

Newborn Genetic Testing – Year-by-Year History

Original 1965 Legislation:

MS 144.78: Phenylketonuria; tests of infants for inborn metabolic errors causing mental retardation

Language: “It is the duty of (1) the administrative officer or other person in charge of each institution caring for infants 28 days or less of age and (2) the person required in pursuance of the provisions of Minnesota Statutes, Section 144.159, to register the birth of a child, to cause to have administered to every such infant or child in its or his care tests for phenylketonuria and other inborn errors of metabolism causing mental retardation in accordance with rules or regulations prescribed by the state board of health. Testing and the recording and reporting of the results of such tests shall be performed at such times and in such manner as may be prescribed by the state board of health. The provisions of this section shall not apply to any infant whose parents object thereto on the grounds that such tests and treatment conflict with their religious tenets and practices.”

Year	Legislative Action	Implications
1965	Enacted the first genetic testing statute for phenylketonuria (PKU) “and other inborn errors of metabolism causing mental retardation” Parents allowed to object to tests and treatment based on “religious tenets and practices.”	Government-imposed genetic testing - specific to mental retardation Most parents lose right to say no to medical procedures done on their children. Right to object based only on religion
1977	References to “board of health” repealed throughout MN statutes	Language changed to refer to “commissioner of health”
1981	Change of statutory reference within genetic testing statute: 144.159 becomes 144.215.	Reference to birth certificate/requirement to register births
1985	References to regulations become “rules”	The word “regulations” is deleted
1985 – first Special Session	New section (144.125) requires statewide “treatment control tests” without charge	Clarifies statewide requirement, and begins state-funded genetic testing
1985 – first Special Session	New section (144.128) requires commissioner to make arrangements for (fund) treatment if family is uninsured, maintain a state registry (database) of cases of PKU and other metabolic diseases for the purpose of follow-up services to prevent mental retardation, and adopt rules for implementing 144.126 and 144.128.	State-funded treatment for the uninsured. Government registry of those with positive findings Authority for details of implementation move away from legislature and into health department through rulemaking
1986	Minnesota statutes made gender neutral	--

1988	References to mental retardation eliminated from 144.125 (tests for inborn metabolic errors), testing for hemoglobinopathy required in 144.125, laboratory services fees charged for conducting tests, and commissioner required to consider 3 conditions prior to determining which tests to conduct on newborns: <ul style="list-style-type: none"> - Ability to detect metabolic errors - Ability to treat or prevent medical conditions - Severity of the medical conditions caused by metabolic error 	Testing broadened beyond mental retardation. “Hemoglobinopathy is a group of rare, inherited disorders involving abnormal structure of the hemoglobin molecule. These disorders include hemoglobin C disease, hemoglobin S-C disease, sickle cell anemia, and various types of thalassemia.” (Medline Plus, accessed 2/2006)
1991	References to mental retardation deleted from 144.126 (PKU testing program), required testing for hemoglobinopathy added to 144.126, and all references to “metabolic diseases” changed to “inborn errors of metabolism” in 144.126 (PKU testing) and 144.128 (treatment/registry).	Testing broadened beyond mental retardation in two sections apparently missed in 1988 (144.126 and 144.128).
1994	Right of parents to object for religious reasons stricken from law.	Parents lose all rights to protect their children from government-sponsored genetic testing, or unwanted medical/genetic tests as determined by government.
1997	Health Department to add the cost of implementing and maintaining a system to follow-up on infants with inborn metabolic errors to laboratory service fees. Slight change of terminology. From “inborn errors of metabolism” to “inborn metabolic errors”	Cost of testing increases to fund government follow-up of newborns that test positive for tested conditions.
1997	Midwives required to arrange testing...and language specifying PKU and hemoglobinopathy is repealed	Broadening the types of professionals required to arrange testing to include those who may provide services to parents who choose home births...and broadening the array of possible tests.
2003 – first Special Session	All references to “metabolic errors” removed and replaced by “heritable and congenital disorders.” Laboratory Service fee set at \$61. Health Commissioner authorized to expand and	Title/references better signify genetic testing Little public input, notification, or knowledge of the genetic testing decisions.

	<p>revise the list of tests without public comment. The revision is exempt from rulemaking requirements.</p> <p>Advisory Committee to the Commissioner is established established.</p> <p>Health Department officials must share test results with each child’s physician.</p> <p>Health Department must now make referrals, not “arrangements.”</p> <p>Registry must retain “cases of heritable and congenital disorders detected by the screening program.”</p> <p>Persons performing genetic tests must advise parents that the tests and tissue specimens may be retained by the health department, that there are benefits to retaining the specimens, and that they have a right to opt-out of testing, or to agree to testing but require that the tissue/tests be destroyed in 24 months.</p> <p>Parents who decline testing must do so in writing on a form that is signed by one parent/guardian and retained in the infant’s medical record.</p>	<p>22-member group (current #) allowed to push corporate, research and other genetic testing goals.</p> <p>Government communication with personal physician without parent consent. Test results added to medical record without parent consent.</p> <p>Appears to mean that State obligation to provide care once a disorder is found is eliminated.</p> <p>Registry becomes a database of genetic disorders. First statutory reference to the term “screening” despite program commonly being referred to as “newborn screening.”</p> <p>Parents must be advised of retention, and the possible benefits, but not the dangers, of retention.</p> <p>Opt-out provisions assume a government right to test unless parents take explicit and informed action. Opt-out provisions place the burden for protection of genetic privacy on new, often harried, and usually uninformed parents.</p> <p><i>There is no requirement that parents be told that this testing is genetic testing, that genetic counseling be provided for them, that they be told they have a right to private testing, or that private testing be made available to them.</i></p> <p>Language on MDH forms (including notary requirement) may cause parents to fear future legal or other repercussions for opting out.</p>
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