



# Hawaii State Immunization System (HiSIS) Confidentiality and Privacy Policy

## I. Introduction

The Hawaii State Immunization System is a statewide web-based immunization information system that is capable of establishing and maintaining a repository of lifespan immunization data for the population of the State of Hawaii. The Hawaii State Immunization System, hereinafter referred to as "the Registry" or "Registry," was developed through the efforts of the Hawaii Immunization Registry Coalition, which was composed of over 70 representatives from health-related organizations statewide and was overseen by the Department of Health Immunization Branch.

This document, hereinafter referred to as "Confidentiality and Privacy Policy" or "Policy", shall govern the Registry's collection, maintenance, and use of patient immunization data and other individually identifiable health information. This Policy shall apply to all individually identifiable information in all formats, including paper-based and electronic records. Although the Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards for Confidentiality and Privacy were used as a guide to assist in developing this document, the Registry and the Department of Health Immunization Branch, hereinafter referred to as the "Immunization Branch" or "Branch," are not considered "covered entities" under HIPAA.

## II. Statement of Purpose

- A. The Registry is a web-based computerized system that ensures secure, electronic access to immunization records to:
  - 1. Provide the data necessary to plan, coordinate, and promote efficient and cost-effective communicable disease prevention and control efforts.
  - 2. Aid immunization providers in ensuring that their patients are appropriately immunized, thereby increasing immunization rates in Hawaii.

## III. Definitions

### ***Access***

The ability or the means necessary to read, write, modify, or communicate data/information;

### ***Access, "Read Only"***

A type of access to the Registry which allows authorized users to view specified information contained in the Registry. Users with "read only" access shall not add, delete, or alter any information in the Registry;

***Authorized User***

Those individuals and/or entities that require regular access to patient immunization and other individually identifiable health information to provide immunization services to specific patients, maintain a computerized inventory of their public and private stock of vaccines, assess immunization status to determine immunization rates, and/or ensure compliance with mandatory immunization ordering, administration, and accountability requirements;

The Department of Health Immunization Branch is responsible for oversight of the Registry and therefore shall be designated as an authorized user;

***Confidentiality***

The property that data or information is not made available or disclosed to unauthorized persons or processes;

***Confidentiality and Security Statement***

A written statement, signed and dated by an authorized user, which certifies that the authorized user has received a copy of the Hawaii Immunization Registry Confidentiality and Privacy Policy and the Hawaii Immunization Registry Security Policy, understands the terms, and agrees to comply with the policies;

***De-Identified Health Information***

Health information that does not identify a patient or may not reasonably be used to identify a patient;

***Disclosure***

The release, transfer or provision of; access to; or divulgence in any other manner of a patient's individually identifiable health information to parties outside the Registry and/or its authorized users;

***Health Organization***

A health insurance company, fraternal benefit society, mutual benefit society, health care service plan or health maintenance organization or any other entity delivering or issuing accident and health or sickness insurance in the State of Hawaii;

***Immunization Assessment Report***

Any Registry-produced report designed to provide a detailed listing of the immunizations an individual has received as well as immunizations that are currently due or overdue.

Immunization assessment reports may also include aggregate reports produced to monitor and improve the health of a specific population or public health in general;

***Implied Consent***

The process of establishing a patient's immunization and other individually identifiable health information in the Registry and making this information available to other Registry authorized users without prior patient or parent/guardian consent;

***Individually Identifiable Health Information (IIHI)***

Information, including demographic and immunization record data, as well as other information, that relates to the provision of immunizations to the patient;

***Notification***

A written description of the purpose and benefits of the Registry as well as the procedure for refusing inclusion in the Registry (refer to Section XII: Privacy Information, Item A);

***“Opt-Out”***

A patient’s decision to refuse inclusion of their immunization data in the Registry. Patients must indicate this choice in writing via completion of the Hawaii State Immunization System Opt-Out Form;

***Patient***

Person receiving immunization services, or in the case of a minor, his/her parent or legal guardian;

