

**FISCAL NOTE**  
**Requested by Legislative Council**  
**01/23/2015**

Amendment to: SB 2334

- 1 A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2013-2015 Biennium		2015-2017 Biennium		2017-2019 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues						
Expenditures						
Appropriations						

- 1 B. **County, city, school district and township fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

	2013-2015 Biennium	2015-2017 Biennium	2017-2019 Biennium
Counties			
Cities			
School Districts			
Townships			

- 2 A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

This bill amends existing NDCC regarding the state's newborn screening program and adds a new section to NDCC regarding testing and reporting requirements.

- B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

This bill does not have a fiscal impact.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*

- A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*
- B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*
- C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation or a part of the appropriation is included in the executive budget or relates to a continuing appropriation.*

**Name:** Brenda M Weisz

**Agency:** Department of Health

**Telephone:** 328-4542

**Date Prepared:** 01/27/2015

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**2015 SENATE HUMAN SERVICES**

**SB 2334**

# 2015 SENATE STANDING COMMITTEE MINUTES

Human Services Committee  
Red River Room, State Capitol

SB 2334

2/2/2015

22941

- ☐ Subcommittee  
☐ Conference Committee

Committee Clerk Signature

*Donald Mueller*

## Explanation or reason for introduction of bill/resolution:

A bill relating to the state's newborn screening program.

## Minutes:

Attach #1: Testimony by Katie Bentz  
Attach #2: Proposed Amendment by Sen J. Lee

**Chairman Judy Lee**, District 13, introduced SB 2334 to the Senate Human Services Committee. Newborns have their heel pricked for blood and genetic testing, which may determine what genetic conditions might be present for those newborns. The Department of Health want to store these appropriately, it confirms the opportunities for families to opt out if they choose not to have screening. We have previously seen bills come through for PKU and Maple Syrup Urine disease (MSUD) both of which are a metabolic problem that interferes with the proper processing of food, and there can be a buildup of chemicals in the brain that causes mental retardation. By having the proper metabolic food, this condition is preventable. Our current law provides food for females up to the age of 42 in order to go past child bearing age, and the age 21 for men. Chairman Judy Lee will be providing an amendment so both young men and women the same opportunity to get this food.

**Katie Bentz**, Nurse Consultant for the Newborn Screening Program for North Dakota Department of Health, Division of Family Health testified IN FAVOR of SB 2334, and went through the language of the bill and changes. (attach #1) (5:00-14:27)

**Senator Warner** asked can you outline some of the issues relative to creating an identity; a traceable dealing with DNA research, where identity can be used by law enforcement or other agencies, where they may want to profile risk analysis growing to adulthood.

**Ms. Bentz** stated the blood spots that we store would hold the DNA and all the information attached to the blood spot card. We would be able to trace that specific child to that blood spot card. It would require authorization from parent, guardian or child themselves if they were close to the age of 18. Card is stored until someone is 18 years of age, and then destroyed.

**Senator Howard Anderson, Jr.** asked if we are going to do research on specific metabolic disease, key identified information may be made available through an algorithm versus individual personal information. There are research protocols. Senator Howard Anderson,

Jr. indicated that he wished we kept the blood spot cards forever as we may want to do more research later.

**Ms. Bentz** confirmed that is correct. If used for research, they are de-identified. Anything used by specific family where they would want access to that blood spot card, they would still have identifying information so it could be retrieved.

**Chairman Judy Lee** stated that we hear occasionally about people who have been adopted, who want to know about their medical history, and family records are not open. If there is a medical condition that they might be concerned, they could request, even as an adult, some testing could be done to see if there is some genetic pre-disposition to a condition. Correct?

**Ms. Bentz** replied correct, up to the age 18, because we destroy them at that time. Any information related to newborn screening or any medical information would require a court order, including for the child themselves.

**Chairman Judy Lee** agrees that she supports the privacy issue. But with research being done, there may be some opportunities for limited number of people to be able to benefit from that who's other doors might be closed in other ways, such as adoption.

**Ms. Bentz** confirmed, through the age of 18.

**Chairman Judy Lee** even for children if nothing shows up in the initial testing, the possibility that this child might be 6 or 7 years old, and there is some health issue, maybe it will be possible to go back to that blood spot to see if there is something genetic that might have contributed to the new health issue because the discovery is more easily done with new testing than when the child was first screened.

**Ms. Bentz** confirmed; the family would have access up to the age of 18 for additional testing if needed.

**Senator Dever** in looking at the 3<sup>rd</sup> paragraph of testimony, does this require providers to do anything different?

**Ms. Bentz** indicated that there is no change for providers. The changes in bill are to update in how we currently operating, best practice. The language has not been updated in many years.

**Senator Dever** asked if the department is using an out-of-state laboratory to process these, is that only for processing, so the storage of the samples come back to the Department of Health?

**Ms. Bentz** answered the storage is at the Department of Health in North Dakota, and the data is stored also at the Department of Health.

OPPOSED to SB 2334  
No opposing testimony

NEUTRAL to SB 2334  
No Neutral testimony

Closed Public Hearing.

**Chairman Judy Lee** discussed the proposed amendment 15.0979.01001, (attach #2), that discusses the inclusion of males up to the age of 42.

**Senator Howard Anderson, Jr.** asked if we add this amendment, these metabolic foods are expensive, are we looking at assessment of how many we are buying for now versus future if we adopt the bill, and do we have any information on whether the lack of those food affects the male reproductive process? There are differences between men and women, Senator Howard Anderson, Jr. would like some information on that.

**Tammy Galopplem**, Department of Health, Children Special Health Services Division, provided further information. We looked at compiling list of males since the metabolic food program began administration from the Department. This started that in 2001. The numbers projected is not all males that will be in the age group, but what we are aware of. There are currently 9 individuals, 8 with PKU, and 1 with MSUD that would potentially benefit from the expanded program. Based on the metabolic formula, it would require \$146,392 to serve that population for the 2015-2017 biennium. We would have an additional age-off for the 2017-2019 biennium so it would increase again when looking at the projections.

**Chairman Judy Lee** asked if we can get the fiscal note with that, recognizing that we have not adopted the amendment at this point.

**Tammy** indicated she could send email.

**Senator Howard Anderson, Jr.** asked do we have any research information about the effect on the reproductive abilities of males related to not having the right food.

**Tammy Johnson**, Department of Health, Program Administrator for Children's Special Health Services, spoke. They provide the metabolic clinics. She had the opportunity to speak with Dr. Alan Kenyan, the physician who oversees the clinic in Fargo, he indicated that there is no implication to the male in their reproductive life.

**Senator Warner** stated the funding used to come from a very specific maternal and child health grant. Is funding more generalized now?

**Tammy** from Department of Health confirmed that it is through the maternal health block grant which is federal with matching state funds.

**Senator Warner** asked if there were limitations providing service to males, because of the funding stream.



**Tammy** answered generally we look at our maternal health population, children with special health care needs, which is usually birth to age 21, and then we look at our partnership through the entire block grant, we look at women through child bearing age. We also look at families, so this would be part of that.

**Senator Warner** asked if this is an adjustment to the funds? Is there money within the grant to cover the males?

**Tammy** indicated the block grant has finite money allocated, so that they would have to forego something else to fund this.

**Senator Warner** asked what goes? What is prioritized as lesser importance?

**Tammy** we would have to do an evaluation of that. \$150,000 would be significant. The \$150,000 would be utilized within the programs current budget, the other \$150,000 would have to be foregone unless there are funds that are appropriated for the other programs.

**Senator Warner** asked what else is covered in the grant.

**Tammy** indicated a variety of direct service programs within the division. They do their specialty care program, where we pay for care for eligible children which is for underinsured children. We do variety of multi-disciplinary clinics, some we manage ourselves and some we contract. Example is clinics for children with autism, clinics for children with spinal bifida, very complex disorders that need multiple different specialties altogether at one place at one time to help coordinate that care. They do some case management care coordination services to help families get linked up to needs. They support health family information and family support activities. It is a wide variety of programs.

**Chairman Judy Lee** spoke about prior year discussion, where it would be covered by insurance. The 8 PKU individuals and 1 MSUD apparently don't have private insurance coverage?

**Tammy** indicated she does not know if insurance is paying.

**Chairman Judy Lee** stated part of the discussion previously was is it fair for insurance companies to pay for the ones they insure and the state to pay for the rest, but we hear that in this committee often.

# 2015 SENATE STANDING COMMITTEE MINUTES

## Human Services Committee Red River Room, State Capitol

SB 2334  
2/3/2015  
23142

- ☐ Subcommittee  
☐ Conference Committee

Committee Clerk Signature

*Donald Myrland*

### Explanation or reason for introduction of bill/resolution:

A bill relating to the state's newborn screening program.

### Minutes:

Attach #1: Draft Bill with Proposed Amendment  
Attach #2: Phenylketonuria Information  
Attach #3: Letter from Tamara Gallup Leim

Chairman Judy Lee reviewed the original bill, about newborn screening. There was a small word change, to confirmatory. Small change on page 5, line 24. Femi provided proposed amendment language changes that was previously discussed. (attach #1). Chairman Judy Lee then read an email from the **Tamara Gallup Leim**, Division Director of Children's Special Health Services, North Dakota Department of Health. (attach #3) (6:40)

**Senator Warner** Wasn't part of the hangup is that we wouldn't cover it because it considered a drug? **Chairman Judy Lee** answered Blue Cross Blue Shield are covering it but other companies are not, so that is the rub.

