

**Testimony**  
**Administrative Rules Committee**  
**Monday, March 14, 2016; 9:30 a.m.**  
**North Dakota Department of Health**

Good morning Chairman Devlin and members of the Administrative Rules Committee. My name is Joyal Meyer, Director 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 changes to the Administrative Rules found in Chapter 33-06-16.

- The revision of these rules resulted from changes made to the newborn screening laws in SB 2334 by the Legislative Assembly during the 2015 Legislative Session.
- The rules are not related to any federal statute or regulation.
- These rules were drafted with input from an advisory committee and department leadership. Public notice was given and a public hearing was held on September 3, 2015 with no attendees. The 10-day period for public comment following the hearing received no comments. The State Health Council adopted the rules on November 10, 2015.
- No comments, written or oral, were submitted to the department indicating any concern, objection, or complaint.
- The approximate cost of public notice, public hearing and development of these rules was \$1,866.00.
- The newborn screening program has previously had rules in place. The updates to these rules reflect changes in the North Dakota Century Code Section 23-01-03.1 and Chapter 25-17. Many of the previous rules were placed into law and no longer need to be stated within rule. Definitions have been updated to be consistent with those used within the law. Information on the process for using the specimens for research was removed as the process is now stated within the law. Rules defining storage of information and specimens used in the newborn screening process were updated to reflect the current practice of storage for eighteen years.
- No regulatory analysis was required as the proposed rules are not expected to have an impact on the regulated community in excess of \$50,000. Neither the Governor nor any member of the Legislative Assembly requested a regulatory analysis.
- A small entity regulatory analysis and small entity impact statement were both completed and copies have been provided.
- There is no fiscal effect on state revenues and expenditures for the adoption of these rules.

- No constitutional takings assessment was required because the rules do not limit the uses of real property.
- These rules were not adopted as emergency rules.

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

**My contact information:**

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**Small Entity Regulatory Analysis for Proposed Changes to Administrative Code 33-06-16 –  
Newborn Screening Program**

1. Was establishment of less stringent compliance or reporting requirements for small entities considered?

Less stringent reporting requirements were not considered. The proposed rules address uniform newborn screening testing and reporting requirements for the newborn screen as mandated in state law in Chapter 23-01-03 and Chapter 25-17.

2. Was establishment of less stringent schedules or deadlines for compliance or reporting requirements considered for small entities?

Less stringent schedules or deadlines are not applicable with these proposed rules. These proposed rules are in compliance with state law related to newborn screening, Chapter 23-01-03 and Chapter 28-17.

3. Was consolidation or simplification of compliance or reporting requirements for small entities considered?

Consolidation or simplification of compliance or reporting requirements was not applicable with these proposed rules.

4. Were performance standards established for small entities for replacement design or operational standards required in the proposed rule?

No changes in performance or operational standards were part of these proposed rules.

5. Was exemption of small entities from all or any part of the requirements in the proposed rule considered?

No exemption of small entities from any part of these rules was considered.

**Small Entity Economic Impact Statement for Changes to Administrative Code 33-06-16 –  
Newborn Screening Program**

1. Which small entities are subject to the proposed rule?

Any physician, physician assistant, nurse practitioner, midwife or birth attendant attending a newborn would be subject to these proposed rules.

2. What are the administrative and other costs required for compliance with the proposed rule?

There is no expected increase in the administrative costs required to comply with these proposed rules.

3. What is the probable cost and benefit to private persons and consumers who are affected by the proposed rule?

There are no probable costs to private persons and consumers. The probable benefit to private persons and consumers is to provide newborns with early identification and timely intervention to lead to a reduction in mortality, morbidity, and associated disabilities.

4. What is the probable effect of the proposed rule on state revenues?

There would be no effect on state revenues.

5. Are there any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule?

Less intrusive or less costly alternative methods were not found.