***Privacy***

A patient’s right to determine whether IIHI is released to Registry authorized users for authorized purposes only, by implied consent or the decision to refuse inclusion in the Registry;

***Reauthorization for Inclusion***

Revocation of a patient’s decision to refuse inclusion in the Registry (“opt-out”). Patients must indicate this choice in writing via completion of the Hawaii State Immunization System Reauthorization Form;

***Security***

A set of policies and procedures that encompass the administrative, physical, and technical safeguards of the Registry;

***User Agreement***

A written agreement, signed and dated by authorized users that defines the terms under which individuals and/or organizations become authorized Registry users; it includes the obligations and responsibilities of the Immunization Branch and authorized users of the Registry.

**IV. Uses of Registry Information**

- A. Registry information shall be entered by and available to authorized users for the uses defined herein.
  - 1. Registry immunization data and other IIHI shall be utilized by authorized users for the purposes of:
    - a. Creating, consolidating, maintaining, and accessing computerized immunization records;
    - b. Consolidating and maintaining vaccine inventory information;

- c. Determining the immunization history of a patient and delivering health care treatment accordingly;
  - d. Generating notices for patients who are due or overdue for immunizations and in the event of a vaccine recall;
  - e. Staying abreast of the complex immunization schedule by utilizing registry-supplied immunization forecasting algorithms;
  - f. Assessing the immunization rate of their patient population (or subsets thereof);
  - g. Generating official immunization records (e.g. Student's Health Record);
  - h. Ensuring compliance with mandatory immunization requirements;
  - i. Recording the distribution of prophylactic and treatment medications administered or dispensed in preparation for and in response to a potentially catastrophic disease threat;
  - j. Complying with Hawaii Vaccines For Children and other State-provided vaccine programs' vaccine ordering and accountability policies and procedures; and
  - k. Other purposes determined at the discretion of the Immunization Branch.
2. Registry immunization data and other IIHI shall be utilized by the Department of Health for the purposes of:
- a. Ensuring compliance with mandatory immunization requirements;
  - b. Performing Quality Improvement/Quality Assessment activities;
  - c. Complying with Hawaii Vaccines For Children and other State-provided vaccine programs' vaccine ordering and accountability policies and procedures;
  - d. Preventing and managing outbreaks of vaccine-preventable diseases and other public health emergencies;
  - e. Producing immunization assessment reports to aid in the development of policies and strategies to improve public health;
  - f. Managing and maintaining the Registry system; and
  - g. Other purposes determined at the discretion of the Immunization Branch.

## V. Compliance With Laws

- A. The Registry shall operate in accordance with all applicable federal and state laws and regulations that govern confidentiality and privacy of patient information.
- 1. Federal Laws
    - a. All authorized users and the Immunization Branch acknowledge that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (PL 104-191 and 45 CFR Parts 160 and 164, "Standards for Privacy of Individually Identifiable Health Information") govern the use and disclosure of individually identifiable information by entities subject to the Privacy Rule. Although HIPAA standards for privacy were used as a guide to assist in the development of this document, the Registry and the Immunization Branch are not considered "covered entities" under HIPAA. Providers, health plans and other covered

entities who are authorized users shall comply with the HIPAA Privacy Rule.

2. State Laws
  - a. All authorized users and the Department of Health Immunization Branch shall comply with Act 275 (12), “Relating to the Hawaii Immunization Registry,” and Hawaii Revised Statutes (HRS), Chapters 92F (Disclosure of Personal Record, Access to Personal Record), Chapter 321 (Department of Health), Chapter 325 (Infectious and Communicable Disease), Chapter 487N (Security Breach of Personal Information), Chapter 487R (Destruction of Personal Information Records), Chapter 577A (Children), Chapter 622-58 (Retention of Medical Records), and Chapter 671-3 (Informed Consent).