(7:25)

**Senator Howard Anderson, Jr.** when reading suggestions including amendment to age of 45, it brings into new light the argument of down syndrome children we discussed the other day. Here we had genetic diseases, and we are considering paying for the up to the age of 45, but telling down syndrome people that we don't want to treat them differently. **Chairman Judy Lee** stated we need to consider consistency. **Senator Howard Anderson, Jr.** stated going to 45 is just an accommodation to pay people for food that they have to pay for themselves otherwise. Can't make good sense for public health issue relative to reproductive.

**Chairman Judy Lee** said it was important to bring to committee for discussion. But she understands the consistent message. She provided information she received regarding Phenylketonuria (attach #2)

In the proposed amendment, top of page 5, confirmatory word is corrected. Institutional review board is the other correction. Those changes are made and no other changes.

**Senator Howard Anderson, Jr.** made a motion to ADOPT AMENDMENT to SB 2334 regarding the correction in the word "confirmatory" and "Institutional Review Board". The motion was seconded by **Senator Dever**. No discussion.

Roll Call Vote to Amend SB 2334 for Grammatical Changes  
6 Yes, 0 No, 0 Absent. Motion passed.

**Senator Warner** made a motion to ADOPT AMENDMENT for the balance of the amendment, provisions for the funding and to include males. The motion was passed by **Senator Axness**.

Discussion

**Chairman Judy Lee** this would be \$17,000 per per person, which would be a lot of money for a 21 year old to absorb. She also asked if these people were on their parent's health insurance because they would be eligible up to the age 26, and whether their insurance covered it, and she has not heard a response.

Roll Call Vote to Amend SB 2334 for Balance of the Amendment  
3 Yes, 3 No, 0 Absent. Motion fails.

Vote is 3-3. Bill fails.

**Senator Dever** newborn screening is purpose of bill.

**Senator Howard Anderson, Jr.** made a DO PASS as Amended, and it does not need to be re-referred to Appropriations because we have removed the funding. The motion was seconded by **Senator Warner**. No discussion.

Roll Call Vote to DO PASS as Amended  
6 Yes, 0 No, 0 Absent. Motion passes.

**Senator Howard Anderson, Jr.** will carry SB 2334 to the floor.

February 3, 2015

TV  
2/4/15

PROPOSED AMENDMENTS TO SENATE BILL NO. 2334

Page 4, line 12, replace "confirmation-diagnostic" with "confirmatory-diagnostic"

Page 5, line 24, replace "Institution" with "Institutional"

Renumber accordingly

Date: 02/03 2015  
Roll Call Vote #: 1

2015 SENATE STANDING COMMITTEE  
ROLL CALL VOTES  
BILL/RESOLUTION NO. SB 2334

Senate Human Services

Committee

☐ Subcommittee

Amendment LC# or Description: Correct words, grammatical fixes

Recommendation: ☒ Adopt Amendment

☐ Do Pass

☐ Do Not Pass

☐ Without Committee Recommendation

☐ As Amended

☐ Rerefer to Appropriations

☐ Place on Consent Calendar

Other Actions:

☐ Reconsider

☐

Motion Made By

Anderson

Seconded By

Dever

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee (Chairman)	✓		Senator Tyler Axness	✓	
Senator Oley Larson (V-Chair)	✓		Senator John M. Warner	✓	
Senator Howard C. Anderson, Jr.	✓				
Senator Dick Dever	✓				

Total (Yes) 6 No 0

Absent 0

Floor Assignment \_\_\_\_\_

If the vote is on an amendment, briefly indicate intent:



Date: 02/03 2015  
Roll Call Vote #: 2

2015 SENATE STANDING COMMITTEE  
ROLL CALL VOTES  
BILL/RESOLUTION NO. SB 2334

Senate	<u>Human Services</u>	Committee
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☐ Subcommittee

Amendment LC# or Description: balance of bill, which includes male

Recommendation: ☒ Adopt Amendment

☐ Do Pass      ☐ Do Not Pass      ☐ Without Committee Recommendation

☐ As Amended      ☐ Rerefer to Appropriations

☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐

Motion Made By Warner Seconded By Arness

[illegible]

Total (Yes) 3 No 3

Absent 0

## Floor Assignment

If the vote is on an amendment, briefly indicate intent:

Date: 02/03 2015  
Roll Call Vote #: 3

**2015 SENATE STANDING COMMITTEE**  
**ROLL CALL VOTES**  
BILL/RESOLUTION NO. SB 2334

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: 15.0979.01002 Title 02000

Recommendation: ☐ Adopt Amendment  
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation  
☒ As Amended ☐ Rerefer to Appropriations  
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ \_\_\_\_\_

Motion Made By Anderson Seconded By Warner

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee (Chairman)	✓		Senator Tyler Axness	✓	
Senator Oley Larson (V-Chair)	✓		Senator John M. Warner	✓	
Senator Howard C. Anderson, Jr.	✓				
Senator Dick Dever	✓				

Total (Yes) 6 No 0

Absent 0

Floor Assignment Anderson

If the vote is on an amendment, briefly indicate intent:

**REPORT OF STANDING COMMITTEE**

**SB 2334:** Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2334 was placed on the Sixth order on the calendar.

Page 4, line 12, replace "confirmation-diagnostic" with "confirmatory-diagnostic"

Page 5, line 24, replace "Institution" with "Institutional"

Renumber accordingly



**2015 HOUSE HUMAN SERVICES**

**SB 2334**

# 2015 HOUSE STANDING COMMITTEE MINUTES

**Human Services Committee**  
Fort Union Room, State Capitol

SB 2334  
3/18/2015  
March 18, 2015

☐ Subcommittee  
☐ Conference Committee

Committee Clerk Signature

*Vicky Crabtree*

## Explanation or reason for introduction of bill/resolution:

Relating to the State's newborn screening program.

## Minutes:

Testimony 1

Chairman Weisz opened the hearing on SB 2334.

Sen. Judy Lee: From District 13 introduced and supported the bill. I was asked to participate in this and the Dept. of Health and the folks involved directly with the new born screening in the Health Dept. This is moving a program forward that is extremely important. Sometimes people close to us benefit from this as well. This update information about many definitions and how they are appropriately stored and going to be taken care of. If the parents chose not to have it done then it isn't. The parents are kept informed about the storage process. On page 4, on line 12 we added, "confirmatory diagnostic" and on page 5 on the last section it should have been "institutional". I encourage your favorable review.

4:08

Joyal Meyer: Director for the Newborn Screen Program for the ND Dept. of Health testified in support of the bill. (See Testimony #1)

12:15

Rep. Porter: The terms clinicians that you put in, I thought naturopaths had the ability to order lab tests and I don't see them included in your list of clinicians.

Meyer: We didn't add that. I can do further research on this if you like.

Rep. Porter: Yes.

NO OPPOSITION

Chairman Weisz closed the hearing on SB 2334.


# 2015 HOUSE STANDING COMMITTEE MINUTES

## Human Services Committee Fort Union Room, State Capitol

SB 2334  
3/24/2015  
25336

☐ Subcommittee  
☐ Conference Committee

Committee Clerk Signature



**Minutes:**

See Handout #1

**Chairman Weisz** took up SB 2334.

**Rep. Porter:** Handed out an amendment (See Handout #1). The component I was looking at dealt with naturopaths and their licensure and their ability. They already have the ability to order tests and to do what this mandate is asking to be done with regards to the newborn screenings. If they are the practitioner then they also need to be part of the mandatory list of practitioners inside of page two lines six and seven. On page two line 23 it also talks about a responsible clinician. When we specifically list people we have to specifically list everyone. When we don't specifically list and say your scope of practice includes this then you are one of these. In this particular bill we still are listing individually so my intent of this amendment is to make sure our list was complete.

**Chairman Weisz:** They are okay with naturopath?

**Rep. Porter:** They were okay in one area but Dr. Dwelle had an issue with the component of treatment not of the testing. Inside of section five is where it talks about the treatment of the diseases and the responsibility of the clinicians but that isn't part of this.

**Chairman Weisz:** You're not adding it into line six?

**Rep. Porter:** In one sense it does because we're changing the definition. To me it's directing the person to get the most appropriate treatment for the follow up care of the child.

**Chairman Weisz:** But they would be considered the responsible clinician by definition.

**Rep. Porter:** Under the current law they are able to order tests. Part of their specific role inside the practice of medicine is metabolic type situations. If you have an out of home delivery and that person's primary practitioner is a naturopath and the midwife is part of it and the test results are out of range we want to make sure that we encompass all of the clinicians that could potentially have an effect on the ordering or the treatment of that child with that disease. Some of them are long term type diseases where a day or week isn't

critical but for some that's the difference between whether or not you have fixed it or not. That was the basis for the amendment.

**Rep. Oversen:** If someone lives in Grand Forks and has their child in East Grand Forks can they still register that birth in the state of North Dakota?

**Rep. Porter:** If they had the birth in East Grand Forks then it was an out of hospital birth because there's no hospital in East Grand Forks.

**Rep. Oversen:** Fargo-Moorhead then.

**Rep. Porter:** Same scenario, there's no hospital in Moorhead.

**Rep. Oversen:** In a scenario where they might have their baby over state lines can they register with the Department of Health?

