CHAPTER 33-06-16
NEWBORN SCREENING PROGRAM

33-06-16-01. Definitions.

As used in this chapter:

1. ~~"Diagnostic test" means a test that is used to establish a definitive diagnosis of some condition in an affected newborn.~~

~~2~~ "Newborn screening ~~system " means the routine testing of newborn infants for congenital conditions by analysis of a dried blood specimen through laboratory procedures that identify infants with an increased risk for specified diseases and conditions, and that justify followup actions and diagnostic tests or procedures.~~

~~3. "Program" means the North Dakota newborn screening program in the community health section of the state department of health.~~ program" means the North Dakota newborn screening program in the state department of health facilitating access to appropriate testing, followup, diagnosis, intervention, management, evaluation, and education regarding metabolic diseases and genetic diseases identified in newborns.

4~~2~~. "Protected health information" ~~has the meaning set forth in North Dakota Century Code section 23-01.3-01.~~

~~5. "Tandem mass spectrometry" is a laboratory technology that uses a machine consisting of two mass spectrometers joined by a fragmentation~~

~~chamber. Tandem mass spectrometry technology allows the identification of an array of metabolic conditions, such as amino acid, fatty acid, and organic acid disorders, from a single dried blood spot. Tandem mass spectrometry can test for multiple disorders in a single screening run and the number of known disorders which may be screened by this technology is constantly changing.~~

~~6. Metabolic disease is a genetically determined disorder in which a specific enzyme defect causes a clinically significant block or alteration in a biochemical pathway or process.~~ means any information, including genetic information, demographic information, and fluid or tissue samples collected from an individual, diagnostic and test results, whether oral or recorded in any form or medium, which:

a. Is created or received by a health care provider, health researcher, health plan, health oversight authority, public health authority, employer, health or life insurer, school or university; and

b. (1) Relates to the past, present, or future physical or health or condition of an individual, including individual cells and their components; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(2) (a) Identifies an individual; or

(b) With respect to which there is a reasonable basis to believe that the information can be used to identify an individual.

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

4. "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.

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

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

7. "Care Coordination" means services that promote the effective and efficient organization and utilization of resources to assure access to necessary comprehensive services for children with special health care needs and their families.

8. "Metabolic Disorders Clinic Team" means medical providers and other professionals that provide comprehensive pediatric evaluations and coordinated care recommendations using a team approach to help effectively manage care for individuals with metabolic disorders.

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

History: Effective December 1, 1996; amended effective March 1, 2003; January 1, 2006.
General Authority: NDCC 23-01-03(3), 23-01-03.1, 23-01-04, 23-01-15, 25-17-01, 25-17-02
Law Implemented: NDCC 23-01-03.1, 25-17-01(3), 25-17-02, 25-17-03

Section 33-06-16-02 is repealed.

~~**33-06-16-02. Testing of newborns.**~~

~~Under the newborn screening system, except as authorized by section 33-06-16-04, each newborn infant born in this state shall be tested for metabolic diseases cystic fibrosis, hypothyroidism, galactosemia, congenital adrenal hyperplasia, biotinidase deficiency, sickle cell disease and other hemoglobinopathies, and a sample of the newborn's blood shall also be tested by tandem mass spectrometry.~~

~~**History:** Effective March 1, 2003; amended effective January 1, 2006.~~
~~**General Authority:** NDCC 23-01-03(3), 23-01-03.1, 23-01-04, 23-01-15, 25-17-01, 25-17-02~~
~~**Law Implemented:** NDCC 23-01-03.1, 25-17-01(3), 25-17-02, 25-17-03~~

Section 33-06-16-03 is repealed.

~~**33-06-16-03. Physician responsibility.**~~

~~1. The physician or other birth attendant shall order that:~~

~~a. A specimen of blood be collected from a newborn in accordance with directions supplied by the laboratory designated by the state department of health and the program; and~~

~~b. The specimen be sent to that laboratory.~~

~~2. If a patient, who has a condition for which the program conducts a screening test, but which has been detected by another mechanism or by~~

~~an out-of-state screening program, the patient's physician shall within thirty days of becoming aware of the patient's condition, notify the program of the patient's name, parent's name if the patient is under eighteen years of age, date of birth, address, and condition.~~

~~**History:** Effective March 1, 2003.~~
~~**General Authority:** NDCC 23-01-03(3), 23-01-03.1, 23-01-04, 23-01-15, 25-17-01, 25-17-02~~
~~**Law Implemented:** NDCC 23-01-03.1, 25-17-01(3), 25-17-02, 25-17-03~~

33-06-16-04. Refusal of testing.