## VI. Breach and Penalties

### A. Breaches

1. A breach of this Confidentiality and Privacy Policy shall occur when there is an unauthorized transfer, disclosure, use, sharing, publishing, or sale of immunization data or other IIHI or any group of facts contained in the Registry that may lead to the identification of any patient. This pertains to the disclosure of information in any medium, including electronic, written, or verbal.
2. Breach of this Policy shall also occur if an authorized user permits access by unauthorized persons to any data provided by or through the Registry.

### B. Civil and Criminal Liability; Penalties

1. Authorized users of the Registry shall not be subject to civil liability for damages by reason of:
  - a. Providing information to the Registry in good faith; or
  - b. Accessing and using information from the Registry in good faith for the purposes specified in Section IV, “Uses of Registry Information.”
2. Any person who intentionally or knowingly discloses Registry information contrary to the confidentiality provisions specified in Act 275 (12), “Relating to the Hawaii Immunization Registry” and/or HRS §§325-121 through 325-126 shall be guilty of a misdemeanor.
3. The penalty for breach of this Policy shall also include any allowable administrative sanctions, such as termination of user access to the Registry.
4. All breaches to this Policy shall be reported to the appropriate authorities. The Immunization Branch shall not impose penalties for the incidental disclosure of confidential information.
5. In the event of a breach of confidentiality, patients shall be notified if their or their child’s record was involved in accordance with HIPAA policies (for covered entities) and the Hawaii Revised Statutes §487N-Security Breach of Personal Information (for entities not covered under HIPAA).

## VII. Confidentiality and Security of Registry Information

### A. Confidentiality of Patient Information

1. The Registry shall maintain and store immunization data and other confidential IHHI.
2. All authorized users shall be required to safeguard the privacy of individual patients by protecting confidential information in the Registry in accordance with this Policy and all applicable State and Federal laws.

### B. Security of Patient Information

1. The Immunization Branch shall ensure the security of patient information by instituting a set of policies and procedures that encompass the administrative, physical, and technical safeguards of the Registry.
2. All authorized users shall be required to adhere to the requirements of the Hawaii State Immunization System Security Policy.

## VIII. Confidentiality and Security Statements and User Agreements

### A. Confidentiality and Security Statements

1. Authorized User Responsibilities:
  - a. All potential authorized users shall sign and date a written Confidentiality and Security Statement indicating that the individual has received a copy of this Policy and the Hawaii State Immunization System Security Policy, understands the terms, including penalties for violation of the policies, and agrees to comply with the policies.
  - b. Confidentiality and Security Statements shall be valid for a one-year period and shall be renewed on an annual basis.
2. Immunization Branch Responsibilities:
  - a. The Immunization Branch shall be responsible for obtaining and storing signed and dated Confidentiality and Security Statements from authorized users.

### B. User Agreements

1. Authorized User Responsibilities:
  - a. The physician-in-chief or equivalent, on behalf of his/herself and all practitioners, nurses, and others associated with his/her medical office, group practice, community health center, pharmacy, other health delivery facility, health organization, school, post-secondary school or departmental program or office shall sign and date a written User Agreement indicating agreement to the terms under which individuals and organizations become authorized users of the Registry, including

- the obligations and responsibilities of the Immunization Branch and the authorized users.
- b. The physician-in-chief or equivalent shall sign and date a User Agreement specific to their organization's level of access. Refer to Security Policy for complete "level of access" definitions.
  - c. User Agreements shall be valid for a one-year period and shall be renewed on an annual basis.
2. Department of Health Immunization Branch Responsibilities:
    - a. The Immunization Branch shall be responsible for obtaining and storing signed and dated User Agreements.

## IX. Other Authorized Users

### A. Schools and Licensed Childcare Facilities

1. Schools and licensed childcare facilities that do not provide immunization services may have a need for "read-only" access to verify a patient's immunization history to ensure compliance with mandatory school entry immunization requirements.
2. When access is granted, school and licensed childcare facility personnel shall adhere to the requirements outlined in this Policy, the Hawaii State Immunization System Security Policy, Confidentiality and Security Statement, and User Agreement.