**Rep. Porter:** Our mandates protesting do not go across state lines so it would be whatever Minnesota's mandates are for metabolic screening or any of the other tests. Some of the other tests we require not everybody across the country had a mandate that said you had to do those certain tests. This bill is good only for the inside of North Dakota.

**Rep. Oversen:** Could I defer that question to the Department of Health?

**Kim Mertz, Division of Department of Health.** A Minnesota baby born in North Dakota would receive the North Dakota panel. If they go back into Minnesota and received treatment then our newborn screening staff would work with Minnesota to make sure that baby gets appropriate care.

**Rep. Oversen:** (Inaudible as microphone was not on.)

**Kim Mertz:** It would be the same way. All states have different requirements. North Dakota does a good job; we are currently screening for 48 different conditions.

**Rep. Fehr:** Does the health council review the handling of metabolic diseases periodically? What are the screenings going to be? What is true today may be different five years from now?

**Kim Mertz:** There is a national newborn screening committee and they look at all the different conditions and if they think that would be a condition the state should consider adding to their panel. We follow those national recommendations because it's a committee of experts from throughout the nation that is looking at that. When a new condition gets added to that national panel then we bring it back to our newborn screening advisory committee and look to them for recommendations to add that condition to our panel. It's a very complex process with a lot of thought that goes into that. We work very closely with the newborn screening panel with the state health council to have that approval and with our state health officer. Once we determine we're going to add a condition there is a significant amount of work that goes into that. The challenging part of adding a condition is

the system; you have to make sure you have all the appropriate follow-up, the referral, specialized physicians in the state, or where we're going to send them.

**Rep. Fehr:** Given the national recommendations I would presume that the states would all be fairly similar because of the national recommendations.

**Kim Mertz:** It depends on the capacity of the state. All states are really doing their best to screen for as many conditions as they have. Newborn screening is complex and it requires very specialized equipment. The state has to be sure they are partnering with another state like we do or they have the capability to do that.

**Chairman Weisz:** Have you seen the suggested minutes?

**Kim Mertz:** I have. We feel very strongly that adding naturopaths to the responsible clinician is where that should be and not into the licensed provider.

**Rep. Porter:** I respect the department's position, but I disagree with them. I think the naturopaths are fully capable to be under the licensing. It's always the same arguments of who is qualified and who isn't. When I looked through their scope of practice inside of their board structure they fit. Once you start listing individual practices then you always run the risk of missing someone that we've fully licensed and vetted out saying they are safe for the public. **I move the amendment.**

**Rep. Fehr: Second.**

**Chairman Weisz:** You're looking up their scope?

**Rep. Porter:** I am.

**Chairman Weisz:** Under the definition a midwife is considered a responsible clinician but we don't want to add naturopath as a responsible clinician.

**Rep. Porter:** Inside of the scope of practice it says a naturopath may perform or order diagnostic purposes of physical or official examination, ultrasound, phlebotomy, clinical laboratory tests, etc. The clinical laboratory tests is this and that's where I looked at it and said we're saying that it's okay for them to do it but on the other hand we're saying that they are not a mandatory person in ordering the test.

**Chairman Weisz:** The language in the bill even includes the birth attendants that are a responsible clinician. I am confused on why we don't want the naturopath; they would be lesser than a birth attendant?

**Rep. Porter:** I'm not going to get in the argument of who is qualified and who isn't; I'm telling you that in their scope of practice we have given them this ability.

**Chairman Weisz:** In the language of the bill they say a birth attendant is a responsible clinician. In section five that means a birth attendant would be a person to notify.

**Rep. Porter:** Where are you seeing the birth attendant?

**Chairman Weisz:** On line 23. We defined a responsible clinician as a licensed clinician, midwife, or birth attendant. Then in section five it says if the responsible clinician is not a licensed clinician then it shall refer to a licensed clinician for appropriate follow-up. We make them someone for the health department to notify. Why would you notify a birth attendant?

**Rep. Becker:** At the end of the day if the committee feels that it meets all the requirements in the bill that would authorize this based on that but there is a different opinion from the Department of Health, who has jurisdiction?

**Chairman Weisz:** We do. Kim, can you explain why you're okay with birth attendant and not naturopath?

**Kim Mertz:** We do recognize a naturopath as a clinician that may be a birth attendant or caring for an infant. We had no concerns with putting the naturopath under responsible clinician because if it's a naturopath, a birth attendant, or a midwife that's attending a birth they can order the newborn screen. But, we don't want the naturopath put under licensed clinician.

**Chairman Weisz:** Earlier you said you didn't want them as responsible clinician or did I misunderstand?

**Kim Mertz:** We are fine with putting them under responsible clinician which is on line 10 of page two. We would not like to see them put under licensed clinician which is on line six and seven of page two. Those responsible clinicians we know are attending births and ordering labs and that is very appropriate. Once they have been diagnosed with a newborn condition they are extremely ill infants that require very specialized care. Dr. Dwelle feels very strongly that limiting the licensed clinician to the physician, physician assistant, or advanced practice nurse is really giving the best quality of care to that newborn.

**Chairman Weisz:** They are a licensed clinician.

**Kim Mertz:** There are lots of licensed clinicians; chiropractors, physical therapists, and so on. Because of the nature of the illness, disease, and condition these babies have it takes very specialized care with a lot of knowledge and skills dedicated to this and that's why we're trying to limit who the licensed clinician is in this case.

**Rep. Mooney:** You would like to see naturopaths on line 23 of page two and not included in line six of page two?

**Kim Mertz:** Yes. We would not like to see naturopaths added on line six page two.

**Rep. Mooney:** But line 23 is okay?

**Kim Mertz:** Yes, line 23 is fine.

**Rep. Fehr:** On page three line four and page three line 30 there are some references to licensed clinicians and I'm assuming that's what you're talking about.

**Kim Mertz:** That is saying the responsible clinician can cause the newborn to be subjected to the appropriate clinical follow up which means if they are attending a birth and ordering a test once they get the results back then it's their responsibility to refer that to the licensed clinician. That licensed clinician is the one with the specialty and the expertise to then make sure that baby receives the specialized care that they need. By putting naturopaths in under responsible clinician that is very true because they could be the one ordering the test but then the responsibility is to refer on to a licensed clinician.

**Rep. Fehr:** I was just making sure that we were talking the same thing and what you were saying relates directly to this.

**Rep. Porter:** It's getting into the he said she said of who can do what inside of that practice. You have a doctorate level trained naturopath that does a residency and has a specialty inside of metabolic disorders then you have a master's trained nurse that is the licensed clinician so the fight is the same traditional medicine fight we hear as these things are approved. They are licensed and they fit the bill. In the bill, whether you agree or disagree, when you look at the licensing provisions of a naturopath they fit the definition of a licensed clinician. If it exceeds their scope of training and they still try to do something of what is being presented then it's malpractice. The amendment as presented is only saying that we as a state have already had that fight and recognized the fact that they are that level.

**Chairman Weisz:** But your amendment doesn't bring naturopaths in.

**Rep. Porter:** It puts them in the licensed clinician part.

**Chairman Weisz:** Where?

**Rep. Porter:** On page two line six.

**Chairman Weisz:** It just says licensed by the North Dakota Board of Medical Examiners.

**Rep. Porter:** That was the part that wasn't in there. This is the health department amendment.

**Chairman Weisz:** Let's take up this amendment first. This adds naturopath as a responsible clinician and clarifies on lines six and seven that they are licensed by their respective boards that are already there.

**Voice vote: Motion carries to adopt the amendment.**

**Rep. Porter:** Whether you agree or disagree with the addition of the word naturopath on line seven I can tell you that inside of their scope of practice they qualify. They are doctorate level practitioners working inside of hospitals and private clinics so now you can't say they can't do something that their board says they can do in another section of the law.

**Chairman Weisz:** We decided a master's degree program was good enough.

**Rep. Porter:** All I'm saying is that as we did that we have allowed it. When you start listing individuals then can you trump existing practices by leaving them out? **Made a motion to further amend on line seven after the word "nurse" add "naturopath."**

**Chairman Weisz:** And licensed by the North Dakota.

**Rep. Porter:** It certainly would be in proper form to say "licensed by the Board of Naturopaths."

**Rep. Becker: Seconded.**

**Rep. Oversen:** I'm concerned about the amendment. The definition of naturopathic healthcare in code says it promote or restore health by the support and stimulation of the individuals inherent self-healing process which is accomplished through education of the patient by a naturopath through the use of natural therapies and therapeutic substances. We are talking about a self-healing process and education of the patient so I don't see how that is possibly going to work for a genetic condition of an infant. I agree that they should practice in the scope of medicine but I think this seems to exceed what a naturopath would be practicing. Genetic and metabolic conditions aren't likely going to be healed by a self-healing process. I'm going to oppose the amendment.

**Rep. Fehr:** On your amendment if you're putting them under licenses clinician then I would think you would remove them from line 22 because licenses clinicians are already mentioned there so you wouldn't need to add them in again.

**Chairman Weisz:** If you want to amend your motion because if the motion passes it would come on and if it doesn't it would stay as a responsible clinician.

