

Immunization Registry Information System (IRIS) Security and Confidentiality Policy October 2024

Background and Purpose of IRIS

IRIS is a statewide immunization and health screening information system that serves the public health goal of preventing and mitigating the spread of vaccine-preventable diseases in Iowa and assuring individuals receive proper health screenings. IRIS combines immunization and health screening records from healthcare providers and consolidates information to create a comprehensive record. This assists healthcare and screening providers to identify which immunizations and health screenings are necessary, regardless of the location services were provided. The IRIS Help Desk is available at irisenrollment@hhs.iowa.gov or 800-374-3958 to answer questions about IRIS or this policy.

Under Iowa Administrative Code 641-7.10; the purposes of IRIS are as follows:

- Maintain a database of immunization histories and health screening information.
- Ensure patients are fully immunized and screened.

The purpose of this policy is to address the need to provide appropriate security and confidentiality protection for the information in IRIS.

Definitions

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

“Department” means the Iowa Department of Public Health and Human Services.

“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 Department.

“Health Screening” includes a vision screening, dental screening, or refugee health screening.

“Immunization Record” includes, but is not limited to: Name of patient; Gender of patient; Date of birth; Race; Ethnicity; Birth state and birth country; Address; Telephone number; Email address; Parents’/Guardians’ names; Mother’s maiden name; Type of vaccination administered; Dose or series number of vaccine; Date vaccination was administered; Lot number; Provider name, license, and business address; and Patient history, including previously unreported doses.

“Immunization registry” or “registry” means the Department of Health and Human Services’ database of confidential, population-based, immunization and health screening records.

“Screening provider” means an ophthalmologist, optometrist, physician, free clinic, child care center, local public health department, public or accredited nonpublic school, community-based organization, advanced registered nurse practitioner (ARNP), physician assistant, dentist or dental hygienist.

Permitted Use of IRIS

Iowa state law [Iowa Code § 22.7(2) and 641 Iowa Administrative Code Chapter 7] specifies immunization and health screening information is confidential, and may only be shared with enrolled users, an individual’s healthcare provider, school, child care facility, local health department, the individuals themselves or the parent/guardian if the person is a minor.

The permitted use of IRIS is to ensure patients are fully immunized with all recommended vaccines and have received appropriate health screenings consistent with Iowa Administrative Code. The purpose and permitted use of IRIS is in accordance with 641 Iowa Administrative Code 7.10.

Use of IRIS for purposes other than as described above and in any other manner which is inconsistent with 641 Iowa Administrative Code 7.10 is not permitted. Unauthorized use of IRIS is prohibited by law and may result in suspension or termination of user access as well as criminal and civil penalties (Iowa Code sections 135.38 and 139A.25, 641 IAC 7.10).

IRIS shall contain immunization and health screening information, including identifying and demographic data, to allow enrolled users to maintain and access immunization and health screening histories for purposes of ensuring patients are fully immunized and screened. IRIS may be used to track inventory or utilization of pharmaceutical agents identified by the Department in preparation for or response to an emergency event. Enrolled users shall not use information obtained from IRIS to market services to patients or nonpatients, to assist in bill collection services, or to locate or identify patients or nonpatients for any purpose other than those expressly provided in this rule.

Healthcare Provider Permitted Use

Healthcare providers may use IRIS to view patient immunization records for the purpose of ensuring patients are age-appropriately immunized or screened. The provider must offer any missing immunizations or screenings or provide referral information for such services if the patient is not appropriately immunized or screened.

Employer Permitted Use

Employers cannot enroll to use IRIS solely for the purpose of verifying employee vaccination status. Employers can obtain vaccination status directly from the employee. However, enrolled users within healthcare facilities may use IRIS to view and maintain a record of immunizations received for the purpose of ensuring employees are

appropriately immunized to prevent the spread of vaccine-preventable diseases. Healthcare facilities are defined as an institution providing healthcare services or a healthcare setting including, but not limited to, hospitals, nursing facilities, and assisted living programs. The employer must offer any missing immunizations or screenings or provide referral information for such services if the employee is not appropriately immunized or screened.

Iowa Schools

Iowa schools, Pre-Kindergarten through 12th Grade, are authorized to use IRIS to view/print student immunization records. Access to IRIS for these users is view-only which allows the user to view records but not to edit or enter additional information.

Iowa Child Care Facilities

Licensed child care centers, registered child development homes, daycares, early learning centers, and preschools in the state of Iowa are not authorized to enroll to access information in IRIS.

