

Newborn Screening and HIPAA

This contains the Minnesota Department of Health's (MDH) analysis of the relationship between the Health Insurance Portability and Accountability Act (HIPAA) and the sharing of newborn screening-related medical information:

How HIPAA Interacts with Minnesota Statutes §§144.125 to 144.128 and 144.966.

Disclaimer of Legal Advice: The following is the Minnesota Department of Health's (MDH) analysis of how Minnesota Statutes §§144.125 to 144.128 and 144.966 interact with the Health Insurance Portability and Accountability Act (HIPAA, privacy rule, 45 CFR 160 and 164). This is not legal advice and you should not rely on it as legal advice. Consult with a lawyer for legal advice.

Issue

 $Does \it HIPAA permit disclosure of specific patient medical information related to newborn screening to \it MDH without patient authorization?$

Finding

MDH has concluded that HIPAA permits a provider and/or the provider's medical records department or staff to release a patient's medical information pertaining to newborn screening in accordance with Minnesota Statutes §§144.125 to 144.128 and 144.966 without the patient's authorization, unless the patient's parent has elected in writing not to have the testing performed. This conclusion is based on review of the HIPAA privacy rule, available on the Web site of the U.S. Department of Health and Human Services (DHHS).¹

The medical information being released must be related to the screening. This may include, but is not limited to, personally identifiable information on the patient, information on tests conducted and results of tests conducted, and other pertinent information.

Analysis

HIPAA governs the use and disclosure of protected health information (PHI). It applies to health plans, health care clearinghouses, and health care providers who transmit certain health claims information electronically. These entities are **covered entities** under the rule.

¹U.S. Department of Health and Human Services. https://www.hhs.gov/hipaa/for-professionals/privacy/index.html

A covered entity must obtain a written authorization from the individual, for the use and disclosure of PHI unless the disclosure is to the individual for treatment, payment, or health care operations, or the disclosure falls under one of the specified exceptions.

The HIPAA privacy rule, specifically 45 CFR² §164.512, addresses the uses and disclosures of PHI for which an authorization or an opportunity to agree or object is not required. Specifically:

- Section 164.512(a) permits disclosures that are required by law, including statutes and rules³; and
- Section 164.512(b) permits a covered entity to disclose PHI to:
 - "(i) A public health authority that is **authorized by law to collect or receive** such information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; . . ."

Under the HIPAA privacy rule, 45 CFR 164.501, public health authority is defined as "an agency or authority of ... a State . . . that is responsible for public health matters as part of its official mandate."

Therefore, to the extent that a public health authority is authorized by law to collect or receive information for public health purposes, covered entities may disclose PHI to the public health authority without the patient's authorization.

Analysis Summary

In summary, Minnesota Statutes §§144.125 to 144.128 and 144.966 allow MDH to collect health information pertinent to newborn screening. Therefore, providers, their medical records departments, and their staff can share medical information pertaining to newborn screening without patient authorization.

For questions about this analysis, contact: Dave Orren MDH Chief Legal Counsel (651) 201-5742

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²CFR is the Code of Federal Regulations

³ 45 CFR 164.103, Definition of "Required by law."