**Rep. Porter:** I would certainly amend it to do that.

**Roll call vote on the amendment: 12 yes 1 no 0 absent**

**Motion carries.**

**Rep. Porter:** Made a motion for a do pass as amended.

**Rep. Anderson: Second.**

**Roll call vote: 13 yes 0 no 0 absent**

**Rep. Muscha will carry this bill.**



PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL No. 2334

Page 2, line 6, replace the first comma with "or"

Page 2, line 6, after "assistant," insert "licensed by the North Dakota Board of Medical Examiners,"

Page 2, line 7, after nurse insert "licensed by the North Dakota Board of Nursing"

Page 2, line 23, after "midwife," insert "naturopath,"

Renumber Accordingly

SLL  
3/24/15

March 24, 2015

PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL NO. 2334

Page 2, line 6, replace the first underscored comma with "or"

Page 2, line 6, replace ", or" with "licensed by the state board of medical examiners,"

Page 2, line 7, after "nurse" insert "licensed by the state board of nursing, or naturopath  
licensed by the state board of integrative health care"

Renumber accordingly

Date: 3-24-15  
Roll Call Vote #: 1

2015 HOUSE STANDING COMMITTEE  
ROLL CALL VOTES  
BILL/RESOLUTION NO. 2334

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description: See description below

Recommendation: ☒ Adopt Amendment  
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation  
☐ As Amended ☐ Rerefer to Appropriations  
☐ Place on Consent Calendar  
Other Actions: ☐ Reconsider ☐ \_\_\_\_\_

Motion Made By Rep. Porter Seconded By Rep. Fehr

Representatives	Yes	No	Representatives	Yes	No
Chairman Weisz			Rep. Mooney		
Vice-Chair Hofstad			Rep. Muscha		
Rep. Bert Anderson			Rep. Oversen		
Rep. Dick Anderson					
Rep. Rich S. Becker					
Rep. Damschen					
Rep. Fehr					
Rep. Kiefert					
Rep. Porter					
Rep. Seibel					

Total (Yes) \_\_\_\_\_ No \_\_\_\_\_

Absent \_\_\_\_\_

Floor Assignment \_\_\_\_\_

If the vote is on an amendment, briefly indicate intent:

Page 2, line 6, replace the first comma with "or"

Page 2, line 6, after "assistant," insert "licensed by the North Dakota Board of Medical  
Examiners."

Page 2, line 7, after nurse insert "licensed by the North Dakota Board of Nursing"

Page 2, line 23, after "midwife," insert "naturopath."

Date: 3-24-15  
Roll Call Vote #: 2

2015 HOUSE STANDING COMMITTEE  
ROLL CALL VOTES  
BILL/RESOLUTION NO. 2334

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description: \_\_\_\_\_

Recommendation: Further amend  
☒ Adopt Amendment  
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation  
☐ As Amended ☐ Rerefer to Appropriations  
☐ Place on Consent Calendar  
Other Actions: ☐ Reconsider ☐ \_\_\_\_\_

Motion Made By Rep. Porter Seconded By Rep. Rich Becker

Representatives	Yes	No	Representatives	Yes	No
Chairman Weisz	✓		Rep. Mooney	✓	
Vice-Chair Hofstad	✓		Rep. Muscha	✓	
Rep. Bert Anderson	✓		Rep. Oversen		✓
Rep. Dick Anderson	✓				
Rep. Rich S. Becker	✓				
Rep. Damschen	✓				
Rep. Fehr	✓				
Rep. Kiefert	✓				
Rep. Porter	✓				
Rep. Seibel	✓				

Total (Yes) 12 No 1

Absent 0

Floor Assignment \_\_\_\_\_

If the vote is on an amendment, briefly indicate intent:

on line 7 after the word "nurse" add  
"naturopath licensed by the  
Board of Naturopaths"

Date: 3-24-15  
Roll Call Vote #: 3

2015 HOUSE STANDING COMMITTEE  
ROLL CALL VOTES  
BILL/RESOLUTION NO. 2334

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description: 15.0979.02001

Recommendation: ☐ Adopt Amendment  
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation  
☒ As Amended ☐ Rerefer to Appropriations  
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ \_\_\_\_\_

Motion Made By Rep. Porter Seconded By Rep. D. Anderson

Representatives	Yes	No	Representatives	Yes	No
Chairman Weisz	✓		Rep. Mooney	✓	
Vice-Chair Hofstad	✓		Rep. Muscha	✓	
Rep. Bert Anderson	✓		Rep. Oversen	✓	
Rep. Dick Anderson	✓				
Rep. Rich S. Becker	✓				
Rep. Damschen	✓				
Rep. Fehr	✓				
Rep. Kiefert	✓				
Rep. Porter	✓				
Rep. Seibel	✓				

Total (Yes) 13 No 0

Absent 0

Floor Assignment Rep. Muscha

If the vote is on an amendment, briefly indicate intent:

**REPORT OF STANDING COMMITTEE**

**SB 2334, as engrossed: Human Services Committee (Rep. Weisz, Chairman)**  
recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends  
**DO PASS** (13 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed SB 2334  
was placed on the Sixth order on the calendar.

Page 2, line 6, replace the first underscored comma with "or"

Page 2, line 6, replace ", or" with "licensed by the state board of medical examiners."

Page 2, line 7, after "nurse" insert "licensed by the state board of nursing, or naturopath  
licensed by the state board of integrative health care"

Renumber accordingly

**2015 CONFERENCE COMMITTEE**

**SB 2334**

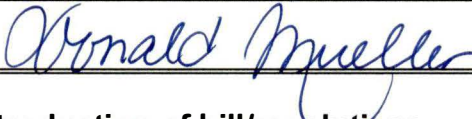
# 2015 SENATE STANDING COMMITTEE MINUTES

Human Services Committee  
Red River Room, State Capitol

SB 2334  
4/7/2015  
25876

☐ Subcommittee  
☒ Conference Committee

Committee Clerk Signature



## Explanation or reason for introduction of bill/resolution:

A bill relating to the state's newborn screening program.

## Minutes:

No attachments

The following conference committee members were present for SB 2334 on April 7, 2015, 3:00 p.m.

Senator Howard Anderson, Jr., Senator Lee, Senator Warner  
Representative Porter, Representative Rich Becker, Representative Mooney

**Senator Howard Anderson, Jr.** asked the House to explain the amendments and why they did them.

**Representative Porter** indicated we had actually a lot of discussion on this particular bill. It centered a lot around the context of licensed clinician, page 2, line 6.

**Senator Howard Anderson, Jr.** stated in addition to the the responsible clinician - page 2, line 25, sub 10.

**Representative Porter** indicated the green is the amendment of the House. So as we were looking at this, the House was looking at the screening process over, and looking at scopes of practices and the House human services committee felt the scope of practice inside of the doctors of naturopaths fit under the licensed clinician. That didn't come without objection. The objection was that it was felt by others that it should fit better under the responsible clinician component of the bill. After going through the naturopath bill in the House last week, the spot where this best fits is up in the air. The naturopaths, scope of practice - (read their scope of practice) - the majority of House human services committee felt that it did fit the license clinician definition. Representative Porter expressed his frustration with the turf battles and would just assume take physician, physician assistant, advanced practice nurse completely out of the bill. Then replace that a licensed clinician means anyone who's scope of practice allows them to be considered to be a licensed clinician inside of the bill. He voiced his frustration with the turf battles. The last physician who talked to him after the naturopath bill told him that the next quacks that we allow to



take part of the their Blue Cross Blue Shield payments - when is it going to end. We let the chiropractor's in - everyone is taking their money. Representative Porter looked at him and said he thought this bill wasn't about money. Apparently it was. He again voiced his unhappiness.

**Senator Howard Anderson, Jr.** understands. The majority of Senate voted in favor of the naturopath bill.

**Representative Porter** feels he is amongst friends.

**Senator Howard Anderson, Jr.** stated however, now that the naturopath bill failed, their scope of practice no longer includes the birthing authority. We know a midwife with no training can have birthing authority in North Dakota with a family. But now the naturopaths, even one who is trained because their practice act specifically restricts to what they can do to what's in their practice act, they can no longer do that. You amended this bill before the failure of SB 2194 with the intention that they would have that authority. So the question would be, do you want to recede from your amendments or do you want to try to make some other compromise here.

**Representative Porter** asked if you want to add midwifery for naturopaths to this bill?

**Senator Howard Anderson, Jr.** did suggest to the naturopaths that if they added their responsibilities incrementally, they might be better off because they only came around in 2011. They probably tried to go for too much all at once. We had a long discussion with the naturopaths when they had their bill in the Senate, and some of the senators said they would much rather have somebody with some kind of board certification and training for midwifery than just somebody who says they are a midwife. Senator Howard Anderson, Jr. thinks it would be a step too far to try to amend this bill to include something like that. It might not fare well when it gets back over to the House.

**Representative Porter** stated even without the component of midwifery, the licensed clinician is not the individual who is doing the birth. That is the responsible clinician, because that's where the midwife birth attendant resides. The licensed clinician is the clinician attending a patient with a metabolic disease or genetic disease that was not detected, or that was detected by the states newborn screening program. So he still goes back to his original comment - inside of the naturopath scope of practice in chapter 43 - and Representative Porter read from this chapter. They can treat them.

**Senator Lee** asked does it say "treat".

**Representative Porter** looked - they may prescribe and administer for preventative and therapeutic purposes a prescriptive device in the following non-prescriptive natural therapeutic substances, drugs and therapies. He continued reading from the naturopath Chapter 43. So the question comes down to inside these metabolic diseases, if the treatment is prescriptive, then they don't fit. If there are treatments that are non-prescriptive for treating these kids for their metabolic illnesses, then it does fit. So he goes back to his earlier comment of, should we just look at it from the standpoint if their scope of practice covers it inside of Chapter 43, then we don't worry about the fences that are built. If they

cover it, they can do it. If they don't, then they don't and they fit wherever their scope of practice inside of Chapter 43 allows them to fit.