Confidentiality

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

- 1) Information in IRIS is confidential under Iowa law. Enrolled users shall not release immunization or health screening data obtained from IRIS except to the person immunized or screened, the parent or legal guardian of the person immunized or screened, admitting officials of licensed child care centers and schools, medical or healthcare providers providing continuity of care, and other enrolled users of IRIS.
- 2) Immunization and health screening information, including identifying and demographic data maintained in IRIS, is confidential and may not be disclosed except under the following limited circumstances:
 - a) The Department may release information from IRIS to the following:
 - i) The person immunized or screened, the parent or legal guardian of the person immunized or screened.
 - ii) Enrolled users of IRIS who have completed an enrollment form that specifies the conditions under which IRIS can be accessed and who have been issued an identification code and password by the Department.
 - iii) Persons or entities requesting immunization or health screening data in an aggregate form that does not identify an individual either directly or indirectly.
 - iv) 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 IRIS 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 policy.
 - v) A representative of a state or federal agency, or entity bound by that state or federal agency, to the extent 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 IRIS 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.

- vi) The admitting official of a licensed child care center, elementary school, or secondary school; or medical or healthcare providers providing continuity of care.
 - vii) Enrolled users from other states or jurisdictions who have signed and completed enrollment in the state's or jurisdiction's immunization registry.
- b) Enrolled users
- i) All enrolled users are required to complete the IRIS Authorized Site Agreement-Organization or the Individual User Agreement, and to read and abide by this security and confidentiality policy.
 - ii) Only enrolled users of IRIS may provide information to or receive information from IRIS.
 - iii) Written or verbal permission from the parent or guardian is not required to release information from IRIS if releasing to anyone in the following list. Information from the immunization or health screening record may only be accessed and shared to perform a legally authorized function of the enrolled users as follows:
 - (1) with other enrolled users
 - (2) with the patient's healthcare provider or another clinician
 - (3) with a school the patient attends
 - (4) with a licensed child care center the patient attends
 - iv) An enrolled user shall shred any paper copy of information from IRIS before disposal.
 - v) Information from IRIS may only be used by enrolled users to contact individuals (or parents or guardians 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 or screenings. This information may be accessible for entry and updates via the IRIS user interface for healthcare providers and staff to ensure accurate data. However, access to and use of this information is restricted to the purposes outlined in this policy.
 - vi) The IRIS database will maintain detailed audit trails of all actions in IRIS.
 - vii) The Department shall seek appropriate penalties for any misuse of IRIS by any enrolled user or any other party, including pursuing any sanction authorized under state or federal law.

Security

Security addresses the physical and other measures taken to guard against attack or breach of IRIS information.

1. Access to IRIS is authorized under the conditions required to perform a legally authorized function of the organization.
2. An enrolled user shall:

- a. Review and abide by the IRIS Security and Confidentiality Policy.
 - b. Renew the security certification within IRIS annually.
 - c. Maintain confidentiality of data within IRIS.
 - d. Ensure the accuracy of all immunization and demographic information entered or edited.
 - e. Enter data timely and accurately, and not knowingly enter invalid/false data, falsify any document or data obtained from IRIS.
 - f. Maintain a unique login to access IRIS. Under no circumstances shall usernames and passwords be shared.
 - g. Make every effort to protect IRIS from unauthorized views.
 - h. Assure virus protection is in place for each computer or device on which IRIS is accessed within the organization.
 - i. Encrypt and send securely all data from IRIS before transmission.
 - j. Not copy confidential data onto personal or removable devices (including, but not limited to, flash drives, portable hard drives, memory cards, DVDs, CDs, cell phones, etc.).
3. IRIS must only be accessed using an approved work device for the organization which completed the IRIS enrollment. IRIS users shall not access IRIS using a personal computer or other personal devices.
 4. Enrolled users must have physical security and password screensavers for all computers or devices, which must lock or terminate to protect patient information, in accordance with organizational policies and practices, when the computers or devices are not being used.
 5. IRIS information in a paper copy shall not be left where it is visible for unauthorized personnel and must be shredded before disposal.
 6. Any activity that could jeopardize the proper function and security of IRIS shall not be conducted.
 7. The IRIS Administrative User at each organization must terminate access for an enrolled user who no longer requires access.
 8. Violators of this policy will be restricted from IRIS by the IRIS Administrative User at the organization or by the IRIS Coordinator. The Department shall seek appropriate penalties for any misuse of information in IRIS by any enrolled user or any other party, including pursuing any sanction authorized under state and federal law. Unauthorized use of this system is prohibited by law and may result in criminal and civil penalties (Iowa Code sections 135.38 and 139A.25, 641 IAC 7.10).

Annual Review of Security and Confidentiality Policy

Enrolled users shall annually review this IRIS Security and Confidentiality Policy, the IRIS Security Notification within IRIS, and review the Individual User Agreement / Authorized Site Agreement-Organization form.

