



COLORADO

Department of Public
Health & Environment

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Colorado Immunization Information System (CIIS) Privacy and Confidentiality Policy

Published/Revised Date	Version #	Author	Section/Revision Description
04/01/2001	1.0	CIIS	Draft for initial implementation
09/13/2001, 01/10/2003, 08/29/2003, 06/18/2004, 04/03/2006, 05/03/2006, 05/17/2006, 05/17/2007, 12/12/2008	1.1 - 1.9	CIIS	Various updates
06/14/2013	2.0	CIIS	Complete revision
06/06/2014	2.1	CIIS	Website updates

I. Overview

Background

The Colorado Immunization Information System (CIIS), also known as the state immunization registry, is a confidential, computerized, population-based system that collects and consolidates immunization data for all persons born, residing in or receiving immunizations in the State of Colorado and provides tools for designing and sustaining effective immunization strategies at the provider and program levels. CIIS is an important tool to increase and sustain high vaccination coverage by consolidating patient vaccination records from multiple providers and providing official vaccination forms and vaccination coverage assessments. The Colorado Department of Public Health and Environment (CDPHE) operates CIIS pursuant to the Immunization Registry Act - Colorado Revised Statute (CRS) § 24-4-2403.

The Immunization Registry Act provides for the disclosure and use of immunization information in order to meet statutory immunization requirements and to control disease outbreaks. It is the official duty of CDPHE and local public health agencies to use the birth certificate of any person to enroll the person in CIIS.

Purpose

The purpose of this policy is to address the need to provide appropriate confidentiality protections of the information in CIIS as well as explain the privacy rights of individuals to exclude their information from CIIS. Privacy relates to the control individuals exert over their personal information; whereas, confidentiality relates to ensuring that information is accessible only to those authorized to have access.

Note: This policy does not cover non-immunization related data and, as such, provider access to the Newborn Hearing/Newborn Screening module within CIIS. Providers are required to sign and abide by a separate Newborn Hearing/Newborn Screening Confidentiality Agreement provided by the Early Childhood Screening program at CDPHE.

General Provisions

- a. A copy of this policy can be obtained at www.ColoradoIIS.com under the “Policies and Procedures” tab.
- b. This policy will be reviewed at least annually to ensure that it is consistent with applicable Federal and State laws and regulations.
- c. This policy applies to all individually identifiable immunization information sent to (regardless of method) and maintained within CIIS.
- d. This policy applies to all persons who have authorized access to the immunization information maintained within CIIS pursuant to CRS § 25-4-2403.

II. Health Insurance Portability and Accountability Act of 1996 (HIPAA): CIIS is not a Covered Entity

CDPHE is a public health authority and is authorized to maintain and operate CIIS and collect and receive immunization information for the purpose of preventing or controlling disease and public health interventions under the Colorado Immunization Registry Act. HIPAA allows a public health authority to collect immunization information without an authorization (45 CFR § 164.512 (b)).

The HIPAA Privacy Rule applies to Covered Entities. A Covered Entity (CE) is a health plan, a health care clearinghouse or a health care provider who transmits certain health claims information electronically (45 CFR § 164.104). CIIS does not provide, pay for or arrange for payment for health care and does not transmit any data in a covered transaction. Therefore, CIIS is not a Covered Entity under the Privacy Rule.

More detail regarding the application of HIPAA to CIIS can be found under the “Policies and Procedures” tab at www.ColoradoIIS.com.

III. Privacy: Patients Right to Opt Out

All persons have the statutory right to exclude their information from CIIS at any time. Per the Immunization Registry Act, an individual or a parent or legal guardian who consents to the immunization of an infant, child, or student (pursuant to CRS § 25-4-9, CRS § 25-4-17 or CRS § 25-4-24) may exclude immunization information from CIIS. Physicians, licensed health care practitioners, clinics, hospitals, or local health departments shall inform the individual, parent, or legal guardian of the option to exclude such information from CIIS and the potential benefits of inclusion.