**Senator Lee** agreed with how tiring the turf battles are. She also agrees that one profession doesn't have the right to tell another profession what they ought to have in their scope of practice, but nobody has exclusive access to her ankle, as an example. However, her perception and the reason she would have supported the naturopath enabling legislation in the first place is that it was going to be limiting. They have the same number of years of college after their bachelor's degree as a dentist, which is four years after their bachelor's degree. This is not the same as a physician has. Her concern having stuck a lot of babies heels as her life as a med-tech, that she knows how very important the screening process, and there are more and more tests available all the time for that early screening. She wants whoever assists at the birth of the baby to be required to do the sticking unless the family has opted out. But she really has a problem with somebody other than a physician being the one who is going to - the naturopath's have limited prescriptive practice privileges. She would want that newborn to have a much more comprehensive evaluation of what kind of treatment is appropriate depending on the condition(s), and she would have a hard time supporting the idea that a naturopath is in a position to do that. She really thinks it needs to be a specialist in that area. And that's separate from the fact that anybody in this room could go out and say they are a midwife in North Dakota and we can't do a thing about it - that's a different deal.

**Senator Warner** asked about the mechanics of it. There must be a kit. He understands the sticking of the newborn. How do you establish the chain of custody of the lines of communication?

**Senator Lee** indicated that's in the bill.

**Representative Becker** commented that if he recalls correctly, the naturopaths have this authority in 19 states, not certain about the number. The two points he wanted to bring up in discussion is they do have approval in a number of states, and if they are qualified, and are not taking a good solid look at it, it may take a time or two. One of the points that stuck with him was the number of naturopaths that might have to leave North Dakota for employment because there are more opportunities out of state.

**Senator Howard Anderson, Jr.** indicated the Senate heard in testimony that there were seven states for that gave them the birthing authority. He thinks that nobody objects if they had the authority to do the birthing to then do the stick or order it. Nobody objects to them getting the report, because if they are attending the family, they'll expect them to get the report back. The problem is when we give the impression that they are going to treat the person for a metabolic disease. That's perhaps where a referral to somebody else is more appropriate. When a clinician includes all those people, well then when the test comes back and the Health Department refers the test back to this person for treatment, that's where the rub comes. We are not comfortable at this point with the naturopath treating the metabolic disease. If we want to leave the naturopath in there as the clinician to do the test, he thinks that is probably contingent on them getting the birthing authority. Now we could take them out of the clinician definition. He thinks Representative Porter indicated that was some of their discussion and add them to the definition of the responsible person.

And that way it would be clear if they would be the one attending the family being responsible for the blood test and getting the report back, but then the clinician would be the one who be assigned to follow up by the Health Department. That's an option.

**Representative Porter** stated inside the bill on page 2, it talks about low protein modified food, medical food. He's not sure if any of those require a prescription to formulate those. When you look at sub 6 in engrossed version of bill, it goes back to talking about that it has to be a medical evaluation, and is formulated to be consumed or administered under the direction of a physician. That's indirect competition to who we determine to be a licensed clinician. So we are saying a physician has to do that, but up above, we are saying an advanced practice registered nurse is allowed to do that. So we have conflict inside of this bill, saying that some things are reserved for physicians; some things are reserved for advanced practice nurse and physician assistants to be licensed clinician. This is why he leans back to getting rid of the word physician - and just talking about if they are licensed in their scope, in Chapter 43, that they can be a licensed clinician. Their scope of practice determines what they do, not the words that we choose to put in the century code. He doesn't know that we have the ability to recognize who should be who inside of this. He understands on the responsible clinician we do need to name things, because midwives and birth attendants are unlicensed people in the state of North Dakota. So there he understands we need to say that it's either the licensed clinician. The responsible clinician can do the blood spot and do the test and send that sample in. The results come back to the licensed clinician. If the licensed clinician who gets the results back is an advanced practice nurse, they still can't treat the patient. They still have to send them back to a physician, according to what sub 6 says.

**Senator Howard Anderson, Jr.** indicated that his guess is that when the Health Department suggested the changes in the language here, they missed that part. They would have changed physician to include those others as well.

**Dr. Dwelle**, State Health Officer with the Department of Health, responded that is correct. We missed that word. It should be a licensed clinician.

**Senator Lee** asked about low protein modified food product and medical food are by prescription.

**Dr. Dwelle** answered yes, these are very specific medications and even though they are called food, they are very specific for metabolic diseases.

**Senator Howard Anderson, Jr.** indicated that if they were not legend drugs, anybody could buy them and take them. But if some third party is going to pay for them, somebody would need to prescribe them and be part of their treatment. **Dr. Dwelle** confirmed that is true.

**Senator Howard Anderson, Jr.** commented so if we were going to be consistent, we could fix those words. He understands if we are leaning Representative Porter's idea here that we remove the language to the professions and stick with their practice act, or if we go back and fix those definitions to take naturopath out of that and add the naturopath into the responsible clinician.

**Representative Porter** voiced he likes his option.

**Senator Lee** indicated with all due respect, she likes the other option. The physician's assistant works under the direction of a physician. And now advanced practice registered nurses all have doctorate degrees and are obviously responsible to their board. But she is not comfortable with the idea that the naturopath is going to be the only professional who is going to be looking at these newborns. She thinks we have a tremendous responsibility to these newborns. She recognizes that families who get to choose who their providers are. And if they choose to go to a naturopath once they've seen a physician and keep things in the loop, okay. But the prescriptive authority that naturopaths have is quite limited. There are some products here that are available for some of these genetic and metabolic diseases that are not going to be permitted to be prescribed by a naturopath. She doesn't want these newborns to have any potential barriers to not having a healthy life if it's possible to do that. She thinks that she would love to see it be a specialist, but we know they don't have them everywhere. She is okay with the naturopath being part of the screening process, but not the treatment.

**Senator Howard Anderson, Jr.** stated the standard definition that we use in 19.02, which is the food, drug and cosmetic act, if it is used to treat or mitigate disease, then it is a legend drug. Even when we get to where a physical therapist might use a certain therapy, if a practitioner prescribes that therapy, even the simple over-the-counter ingredient that is used to treat or mitigate disease becomes a legend drug, because that's what it's use is. So that would be true for these metabolic disease supplements as well.

**Representative Porter** asked to have some time to think this one through.

**Senator Howard Anderson, Jr.** indicated that he will come up with some copies of options and proposed amendments.

**Senator Howard Anderson, Jr.** adjourned the meeting.

# 2015 SENATE STANDING COMMITTEE MINUTES

Human Services Committee  
Red River Room, State Capitol

SB 2334  
4/8/2015  
25914

☐ Subcommittee  
☒ Conference Committee

Committee Clerk Signature



## Explanation or reason for introduction of bill/resolution:

A bill relating to the state's newborn screening program.

## Minutes:

Attach #1: Suggested fixes by Senator Howard Anderson, Jr.

The following conference committee members were present for SB 2334 on April 8, 2015, 10:00 a.m.

Senator Howard Anderson, Jr., Senator Lee, Senator Warner  
Representative Porter, Representative Rich Becker, Representative Mooney

**Senator Howard Anderson, Jr.** asked if anybody came up with a resolution for the conference committee.

**Senator Howard Anderson, Jr.** handed out discussion document with two options (attach #1). Senator Howard Anderson, Jr. reviewed option one in the document, and then option two in the document, as per attached.

**Representative Porter** stated in the amendment, on line 16 where we are taking out the direction of a physician, he believes we want that to be licensed clinician, not the responsible clinician.

**Senator Howard Anderson, Jr.** confirmed correct. So that should say licensure in both those places.

**Representative Porter** indicated page 2, line 12, yes. That should be the licensed clinician. So on line 4, we would take out the words of the people, and just put in their practice act. Then we are going to move licensed clinician down on 2 and 16, add naturopath on.

**Representative Porter** moved the House recede from the House amendments and amend as follows - to make the changes as stated above. The motion was seconded by Representative Mooney.

Discussion

**Senator Lee** asked for clarification.

**Representative Porter** indicated on line 16, it would be licensed clinician. **Senator Lee** responded yes. **Representative Porter** continued. On page 2, line 12, it would be licensed clinician. The rest would be the same as stated in option 1 from Senator Howard Anderson, Jr.

**Senator Howard Anderson, Jr.** provided a copy of the option one and two to a representative from the Health Department to see if it is practical.

(recording time 6:00)

**Ms. Kim Mertz**, Director for the Division of Family Health with the Health Department, first thanked Representative Porter for catching the error of physician in a few places. As far as the amendment, page 2, line 6, under licensed clinician, how the amendment is written here, if it would stay like this, it says an individual licensed and authorized by the practice act to provide newborn, screening, diagnosis - it should be newborn screening and the commas are in the wrong place, but we can help with that. She would like to stress that the Health Department spent a significant amount of time on the bill because it was outdated. We feel very strongly that we would like to see the language as we had it. The amendment, option 2, would be more comfortable with that option. We would like to reiterate with all due respect to the practice of naturopaths. We believe there is room for all sorts of different medicine in the world today, and we recognize that. The type of treatment that naturopaths provide, however, even within their scope, because of the limits they have on the prescriptive authority are not appropriate to be treating these infants with these severe genetic and metabolic conditions. Because of that, we prefer option 2. She has visited with Beth, a naturopath in town, and she is comfortable with that option.