Release of IRIS Information

IRIS records are confidential and may only be released to the following individuals authorized by law:

1. A parent or legal guardian.
2. A legal guardian for a ward (protected person) regardless of the age of the ward.

3. Individuals over the age of 18.

Requests for IRIS records may not be accepted for a spouse, partner, child over the age of 18, or employee. Individuals, parents and guardians may request immunization or health screening data by completing the IRIS Record Request Form, which is found under the 'Forms' tab of IRIS at <https://iris.iowa.gov>. The Record Request Form and a copy of a state-issued ID (such as Driver's License) shall be emailed to irisenrollment@hhs.iowa.gov. By signing the IRIS Record Request form, the requester declares under penalty of perjury under the laws of the State of Iowa that she/he is the subject of the record or the parent or legal guardian of the subject of the record and are therefore authorized to access the record. By completing this record request form, the requester verifies the information is true and accurate, and the requester is authorized by law to have the record. All subpoenas, requests for production, warrants, and court orders will immediately be referred to the Office of the Attorney General. Unauthorized use of IRIS is prohibited by law and may result in criminal and civil penalties (Iowa Code sections 135.38 and 139A.25, 641 IAC 7.10 (5)).

IRIS and HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) governs the use and disclosure of protected health information. It applies to:

- Health plans and providers ("covered entities")
- Business associates of who perform legal, accounting or other services for covered entities

HIPAA regulations pursuant to 45 CFR 164.512(b) permit a covered entity to disclose protected health information for public health activities.

Impact of HIPAA on Immunization Information Systems (IIS):

HIPAA does not limit IIS activities because the Privacy Rule permits disclosure to public health authorities and their authorized agents for public health purposes.

- The Department, Public Health Division is the public health authority operating IRIS in Iowa.
- Iowa state law allows the sharing of IRIS information with enrolled users [Iowa Code § 22.7(2) and 641 IAC Chapter 7].

Impact of HIPAA on clinic and health plan release of immunization data to IRIS:

Enrolled users can submit electronic, hard copy, or web entered immunization data to IRIS. Covered entities (providers, clinics, health plans, etc.) may disclose protected health information to IRIS without obtaining advance permission from patients pursuant to 45 CFR 164.512(b). Information from IRIS can be re-disclosed to enrolled users in accordance with Iowa Administrative Code [641 IAC Chapter 7].

Impact of HIPAA on accounting for public health disclosures:

A simplified accounting for Public Health purposes may be used if during the accounting period the covered entity made multiple disclosures to the same recipient for the same purpose. In such cases, the covered entity need only identify the recipient [IRIS] of such repetitive disclosures, the purpose of the disclosure, and describe the protected health

information [immunization records] routinely disclosed. The date of each disclosure need not be tracked. The covered entity would not need to annotate each patient's medical record whenever a routine public health disclosure was made (MMWR April 11, 2003 / 52; Pg.9).

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. IRIS is routinely backed up and archived. Audit tables within IRIS are maintained for five years and may include but are not limited to patient searches, reminder/recall reports, user names, inventory reports, and ad hoc reports.

Participation in IRIS

Enrolled users can submit electronic or web-entered immunization data to IRIS. Covered entities (providers, clinics, health plans, etc.) may disclose protected health information to IRIS without having to obtain advance permission from patients pursuant to 45 CFR 164.512(b). In circumstances in which a parent or guardian specifically requests the removal of information for their child from IRIS, or an adult over the age of 18 requests their information be removed, the record will be removed from the IRIS database. Patients, parents, and guardians requesting voluntary opt-out must also notify each of their healthcare provider(s) to prevent creation of additional records in IRIS, either via electronic submission from an electronic health record system or direct entry in IRIS. Requests to remove records must be submitted using the IRIS Opt-Out Request form and be submitted either by mail or email. Requests must include a copy of a state-issued ID (such as Driver's License). By signing the IRIS Opt-Out Request form, the requester declares under penalty of perjury under the laws of the State of Iowa that she/he is the subject of the record or the parent or legal guardian of the subject of the record and is authorized to request the record be removed from IRIS.

Requests must be sent to the attention of the IRIS Coordinator. If sent by email, the subject line should be titled 'IRIS Opt-Out Request'.

IRIS Coordinator
Iowa Department of Health and Human Services
Immunization Program
321 East 12th Street
Des Moines, IA 50319-0075
irisenrollment@hhs.iowa.gov

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. Enrolled users may share IRIS data with contracted entities only to perform a legally authorized function of the enrolled user.

Penalties

The Department shall seek appropriate penalties for any misuse of information in IRIS by any enrolled user or any other party, including pursuing any sanction authorized under state and federal law. The Department may suspend or terminate an enrolled

user's access consistent with Department policy if the user violates Iowa Administrative Code Chapter 7, the IRIS Authorized Site Agreement-Organization, the IRIS Authorized Individual User Agreement, or the IRIS Security and Confidentiality Policy. The Department shall approve, suspend, terminate, and reinstate user access in accordance with Iowa Administrative Code Chapter 7 and Department policy. Unauthorized use of IRIS is prohibited by law and may result in criminal and civil penalties (Iowa Code sections 135.38 and 139A.25, 641 IAC 7.10).