Participating Sites that have signed a Letter of Agreement with CIIS agree to provide notice to individuals, parents or guardians as required by CRS § 25-4-2403(7) stating that the individual, parent or guardian can choose to have their (or their child’s) immunization information excluded from CIIS at any time.

Procedures for excluding immunization information from CIIS or rescinding a previously submitted Opt-Out Form can be found at: <http://www.ColoradoIIS.com> under the “Policies and Procedures” tab.

IV. Confidentiality: Authorized Access and Release of CIIS Information

CIIS and all persons and entities that access immunization records are required to maintain the confidentiality of those records. The responsibility of protecting confidentiality extends to anyone having access to information contained in the registry, whether it is accessed directly or

indirectly through interoperability with a provider's electronic health record (EHR) or through a health information exchange (HIE).

- a. Records in CIIS shall be strictly confidential and shall not be released, shared with any agency or institution, or made public upon subpoena, search warrant, discovery proceedings, or otherwise, except under the following circumstances:
 - i. Medical and epidemiological information may be released in a manner such that no individual person can be identified.
 - ii. Immunization records and epidemiological information may be released to the extent necessary for the treatment, control, investigation, and prevention of vaccine-preventable diseases; except that every effort shall be made to limit disclosure of personal identifying information to the minimum amount necessary to accomplish the public health purpose.
 - iii. Immunization records and epidemiological information may be released to the individual who is the subject of the record, to a parent of a minor individual, to a guardian or person authorized to consent to immunization under CRS § 25-4-1704, to the physician, clinic, hospital, or licensed health care practitioner treating the person who is the subject of an immunization record, to a school in which such person is enrolled, or any entity or person described in paragraph (f), (h), or (i) of subsection (2) of this section.
- b. Physicians, licensed health care practitioners, clinics, schools, licensed child care providers, hospitals, managed care organizations or health insurance plans in which an individual is enrolled as a member or insured, persons or entities that have contracted with CDPHE to implement or operate CIIS and public health officials may release any immunization records in their possession, whether or not such records are in CIIS, to each other and to schools, individuals who are the subject of the immunization record, parents, legal guardians, persons authorized to consent to immunizations for minors, and the Department of Health Care Policy and Financing for individuals who are eligible for Medicaid, to provide treatment for an individual and complete immunization records for the individual.
- c. No officer or employee or agent of CDPHE or local department of health may be examined in any judicial, executive, legislative, or other proceeding as to the existence or content of any individual's report obtained by the department without consent of the individual or the individual's parent or guardian. However, this provision shall not apply to individuals who are under isolation, quarantine, or other restrictive action.

V. Participating Site Responsibility

- a. Each Participating Site has signed a Letter of Agreement in which it agrees that it is responsible for ensuring that all persons or entities (including providers, staff, contractors and agents) who access information through CIIS are authorized to receive access to such information and will comply with CIIS policies, the Immunization Registry Act and all other applicable state and federal laws and regulations.
- b. Each Participating Site will abide by this Confidentiality Policy and will establish appropriate internal policies and procedures to ensure compliance by all employees, volunteers, and any other persons who the Participating Site has allowed to have access to CIIS. The Participating Site agrees that it is responsible for the actions of all persons it allows to have access to individually identifiable information in CIIS.

- c. Each Participating Site may establish internal policies and procedures that limit release of individually identifiable information of patients registered to that Participating Site in CIIS subject to the following:
 - i. If there is substantial evidence that the information in the record (e.g., individual's address) if released, could reasonably be expected to cause substantial harm to the individual or others, then access can be limited. Evidence of substantial harm includes, but is not limited to, evidence that the individual or a person responsible for a child has: been a victim of domestic violence; contacted a law enforcement official regarding domestic violence as evidenced by a police report involving domestic violence of other physical abuse; obtained a temporary restraining order to protect the individual from future physical abuse; or filed other criminal or civil legal proceedings regarding physical protection.
 - ii. Limitation of access means releasing medically necessary immunization information without demographic information that identifies a physical location.
 - iii. If access is limited, the person requesting access should be given written notice of the reasons for the denial and an opportunity to appeal the denial.

