CHAPTER 4615

DEPARTMENT OF HEALTH

MATERNAL AND INFANT HEALTH

TESTS OF INFANTS FOR INBORN METABOLIC DEFECTS

METABOLIC DEFECT TESTING, TREATMENT, AND REGISTRY

REPORTING OF MATERNAL DEATHS

TERMINATION OF PREGNANCY

4615.0200 [Repealed, 11 SR 1887]

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TESTS OF INFANTS FOR INBORN METABOLIC DEFECTS

4615.0300 PURPOSE AND SCOPE.

Parts 4615.0300 to 4615.0700 describe the responsibilities of the hospitals, physicians, and the Minnesota Department of Health to assure that all newborn infants are screened for hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia.

Statutory Authority: *MS s 144.125; 144.128*

History: *17 SR 1758*

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4615.0400 DEFINITIONS.

Subpart 1. **Scope.** For the purpose of this chapter, the following terms have the meanings given them.

Subp. 2. **Attending physician.** "Attending physician" means the physician who is identified on the specimen card as the physician submitting the specimen.

Subp. 3. **Newborn infant.** "Newborn infant" means a child from birth through the first five days of life.

Subp. 4. **Positive screening results.** "Positive screening results" means that laboratory tests clearly indicate that the child has a high risk for developing one or more of the diseases covered by parts 4615.0300 to 4615.0700.

Subp. 5. **Responsible party.** "Responsible party" means the administrative officer or other person in charge of the hospital where the child is born, and the physician or other person operating under the supervision of a physician in attendance at the birth, or if not so attended, one of the parents.

Subp. 6. **Screen.** "Screen" means to carry out a series of laboratory tests on a dried capillary blood specimen which will identify those newborn infants who may develop hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia.

Subp. 7. **Specimen.** "Specimen" means a specimen of dried blood from the newborn infant collected on a specimen card.

Subp. 8. **Specimen card.** "Specimen card" means a filter paper card provided by the Minnesota Department of Health and used to collect the specimen.

Statutory Authority: *MS s 144.125; 144.128*

History: *17 SR 1758*

Published Electronically: *August 12, 2013*

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

The responsible party shall do all of the following:

A. inform the parent(s) or legal guardian that their newborn(s) will be screened for the metabolic diseases hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia, and explain the reasons for such screening and their right to refuse this screening on the grounds that such tests conflict with their religious tenets and practices;

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 phenylketonuria 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;

C. record on a permanent record the date the specimen is collected;

D. send the specimen card including all of the required information as indicated on the card to the Minnesota Department of Health laboratory within 24 hours after collection; and

E. if the newborn infant is transferred to a second health care facility before the specimen is collected, the responsible party shall inform the second facility of this fact and may delegate to it the responsibility for collecting and transmitting the specimen.

Statutory Authority: *MS s 144.125; 144.128*

History: *10 SR 276; 17 SR 1758*

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4615.0600 DUTIES OF DEPARTMENT OF HEALTH.

The Minnesota Department of Health shall do all of the following:

A. develop specimen cards and make them available to the responsible party;

B. maintain a record of all cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia reported to it; and

C. notify the attending physician within 24 hours of obtaining the results, verbally and in writing by deposition in first class mail, of positive screening results and provide consultation on diagnostic and treatment sources available.

Statutory Authority: *MS s 144.125; 144.128*

History: *17 SR 1758*

Published Electronically: *October 11, 2007*

4615.0700 DUTIES OF ATTENDING PHYSICIAN.

The attending physician shall do all of the following:

A. report, in writing, results of diagnostic evaluation of all instances of positive newborn screening results of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia to: Human Genetics Unit, Minnesota Department of Health, 717 SE Delaware Street, P.O. Box 9441, Minneapolis, MN 55440-9441; and

B. however, if the attending physician refers a patient with positive screening results to a medical specialist for diagnosis and/or treatment, the attending physician may delegate the responsibility for reporting a confirmed diagnosis to the medical specialist.

Statutory Authority: *MS s 144.125; 144.128*

History: *17 SR 1758*

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METABOLIC DEFECT TESTING, TREATMENT, AND REGISTRY

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 hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia will: (1) have access to approved laboratory treatment control tests when available; (2) have necessary financial assistance for treatment of diagnosed cases when indicated; and (3) be included in a registry of cases for the purpose of coordinating follow-up services.

Statutory Authority: *MS s 144.125; 144.128*

History: *10 SR 2290; 17 SR 1758*

Published Electronically: *October 11, 2007*

4615.0755 DEFINITIONS.

Subpart 1. **Scope.** For the purpose of parts 4615.0750 to 4615.0760, the following terms have the meanings 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. [Repealed, 17 SR 1758]

Subp. 5. **Patient.** "Patient" means the person who has been diagnosed with hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia 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. [Repealed, 17 SR 1758]

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 hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia.

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 144.125; 144.128*

History: *10 SR 2290; 17 SR 1758*

Published Electronically: *August 7, 2013*

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 in diagnosed cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia 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, MinnesotaCare, and Services for Children with Disabilities.