1. If the parents or guardians refuse to have their infant receive newborn screening testing ~~as authorized by North Dakota Century Code section 25-17-04~~after being provided written information, that refusal shall be documented by a written statement signed by the parents or guardians.
2. The original refusal statement shall become a part of the infant's medical record and a copy of the statement must be submitted to the newborn screening program within six days after testing was refused.

History: Effective March 1, 2003; amended effective January 1, 2006.
General Authority: NDCC 23-01-03(3), 23-01-03.1, 23-01-04, 23-01-15, 25-17-01, 25-17-02
Law Implemented: NDCC 23-01-03.1, 25-17-01(3), 25-17-02, 25-17-03

33-06-16-05. Research and testing materials.

Information and testing materials received or generated by the newborn screening program under North Dakota Century Code chapter 25-17 are ~~strictly~~

confidential ~~information subject to North Dakota Century Code chapter 23-01.3, and section 23-01-15~~except as provided by law or regulation~~.~~

1. Access to information or testing materials may be obtained only as follows:

   a. Information may be disclosed for statistical purposes in a manner such that no individual person can be identified.

   b. Information may be disclosed to the individual tested, that person's parent or guardian, or that person's ~~physician or~~licensed clinician, responsible clinician,dietitian, metabolic disorders clinic team, screening laboratory, other employees and contractors of the department with need for the information, or to ~~the~~ children's special health services ~~program of~~within the department of ~~human services~~health for purposes of care coordination ~~of services~~ and provision of medical and low-protein modified foods.

   c. Information and testing materials may be disclosed to a person engaged in a ~~bona fide~~ research project concerning medical, psychological, or sociological issues provided all of the following conditions are met:

      (1) Written authorization from the parent or guardian must be obtained by the researcher for the information or testing materials requested.

      (2) The research project must be sponsored by a public or private college or university; a governmental entity; a

nonprofit medical, sociological, or psychological association; or the pharmaceutical industry.

~~(2)~~(3) The research project must be reviewed and approved pursuant to policies and procedures pertaining to research utilizing human subjects by the institutional review board or equivalent panel of the institution or entity where the research is being done or which is sponsoring the research.

~~(3)~~(4) Protected health information may not appear in any report, summation, thesis, or other document arising out of the research project.

~~(4)~~(5) Protected health information may not be provided to a person engaged in a ~~bona fide~~ research project until that person has submitted a written proposal explaining and justifying the need to examine such information ~~which is satisfactory to the state health officer. The state health officer may require the research to be approved by the university of North Dakota institutional review board~~.

~~(5) All documents or testing materials received by the researcher and all documents containing protected health information made by or on behalf of the researcher, by whatever means, including hard copies, typewritten or handwritten copies, photocopies, facsimiles, or electronic or electromagnetic recording or imaging, must be returned to~~

~~the department on or before a date that the state health officer shall set.~~

~~(6) The researcher shall submit a written plan explaining how all protected health information in the researcher's possession will be kept secure to the satisfaction of the state health officer who shall obtain written assurance that the plan will be implemented.~~

~~(7) The researcher shall agree to provide the state health officer a copy of any report, summation, thesis, or other document arising out of the research project for departmental review of compliance with this section before providing it to the publisher.~~

~~(8) The researcher shall consent in writing to the use and reproduction of the document by the department.~~

~~(9)~~(6) The researcher shall agree in writing to pay all costs of ~~the state health officer or~~ the department incurred in providing access to testing materials or other information, including copy or research services.

~~d. Disclosure may be made as otherwise provided by statute.~~

2. ~~Retention and destruction~~Storage, maintenance and disposal of information and testing materials.

a. Information and testing materials shall be stored in such a way as to protect the integrity of the materials and the privacy of patients.

b. Information and testing materials provided to the ~~university of North Dakota school of medicine and health sciences~~department of health may be retained indefinitely or destroyed according to this subsection.

~~b~~c. Information and testing materials may be destroyed by any available means that preserves individual confidentiality and, for the testing materials, complies with any applicable standards for destruction of human blood samples.

~~c~~d. Information and testing materials may be destroyed based upon the following schedule:

(1) Information and testing materials created less than ~~ten~~ eighteen years before the present date may be destroyed only with the state health officer's prior written approval.

(2) After ~~ten~~ eighteen years, information and testing materials may be destroyed without prior approval.

History: Effective March 1, 2003.
General Authority: NDCC 23-01-03(3), 23-01-03.1, 23-01-04, 23-01-15, 25-17-01, 25-17-02
Law Implemented: NDCC 23-01-03.1, 25-17-01(3), 25-17-02, 25-17-03