CHAPTER 33-06-16
NEWBORN SCREENING PROGRAM

33-06-16-01. Definitions.

As used in this chapter:

1. "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.

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

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

4. "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.

5. "Newborn screening program" means the North Dakota screening program in the department of health and human services facilitating access to appropriate testing, followup, diagnosis, intervention, management, evaluation, and education regarding metabolic diseases and genetic diseases identified in newborns.

6. "Protected health information" 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.

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

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

9. "Screening laboratory" means the laboratory the department of health and human services selects to perform screening.

History: Effective December 1, 1996; amended effective March 1, 2003; January 1, 2006; April 1, 2016; January 1, 2025.
General Authority: NDCC 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

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

Repealed effective April 1, 2016.

33-06-16-03. Physician responsibility.

Repealed effective April 1, 2016.

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

1. If the parents or guardians refuse to have their infant receive newborn screening testing 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; April 1, 2016.
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.

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

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

3. Dried blood spots must be destroyed thirty days after completion of testing. Residual specimens may be retained for laboratory quality assurance purposes and must be destroyed after completion of quality assurance activities.

4. 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.

History: Effective March 1, 2003; amended effective April 1, 2016; January 1, 2025.

General Authority: NDCC 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