**Senator Howard Anderson, Jr.** stated by leaving the definition broad and referring to their practice act doesn't automatically mean that naturopaths will be included if their practice act doesn't allow them to do that.

**Ms. Mertz** indicated she guesses that would be true. For us at the Health Department who are responsible for the screening and who are responsible to be sure that these infants receive appropriate and safe and effective treatment and follow-up services, she indicated that they are more comfortable with the defined language.

**Representative Mooney** asked if her concern that a group would interpret wrongly according to their act.

**Ms. Mertz** indicated that could be a concern. We worked for about a year on this language with attorney general's office. We are comfortable with this language. By leaving the language like it is and taking the naturopaths out of the licensed clinician, we are confident that these babies are going to get the care and treatment that they need. She would hate to have misrepresentation or misinterpretation of that.

**Senator Lee** commented as she said yesterday, including subsections 5 and 6 about PKU and maple syrup urine disease and all the other products, these are pharmaceuticals. She

is very concerned about something that is being prescribed. We have limited prescriptive practice for naturopaths, and frankly she would think they would want it that way because they are into a different kind of medicine. Their goal is not to do high-level prescribing. She is not even comfortable with changing to licensed clinician. She totally supports the idea of recognizing the scope of practices, but she is not quite ready to leap over the fence and see naturopaths in the same way she sees a physician, or an advanced practice nurse, and a physician assistance under the supervision of a licensed physician. She is much more comfortable with a medical model on the treatment of these diseases. These children need to be treated promptly. Not waiting for 6 months or a year to find out if a holistic approach is going to do it, because by that time, it's too late. Some of these proteins accumulate in the brain and it affects their intellectual capabilities, and we have an extraordinary responsibility to pay attention to that. She resists the part of the amendment that does change all of this to licensed clinician. She thinks it needs to say physician in those two lines. My choice would be that we delete on page 2, line 8 and 9, the portion that says, or naturopath licensed by the state board of integrated health care, and leave everything else the way it was as physician. And then we could add naturopath under responsible clinician on line 25.

**Representative Porter** said the licensed clinician component needs to be the person with the prescriptive authority. So it needs to be on those two lines where it is physician only now either expanded to specifically list who those individuals are or use generic version of licensed clinician because the advanced practice registered nurse is currently treating them and has full prescriptive authority inside of that formulary to do that treatment. In some of the areas of the state where some of these kids may live, there may not be a physician where they need the advanced practice nurse. The physician component on lines 16 and 12, even from the testimony of the department, is that it should say licensed clinician, and they missed that. Going back to comments, it is highly unlikely that if we use the generic language that if you are authorized by your practice act to do those type of things to qualify as a licensed clinician, it is highly that anyone is going to blatantly expand their own scope of practice without losing their right to practice if we don't specifically list them. He would very much disagree with the department's position that someone is going to expand when it is not part of their practice act. In looking at it, he understands that they like their language.

**Senator Lee** thinks APRN's to be able to treat. If we have the licensed clinician in lines 12 and 16, she is fine with that as long as the naturopath licensed by the state board of integrated health care is out of line 8 and 9. If they change their scope of practice, it has to go to administrative rules committee. She has great confidence in the administrative rules process. However, it's not the same as the public hearings as far as the level of engagement. She thinks it is extremely important that the physician or APRN be the one who is following through on this. The family can be in conjunction with a naturopath. But she is really uncomfortable with them being the primary care provider early on in this process, because it doesn't take long before it's too late.

**Representative Porter** stated under the amendment, they are removed under that licensed clinician component. Your argument is the actual amendment.

**Senator Howard Anderson, Jr.** stated that option 1, first sentence says the House recedes from their amendment. We would change definition of licensed clinician. Senator

Howard Anderson, Jr. offered his opinion that either option will work. He thinks it is more difficult for Health to administer, and they have to read the practice act. If they change practice act, they will automatically be included without having to change this particular law as well.

**Representative Becker** stated it's interesting to see the progress that we are making and time and effort to get the wording exactly right. Compliment to all of us. Question/Comment yesterday the comment was made that sometimes it is better to go incremental steps and not overreach and give practice capabilities to naturopaths that they don't have. This seems not to be overreach, wording is precise. Sounds like option 1 is getting us close to the goal line.

**Senator Lee** stated her concern is even with the deleting the green language in line 7 through 9. If we are adding, as the motion is, an individual licensed and authorized by their practice act to provide newborn screening, diagnosis, confirmation and treatment, it means that anybody who's scope says it's okay gets to do it. She's not okay with that addition. She's okay with deleting the amendment. She doesn't like the addition.

**Representative Porter** stated the expansion of scope can only happen through the legislative process. The expansion of scope of practice cannot happen inside of administrative rules. Listing the language in option 1 does not increase anyone's scope; it doesn't expand any other profession than what is listed. What it does do is it takes the language. If anybody gets their scope expanded, then it is just automatic without coming back in front of the legislative assembly. No one can expand their scope without us saying they can expand it, inside of rules or anywhere else.

**Representative Mooney** understands that we have a motion on the table for option 1. The more that she's heard all of the discussion and hearing the Department of Health, she would be more inclined to appreciate option 2 as an end result. She supports Representative Porter's frustrations on the turf wars. However, she shares Senator Lee's concern that a crack could occur. She doesn't want to make it easier to see that crack occur.

Roll Call Vote

Senators: 1 Yes, 2 No, 0 Absent  
Representatives: 2 Yes, 1 No, 0 Absent.  
MOTION FAILS 3-3.

**Senator Lee** move House recede from House Amendments and amend as follows, to option 2 as discussed, with the change also from responsible to licensed to the two references made. The motion was seconded by **Senator Warner**. No discussion.

Roll Call Vote

Senators: 3 Yes, 0 No, 0 Absent  
Representatives: 2 Yes, 0 No, 0 Absent.  
MOTION PASSES 5-1.



Senate Human Services Committee

SB 2334

04/08/2015

Page 5

**Senator Howard Anderson, Jr.** will carry SB 2334 to the Senate floor.

**Representative Becker** will carry SB 2334 to the House floor.

Conference Committee on SB 2334

Suggested fixes Howard Anderson 4-8-2015

**Option One**

House moves to recede to their amendments and further amend by:

On Page 2, Line 4 after "Licensed clinician" means, insert an individual licensed and authorized by their practice act to provide newborn, screening, diagnosis confirmation and treatment.

On Page 2, Line 12 Cross out ~~physician~~ and replace with responsible clinician

On Page 2, Line 16 Cross out ~~physician~~ and replace with responsible clinician

On Page 2, Line 25 after midwife, add naturopath,

**Option Two**

On Page 2, Lines 6-9 remove the House Amendment

On Page 2, Line 12 Cross out ~~physician~~ and replace with responsible clinician

On Page 2, Line 16 Cross out ~~physician~~ and replace with responsible clinician

On Page 2, Line 25 after midwife, add naturopath,

April 8, 2015

JD  
4/8/15

PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL NO. 2334

That the House recede from its amendments as printed on page 1033 of the Senate Journal and page 1152 of the House Journal and that Engrossed Senate Bill No. 2334 be amended as follows:

Page 2, line 10, overstrike "physician" and insert immediately thereafter "licensed clinician"

Page 2, line 14, overstrike "physician" and insert immediately thereafter "licensed clinician"

Page 2, line 23, after the second underscored comma insert "naturopath."

Renumber accordingly

**2015 SENATE CONFERENCE COMMITTEE  
ROLL CALL VOTES**

BILL/RESOLUTION NO. SB 2334 as engrossed

Senate "Enter committee name" Committee

- Action Taken    ☐ SENATE accede to House Amendments  
                      ☐ SENATE accede to House Amendments and further amend  
                      ☐ HOUSE recede from House amendments  
                      ☒ HOUSE recede from House amendments and amend as follows
- ☐ **Unable to agree**, recommends that the committee be discharged and a new committee be appointed

Motion Made by: Rep. Porter                      Seconded by: Rep. Mooney

Senators	07	08		Yes	No		Representatives	07	08		Yes	No
Senator Anderson	X	X		X			Representative Porter	X	X		X	
Senator Lee	X	X			X		Representative Rich Becker	X	X		X	
Senator Warner	X	X			X		Representative Mooney	X	X			X
Total Senate Vote				1	2		Total Rep. Vote				2	1

Vote Count            Yes: 3                      No: 3                      Absent: 0

Senate Carrier        \_\_\_\_\_ House Carrier        \_\_\_\_\_

LC Number    None                      .                      of amendment

LC Number        \_\_\_\_\_ .                      of engrossment

Emergency clause added or deleted

Statement of purpose of amendment

**Using proposed Option 1.**

**MOTION FAILS.**

**2015 SENATE CONFERENCE COMMITTEE  
ROLL CALL VOTES**

BILL/RESOLUTION NO. SB 2334 as engrossed

Senate "Enter committee name" Committee

- Action Taken ☐ SENATE accede to House Amendments  
☐ SENATE accede to House Amendments and further amend  
☐ HOUSE recede from House amendments  
☒ HOUSE recede from House amendments and amend as follows  
  
