CHAPTER 4615
DEPARTMENT OF HEALTH
MATERNAL AND INFANT HEALTH

4615.0500 DUTIES OF RESPONSIBLE PARTIES INVOLVED IN THE NEWBORN METABOLIC SCREENING PROGRAM.

The responsible party shall do all of the following:

[For text of item A, see M.R. 1985]

B. Collect or have collected a specimen for screening no later than the fifth day after the infant's birth, unless the parents lawfully object to such screening. If this specimen is taken prior to 24 hours after birth, the responsible party shall notify the parents or legal guardian verbally and in writing of the necessity of having the PKU test repeated on their newborn not later than the 14th day of life. If taking a blood sample at the times specified above is medically contraindicated, the sample shall be taken as soon as the infant's condition permits.

[For text of item C, see M.R. 1985]

D. Send the specimen and the following information to the Minnesota Department of Health laboratory within 24 hours after collection:

(1) newborn infant's name;
(2) sex;
(3) mother's name;
(4) home address;
(5) date of birth;
(6) date of first feeding;
(7) date specimen collected;
(8) name and address of attending physician and hospital submitting specimen;
(9) county;
(10) birth weight or gestational age; and
(11) bottle, breast, both.

[For text of item E, see M.R. 1985]

Statutory Authority: *MS s 144.125*

History: *10 SR 276*

PHENYLKETONURIA TESTING PROGRAM; TREATMENT FOR POSITIVE DIAGNOSIS; REGISTRY OF CASES

4615.0750 PURPOSE AND SCOPE.

The purpose and scope of parts 4615.0750 to 4615.0760 is to describe the responsibilities of the Minnesota Department of Health to assure that persons diagnosed as having phenylketonuria and other metabolic diseases causing mental retardation will have access to treatment control tests and necessary financial

assistance for treatment of diagnosed cases when indicated, and will be included in a registry of cases for the purpose of coordinating follow-up services.

Statutory Authority: *MS s 144.128*

History: *10 SR 2290*

4615.0755 DEFINITIONS.

Subpart 1. **Scope.** For the purpose of parts 4615.0750 to 4615.0760 the following terms have the meaning given them.

Subp. 2. **Department.** "Department" means the Minnesota Department of Health.

Subp. 3. **Follow-up services.** "Follow-up services" means assisting the patient in accessing appropriate treatment and other services.

Subp. 4. **Other metabolic diseases causing mental retardation.** "Other metabolic diseases causing mental retardation" means those diseases identified in part 4615.0500.

Subp. 5. **Patient.** "Patient" means the person who has been diagnosed with phenylketonuria or other metabolic disease causing mental retardation or the person's parents or legal guardian.

Subp. 6. **Physician.** "Physician" means the medical doctor licensed under Minnesota Statutes, chapter 147, who is supervising the ongoing treatment of the patient. The patient may identify more than one such physician.

Subp. 7. **Recipient.** "Recipient" means patient.

Subp. 8. **Registry.** "Registry" means a permanent record maintained by the department on each patient diagnosed by a physician and reported to the department as having phenylketonuria or other metabolic disease causing mental retardation.

Subp. 9. **Treatment control test.** "Treatment control test" means a laboratory test to monitor medical treatment in diagnosed patients to assist in the medical management of the patient's metabolic disease.

Subp. 10. **Treatment control test specimen.** "Treatment control test specimen" means a specimen of blood or other body fluid collected from a patient.

Subp. 11. **Treatment control test specimen kit.** "Treatment control test specimen kit" means a kit containing suitable containers and other materials provided by the department and used to collect and transport a treatment control test specimen.

Statutory Authority: *MS s 144.128*

History: *10 SR 2290*

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

Subpart 1. **Treatment control test specimen kits.** The department shall develop and make available treatment control test specimen kits to physicians and patients as medically indicated to effectively monitor treatment, and provide the treatment control test specimen kit and the laboratory evaluation of the treatment control test specimen at no cost to the patient.

Subp. 2. **Reporting of test results.** The department shall report the laboratory results of the treatment control tests to the physician or patient submitting the treatment control test specimen. If the treatment control test specimen is submitted directly by the patient, the patient shall identify a physician who shall receive a copy of the laboratory results.

Subp. 3. **Assistance in obtaining treatment.** The department shall make arrangements for the medically indicated treatment of the metabolic defect causing mental retardation in diagnosed cases of phenylketonuria and other metabolic disease causing mental retardation when the patient is uninsured or is unable to pay the cost of treatment because of a lack of available income. The

arrangements include referral to appropriate agencies which have financial resources to pay for medically indicated treatment such as private health insurance companies, medical assistance, and Services for Children with Handicaps.

Subp. 4 **Registry of cases.** The department shall maintain a registry of all diagnosed cases of phenylketonuria and other metabolic diseases causing mental retardation reported to the department. The registry shall be updated not more often than annually by direct contact with the patient to determine their address and their need for medical treatment services, educational materials and counseling related to their metabolic disease. The registry shall include the following minimum data on each patient:

A. name of patient;

B. gender;

C. date of birth;

D. place of birth;

E. parents' names,

F. current address of patient;

G. diagnosis;

H. name and address of physician; and

I other data the commissioner deems necessary for follow-up services.

Subp. 5. **Classification of data.** The department shall treat all data in the registry as private pursuant to Minnesota Statutes, section 13.38, the Minnesota Government Data Practices Act.

Statutory Authority: *MS s 144 128*

History: *10 SR 2290*