control of vaccine preventable diseases, including pandemic influenza.

MEANS:

Add a new part to chapter 325 and amend section 325-13, Hawaii Revised Statutes.

JUSTIFICATION:

Currently operational in 47 other states, immunization registries are confidential, computerized systems that contain information regarding an individual's vaccinations. As the immunization schedule becomes increasingly complex, registries provide a critical tool for increasing and sustaining vaccination coverage. Registries also have the capability to instantly assess a person's immunization status and generate immunization reminders to patients or their parents or legal quardians. With an immunization registry, as individuals and families move or change health care providers, their immunization records will remain easily accessible to new immunization providers, ensuring that patients receive the immunizations that they need and that they do not receive additional, unneeded doses of vaccine due to missing or unavailable immunization records.

In the event of an influenza pandemic or other public health emergency, the Hawaii Immunization Registry will provide the department with the ability to record, track, and monitor the administration of

vaccinations as well as the distribution of antiviral and other medications. This information is essential for the department rapidly to assess who has been vaccinated and identify under-immunized areas at risk for disease. This information is especially critical in public health emergency situations to direct effectively scarce or otherwise limited departmental resources to the populations or areas most in need. The Hawaii Immunization Registry is also the means through which the department will be able to report vaccine administration and medication distribution to the Centers for Disease Control and Prevention.

The individual's right to privacy and the protection of confidential information contained in the Hawaii Immunization Registry are critically important; therefore rigorous safeguards to ensure the confidentiality of the information have been engineered into the Hawaii Immunization Registry. Confidentiality provisions have been included in the proposed bill, and the Immunization Branch has developed the Hawaii Immunization Registry Confidentiality and Privacy Policy that has been reviewed and approved by the department's HIPAA Privacy Officer, Department of the Attorney General, and the Centers for Disease Control and Prevention Immunization Information Systems Support Branch.

Impact on the public: The Hawaii
Immunization Registry will benefit
individuals (and parents and legal
guardians) by providing a reliable
repository of easily accessible,
consolidated immunization records that are
essential for immunization providers to
ensure their patients' protection from
serious vaccine preventable diseases,
including pandemic influenza, ultimately
ensuring the protection of the health of the
people of Hawaii.

Impact on the department and other agencies:
Patient-specific data stored in the Hawaii
Immunization Registry will be critical to
the management of the department's pandemic
influenza vaccination efforts. Aggregate
data produced by the Hawaii Immunization
Registry will also be used to identify
populations that are at greatest risk for
under-immunization and provide the data
necessary to target and evaluate appropriate
interventions, thus optimizing the use of
state and federal public resources.

GENERAL FUND:

None.

OTHER FUNDS:

Federal funding, Hawaii Medical Services

Association grant.

PPBS PROGRAM

DESIGNATION:

HTH-131.

OTHER AFFECTED

AGENCIES:

None.

EFFECTIVE DATE:

Upon approval.