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Fifty-seventh
Legislative Assembly
of North Dakota

SECOND ENGROSSMENT

REENGROSSED SENATE BILL NO. 2239

Introduced by

Senators Fischer, Flakoll, Lee

Representatives Delmore, Kliniske

A BILL for an Act to create and enact a new section to chapter 25-17 of the North Dakota Century Code, relating to definitions for the newborn screening law; and to amend and reenact sections 25-17-01, 25-17-02, 25-17-03, 25-17-04, 25-17-05, and 26.1-36-09.7 of the North Dakota Century Code, relating to services and insurance coverage for treatment of metabolic diseases.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 25-17 of the North Dakota Century Code is created and enacted as follows:

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

1. "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. "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. "Metabolic disease" means 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.

SECTION 2. AMENDMENT. Section 25-17-01 of the North Dakota Century Code is amended and reenacted as follows:

25-17-01. ~~Phenylketonuria and galactosemia~~ Newborn screening education programs and tests. The state department of health shall:

1. Develop and ~~carry out an intensive~~ implement a metabolic disease educational program among physicians, hospital staffs ~~of hospitals~~, public health nurses, and the citizens of this state ~~concerning the diseases phenylketonuria and galactosemia, and other metabolic diseases causing mental retardation for which appropriate methods of detection, prevention, or treatment are available~~. This educational program must include information about the nature of the diseases and ~~examinations~~ about screening for the early detection of ~~such~~ these diseases ~~in order~~ so that proper measures may be taken to ~~prevent mental retardation~~ reduce mortality, morbidity, and associated disabilities.
2. Provide, on a statewide basis, a newborn screening~~, diagnostic,~~ system and ~~treatment control tests~~ short-term followup services for ~~which approved laboratory procedures are available for phenylketonuria, galactosemia, and other~~ metabolic diseases ~~causing mental retardation~~.
3. ~~Provide that, upon completion of the testing, the actual testing materials must be returned to the department. The department shall forward the actual testing materials to the university of North Dakota school of medicine for storage and research purposes. The materials in the possession of the university of North Dakota school of medicine may not be destroyed without the authorization of the department.~~ Coordinate with or refer individuals to public and private health care service providers for long-term followup services for metabolic diseases.

SECTION 3. AMENDMENT. Section 25-17-02 of the North Dakota Century Code is amended and reenacted as follows:

25-17-02. ~~Establishment of testing regulations~~ Rulemaking requirement. The state ~~department of~~ health council shall ~~establish standards and methods of testing to be employed for the determination of the diseases referred to in section 25-17-01 for which statewide testing programs are established~~ adopt rules necessary to implement this chapter.

SECTION 4. 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 ~~all~~ with attending physicians cases with positive tests for ~~phenylketonuria, galactosemia, and other~~ metabolic diseases ~~with the attending physician~~ in order to determine the exact diagnosis.
2. ~~Make arrangements~~ Refer every diagnosed case of a metabolic disease to a qualified health care provider for ~~the~~ necessary treatment ~~for diagnosed cases where treatment is indicated and the family is unable to pay the cost of such treatment~~ of the metabolic disease.
3. 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.
4. 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 the medical food.
5. Deposit any money collected under subsections 3 and 4 in the department's operating account for the purpose of defraying the expenses of providing treatment services under this section.
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.
7. Maintain a registry of cases of ~~phenylketonuria, galactosemia, and other~~ metabolic diseases ~~for the purpose of followup services to prevent mental retardation~~.

SECTION 5. AMENDMENT. Section 25-17-04 of the North Dakota Century Code is amended and reenacted as follows:

25-17-04. ~~Physician to initiate test and report positive diagnosis~~ Testing and reporting requirements. The physician attending a newborn child, or the birth attendant in the case of an out-of-hospital birth, shall cause that newborn child to be subjected to testing for

~~phenylketonuria, galactosemia, and other~~ metabolic diseases, in the manner prescribed by the state department of health. A physician attending a ~~case of phenylketonuria, galactosemia, or other~~ patient with a metabolic disease ~~which may cause mental retardation~~ shall report the case to the state department of health. ~~This~~ The testing requirements of this section ~~does~~ do not apply if the parents of a newborn child object ~~thereto~~ to the testing on the grounds that testing for metabolic diseases conflicts with their religious tenets and practices.

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 ~~department of~~ health ~~shall~~ 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.

SECTION 7. AMENDMENT. Section 26.1-36-09.7 of the 1999 Supplement to the North Dakota Century Code is amended and reenacted as follows:

26.1-36-09.7. Foods and food products for inherited metabolic diseases.

1. As used in this section:
   a. "Inherited metabolic disease" means maple syrup urine disease or phenylketonuria.
   b. "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 an inherited metabolic disease. The term does not include a natural food that is naturally low in protein.
   c. "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.
2. An insurance company, nonprofit health service corporation, or health maintenance organization may not deliver, issue, execute, or renew any health insurance policy, health service contract, or evidence of coverage that provides prescription coverage on an individual, group, blanket, franchise, or association

basis, unless the policy or contract provides, for any person covered under the policy or contract, coverage for medical foods and low-protein modified food products determined by a physician to be medically necessary for the therapeutic treatment of an inherited metabolic disease.

3. This section applies to any covered individual born after December 31, 1962. This section does not require coverage ~~for low protein modified food products~~ in excess of three thousand dollars per year total for low-protein modified food products or medical food for an individual with an inherited metabolic disease of amino acid or organic acid.

4. This section does not require medical benefits coverage for low protein modified food products or medical food for an individual to the extent those benefits are available to that individual under a department of health program.