

Testimony
Senate Bill 2334
Senate Human Services Committee
February 02, 2015; 9:00 a.m.
North Dakota Department of Health

Good morning Madam Chair and members of the Senate Human Services Committee. My name is Katie Bentz, Nurse Consultant for the Newborn Screening Program for the North Dakota Department of Health, Division of Family Health. I am here today to testify in support of Senate Bill 2334.

Newborn screening is a simple blood test that is performed on babies within the first few days of life. This test provides early detection of many disorders and diseases that may cause disability or even death if not treated early. Newborn screening has been listed as one of the ten great public health achievements during the 20th century, contributing to improvements in population health and increases in life expectancy. Newborn screening has been performed in North Dakota since 1964.

The purpose of SB 2334 is to update North Dakota's Century Code relating to the state's newborn screening program to reflect current and best practices. Following is an overview of the changes:

Section 1 of the bill proposes changes to Chapter 23-01-03.1 concerning newborn metabolic and genetic disease screening tests.

1. The language relating to research was removed from this section. A new section, Chapter 25-17-07, was added to define the Institutional Review Board's role in research (page 5, lines 24-27). Wording was also added to this section giving the health council authority to adopt rules relating to the storage, maintenance and disposal of blood spots. Reasons for retaining residual blood spot specimens include legal accountability (e.g., the existence of a sample and its adequate collection), future DNA testing as requested by the family, and reconfirmation of newborn screening results.
2. Language was added to this section that allows the health council to specify diseases screened for as selected by the state health officer and with input from an advisory committee. Currently, rules list specific diseases that are screened for. This change allows the health council to

specify diseases without changing rules every time a new disease is added to the screening panel.

Section 2 of the bill adds definitions to Chapter 25-17-00.1 to provide clarification and consistency of terms.

Section 3 of the bill proposes to change Chapter 25-17-01 concerning newborn screening education programs and tests.

- 1-3. Language was updated in these sections to provide consistency throughout the century code.
4. Language was added to give authority to the health department to select a screening laboratory. When newborn screening first started in 1964, the North Dakota State Laboratory performed the screening services. As more conditions were added to the screening panel, the state's lab was no longer able to provide these services due to the expense of the equipment required. In 1992, the Newborn Screening Program entered into a collaborative partnership with the State Hygienic Lab at the University of Iowa to process North Dakota's specimens. Iowa also processes South Dakota's newborn screening specimens. This collaboration between states is essential to allow access to current technology and to decrease the costs of the screening. In Section 6 of the bill, Chapter 25-17-05 (page 5, lines 5-10), language for the health council to set fees and for the department to collect fees has been removed to reflect this change.
5. Language was added to allow the department to store, maintain, and dispose of blood spot specimens as was previously discussed.

Section 4 of the bill proposes to change Chapter 25-17-02.1 concerning testing and reporting requirements. Several components of this section were listed in Section 25-17-04, which was repealed. The new section was added to more clearly identify the newborn screening process from testing to follow up and treatment.

1. Language was updated to more clearly define the role of the clinician and to outline the process for parent or guardian refusal.
2. The language in this section was updated to include the newly defined term of "responsible clinician."
3. Language was added to ensure the newborn screening specimens would be returned from the screening laboratory to the department. Reasons for retaining residual blood spot specimens were discussed with the changes to Section 1 and 3.

4. Language was added to outline the obligation of the responsible clinician in the event of an out-of-range screening result that would require further follow up. The language ensures that the newborn will be referred to a licensed clinician for proper medical follow up and treatment if necessary.
5. The language from this section is maintained from the original century code. The term “physician” has been updated to “licensed clinician.” This change was made to provide consistency in definitions.

Section 5 of the bill proposes to change Chapter 25-17-03 with regard to treatment for positive diagnosis and registry of cases.

1. Language was updated to reflect newly defined terms and to clarify the role of the responsible clinician in the event the newborn requires additional follow up care. This ensures that if further medical testing or treatment is required, the newborn will be referred to a licensed clinician for that care.
2. The term “qualified health care provider” has been updated to “licensed clinician.” This change was made to provide consistency in definitions.
3. The word “diseases” was added to provide consistency in definitions.

Section 6 of the bill proposes to change Chapter 25-17-05 regarding testing charges. Language for the health council to set fees and for the department to collect fees has been removed to reflect the change that the North Dakota Laboratory no longer processes the state’s newborn screening specimens. Language has been added to ensure that the testing laboratory selected by the department may charge fees for the necessary screening services.

Section 7 of the bill adds guardians to those who can object to critical congenital heart defect screening to provide consistency.

Section 8 of the bill creates a new section, NDCC 25-17-07, with the research provisions that were deleted from 23-01-03.1 in Section 1 of this bill. This new section provides language clarifying the process for research that may be conducted on the newborn screening blood spots or the data that is obtained from testing. This section ensures that any research request would go through an institutional review board and would require parent or guardian authorization.

Section 9 of the bill repeals Chapter 25-17-04 because these provisions are included in other sections.

An amendment to this bill is being suggested. On page 4, line 12, it states “confirmation-diagnostic” and should state “confirmatory-diagnostic” to align with the definition listed in Section 2.

Early identification from newborn screening and proper follow up can save a child’s life and prevent serious complications with early intervention and treatment. The changes proposed in this bill will reflect newborn screening current practices and provide additional clarity to North Dakota Century Code relating to the state’s newborn screening program.

This concludes my testimony. I am happy to answer any questions you may have.