

# **Application of the Health Insurance Portability and Accountability Act of 1996 to the Colorado Immunization Information System**

Revised February 15, 2009

## **Colorado Immunization Registry Law**

Pursuant to C.R.S. § 25-4-2401 et seq., authorizes Colorado Department of Public Health and Environment (CDPHE) to establish a comprehensive immunization tracking system. State and local health departments may gather immunization information for such tracking systems from the following sources:

- (a) Practitioners (“Practitioner” is defined in 25-4-1703, C.R.S., as a duly licensed physician or other person who is permitted and otherwise permitted and qualified to administer vaccines under the laws of the State of Colorado);
- (b) Clinics;
- (c) Schools;
- (d) Parents, legal guardians, or persons authorized to consent to immunizations;
- (e) Individuals;
- (f) Managed care organizations or health insurers in which an individual is enrolled as a member or insured, if such managed care organization or health insurer reimburses or otherwise financially provides coverage for immunizations;
- (g) Hospitals;
- (h) The Colorado Department of Health Care Policy and Financing with respect to individuals who are eligible for coverage under the Colorado Medical Assistance Act;
- (i) Persons and entities that have contracted with the State pursuant to section 25-4-2403 (9) (d), C.R.S. Section 25-4-2403 (9) (d), C.R.S. allows the Colorado Department of Public Health and Environment (CDPHE) to enter into contracts that are necessary for the implementation and operation of the immunization tracking system; or
- (j) From birth certificates. Section 25-4-1705 (8), C.R.S. and Section 25-4-2403 (10), C.R.S. provide that local health departments and CDPHE are required to use the birth certificate of any infant to enroll the infant in the immunization tracking system created under Section 25-4-2403 (2), C.R.S. as an official duty of local health departments and CDPHE.

Section 25-4-2403 (3), C.R.S. provides that the records in the immunization tracking system established pursuant to Section 25-4-2403 (2), C.R.S. are strictly confidential and may 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:

- (a) Medical and epidemiological information may be released in a manner such that no individual person can be identified;

- (b) 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 minimal amount necessary to accomplish the public health purpose;
- (c) Immunization records and epidemiological information may be released to:
  - (i) The individual who is the subject of the record;
  - (ii) A parent of a minor individual;
  - (iii) A guardian or person authorized to consent to immunization;
  - (iv) The physician, clinic, hospital or licensed health care practitioner who is treating the person who is the subject of an immunization record;
  - (vi) A school in which such person is enrolled;
  - (vii) A managed care organization in which the individual is enrolled as a member or insured, if the managed care organization or health insurer reimburses or otherwise financially provides coverage for immunizations;
  - (viii) Hospitals;
  - (ix) Persons or entities that have contracted with the State to implement or operate the immunization tracking system; or
  - (x) The Colorado Department of Health Care Policy and Financing with respect to individuals who are eligible for coverage under the Colorado Medical Assistance Act.

Releasing or making public confidential immunization records in the immunization tracking system in an unauthorized manner is a misdemeanor (Sections 25-4-2403 (5) (b) and (c), C.R.S).

An individual, parent or guardian may exclude immunization information from the immunization tracking system. The physician, licensed health care practitioner, clinic, or local health department is required to inform the individual, parent or guardian of the option to exclude immunization information from the immunization tracking system and the potential benefits of inclusion in the system. (Section 25-4-2403 (7), C.R.S.).

Pursuant to a contract dated April 15, 2002, as extended, CDPHE granted authority to the University of Colorado Health Science Center (UCHSC) to maintain and operate the Colorado Immunization Information System (CIIS) under and in compliance with the

Colorado Immunization Registry Act. CDPHE will operate CIIS on and after January 1, 2009.

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

- 1) CDPHE is authorized to maintain and operate CIIS under the Colorado Immunization Registry Act.
- 2) HIPAA allows a public health authority to collect immunization information without an authorization (45 C.F.R., Section 164.512 (b)). The requirement to track the disclosure applies, however.
- 3) CIIS provides free of charge a feature that complies with HIPAA disclosure tracking requirements.

