
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;

1 "Post-secondary school" means any adult education school,
2 business school, trade school, community college, college, or
3 university enrolling or registering students above the age of
4 compulsory attendance;

5 "Registry" means the Hawaii immunization registry;

6 "School" means any child care center, preschool, day care
7 center, day nursery, Head Start program, group child care home,
8 kindergarten, elementary, intermediate, middle, or secondary
9 school, that is responsible for ensuring student compliance with
10 mandatory school immunization entrance requirements;

11 "Student" means any child or adult enrolled in any school or
12 post-secondary school in the State.

13 **§325-B Hawaii immunization registry; establishment and**
14 **purposes.** The department of health may establish and maintain
15 an immunization information system to be designated as the
16 "Hawaii Immunization Registry." The purposes of the registry
17 shall be to maintain a single statewide repository of
18 immunization records to aid, coordinate, and help promote
19 efficient and cost-effective screening, prevention, and control
20 of vaccine preventable diseases, including pandemic influenza.

21 **§325-C Confidentiality and content of registry records.**

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

1 of this part and directly or indirectly identifying a person
2 shall be kept confidential and shall not be disclosed by any
3 person except so far as:

4 (1) The person identified, the person's legal guardian, or
5 in the case of a minor, the parent or guardian,
6 consents;

7 (2) Disclosure may be deemed necessary by the director of
8 health to carry out this chapter;

9 (3) A court may direct upon its determination that
10 disclosure is necessary for the conduct of proceedings
11 before it;

12 (4) Disclosures are made between the person's health care
13 provider and payor to obtain reimbursement for
14 services rendered to the person; provided that
15 disclosure shall be made only if the provider informs
16 the person that a reimbursement claim will be made to
17 the person's payor, the person is afforded an
18 opportunity to pay the reimbursement directly, and the
19 person does not pay; or

20 (5) The department of health may release aggregate
21 immunization information that does not disclose any

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

1 individuals; by employees of these health care providers; and by
2 authorized department of health personnel assigned to monitor
3 the immunization or health status of these individuals for the
4 purposes of:

- 5 (1) Recording the administration of any vaccination,
6 including pandemic influenza vaccine;
- 7 (2) Determining the immunization history of a patient to
8 deliver health care treatment accordingly;
- 9 (3) Notifying individuals or parents or legal guardians of
10 the need to schedule a visit for an immunization;
- 11 (4) Generating official immunization records;
- 12 (5) Ensuring compliance with mandatory immunization
13 requirements; or
- 14 (6) Recording the distribution of prophylactic and
15 treatment medications administered or dispensed in
16 preparation for and response to a potentially
17 catastrophic disease threat.

18 (c) Registry information regarding specific individuals in
19 the registry may be accessed by school and post-secondary school
20 personnel authorized by the director of health, the
21 superintendent of education, or the administrator of a private
22 or post-secondary school for the purpose of ensuring compliance
23 with mandatory student immunization requirements.

1 (d) Registry information regarding specific individuals in
2 the registry 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 section shall be limited to the purposes for which access
21 is granted.

22 **§325-E Registry record requirements; duration of**
23 **retention.** (a) 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
5 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
11 of this part shall be guilty 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;

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 guardians. 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.