Iowa's Immunization Registry Information System (IRIS)
Confidentiality Policy
October 2013

I. Background

IRIS is a statewide immunization information system managed by the Iowa Department of Public Health's Immunization Program. IRIS was developed to achieve complete and timely immunization of all Iowans. A barrier to reaching this goal is the continuing difficulty of keeping immunization records accurate and up-to-date. IRIS addresses this problem by collecting immunization information from public and private health care providers and linking individual immunization records. Even if an individual receives immunizations from more than one health care provider, IRIS will merge the immunization information from all providers to create a comprehensive record. This assists health care providers to track which immunizations are needed for individuals in their care regardless of where they received previous vaccines.

II. Statement of purpose

IRIS is an immunization information system that serves the public health goal of preventing and mitigating the spread of vaccine-preventable diseases in Iowa. IRIS accomplishes this goal through providing accurate and timely immunization information for all Iowans to assist health care providers offering age-appropriate immunizations to their patients.

The success and effectiveness of IRIS in achieving its public health goal is dependent on the level of participation by health care providers.

Under Iowa Administrative Code 641-7.11(22); the purposes of IRIS are to:

- maintain a database of immunization histories
- ensure patients are fully immunized.

III. Purpose of confidentiality policy

The purpose of this policy is to address the need to provide appropriate confidentiality protection to the information in IRIS. The confidentiality of this information must be distinguished from issues of privacy. Privacy is concerned with the control individuals exert over the release of their personal information. Under IRIS's policy, confidentiality is concerned with how the information provided to IRIS by individuals is accessed, collected, stored, used, and provided to other individuals and organizations.

IV. Definitions

A. All terms used in this policy have the same meaning as those terms used in the state law and administrative rules that authorize IRIS.

B. "Enrolled User" means a user of the registry who has completed an enrollment form that specifies the conditions under which the registry can be accessed and who has been issued an identification code and password by the Iowa Department of Public Health.

C. "Confidentiality" means

1. limiting the collection, access, use, storage, and release of information from enrolled users to IRIS and from IRIS to enrolled users in a manner that information will not be shared with non-enrolled users, and
2. information will only be used for the purposes permitted under the applicable laws, rules, and policies.

D. "Immunization Record" includes, but is not limited to:

1. Name of patient;
2. Gender of patient;
3. Date of birth;
4. Race;
5. Ethnicity;
6. Birth state and birth country;
7. Address;
8. Parents' names;
9. Mother's maiden name;
10. Type of vaccination administered;
11. Dose or series number of vaccine;
12. Date vaccination was administered;
13. Lot number;
14. Contraindications, precautions;
15. Provider name, license, and business address; and
16. Patient history, including previously unreported doses.

E. "Immunization tracking and recall record" includes but is not limited to:

1. The patient's name;
2. The patient's date of birth;
3. Parent/Guardian;
4. Address of the patient;
5. Telephone number;
6. Vaccines needed for the purposes of informing the patient, parent or guardian that the patient is due or past due to receive the recommended immunizations.

V. Confidentiality

Based on the law (Iowa Code § 22.7(2) and 641IAC Chapter 7), rules, and general principles of confidentiality, the confidentiality policy for IRIS is as follows:

A. Information in IRIS is confidential under Iowa law. Enrolled users shall not release immunization data obtained from the registry except to the person immunized, the parent or legal guardian of the person immunized, admitting officials of licensed child care centers and schools, medical or health care providers providing continuity of care, and other enrolled users of the registry

B. Immunization information, including identifying and demographic data maintained on the registry, is confidential and may not be disclosed except under the following limited circumstances:

   1. The person immunized or the parent or legal guardian of the person immunized;
   2. Enrolled users of the registry who have completed an enrollment form that specifies the conditions under which the registry can be accessed and who have been issued an identification code and password by the department;
   3. Persons or entities requesting immunization data in an aggregate form that does not identify an individual either directly or indirectly.
   4. Agencies that complete an agreement with the department which specifies conditions for access to registry data and how that data will be used. Agencies shall not use information obtained from the registry to market services to patients or non-patients, to assist in bill collection services, or to locate or identify patients or non-patients for any purposes other than those expressly provided in this rule.
   5. A representative of a state or federal agency, or entity bound by that state or federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state or federal agency is subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa. State or federal agencies shall not use information obtained from the registry to market services to patients or non-patients, to assist in bill collection services, or to locate or identify patients or non-patients for any purposes other than those expressly provided in this rule.
   6. The admitting official of a licensed child care center, elementary school, or secondary school; or medical or health care providers providing continuity of care.

C. Code of Fair Information Practices

   The principles in the Code of Fair Information Practices will be applied to IRIS. This means:

   1. the existence of IRIS and its purposes will be made known to all patients, including parents or guardians as applicable;
   2. patients, including parents or guardians as applicable, will be informed about what information is maintained in IRIS and how that information is used;
   3. information collected for the purposes of IRIS will not be used for other purposes without the consent of the individual or of the parent or guardian of the child (Note: additional demographic data [i.e., social security number, Medicaid number] may be collected for matching purposes only but are not viewable by registry users);
   4. patients, including parents or guardians as applicable, may review records in IRIS;
   5. IRIS will assure the reliability of the information it creates, maintains, uses, or disseminates and will take precautions to prevent the misuse of the information it creates, maintains, uses, or disseminates.