Subp. 4. **Registry of cases.** The department shall maintain a registry of all diagnosed cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia 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 13.3805, the Minnesota Government Data Practices Act.

Statutory Authority: *MS s 144.125; 144.128*

History: *10 SR 2290; 17 SR 1758; L 1995 c 234 art 8 s 56; L 1999 c 227 s 22; L 2005 c 56 s 2*

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REPORTING OF MATERNAL DEATHS

4615.0800 PROCEDURES FOR REPORTING OF MATERNAL DEATHS.

Any death associated with pregnancy, including abortion and extrauterine pregnancy, or the puerperium for a period of three months postpartum, whether or not it is the actual cause of death, shall be reported by mail within three days after death to the Minnesota Department of Health, Section of Maternal and Child Health, by the attending physician and by the hospital where the death occurred.

Statutory Authority: *MS s 144.05; 144.12*

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4615.2100 [Repealed, 25 SR 805]

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4615.2200 Subpart 1. [Repealed, 25 SR 805]

Subp. 2. [Repealed, 25 SR 805]

Subp. 3. [Repealed, 25 SR 805]

Subp. 4. [Repealed, 25 SR 805]

Subp. 5. [Repealed, 25 SR 805]

Subp. 6. [Repealed, 25 SR 805]

Subp. 7. [Repealed, 25 SR 805]

Subp. 8. [Repealed by amendment, L 1977 c 305 s 39]

Subp. 9. [Repealed, 25 SR 805]

Subp. 10. [Repealed, 25 SR 805]

Subp. 11. [Repealed, 25 SR 805]

Subp. 12. [Repealed, 25 SR 805]

Subp. 13. [Repealed, 25 SR 805]

Subp. 14. [Repealed, 25 SR 805]

Subp. 15. [Repealed, 25 SR 805]

Subp. 16. [Repealed, 25 SR 805]

Subp. 17. [Repealed, 25 SR 805]

Subp. 18. [Repealed, 25 SR 805]

Subp. 19. [Repealed, 25 SR 805]

Subp. 20. [Repealed, 25 SR 805]

Subp. 21. [Repealed, 25 SR 805]

Subp. 22. [Repealed, 25 SR 805]

Subp. 23. [Repealed, 25 SR 805]

Subp. 24. [Repealed, 25 SR 805]

Subp. 25. [Repealed, 25 SR 805]

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4615.3300 [Repealed, 25 SR 805]

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TERMINATION OF PREGNANCY

4615.3400 DEFINITIONS.

Subpart 1. **Scope.** The applicable definitions to these rules printed herein from MHD 342 (7 MCAR Section 1.342) are as follows.

Subp. 2. **Abortion.** The term "abortion" is not used in these regulations, since it also applies to spontaneous early terminations of pregnancy. These rules do not apply to spontaneous abortions.

Subp. 3. **Ambulatory facility.** "Ambulatory facility" shall mean any institution, place or building, or part thereof, including hospital outpatient services, devoted primarily to, as determined by the department, the maintenance and operation of facilities for the performance of procedures designed to terminate a pregnancy on an outpatient basis irrespective of whether the entire structure is devoted primarily to this purpose.

Subp. 4. **Termination of pregnancy.** "Termination of pregnancy," "pregnancy termination," or "termination procedure," shall mean administering to a woman any medicine, drug, substance, or thing whatever, or the employment upon her of any instrument or other means whatever, with intent to induce or procure miscarriage of such a woman.

Statutory Authority: *MS s 145.413*

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4615.3500 INTERNAL RECORDS OF THE AMBULATORY FACILITY.

The pregnancy termination facility shall keep a signed consent form of each patient undergoing a pregnancy termination procedure.

Statutory Authority: *MS s 145.413*

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4615.3600 REPORTS TO THE COMMISSIONER OF HEALTH.

Subpart 1. **Statistical reports.** Each ambulatory facility shall submit a written compilation of statistical data quarterly to the commissioner of health on such forms and in such manner as the commissioner may prescribe.

Subp. 2. **Reporting terminations.** An ambulatory facility shall report all pregnancy terminations performed by its staff as follows:

A. By the tenth of each month all pregnancy terminations performed in the ambulatory facility during the preceding month shall be reported on forms prescribed by the commissioner which shall include but not be limited to the following items:

(1) patient's city, county and state of residency;

(2) census tract for city of Minneapolis and city of Saint Paul;

(3) patient or chart number;

(4) age;

(5) race;

(6) marital status;

(7) number of living children;

(8) facility name;

(9) facility address;

(10) number of previous induced pregnancy terminations patient;

(11) estimate of gestational age;

(12) date of pregnancy termination; and

(13) type of termination procedure.

B. All surgery-related or anesthesia-related complications which result in morbidity or death of a patient shall be reported in writing to the commissioner within 15 days from the notification to the ambulatory facility of the morbidity or death of the patient.

C. The commissioner shall ensure and maintain confidentiality of all individual pregnancy termination records.

Statutory Authority: *MS s 145.413*

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