

Newborn Screening Program

HF3438 / SF3138

Newborn Screening Program

Approximately 73,000 infants are born in Minnesota each year. **Shortly after birth, infants are screened for 53 rare and serious medical conditions.** If not detected and treated early, these conditions can lead to chronic illness, physical disability, mental retardation, developmental problems, or infant death.

Minnesota's Newborn Screening Program assures that all babies have access to screening and that babies who have one of the conditions are linked quickly with needed care. **Diagnosis and treatment soon after birth can make the difference between life-long disability and healthy development.**

Background

There is a conflict between the newborn screening statute (M.S. § 144.125) and the genetic privacy statute (M.S. § 13.386). The genetic privacy statute was passed in 2006. It specifies that collection, storage, use, and dissemination of genetic information may be used only for the purposes to which an individual has provided written informed consent, and may only be stored for a period of time indicated in that consent.

Currently, M.S. § 144.125 **requires that all infants be tested** for rare and serious conditions.

However, **parents must be informed** that:

- They have the **right to decline to have the tests;**
- If they have their infants tested, **blood samples** used to perform testing **may be retained** by MDH – this explanation must include the benefits to retaining specimens; and
- They have the **right to have the tests and require that all blood samples** and records of test results be **destroyed within 24 months** of the testing.

Proposed Statutory Changes

The changes being proposed clarify the statutory interactions between the newborn screening statute and the genetic privacy statute. The Minnesota Department of Health wants to be able to better inform parents of their rights and to ensure that residual blood samples can be used to periodically revise the list of tests conducted, improve testing methods, and protect the public's health. Therefore, MDH proposes the following statutory amendments:

- **Clarify that M.S. §§ 144.125 to 144.128 govern** MDH's collection, storage, use, and dissemination of **genetic information and specimens for testing infants** for heritable and congenital disorders (**Lines 1.21 to 1.23**);
- **Clarify that residual samples and results may be used** for quality assurance, development of new test methods, and for the purposes of public health practice and related research (**Lines 2.23 to 2.27**);
- **Provide parents with additional options,** including the right to have the tests, but to decline to have the test results and samples used for newborn public health studies and related research (**Lines 2.10 to 2.13**);
- **Require MDH to provide parents with additional information** regarding what data may be collected as the result of testing and how samples and data will be stored and utilized (**Lines 2.3 to 2.27**); and
- **Require MDH to report to the Legislature** on efforts to ensure that parents of newborns are fully informed of rights and options regarding newborn screening (**Lines 2.28 to 2.34**).



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Use of Blood Samples in Newborn Screening Process

Blood samples obtained through newborn screening are used for three critical purposes:

1. Testing Infants

Small samples of blood collected from each newborn are applied to specialized cards, air dried, and then sent to MDH for screening. MDH partners with the Mayo Medical Laboratories to test these dried blood specimens using tandem mass spectrometry at Mayo's Biochemical Genetics Laboratory. The Mayo laboratory screens for 42 disorders and the MDH laboratory screens for 11 disorders. For children identified as having one of these disorders, confirmatory testing and specialty medical services are provided by the Mayo Clinic, Children's Hospital and Clinics of Minnesota or the University of Minnesota.

2. Quality Assurance and New NBS Tests

After all testing is completed, the residual dried blood specimen of each newborn is stored at MDH indefinitely, unless otherwise directed in writing by the child's parent. These stored blood specimens are used to perform the quality assurance and instrument calibration activities required by the federal Clinical Laboratory Improvement Act (CLIA) and for the evaluation of new screening tests to benefit newborns and their families.

3. Method Development and Public-Health Related Research

Residual dried blood specimens are used by MDH, in collaboration with the Mayo Clinic and the University of Minnesota to conduct research essential for the development of additional tests of importance to public health. Residual specimens could also be used for other research studies designed to answer questions of public health significance. Whenever the specimens are used in this way, **the following protections would be applied:**

- **Individual identifying information** associated with specimens **would be removed.**
- Researchers would be **prohibited from using specimens in any way that could identify** the individual who provided the specimen.
- **All research would be reviewed by an Institutional Review Board** that ensures that research **protocols provide all required protections**, including privacy protections.

Newborn Screening Advisory Committee

To ensure that the screening program meets the needs of Minnesota's parents, children, and physicians, the MDH program staff meets regularly with a broad-based Newborn Screening Advisory Committee established in statute.

- The Newborn Screening (NBS) Advisory Committee is made up of parents of affected children, primary care physicians, genetic and metabolic specialists, as well as advocacy groups such as the March of Dimes.
- The NBS Advisory Committee assists MDH in rulemaking by providing advice and guidance on proposed rules.

Questions or Comments?

If you have questions or comments about the Newborn Screening Program or this legislation, contact Mark McCann, manager of the Newborn Screening Program, at (651) 201-5450 or Mark.McCann@health.state.mn.us

Learn More

To learn more, visit our Newborn Screening Program Web site:
www.health.state.mn.us/newbornscreening