☐ Unable to agree, recommends that the committee be discharged and a new committee be appointed

Motion Made by: Sen. Lee Seconded by: Sen. Warner

Senators	07	08		Yes	No		Representatives	07	08		Yes	No
Senator Anderson	X	X		X			Representative Porter	X	X			X
Senator Lee	X	X		X			Representative Rich Becker	X	X		X	
Senator Warner	X	X		X			Representative Mooney	X	X		X	
Total Senate Vote				3	0		Total Rep. Vote				2	1

Vote Count Yes: 5 No: 1 Absent: 0

Senate Carrier Sen. Anderson House Carrier Rep. Becker

LC Number 15.0979.02002 . Title .04000 of amendment

LC Number \_\_\_\_\_ . \_\_\_\_\_ of engrossment

Emergency clause added or deleted

Statement of purpose of amendment

Document provided by Senator Howard Anderson, Jr., Option 2 language

**MOTION PASSES.**

**REPORT OF CONFERENCE COMMITTEE**

**SB 2334, as engrossed:** Your conference committee (Sens. Anderson, J. Lee, Warner and Reps. Porter, Rich S. Becker, Mooney) recommends that the **HOUSE RECEDE** from the House amendments as printed on SJ page 1033, adopt amendments as follows, and place SB 2334 on the Seventh order:

That the House recede from its amendments as printed on page 1033 of the Senate Journal and page 1152 of the House Journal and that Engrossed Senate Bill No. 2334 be amended as follows:

Page 2, line 10, overstrike "physician" and insert immediately thereafter "licensed clinician"

Page 2, line 14, overstrike "physician" and insert immediately thereafter "licensed clinician"

Page 2, line 23, after the second underscored comma insert "naturopath."

Renumber accordingly

Engrossed SB 2334 was placed on the Seventh order of business on the calendar.

**2015 TESTIMONY**

**SB 2334**

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

SB 2334  
02/02/15  
Attach#1  
J# 22941

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 20<sup>th</sup> 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.

15.0979.01001  
Title.

02/02/15 Attach #2  
Prepared by the Legislative Council staff for  
Senator J. Lee

January 27, 2015

SB 2334

J# 22941

from Sen. Lee

PROPOSED AMENDMENTS TO SENATE BILL NO. 2334

Page 1, line 4, after the first "to" insert "medical foods and"

Page 4, line 19, overstrike "males under age twenty-two and females" and insert immediately thereafter "individuals"

Page 4, line 25, overstrike "females" and insert immediately thereafter "individuals"

Page 4, line 25, overstrike "and to males age"

Page 4, line 26, overstrike "twenty-two and over"

Page 4, line 30, overstrike "females" and insert immediately thereafter "individuals"

Page 4, line 30, overstrike "and males under age"

Page 5, line 1, overstrike "twenty-two"

Renumber accordingly

**SB 2334 DRAFT AMENDMENT**

Attach #1  
SB 2334  
02/03/15 @ 4:00pm  
JH 23142

A BILL for an Act to create and enact sections 25-17-02.1 and 25-17-07 of the North Dakota Century Code, relating to the state's newborn screening program; to amend and reenact sections 23-01-03.1, 25-17-00.1, 25-17-01, 25-17-03, 25-17-05, and 25-17-06 of the North Dakota Century Code, relating to medical foods and the state's newborn screening program; and to repeal section 25-17-04 of the North Dakota Century Code, relating to the state's newborn screening program.

**BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

**SECTION 1. AMENDMENT.** Section 23-01-03.1 of the North Dakota Century Code is amended and reenacted as follows:

**23-01-03.1. Newborn metabolic and genetic disease screening tests.**

1. ~~The health council may authorize the use of newborn metabolic and genetic disease screening tests, as provided for in chapter 25-17, for research purposes. The council shall adopt rules to ensure that the results are used for legitimate research purposes and to ensure that the confidentiality of the newborns and their families is protected.~~ shall adopt rules relating to the storage, maintenance, and disposal of bloodspots or other newborn screening specimens.
2. The health council shall specify a panel of metabolic diseases and genetic diseases for which newborn screening must be performed. The screening panel must include disorders and diseases selected by the state health officer with input from an advisory committee that is approved by the health council.

**SECTION 2. AMENDMENT.** Section 25-17-00.1 of the North Dakota Century Code is amended and reenacted as follows:

**25-17-00.1. Definitions.**

As used in this chapter, unless the context otherwise requires:

1. "Confirmatory-diagnostic testing" means testing to prove or disprove the presence of a specific metabolic disease or genetic disease.

2. "Confirmatory-diagnostic testing laboratory" means a laboratory performing confirmatory-diagnostic testing.

3. "Department" means the state department of health.

4. "Licensed clinician" means a currently licensed physician, physician assistant, or advanced practice registered nurse.

5. "Low-protein modified food product" means a food product that is specially formulated to have less than one gram of protein per serving and is intended to be used under the direction of a physician for the dietary treatment of a metabolic disease. The term does not include a natural food that is naturally low in protein.

2.6. "Medical food" means a food that is intended for the dietary treatment of a disease or condition for which nutritional requirements are established by medical evaluation and is formulated to be consumed or administered under the direction of a physician.

3.7. "Metabolic disease" and "genetic disease" mean a disease as designated by rule of the state health council for which early identification and timely intervention will lead to a significant reduction in mortality, morbidity, and associated disabilities.

8. "Newborn screening program "means a program facilitating access to appropriate testing, followup, diagnosis, intervention, management, evaluation, and education regarding metabolic diseases and genetic diseases identified in newborns.

9. "Out-of-range screening result "means a screening result that is outside of the expected range of testing results established for a particular disease.

10. "Responsible clinician" means the licensed clinician, midwife, or birth attendant attending a newborn.

11. "Screening" means initial testing of a newborn for the possible presence of metabolic disease or genetic disease.

12. "Screening laboratory" means the laboratory the department selects to perform screening.

**SECTION 3.AMENDMENT.** Section 25-17-01 of the North Dakota Century Code is amended and reenacted as follows:

**25-17-01. Newborn screening education programs and tests.**

The state department of health shall:

1. Develop and implement a metabolic disease and genetic disease educational program among physicians licensed clinicians, hospital staffs, public health nurses, and the citizens of this state.

This educational program must include information about the nature of the diseases and about screening for the early detection of these diseases so that proper measures may be taken to reduce mortality, morbidity, and associated disabilities.

2. Provide, on a statewide basis, a newborn screening system and short-term followup services for metabolic and genetic diseases program.

3. Coordinate with or refer individuals to public and private health care service providers for long-term followup services for metabolic diseases or and genetic diseases, or both.

4. Select a screening laboratory.

5. Store, maintain, and dispose of blood spots used for screening.

**SECTION 4.** Section 25-17-02.1 of the North Dakota Century Code is created and enacted as follows:



### **25-17-02.1. Testing and reporting requirements.**

1. A responsible clinician shall provide the parents and guardians of a newborn written information on the nature of newborn screening and confirmatory-diagnostic testing. The parents or guardians of a newborn may object to screening after receiving the written information. A newborn may not be subject to screening to which the newborn's parents or guardians object. In the case of an objection, the responsible clinician shall record the objection in a document signed by the parents or guardians and shall submit the document to the department.
2. The responsible clinician attending a newborn shall cause that newborn to be subjected to screening in the manner prescribed by the department.
3. The screening laboratory shall provide to the department screening results and any blood spots used in screening.
4. If screening shows an out-of-range screening result, the responsible clinician shall cause the newborn to be subjected to appropriate clinical followup by a licensed clinician which may include confirmatory-diagnostic testing. The responsible clinician shall ensure the department receives any confirmatory-diagnostic testing results.
5. A licensed clinician attending a patient with a metabolic disease or genetic disease that was not detected by the state's newborn screening program shall report the case to the department.

**SECTION 5. AMENDMENT.** Section 25-17-03 of the North Dakota Century Code is amended and reenacted as follows:

### **25-17-03. Treatment for positive diagnosis - Registry of cases.**

The state department of health shall:

1. ~~Follow up with attending physicians~~ Notify responsible clinicians regarding cases with positive tests for metabolic diseases or genetic diseases, or both, out-of-range screening results or positive



~~confirmation~~confirmatory-diagnostic testing result in order to determine the exact diagnosis ~~facilitate access to appropriate treatment. If the responsible clinician is not a licensed clinician,~~  
the responsible clinician shall refer the patient to a licensed clinician for appropriate followup  
care.

2. Refer every diagnosed case of a metabolic disease or genetic disease, ~~or both,~~ to a qualified ~~health care provider~~licensed clinician for necessary treatment.

3. Maintain a registry of cases of metabolic diseases and genetic diseases.

4. Provide medical food at no cost to ~~males under age twenty-two and females~~individuals under age forty-five who are diagnosed with phenylketonuria or maple syrup urine disease, regardless of income. If treatment services under this subsection are provided to an individual by the department, the department may seek reimbursement from any government program that provides coverage to that individual for the treatment services provided by the department.

5. Offer for sale at cost medical food to ~~females~~individuals age forty-five and over ~~and to males~~  
~~age twenty-two and over~~ who are diagnosed with phenylketonuria or maple syrup urine disease, regardless of income. These individuals are responsible for payment to the department for the cost of medical food.

