

HIPAA and Newborn Screening

NEWBORN SCREENING AND LONGITUDINAL FOLLOW UP PROGRAMS

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 interacts 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.

Question

Does HIPAA permit disclosure of specific patient medical information related to newborn screening and follow-up information for cases of heritable and congenital disorders included on Minnesota's newborn screening panel to MDH and its contractors working on behalf of MDH (including local public health agencies) without patient authorization?

Answer

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 and related follow-up information for cases of heritable and congenital disorders identified by 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 or legal guardian has elected in writing not to have the testing performed. This conclusion is based on review of the HIPAA privacy rule, available on the website of the [U.S. Department of Health and Human Services \(www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html\)](http://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html).

The medical information being released must be related to newborn screening, diagnosis/identification, and management/medical interventions for cases of heritable and congenital disorders. This may include, but is not limited to, personally identifiable information on the patient, information on tests conducted and results of tests conducted, management/interventions, and other pertinent information

Rationale

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.

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 CFR §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 rules; 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.

Minnesota Statutes, sections 144.125 to 144.128, and 144.966, establish newborn screening programs for heritable and congenital disorders under the supervision of MDH. Under these statutes, MDH is required to collect, and health care providers are required to report to MDH, health information relating to newborn screening, diagnosis, and follow-up/interventions.

Summary

In summary, Minnesota Statutes §§144.125 to 144.128 and 144.966 allow MDH to collect health information pertinent to newborn screening and management for cases of heritable and congenital disorders identified by newborn screening. Therefore, HIPAA does not prevent health care providers, including their medical records departments and their staff, from sharing protected health information pertaining to newborn screening and follow-up for cases of heritable and congenital disorders identified by newborn screening with the following entities without patient authorization: MDH, contractors working on behalf of MDH, or local public agencies.

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To obtain this information in a different format, call the Newborn Screening Program: 651-201-5466.