Newborn Screening and HIPAA

This memo contains Minnesota Department of Health (MDH) analysis of the following issue related to the Health Insurance Portability and Accountability Act (HIPAA) and the sharing of newborn screening-related medical information:

How HIPAA Interacts with the Minnesota Maternal and Infant Health Rule and Minnesota Statutes §144.125 to §144.128.

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How HIPAA Interacts with Newborn Screening

Disclaimer of Legal Advice: The following is Minnesota Department of Health (MDH) analysis of how the Minnesota Maternal and Infant Health Rule, Parts 4615.0300 to 4615.0760, and Minnesota Statutes §144.125 to §144.128 interact with the Health Insurance Portability and Accountability Act (HIPAA, privacy rules, 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

The following question has been raised by some providers, their medical records departments, and their staff: Does HIPAA permit disclosure of specific patient medical information related to newborn screening to MDH or other local public health authorities 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 the Minnesota Maternal and Infant Health Rule¹, Parts 4615.0300 to 4615.0760, and Minnesota Statutes §144.125 to §144.128² without the patient’s authorization. This conclusion is based on review of HIPAA privacy rules and guidance from the U.S. Centers for Disease Control and Prevention (CDC) and U.S. Department of Health and Human Services (DHHS).³

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¹ Minnesota Rules, Chapter 4615.0200 to 4615.0760. http://www.revisor.leg.state.mn.us/areule/4615/
² Minnesota Statutes §144.125 to §144.128 were amended in 2003. The amendment begins on page 460 of a 758-page bill. To see these amendments, go to: http://www.revisor.leg.state.mn.us/spo/2003/H0006.1031.html then use the page and line numbers in the left margin to go to page 460, line 20.
The medical information being released must be related to newborn 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.

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.

HIPAA privacy rules, specifically 45 CFR\(^4\) §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;\(^5\) 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 HIPAA, 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 such public health authority without the patient’s authorization.

**Analysis Summary**

In summary, Minnesota Statutes §144.125 to §144.128, and the Minnesota Maternal and Infant Health Rule, Parts 4615.0300 to 4615.0760, allow MDH and local public health authorities 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.**

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*Minnesota Department of Health*

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\(^4\) CFR is the Code of Federal Regulations

\(^5\) 45 CFR 164.501, Definition of “Required by law.”