6. Provide low-protein modified food products, if medically necessary as determined by a qualified health care provider, to ~~females~~individuals under age forty-five ~~and males under age~~  
~~twenty-two~~ who are receiving medical assistance and are diagnosed with phenylketonuria or maple syrup urine disease.

**SECTION 6. AMENDMENT.** Section 25-17-05 of the North Dakota Century Code is amended and reenacted as follows:

**25-17-05. Testing charges.**

~~The state health council may adopt rules that establish reasonable fees and may impose those fees to cover the costs of administering tests under this chapter. All test fees collected by the state department of health must be deposited in the state department of health operating~~  
accountA screening and confirmatory-diagnostic testing laboratory may charge fees for necessary services.

**SECTION 7. AMENDMENT.** Section 25-17-06 of the North Dakota Century Code is amended and reenacted as follows:

**25-17-06. Pulse oximetry screening for critical congenital heart defects - Exception.**

Before discharge of a newborn child born in a hospital with a birthing center, the newborn child must receive a pulse oximetry screening for critical congenital heart defects. The screening requirement of this section does not apply if the parents or guardians of a newborn child object to the screening. The state department of health shall provide medical staff and facilities that provide birthing services with notice regarding this screening requirement. For purposes of this chapter, pulse oximetry screening is not a test under section 25-17-05 and a congenital heart defect detected by screening under this section is not a metabolic disease or genetic disease as those terms are used under this chapter.

SECTION 8. Section 25-17-07 of the North Dakota Century Code is created and enacted as follows:

**25-17-07. Institutional review board.**

A person that conducts research on blood spots, other specimens, or registry data that is maintained by the department shall follow institutional review board processes for human research which must include obtaining parent or guardian authorization.

**SECTION 9.REPEAL.**Section 25-17-04 of the North Dakota Century Code is repealed.

Information from: Phenylketonuria - Intelihealth

Attach #2  
SB 2334  
02/03/15  
J# 23142

A woman who has PKU herself and is pregnant must strictly control her phenylalanine levels before and during pregnancy to avoid causing damage to her unborn child. High levels of phenylalanine in a pregnant woman can cause her child to have slow growth, developmental delays, small head size and other disorders. With careful monitoring and control, women with PKU can give birth to healthy children. A woman with PKU can pass the PKU gene to her child, but the child will not develop PKU unless another copy of the gene is inherited from the father.

If you are a woman with phenylketonuria, your child can be affected even if your partner is not a carrier. Children of women with PKU can suffer serious problems, such as intellectual disability and heart defects, if the mother's phenylalanine levels are even slightly high during pregnancy. Your child can develop problems even if he or she did not inherit two copies of the gene for PKU.

So, if you're a woman with PKU and are planning a pregnancy, talk to a doctor experienced with PKU before you become pregnant. You will need to monitor your phenylalanine levels closely during the entire pregnancy to ensure the health of your baby.

### **Information from the National PKU News, Question and Answer**

*Dr. Richard Koch, a world-renowned expert in PKU, regularly answers diverse questions from all over the globe about PKU and its treatment via his participation in our internet PKU Listserv group. He has truly become our "resident doctor for all families" and we continually benefit from his vast experience and knowledge acquired over more than 50 years of work with PKU. Here are his answers to some of the many questions posed by families.*

### **PKU and Male Fertility**

**Q.** *Is there any effect of PKU on male fertility? I am married and want to start a family and have heard that I might have decreased fertility as a result of my PKU.*

**A.** Seven years ago, Dr. Harvey Levy in Boston published a paper concerning fertility in PKU men and concluded that they were normal. However, Dr. Robert Fisch in Minneapolis published an article that suggested the sperm count was low in PKU men who were not on the diet. I know of no other studies that have been done in this area of research. If a PKU man is having difficulty with conception, I would suggest that diet treatment be resumed and I would bet money he would be virile.

### **Pregnancy and Phenylketonuria (PKU)**

By **Gabriella Coletti Pridjian, MD**

Dr. Pridjian is Associate Professor in the Departments of Obstetrics & Gynecology and Pediatrics at Tulane Health Sciences Center. She is director of Maternal - Fetal Medicine (High Risk Pregnancies) as well as a clinical geneticist in the Human Genetics Program. As a high risk obstetrician

and geneticist, she is ideally suited for the management of maternal PKU. Through the Human Genetics Program at Tulane, in recent years she has helped manage nearly all the pregnancies of mothers with PKU in the state of Louisiana.

Males with PKU appear not to have major difficulty in production of sperm and thus fathering children. The wife of a man with PKU does not have extra problems becoming pregnant, or having a healthy baby. There appears to be no increase in birth defects if the father of a baby has PKU. It should be remembered that all couples have a small chance of having a baby with a birth defect or genetic problem even if they do not have PKU.



SB 2334  
Attach #3  
02/03/15  
J#23142

**From:** Lelm, Tamara G.  
**Sent:** Monday, February 02, 2015 11:16 AM  
**To:** Lee, Judy E.  
**Cc:** Mertz, Kim N.; Bentz, Katie R.; Meyer, Joyal B.; Johnson, Tammie M.  
**Subject:** SB 2334 - Response to information request

Senator Lee,

On behalf of the North Dakota Department of Health (NDDoH), I am coordinating a response to provide you with information that was requested during the hearing on SB 2334, which relates to the state's newborn screening program.

**1. Conditions screened for by ND's newborn screening program:**

- Below is a link to the list of conditions screened for by the newborn screening program.  
<http://www.ndhealth.gov/newbornscreening/Disorder%20List.pdf>

**2. Potential fiscal note if the NDDoH would expand the metabolic food program to include males age 22 through 44 with PKU or MSUD:**

- This projection assumes medical food would be provided at no cost to males with PKU or MSUD under age 45 regardless of income and that low-protein modified food products would also be provided to males who are receiving medical assistance who are under age 45 with PKU or MSUD.
- To expand the metabolic food program as specified above, the NDDoH projects expenditures of \$146,392 for the 2015-2017 biennium and \$170,513 for the 2017-2019 biennium.
- Although the potential number of men age 22 through 44 who might be served could be higher based on screening data which indicates there is an average of one case/year, the NDDoH used a more conservative projection that only included males with PKU or MSUD in the 22 through 44 age group that were known to the Children's Special Health Services Division.
- The NDDoH estimates nine additional males would be served in the 2015-2017 biennium and 10 additional males would be served in the 2017-2019 biennium.
- Costs were projected based on use of recommended amounts of Phenex II and Ketonex formulas with an inflationary increase of 5% during each biennium. These two formulas are commonly ordered by individuals and families served through the metabolic food program. The inflationary percentage was based on average formula cost increases experienced from 2012-2014. Low-protein modified food products were not included in the potential expenditures for either biennium as the number of males in the 22 through 44 age group who are receiving medical assistance (Medicaid) is unknown.
- Current staff within the NDDoH would need to absorb the increased workload with service to the additional 9-10 individuals (e.g., maintaining increased formula inventory, increased mailing of formula orders throughout the year, increased data entry associated with the administration of the metabolic food program, increased volume of care coordination services, etc.).

**3. Potential impact on Male Reproduction:**

- As mentioned at the hearing, Dr Kenien, the physician at the Metabolic Disorders Multidisciplinary Clinic indicated there are no reproductive issues for males who have PKU or MSUD who are not managing their diet appropriately. Attached is a brief compilation from

various sources that addresses male and female reproductive impact that could be found on short notice. Additional information has been requested from two medical geneticists who have not yet responded.

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#1

**Testimony**  
**Senate Bill 2334**  
**House Human Services Committee**  
**Wednesday, March 18, 2015; 10:45 a.m.**  
**North Dakota Department of Health**

Good morning Chairman Weisz and members of the House Human Services 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 Senate Bill 2334.

Newborn screening is a simple blood test that is performed on babies within the first few days of life. This test allows 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 20<sup>th</sup> 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 added to this section gives 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 for screening as selected by the state health officer and with input from an advisory committee. Currently, rules list specific diseases for which screening is done. This change allows the health council to specify diseases without changing rules every time a new disease is added to the screening panel.

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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 authorize 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 Sections 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.

Early identification of diseases as a result of 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 the 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.

SB 2334  
3-24-15 #1

PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL No. 2334

Page 2, line 6, replace the first comma with "or"

Page 2, line 6, after "assistant," insert "licensed by the North Dakota Board of Medical  
Examiners,"

Page 2, line 7, after nurse insert "licensed by the North Dakota Board of Nursing"

Page 2, line 23, after "midwife," insert "naturopath,"

Renumber Accordingly

Conference Committee on SB 2334

Suggested fixes Howard Anderson 4-8-2015

Attach #1  
04/08/2015  
SB 2334.  
J# 25914

**Option One**

House moves to recede to their amendments and further amend by:

On Page 2, Line 4 after "Licensed clinician" means, insert an individual licensed and authorized by their practice act to provide newborn, screening, diagnosis confirmation and treatment.

On Page 2, Line 12 Cross out ~~physician~~ and replace with responsible clinician

On Page 2, Line 16 Cross out ~~physician~~ and replace with responsible clinician

On Page 2, Line 25 after midwife, add naturopath.

**Option Two**

On Page 2, Lines 6-9 remove the House Amendment

On Page 2, Line 12 Cross out ~~physician~~ and replace with responsible clinician

On Page 2, Line 16 Cross out ~~physician~~ and replace with responsible clinician

On Page 2, Line 25 after midwife, add naturopath.