

ALJ Ruling: Newborn Screening Rule (MN)

Selected Excerpts from March 27, 2007 Ruling¹

“Defects” in MN Department of Health’s Proposed Newborn (Genetic) Screening Rule²

- **Failure to Give Parents a Tennesen Warning:**
(*Notice of State Government Collection and Use of Personal and Medical Data and Genetic Information in Newborn (Genetic) Testing Process and Parent Rights Related to that Collection and Use*)
 - **Judge Says:** “The Department’s contention that the Tennesen warning statute does not apply to the newborn screening program [is] *flawed*.” (pg 22). “The proposed rule’s failure to incorporate the [Tennesen] requirements...constitutes a *defect*.” (pg 23).*
 - **Advised Cure:** “[T]he warning *must be provided* to parents by the responsible parties”...[and] “[A]dditional language should be added...requiring that the Department provide language for responsible parties to use to fulfill this requirement.” (p. 23)
- **Failure to Obtain Parent Consent for Government Storage of Blood Specimens or Provision of Genetic Information (blood) to Researchers** (*Currently, DNA of 670,000 children in state databank³*):
 - **Judge Says:** “There is *no express authorization* in the newborn screening statute⁴ (*footnote added*) for the Department’s current practice of retaining the [genetic] information indefinitely without consent and permitting the [genetic] information to be used without consent for purposes other than the detection, treatment, and follow-up of heritable and congenital disorders as contemplated by the newborn screening statute...” (p. 25)
 - **Judge Says:** “[T]he newborn screening statute does not expressly authorize the Department to store genetic information indefinitely or disseminate that information to researchers without written informed consent provided by parents...the failure to incorporate [the government data practices 2006 genetic information law] requirements into [the rule] constitutes a *defect*...” (p. 26)
 - **Advised Cure:** “This defect may be cured by inserting a new item...with language similar to the following:...“require a parent who chooses not to elect to have the Department destroy the newborn infant’s blood sample and test results to sign a form provided by the Department which state the purposes for which the blood and test results will be used, including provision of the child’s blood or test results to outside entities for research purposes, and the period of time for which the blood and test results will be stored.”

* All italics to quotes added

¹ Selected quotes from OAH Docket No. 11-0900-17586-1; Governor’s Tracking No. AR 232. Minnesota Office of Administrative Hearings, March 27, 2007. **NOTE:** More defects are noted in Judge Barbara Neilsen’s ruling than are included in this handout.

² *Minnesota Rules, Chapter 4615 (MN Newborn Screening Rule).*

³ *St. Paul Pioneer Press*, April 11, 2007.

⁴ *Minnesota Statutes, Chapter 144.125 – 144.128 (MN Newborn Screening Law).*