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Sixty-fourth
Legislative Assembly
of North Dakota

FIRST ENGROSSMENT

ENGROSSED SENATE BILL NO. 2334

Introduced by

Senators J. Lee, Anderson

Representatives Delmore, Hofstad, Weisz

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 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 blood spots 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~~,~~or physician assistant~~, or~~ licensed by the state board of medical examiners, advanced practice registered nurse licensed by the state board of nursing, or naturopath licensed by the state board of integrative health care.
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 confirmatory-diagnostic testing results 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 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 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 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 account~~A 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.