VI. Research using CIIS data

It may become necessary for a researcher or specifically authorized person to obtain potentially identifying data from confidential records held by CIIS in order to conduct legitimate research on the treatment, control, investigation, and prevention of diseases and conditions dangerous to the public's health. Access to potentially identifying information may be provided if the Data User agrees to all of the following conditions:

- a. CIIS is the Data Owner. Data Users do not obtain any right, title or interest in any of the data provided by CIIS.
- b. Persons requesting data will provide complete information about the aims and intentions of the data use, as well as the names of all persons who will have access to the confidential information, by completing all items in the *Request for Data Form*. CIIS requires submission of a detailed study protocol including the following information: background, anticipated scientific benefits, target population, sample size(s), Institutional Board Review (IRB) approval status, specific research questions, procedures to be used to ensure confidentiality of the data, and the form in which, and to whom, results of the study will be released. Additionally, completed consent forms (if required per IRB approval) must be submitted for all persons included in the study.
- c. Copies of records or other materials containing confidential information are not to be made without the specific, written approval of CIIS. This also applies to making copies of electronic data.
- d. Data Users shall use and disclose the confidential information provided by CIIS only for the activity described in the data request. Data Users shall limit access to confidential information strictly to those individuals or classes of individuals who shall have access in order to perform the duties set forth in the application, and each of these individuals shall read and sign the Data Use Agreement.
- e. Except as provided in this agreement, the Data User shall not use or further disclose the confidential data except as specified in the Data Use Agreement.
- f. Data Users agree to take appropriate administrative, technical, and physical safeguards to protect the data from any unauthorized use or disclosure not provided for in this Agreement. The Data Owner shall ensure that no identifying information is transmitted through unsecured communications, including e-mail or other unsecured Internet connections.
- g. The Data Use Agreement shall also serve as a Confidentiality Agreement and *shall be signed by all persons having access to the confidential information*. This includes, but is not limited to, all interns, subcontractors, staff, other workforce members, and consultants.

- h. Within 48 hours of the Data User's discovery, Data Users shall report to CIIS any use or disclosure of the confidential information that violates either the Data Use Agreement or applicable state or federal laws or regulations.
- i. No confidential information shall be publicly released. Furthermore, any reports or aggregate tabulations that are prepared shall suppress all counts and rates where the number, the numerator, or the denominator is smaller than three.
- j. Records shall be destroyed or returned to CIIS upon completion of the work described in the application. Data Users agree to send CIIS written notification that the data have been destroyed or returned within 30 days of the completion of work described in the application unless CIIS provides a specific date for destruction or return.
- k. Data Users attest that the confidential information requested represents the minimum information necessary for the Data User to perform duties described in the application and that only the minimum necessary individuals shall have access to the confidential information in order to perform such work.
- l. Data Users agree to furnish a research protocol and all documentation concerning IRB reviews and to submit required documentation to an IRB or Privacy Board in the event that research protocols change. Data Users also agree to submit to CIIS any change in either the waiver status or conditions for IRB approval of the project related to work described in the application.
- m. Data Users agree to obtain individual authorizations to the confidential information if the activity entails research, unless the IRB approves a waiver of such an authorization. Documentation shall be provided prior to receipt of the confidential information.
- n. Any release of results from the research project derived from CIIS data is to be in accordance with the terms of the Data Use Agreement and must be submitted to CIIS for review prior to release. The following statement is to be included in the release of data derived from CIIS records: "These data were supplied in part by the Colorado Immunization Information System of the Colorado Department of Public Health and Environment, which specifically disclaims responsibility for any analyses, interpretations, or conclusions based on the given data." In addition, Data Users shall notify CIIS when the publication or presentation is available and, further, shall provide a final copy of the product produced using CIIS data.

