

1 Department of Health

2

3 Adopted Rules Relating to Phenylketonuria Testing Program, the
4 Treatment for Positive Diagnosis, and a Registry of Cases

5

6 Rules as Adopted

7 4615.0750 PURPOSE AND SCOPE.

8 The purpose and scope of parts 4615.0750 to 4615.0760 is to
9 describe the responsibilities of the Minnesota Department of
10 Health to assure that persons diagnosed as having
11 phenylketonuria and other metabolic diseases causing mental
12 retardation will have access to treatment control tests and
13 necessary financial assistance for treatment of diagnosed cases
14 when indicated, and will be included in a registry of cases for
15 the purpose of coordinating follow-up services.

16 4615.0755 DEFINITIONS.

17 Subpart 1. Scope. For the purpose of parts 4615.0750 to
18 4615.0760 the following terms have the meaning given them.

19 Subp. 2. Department. "Department" means the Minnesota
20 Department of Health.

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

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

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

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

35 Subp. 7. Recipient. "Recipient" means patient.

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

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

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

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

17 4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

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

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

31 Subp. 3. Assistance in obtaining treatment. The
32 department shall make arrangements for the medically indicated
33 treatment of the metabolic defect causing mental retardation in
34 diagnosed cases of phenylketonuria and other metabolic disease
35 causing mental retardation when the patient is uninsured or is

1 unable to pay the cost of treatment because of a lack of
2 available income. The arrangements include referral to
3 appropriate agencies which have financial resources to pay for
4 medically indicated treatment such as private health insurance
5 companies, medical assistance, and Services for Children with
6 Handicaps.

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

- 16 A. name of patient;
- 17 B. gender;
- 18 C. date of birth;
- 19 D. place of birth;
- 20 E. parents' names;
- 21 F. current address of patient;
- 22 G. diagnosis;
- 23 H. name and address of physician; and
- 24 I. other data the commissioner deems necessary for
25 follow-up services.

26 Subp. 5. Classification of data. The department shall
27 ~~classify~~ treat all data in the registry as private pursuant to
28 Minnesota Statutes, section 13.38, the Minnesota Government Data
29 Practices Act.