### B. Health Organizations

1. Read-only registry information regarding specific individuals may be accessed by authorized health organizations that have been contracted to provide health insurance or health plan coverage for those individuals; provided that access is limited only to the records of the enrollees, members, subscribers, and insureds of the authorized health organization.
2. Health organizations may only access the Registry for the purpose of producing immunization assessment reports.
3. When access is granted, authorized health organizations shall adhere to the requirements outlined in this Policy, the Hawaii State Immunization System Security Policy, Confidentiality and Security Statement, and User Agreement.

## X. Data Access, Maintenance, and Release

### A. Data Access Parameters

1. All authorized users with access to the Registry shall limit their access to the purposes specified in Section IV, "Uses of Registry Information."
2. All authorized users shall limit their access to the minimum necessary patient information required to perform their duties.

3. Patients shall be allowed to request a hard copy of their or their child's immunization record. Patients may only obtain their copy via their healthcare provider or from the Immunization Branch.
4. Patients may inspect, copy, correct, or amend their or their child's immunization record via their or their child's immunization provider or the Immunization Branch.
  - a. Patients shall be denied this right if there is substantial evidence that the information in the record, if released or altered, could reasonably be expected to cause harm to the patient or others (e.g. releasing address information in cases of domestic violence, abuse, possibility of Immigration and Naturalization Service [INS] deportation).
  - b. Corrections or amendments to a record shall be made by an authorized user only when the patient is able to demonstrate that the record is incorrect by a credible source.
  - c. Requests to inspect, copy, correct or amend patient immunization records that are submitted to the Immunization Branch shall be made in writing. The Branch shall make the information available and/or make corrections/amendments within ten working/business days of the request. The ten-day period may be extended for an additional twenty working/business days if the Immunization Branch provides to the patient, within the initial ten working/business days, a written explanation of the unusual circumstances causing the delay, and provides the record itself within thirty working/business days from the receipt of the initial request.
  - d. If the Immunization Branch denies a patient's request to inspect, copy, correct, or amend their immunization information, the patient shall receive written notification of the reason(s) for the denial within five working/business days of the Immunization Branch's receipt of the request.
  - e. Patients shall be given the opportunity to appeal such denials. Appeals shall be made in writing to the Department of Health Immunization Branch within 30 business/working days of receipt of written notification of the reason(s) for denial.

#### B. Data Maintenance and Retention

In accordance with State law, information for any individual included within the Registry shall be retained as a part of the Registry for twenty-five years after the last entry, except in the case of minors, whose records shall be retained during the period of minority plus twenty-five years after the minor reaches the age of majority. At the conclusion of the retention period, the data stored in the registry for that individual shall be archived.

#### C. Release of Registry Information

1. Authorized User Responsibilities:



- a. Release of immunization data and other IIHI by authorized users to non-authorized individuals or entities is strictly prohibited unless authorization is received from the patient for the release of information.
  - b. All Registry data shall be released in compliance with this Policy, the Hawaii Immunization Branch Policy for the Release of Individually Identifiable Health Information, the Hawaii State Immunization System Security Policy, and all applicable State and Federal laws.
- 2. Department of Health Immunization Branch Responsibilities:
  - a. Releases without patient authorization shall only be allowed when the Immunization Branch is court ordered to release this information.
  - b. The Immunization Branch shall immediately refer all subpoenas, requests for production, warrants, and court orders to the State of Hawaii Department of the Attorney General.
  - c. In response to specific requests for Registry data, the Immunization Branch, at its sole discretion, may make available only de-identified data to individuals or organizations that are not authorized users.