VII. Prohibition of Unauthorized Re-disclosure

Individually identifiable information obtained in an authorized manner may not be redisclosed unless the redisclosure complies with this policy. Authorized users are not permitted to transfer data, either in paper or electronic form, to non-authorized users. Non-authorized users include, but are not limited to, software vendors, contractors, and quality improvement organizations. Potential users should be considered non-authorized unless specifically approved in writing by the Director and the Immunization Program Manager in advance of data transfer.

VIII. Penalties for Inappropriate Use or Disclosure of Information

- a. Any employee, or agent of CDPHE or any other person who releases or makes public confidential immunization records or epidemiological information in CIIS any unauthorized manner commits a class 1 misdemeanor and upon conviction thereof, shall be punished by 6-18 months in jail or a fine of \$500 to \$5000, or both. The unauthorized release of each record shall constitute a separate offense.
- b. A natural person who, in exchange for money or any other thing of value, wrongfully releases or makes public confidential immunization records or epidemiological information in CIIS in any unauthorized manner commits a class 1 misdemeanor and, upon conviction thereof, shall

be punished 6-18 months in jail or a fine of \$500 to \$5000, or both. The unauthorized release of each record shall constitute a separate offense.

- c. A business entity that, in exchange for money or any other thing of value, wrongfully releases or makes public confidential immunization records or epidemiological information in CIIS in any unauthorized manner shall be assessed a civil penalty of ten thousand dollars per sale of information per subject of such information.
- d. Upon notice of an inappropriate use or disclosure of individually identifiable information, CIIS may take the following actions:
 - i. First Occurrence: A written statement of the circumstances of the inappropriate use or disclosure;
 - ii. Second Occurrence: A written statement of the circumstances of the inappropriate use or disclosure and warning that additional violations will result in revoked access to CIIS;
 - iii. Third Occurrence: Revocation of access to CIIS.

IX. Data retention and disposal

Per Colorado State Board of Medical Examiners Policy 40-07 *Guidelines Pertaining to the Release and Retention of Medical Records*, all patient records should be retained for a minimum of 7 years after the last date of treatment, or 7 years after the patient reaches 18 years of age - whichever occurs later.

All immunization records in CIIS will be retained permanently according to the Colorado State Archives and Public Records - Records Disposition Schedule 10 - 19. The one exception to this is if a parent or patient exercises their right to exclude their information from CIIS per CRS § 25-4-2403 (7).

Immunization records that are printed for the purposes of providing the record to the parents of or patient who is the subject of the record are securely stored and maintained for one year for verification and proofing purposes; thereafter, they are confidentially shredded.



Colorado Immunization Information System (CIIS)

Policy:	Opt-Out
Date Introduced:	August 1, 2001
Dates Revised:	Nov 25, 2002; Aug 5, 2003; July 7, 2004; Feb 15, 2007; May 21, 2007; Dec 22, 2008; Oct 8, 2014

Colorado Revised Statute (CRS) § 25-4-2403 (7) provides that an individual or a parent or legal guardian has the right to exclude immunization information from the Colorado Immunization Information System (CIIS).

CRS § Section 25-4-2403 (7) requires that the:

- Colorado Department of Public Health and Environment shall ensure that the process to exclude immunization information from CIIS is readily available and not burdensome.
- Physician, licensed health care practitioner, clinic, hospital or local health department shall inform the individual, parent, or legal guardian of the option to exclude immunization information from CIIS and the potential benefits of inclusion in CIIS. In addition, the physician, licensed health care practitioner, clinic, hospital, or local health department shall inform such parent or legal guardian of a minor individual of the option to refuse an immunization on the ground or medical, religious or person belief considerations under CRS Section 24-4-903 (school entry requirements).

