

CHAPTER 25-17

TESTING AND TREATMENT OF NEWBORNS

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 department of health and human services.
4. "Licensed clinician" means a currently licensed physician, physician assistant, or advanced practice registered nurse.
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 licensed clinician for the dietary treatment of a metabolic disease. The term does not include a natural food that is naturally low in protein.
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 licensed clinician.
7. "Metabolic disease" and "genetic disease" mean a disease as designated by rule of the department 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, naturopath, 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.

25-17-01. Newborn screening education programs and tests.

The department shall:

1. Develop and implement a metabolic disease and genetic disease educational program among 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 program.
3. Coordinate with or refer individuals to public and private health care service providers for long-term followup services for metabolic diseases and genetic diseases.
4. Select a screening laboratory.
5. Store, maintain, and dispose of blood spots used for screening.

25-17-02. Rulemaking requirement.

The department shall adopt rules necessary to implement this chapter.

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.

25-17-03. Treatment for positive diagnosis - Registry of cases.

The department shall:

1. Notify responsible clinicians regarding cases with out-of-range screening results or positive confirmatory-diagnostic testing results in order to 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 to a 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-six 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-six 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-six who are receiving medical assistance and are diagnosed with phenylketonuria or maple syrup urine disease.

25-17-04. Testing and reporting requirements.

Repealed by S.L. 2015, ch. 204, § 9.

25-17-05. Testing charges.

A screening and confirmatory-diagnostic testing laboratory may charge fees for necessary services.

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 department 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.

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.