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 C.F.R. Section 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.

### **HIPAA Privacy Rule: Implications for Covered Entities Related to CIIS**

A CE must obtain written authorization for disclosures of PHI except:

- (a) for treatment, payment or health care operations;
- (b) to the individual;
- (c) to public health authorities if reporting is mandated by law (45 C.F.R. Section 164.512 (a) (1) **and/or**;
- (d) to public health authorities for certain public health activities and purposes (45 C.F.R. Section 164.512 (b) (1) (i)). A mandate to report is not required.

A CE can disclose PHI for the activities and purposes described in Section 164.512 (b) (1) (i) to:

“..a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease .. the conduct of public health surveillance, public health investigations, and public health interventions...”

A public health authority means:

- An agent or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe,
- Or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public

agency, or its contractors or persons or entities to whom it has granted authority,

- That is responsible for public health mandates as part of its official mandate (45 C.F.R. §164.501)

The Colorado Department of Public Health and Environment is a public health authority and is authorized by the Colorado Immunization Registry Act (Section 25-4-2403, C.R.S.) to collect and receive immunization information for the purpose of preventing or controlling disease and public health interventions. Preventing communicable disease and public health interventions require the patient's name, other identifying information, address, vaccine type, manufacturer, lot number, date of vaccine administration and Medicaid eligibility to prevent and control disease by identifying and recalling children who are not current for recommended immunizations and to identify geographic and other "pockets of need".

The HIPAA Privacy Rule preempts state laws that are contrary to the Rule (45 C.F.R. Section 160.203) but does not preempt more stringent state privacy laws or laws "for the conduct of public health surveillance, investigation, or intervention..." (45 C.F.R. Section 160.203 (a)(2)(c)). The intent of the Privacy Rule regarding public health is found in the comments in the preamble of the Privacy Rule that refer to the mandate of HIPAA:

"Nothing in this part shall be construed to invalidate or limit the authority, power or procedures established under any law providing for the reporting of disease or injury, child abuse, birth or death, public health surveillance, or public health investigation or intervention."

Therefore, HIPAA allows a CE to disclose immunization information to CIIS without authorization. The CE must make reasonable efforts to limit the use or disclosure of PHI to the minimum amount necessary to accomplish their purpose. (45 C.F.R. §164.502 (b) (1)). The agreement signed by the CE with CDPHE and the CIIS Confidentiality Policy limit the uses and disclosures of the immunization information in CIIS to those authorized by the Colorado Immunization Registry Act. The guidance issued by the Office of Civil Rights on December 3, 2002 states (at page 77):

"For disclosures to a public health authority, covered entities may reasonably rely on a minimum necessary determination made by the public health authority in requesting the protected health information. See 45 CFR 164.514(d)(3)(iii)(A). For routine and recurring public health disclosures, covered entities may develop standard protocols, as part of their minimum necessary policies and procedures, that address the types and amount of protected health information that may be disclosed for such purposes. See 45 CFR 164.514(d)(3)(i)."

Any CE with a direct treatment relationship with the patient must make a good faith effort to obtain written acknowledgement of notice of its privacy practices, including how information may be used and disclosed, including to public health authorities. The CE

must track all disclosures of PHI, including disclosures to non CEs ( 45 C.F.R. Section 164.528). CIIS has complete audit trails of all information necessary for a CE to comply with the tracking requirements related to disclosure of PHI to CIIS and, upon request, will furnish a report of the disclosures to the CE without charge.

**In summary, a Covered Entity is allowed to disclose the immunization information requested by CIIS, including patient identifiers, to CIIS without authorization. The CE should include this disclosure in its notice of privacy practices and minimum necessary policies and procedures. The CE must keep track of disclosures of the immunization information. CIIS can provide a report of disclosures made to the CIIS (without charge) if the CE does not have another system to track disclosures.**