Each Participating Site that discloses immunization information to CIIS is required to provide the individual, parent or legal guardian notice of the option to exclude immunization information from CIIS and the potential benefits of inclusion in CIIS.

Participating Site Responsibilities

All forms can be printed from the CIIS website located at www.ColoradoIIS.com.

A. Notice of Opt-Out Option:

To meet the statutory notice requirement each Participating Site that discloses immunization information to CIIS can choose one or more of the following procedures to inform the individual, or parent or legal guardian of the option to exclude immunization information from CIIS:

1. (a) Post notice, in both English and Spanish, informing individuals, parents and guardians that immunization records are added to CIIS and their right to have that information excluded; **and**

(b) Have the Colorado Immunization Information System--Frequently Asked Questions handout available for distribution, or
2. Give the individual or parent or guardian the Colorado Immunization Information System--Frequently Asked Questions, for example, at the same time the first Vaccine Information Statement is given to the individual or parent or guardian, in the birth hospital, as a part



of a vaccine reference book provided to patients, or at any other appropriate opportunity,
or

3. Any other appropriate means, including notifications on the organization's website.

B. Opt-Out Procedure:

1. The Participating Site must
 - a) Supply individuals, parents or guardians who request to exclude immunization information a CIIS Opt-Out Form.
 - b) Have the individual, parent or guardian complete and sign three copies of the CIIS Opt-Out Form.
 - c) Attach one signed CIIS Opt-Out Form to the patient's medical record in the usual location for the immunization record.
 - d) Give two signed copies of the CIIS Opt-Out Form to the individual or parent or guardian.
2. The individual, or parent or guardian must:
 - a) Mail or fax one copy of the CIIS Opt-Out Form to the Colorado Department of Public Health and Environment at the address shown on the CIIS Opt-Out Form.
 - b) Retain one signed copy of the CIIS Opt-Out Form.

C. Rescind Opt-Out Procedure:

1. The Participating Site must
 - a) Supply individuals, or parents or guardians who request to delete a prior opt-out notification with the CIIS Rescind Opt-Out Form.
 - b) Have the individual, or parent or guardian complete and sign three copies of the CIIS Rescind Opt-Out Form.
 - c) Attach one signed CIIS Rescind Opt-Out Form to the patient's medical record in the usual location for the immunization record.
 - d) Give two signed copies of the CIIS Rescind Opt-Out Form to the individual, or parent or guardian.
2. The individual, or parent or guardian must:
 - a) Mail or fax one copy of the CIIS Rescind Opt-Out Form to the Colorado Department of Public Health and Environment at the address shown on the CIIS Rescind Opt-Out Form.
 - b) Retain one signed copy of the CIIS Rescind Opt-Out Form.

Colorado Immunization Information System Responsibilities:

A. Opt-Out Notice:

1. The Colorado Department of Public Health and Environment will provide the Colorado Immunization Information System--Frequently Asked Questions handout to birthing hospitals for distribution to all parents of newborns. The document includes instructions on how to find the CIIS Opt-Out Form for completion by the parent.
2. CIIS Program staff will generate a standard Opt-Out Notice poster available in English and Spanish from the CIIS office or the CIIS website.
3. CIIS Program staff will generate a standard Colorado Immunization Information System--Frequently Asked Questions handout available in English and Spanish from the CIIS office or the CIIS website.

B. Opt-Out Procedure:

1. CIIS Program staff will complete the opt-out procedure and send an acknowledgment letter to the individual, or parent or guardian.
2. The individual's or child's name and date of birth will be retained in the opt-out table in the registry. The individual's or child's immunization and other demographic information will be removed from the registry.

C. Rescind Opt-Out Procedure:

1. CIIS Program staff will complete the rescind opt-out procedure and send an acknowledgment letter to the individual, or parent or guardian.
2. The individual's or child's name and date of birth will be removed from the opt-out table in the registry. The individual's or child's demographic information will be entered in the registry, and Participating Sites will be able to add immunization information to the patient's record.