

1 Department of Health

2

3 Adopted Permanent Rules Relating to Infants; Newborn Metabolic
4 Error Test

5

6 Rules as Adopted

7 TESTS OF INFANTS FOR INBORN METABOLIC ERRORS

8 4615.0300 PURPOSE AND SCOPE.

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

14 4615.0400 DEFINITIONS.

15 [For text of subps 1 to 4, see M.R.]

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

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

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

28 [For text of subp 8, see M.R.]

29 4615.0500 DUTIES OF RESPONSIBLE PARTIES INVOLVED IN NEWBORN
30 METABOLIC SCREENING PROGRAM.

31 The responsible party shall do all of the following:

32 A. Inform the parent(s) or legal guardian that their
33 newborn(s) will be screened for the metabolic diseases
34 hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism,

1 and congenital adrenal hyperplasia, and explain the reasons for
2 such screening and their right to refuse this screening on the
3 grounds that such tests conflict with their religious tenets and
4 practices.

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

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

16 D. Send the specimen card including all of the
17 required information as indicated on the card to the Minnesota
18 Department of Health laboratory within 24 hours after collection.

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

20 4615.0600 DUTIES OF DEPARTMENT OF HEALTH.

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

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

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

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

32 4615.0700 DUTIES OF ATTENDING PHYSICIAN.

33 The attending physician shall do all of the following:

34 A. Report, in writing, results of diagnostic
35 evaluation of all instances of positive newborn screening

1 results of hemoglobinopathy, phenylketonuria, galactosemia,
2 hypothyroidism, and congenital adrenal hyperplasia to: Human
3 Genetics Unit, Minnesota Department of Health, 717 SE Delaware
4 Street, P.O. Box 9441, Minneapolis, MN 55440-9441.

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

10 HEMOGLOBINOPATHY, PHENYLKETONURIA, GALACTOSEMIA,
11 HYPOTHYROIDISM, AND CONGENITAL ADRENAL HYPERPLASIA TESTING
12 PROGRAM; TREATMENT FOR POSITIVE DIAGNOSIS; REGISTRY OF CASES
13 4615.0750 PURPOSE AND SCOPE.

14 The purpose and scope of parts 4615.0750 to 4615.0760 is to
15 describe the responsibilities of the Minnesota Department of
16 Health to assure that persons diagnosed as having
17 hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism,
18 and/or congenital adrenal hyperplasia will: (1) have access to
19 approved laboratory treatment control tests when available; (2)
20 have necessary financial assistance for treatment of diagnosed
21 cases when indicated; and (3) be included in a registry of cases
22 for the purpose of coordinating follow-up services.

23 4615.0755 DEFINITIONS.

24 [For text of subps 1 to 3, see M.R.]

25 Subp. 4. [See repealer.]

26 Subp. 5. **Patient.** "Patient" means the person who has been
27 diagnosed with hemoglobinopathy, phenylketonuria, galactosemia,
28 hypothyroidism, and/or congenital adrenal hyperplasia or the
29 person's parents or legal guardian.

30 [For text of subp 6, see M.R.]

31 Subp. 7. [See repealer.]

32 Subp. 8. **Registry.** "Registry" means a permanent record
33 maintained by the department on each patient diagnosed by a
34 physician and reported to the department as having
35 hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism,

1 and/or congenital adrenal hyperplasia.

2 [For text of subps 9 to 11, see M.R.]

3 4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

4 [For text of subps 1 and 2, see M.R.]

5 Subp. 3. Assistance in obtaining treatment. The
6 department shall make arrangements for the medically indicated
7 treatment of the metabolic defect in diagnosed cases of
8 hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism,
9 and/or congenital adrenal hyperplasia when the patient is
10 uninsured or is unable to pay the cost of treatment because of a
11 lack of available income. The arrangements include referral to
12 appropriate agencies which have financial resources to pay for
13 medically indicated treatment such as private health insurance
14 companies, medical assistance, Children's Health Plan, and
15 Services for Children with Handicaps.

16 Subp. 4. Registry of cases. The department shall maintain
17 a registry of all diagnosed cases of hemoglobinopathy,
18 phenylketonuria, galactosemia, hypothyroidism, and congenital
19 adrenal hyperplasia reported to the department. The registry
20 shall be updated not more often than annually by direct contact
21 with the patient to determine their address and their need for
22 medical treatment services, educational materials and counseling
23 related to their metabolic disease. The registry shall include
24 the following minimum data on each patient:

25 [For text of items A to I, see M.R.]

26 [For text of subp 5, see M.R.]

27 REPEALER. Minnesota Rules, part 4615.0755, subparts 4 and 7,
28 are repealed.