CHAPTER 33-06-16
NEWBORN SCREENING PROGRAM

SECTION 1. Section 33-06-16-01 is amended as follows:

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 ~~rule of~~ the state health ~~council~~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 ~~state~~ 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(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 2. Section 33-06-16-05 is amended as follows:

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 confidential 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~~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 ~~children's~~ special health services within the ~~state~~ department of health and human services for purposes of care coordination and provision of medical and low-protein modified foods.

~~c. Information and testing materials may be disclosed to a person engaged in a 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.~~

~~(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.~~

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

~~(5) Protected health information may not be provided to a person engaged in a research project until that person has submitted a written proposal explaining and justifying the need to examine such information.~~

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

2. Storage, maintenance, and disposal of information and testing materials.

a. Information and testing materials must 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 state department of health may be retained indefinitely or destroyed according to this subsection~~Dried blood spots must be destroyed thirty days after completion of testing. Residual specimens may be retained for use

for laboratory quality assurance purposes and must be destroyed after completion of quality assurance activities.

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.

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

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

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

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