## XI. Termination of Access

- A. Authorized Users Termination of Access to the Registry
  - 1. The Department of Health Immunization Branch may terminate an authorized user's access to the Registry upon becoming aware of the following conditions:
    - a. The authorized user submits a written request for termination of participation in the Registry;
    - b. Authorized user loses professional licensure to practice in the State of Hawaii;
    - c. Authorized user closes his/her practice, is no longer employed by the health care facility, is suspended, or is reassigned to a position that does not require access to the Registry;
    - d. Authorized user moves out of state; or
    - e. Authorized user fails to renew their signed Confidentiality and Security Statement and/or User Agreement.
  - 2. If an authorized user fails to adhere to this Policy, or any provisions of the Confidentiality and Security Statement, Security Policy, or User Agreement, the Immunization Branch shall impose appropriate administrative sanctions, which may include time-limited access termination.
    - a. Reasonable notice shall be given prior to termination of Registry access. An authorized user may appeal in writing to the Immunization Branch, within 30 days of receiving notice of termination from the Registry.

## XII. Privacy Information

### A. Notification

1. The Department of Health shall make available to the patient or the patient's parent or legal guardian in the case of a minor or dependent, via the patient's health care provider or birthing hospital, a written description of the purpose and benefits of the Registry as well as the procedure for refusing inclusion in the Registry ("opt-out").
2. Notification shall include the following:
  - a. What information may be contained in the Registry;
  - b. The purpose and benefits of the Registry;
  - c. How the information may be used (i.e. the purposes for which IIHI is being collected);
  - d. To whom the information may be made available;
  - e. How the patient may refuse inclusion of immunization data in the Registry ("opt-out");
  - f. How the patient may inspect, copy, correct or amend his/her immunization record; and
  - g. Who to contact should the patient have further questions.
3. Information about the Registry must be given to the patient before patient immunization data and other IIHI is entered into the Registry.
4. Authorized users must make Registry-supplied patient informational sheets/brochures (or copies thereof) available to their patients to satisfy the notification requirements listed above in item 2.
5. To the extent possible, notification should be in a language the patient can understand.
6. If patients are unable to read the Registry informational sheet/brochure, it is the responsibility of the authorized user to ensure that the notification requirements listed above in item 2 are conveyed to the patient.

### B. Choice

1. Patients may refuse inclusion of their immunization data in the Registry.
2. When a patient, or in the case of a minor, the minor's parent or legal guardian, chooses to refuse inclusion in the Registry, minimal demographic information, including the patient's name and date of birth, shall be maintained within the Registry system to identify the patient as having elected to refuse inclusion in the Registry. This information is necessary to enable the Registry to filter and refuse entry of immunization information for the individual. Core demographic data will be for Department of Health use only and will be non-displaying to all other Registry authorized users.
3. Exercising the choice not to include his/her immunization data and other IIHI in the Registry shall be documented in writing on the Hawaii State Immunization System Opt-Out Form.
4. Authorized users must not enter into or transmit immunization data to the Registry for any patient that has completed a Hawaii State Immunization System Opt-Out Form.

5. With the exception of the required minimal demographic information, all other demographic and immunization information entered into the Registry prior to the patient's decision to opt-out will be permanently deleted from the Registry by the Department of Health Immunization Branch upon receipt of the patient's completed Hawaii State Immunization System Opt-Out Form.
6. If a patient elects to revoke his/her decision to opt-out of the Registry, he/she shall indicate this decision on a Hawaii State Immunization System Reauthorization Form.
7. Authorized users are responsible for storing completed Hawaii State Immunization System Opt-Out Forms and Hawaii State Immunization System Reauthorization Forms. Authorized users shall make these forms available to Immunization Branch personnel upon request. Upon completion of the Opt-Out or Reauthorization Forms, authorized users shall transmit a copy of the form to the Department of Health Immunization Branch.
8. The decision whether or not to vaccinate, and the decision not to authorize the inclusion of immunization data and other IIHI in the Registry are separate and distinct decisions. A patient signature indicating refusal to include or revocation of refusal to include information in the Registry *does not* indicate the patient's consent or refusal to vaccinate.
9. Patients may not be penalized for refusing inclusion of immunization data and other IIHI in the Registry for religious, philosophical, privacy, or other reasons.

### XIII. Policy Review

- A. At minimum, this Policy shall be reviewed and/or updated by the Immunization Branch, in consultation with the Hawaii State Immunization System Coalition, on an annual basis.