

**STATE OF MINNESOTA**  
**COUNTY OF HENNEPIN**

**BEFORE THE MINNESOTA**  
**COMMISSIONER OF HEALTH**

**IN THE MATTER OF THE ADOPTION  
OF RULES RELATING TO A  
PHENYLKETONURIA TESTING PROGRAM,  
THE TREATMENT FOR POSITIVE  
DIAGNOSIS, AND A REGISTRY OF  
OF CASES.**

**STATEMENT OF NEED  
AND REASONABLENESS**

The Minnesota Commissioner of Health (hereinafter "Commissioner"), pursuant to Minnesota Statutes 14.23, presents facts establishing the need for and reasonableness of proposed rules relating to treatment control testing for phenylketonuria and other metabolic diseases causing mental retardation, treatment for cases with positive diagnosis, and the establishment of a registry of cases.

In order to adopt the proposed rules, the Commissioner must demonstrate that she has complied with all the procedural and substantive requirements of rulemaking. Those requirements are that: 1) there is statutory authority to adopt the rule, 2) all necessary procedural steps have been taken, 3) the rules are needed, 4) the rules are reasonable, and 5) any additional requirements imposed by law have been satisfied. This statement demonstrates that the Commissioner has met these requirements.

## TABLE OF CONTENTS

1. Statutory Authority
2. Statement of Need
3. Compliance with Procedural Rulemaking Requirements
4. General Statement of Reasonableness
5. Rule-by-rule Justification

## 1. STATUTORY AUTHORITY

The statutory authority of the Commissioner to adopt these rules is Minnesota Statutes, Section 144.128 which requires the agency to adopt rules to carryout the purposes of Minnesota Statutes, Sections 144.126 and 144.128 (Supp. 1985).

## 2. STATEMENT OF NEED

When an individual is diagnosed as having phenylketonuria and other diseases causing mental retardation it is important that the physician and patient have access to appropriate resources for monitoring the treatment of the disease to assure that the potential mental retardation symptom of the disease is as minimal as possible. As the treatment of phenylketonuria and other diseases causing mental retardation may be life long it is appropriate that a centralized treatment control testing resource be a part of the ongoing medical care of the patient.

Patients diagnosed with phenylketonuria and other diseases causing mental retardation should have access to medical treatment of their disease regardless of the ability to pay for treatment.

A registry of all patients with phenylketonuria and other metabolic diseases causing mental retardation diagnosed and reported in Minnesota will provide a resource for follow-up and access to appropriate treatment services, educational material and counseling over a life time if necessary.

The needs for each specific provision in the proposed rules is addressed in the rule-by-rule justification. It is the Department's position that the need of all rules proposed at this time is obvious and well established.

### 3. COMPLIANCE WITH PROCEDURAL RULEMAKING REQUIREMENTS

Minnesota Statutes, Sections 14.05-14.12 and 14.22-14.28, specify certain procedures which must be followed when an agency adopts or amends rules without a public hearing. Procedures applicable to all rules (Minnesota Statute, Section 14.05-14.12) have been complied with by the Commissioner. The Commissioner has determined that the adoption of the rules in 4615.0750, 4615.0755 and 4615.0760 is non-controversial and has elected to follow the procedures set forth in Minnesota Statutes, Sections 14.22-14.28 which provide for an expedited process for the adoption of non-controversial administrative rule changes without the holding of public hearing.

#### Procedural Rulemaking Requirements of the Administrative Procedure Act

Minnesota Statute, Section 14.10 requires an agency which seeks information or opinions in preparation for adoption of rules from sources outside the agency to publish a notice of its action in the State Register and afford all interested persons an opportunity to submit data or comments on the subject. In the State Register issue of Monday, December 16, 1985, the Commissioner published a "Notice of Intent to Solicit Outside Information and Opinions Concerning the Adoption of Rules relating to a Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases.

These rules do incorporate by reference Minnesota Rules, part 4615.0500. These rules do not duplicate any statutory language. See Minnesota Statutes, Section 14.07 subd. 3. The adoption of these rules will not require the

expenditure of public money by local public bodies of greater than \$100,000 in either of the two years following promulgation, nor do the rules have any impact on agricultural land. Minnesota Statutes, Section 14.11. The adoption of these rules will not affect small businesses. Minnesota Statute Section 14.115.

Pursuant to Minnesota Statutes, Section 14.23, the Commissioner has prepared this statement of need and reasonableness which is available to the public. The Commissioner will publish notice of intention to adopt the rules without public hearing in the State Register and mail copies of the notice and proposed rules to persons registered with the Minnesota Department of Health pursuant to Minnesota Statute Section 14.14 subd. 1a. The notice will include the following statements: a) that the public have 30 days in which to submit comments on the proposed rule; b) that no public hearing will be held unless 25 or more persons make a written request for a hearing within 30-day comment period; c) giving information pertaining to the manner in which persons shall request a hearing; d) that the rule may be modified if modifications are supported by data and the views submitted, and e) other information required by Minnesota Statutes, Section 14.22.