D. Enrolled users

1. Only enrolled users of IRIS may provide information to or receive information from IRIS.
2. Information from the immunization record may only be shared as follows:
    a. with other enrolled users
    b. with the patient's health care provider and another clinician
    c. with a school the patient attends
    d. with a licensed child care center the patient attends
3. Information from the immunization tracking and recall record may only be used by enrolled users to contact individuals (or parents of minor children) for the purposes of informing the individual (or parent or guardian) that he/she is due or past due to receive recommended immunizations. This information may be accessible for entry and updates via the IRIS user interface for health care providers and their staff to ensure accurate data captures. However, use of this information is restricted to the purposes outlined in this policy. Information from the immunization and tracking record will not appear on any reports outside of reminder/recall.
4. No information from IRIS will be made available to any party who is not an enrolled user except as provided in Section XI (Research using IRIS data).
5. All enrolled users are required to complete an Individual User Agreement and to read and abide by this confidentiality policy.
6. All enrolled users may receive information from IRIS unless otherwise specified in the agreement between the enrolled user and IRIS.
7. No information from IRIS may be provided to any other party except as required by law.
8. Written or verbal permission from the parent or guardian is not required to release information from IRIS.
9. The IRIS database will maintain an audit trail for all information received from or released from IRIS.
10. The Iowa Department of Public Health shall seek appropriate penalties for any misuse of information in IRIS by any authorized user or any other party, including federal civil penalties as defined in HIPAA rules (Federal Register/Vol. 68, No. 74/Thursday April 17, 2003/Rules and Regulations).
11. Any paper copy of information from IRIS will be shredded before disposal.

VI. Training of IRIS staff

The Immunization Program staff, enrolled health care providers, and other enrolled users shall receive training regarding appropriate confidentiality procedures and HIPAA confidentiality procedures.

VII. Requests for information

A. In the event that a representative of law enforcement requests information from IRIS on a specific individual, the requestor will be referred to the individual's provider.

B. All subpoenas, requests for production, warrants, and court orders will immediately be referred to the Office of the Attorney General.

VIII. Data retention and disposal

IRIS is in compliance with the State Records Commission as all data is entered and maintained in electronic form for the life of the registry. Monthly, the full IRIS database is backed up and archived to tape. Monthly archive backups are maintained for one year.

IX. Voluntary Opt-Out

In any circumstance where a parent or guardian specifically requests that information on their child be removed from IRIS or an adult over the age of 18 request their information be removed, the record will be sealed. Such requests must be in writing, and should be sent to the attention of the IRIS Coordinator.

IRIS Coordinator
Iowa Department of Public Health
Immunization Program
321 East 12th Street
Des Moines, IA 50319-0075

X. Prohibited Transfer of Data or Secondary Use of IRIS data

Enrolled users are not permitted to transfer data, either in paper or electronic form, to non-enrolled users. Non-enrolled users include, but are not limited to, software vendors, contractors, and quality improvement organizations. Potential users should be considered non-enrolled unless specifically approved in writing by the Iowa Department of Public Health in advance of data transfer.

XI. Research using IRIS data

A. Information in IRIS is collected for the purposes noted above and may only be used for these purposes.

B. The Iowa Department of Public Health must approve requests for information from IRIS for research. The research must be shown to address at least one of the purposes of IRIS. Specific uses of IRIS data include:

1. Aggregate data may be used within the Iowa Department of Public Health and shared with authorized users for public health purposes. Examples include identifying under-immunized populations, tracking interventions to improve immunization rates, and monitoring the implementation of changes in the vaccine schedule in Iowa.

2. Patient-identified information may be used within the Immunization Program at the specific request of providers, health plans, and enrolled users to assess immunization rates and identify areas of improvement. Patient name, date of birth and immunization histories may be used for this purpose.

3. Data may be released for research when approved by the Iowa Department of Public Health and by the requesting organization's human subjects review process. Any data used for this purpose must be de-identified of names and other patient identifiers. Addresses or other patient-specific information cannot be released. Any request for information that does not directly address one of the purposes of IRIS or above conditions will be denied.

4. In order to approve a request for research utilizing information in IRIS, the Iowa Department of Public Health must determine the following criteria are met:

a) The request identifies one or more of the purposes for IRIS that the research will address;
b) The researcher signs an agreement to maintain the confidentiality of all information from IRIS;
c) In accordance with IRIS laws, and as determined by the Iowa Department of Public Health, appropriate security provisions will be maintained for all information from IRIS; and
d) The information cannot be obtained from any other source.

5. If the Iowa Department of Public Health determines that each of these criteria is met, the information may be provided to the requestor. Upon completion of any research involving information from IRIS, the researcher will immediately delete all information bases with personal identifying information.

C. Any request for information from IRIS that does not satisfy the above criteria may only be provided to the requestor in aggregate form that does not identify an individual.

D. Notwithstanding the above, the Iowa Department of Public Health may consider other requests for research.

XII. Penalties

The Iowa Department of Public Health shall seek appropriate penalties for any misuse of information in IRIS by any enrolled user or any other party, including federal civil penalties under HIPAA rules (Federal Register/Vol. 68, No. 74/Thursday April 17, 2003/Rules and Regulations) and enforcement under state law as appropriate.

XIII. Review of confidentiality policy

This policy shall be reviewed and revised as needed, but not less than annually.