If twenty-five or more persons submit to the Minnesota Department of Health a written request for a hearing of the proposed rule, the agency shall proceed under the provisions of Minnesota Statutes, Sections 14.131-14.20, and notice of hearing shall be published in the State Register.

If no hearing is required, the Commissioner will submit the proposed rule and notice as published, the rule as proposed for adoption, any written comments which have been received, and this statement of need and reasonableness to the Attorney General for approval.

These rules shall become effective five working days after publication of a notice of adoption in the State Register.

#### 4. GENERAL STATEMENT OF REASONABLENESS.

In order to adopt administrative rules, an agency must demonstrate that the proposed rules are reasonable. Rulemaking is a process which primarily involves policy decisions. There are many differing policy perspectives and biases which can, therefore, result in many reasonable ways to address a subject covered by administrative rules.

These rules provide a framework within which the Commissioner can reasonably assure that patients who have been diagnosed with phenylketonuria and other metabolic diseases causing mental retardation and who have been reported to the Department will have access to appropriate medical care and treatment regardless of their age or ability to pay. The rules will also provide a centralized resource for patients and physicians who have need for treatment control testing laboratory services to assist in the ongoing management of the disease at no cost to the patient. Once the patient's diagnosis and medical treatment program have been firmly established, access to a treatment control resource, especially for older patients, offers an option in periodically monitoring their self administered medical treatment regimen between prescribed visits to their physician.

The rules will allow the Department to maintain a follow-up capability by means of a statewide registry. This registry will permit the Department to maintain contact with patients, help them access appropriate resources regarding the treatment and management of their disease, and serve as a central contact for patients who wish access or reaccess to the medical treatment system.

The Commissioner of Health asserts that the rules proposed here are



reasonable. They have a rational basis in law, medicine, and public health practice; do not represent arbitrary or capricious policies; and meet every procedural and substantive requirement for adoption.

## 5. RULE-BY-RULE JUSTIFICATION

### 4615.0755 DEFINITIONS

1. "Department" This definition is necessary for the purpose of brevity.
2. "Follow-up services" This definition is necessary to clarify the Department's responsibility in identifying and coordinating resources to assist the patient in ameliorating the genetic and medical causes of mental retardation.
3. "Other metabolic diseases causing mental retardation" This definition is necessary to clearly identify those specific diseases for which the Department has responsibility under Minnesota Rules, part 4615.0500. Currently these diseases are phenylketonuria, galactosemia and hypothyroidism. In the future the Department may add other diseases under the authority in Minnesota Statutes 144.125.
4. "Patient" This definition is necessary to identify persons responsible for patients under the age of 18 years.
5. "Physician" This definition is necessary in order to identify the person who has primary responsibility for the ongoing, long term treatment of the patient.
6. "Recipient" This definition is necessary for clarification.
7. "Registry" This definition is necessary to identify the type of registry which the Department will maintain.
8. "Treatment control test" This definition is necessary to clarify that an appropriate laboratory test will be available through the Department for the purpose of monitoring the treatment of the patient's metabolic

disease. There are no governmental or professional standards by which laboratory procedures for treatment control testing of phenylketonuria and other metabolic diseases causing mental retardation are approved. The Department will use those laboratory procedures which are generally accepted as appropriate and acceptable by physicians and other laboratories doing similar testing. These treatment control tests are not intended to substitute or replace medically indicated diagnostic/treatment tests and procedures prescribed by a physician.

9. "Treatment control test specimen" This definition is necessary to identify the general type of specimen necessary for the treatment control test.
10. "Treatment control test specimen kit" This definition is necessary to identify the material which the Department may provide to the patient and physician for collecting the treatment control specimen.

4615.0750 PURPOSES AND SCOPE

As stated in the proposed rules, the purpose is to establish a process and assign responsibility to carry out the provisions of Minnesota Statutes 144.126 and 144.128 with regard to access to treatment control testing, financial assistance for treatment, and development of a registry for persons diagnosed as having phenylketonuria and other metabolic diseases causing mental retardation.

4615.0755 THE DEPARTMENT SHALL DO ALL OF THE FOLLOWING

1. This item is included to comply with Minnesota Statute 144.126.
2. This item is included to assure that the patient will receive the laboratory results of the treatment control test if the patient wishes

them, and also assures that a physician of the patient's choice will receive a copy of the laboratory results to assist the patient in interpreting how the treatment control test evaluation impacts on the ongoing treatment of the disease as appropriate.

3. This item is included to comply with Minnesota Statute, 144.128(1). It identifies the type of treatment related to mental retardation for which the Department will assist the patient in finding financial assistance to cover the cost of treatment. It identifies the Department's role in finding financial assistance regardless of the patient's age.
  
4. This item is included to comply with Minnesota Statute 144.128(2). It identifies the procedures by which the Department will maintain an on-going, current registry and the minimal data the Department will maintain on each patient. The registry will permit the Department to maintain long term contact with patients to assure that they are receiving appropriate medical treatment, have access to appropriate counseling and are informed of any new developments in medical treatment. It will also provide the patients with a centralized resource if they need information or assistance.
  
5. This item is included to assure the privacy of the patient information in the Department's registry and to limit access to that information in as prescribed under the Minnesota government data practices act.