

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH

IN THE MATTER OF AMENDMENTS
TO A RULE RELATED TO THE
DUTIES OF RESPONSIBLE PARTIES
INVOLVED IN THE NEWBORN
METABOLIC SCREENING PROGRAM,
MINNESOTA RULES PART 4615.0500

STATEMENT OF NEED
AND REASONABLENESS

The Minnesota Commissioner of Health (hereinafter "commissioner"), pursuant to Minnesota Statutes 14.05 and 14.21 and rules 1400.0200-1400.0900, presents facts establishing the need for and reasonableness of amendments to rules relating to the duties of responsible parties involved in the newborn metabolic screening program.

In order to adopt the proposed amendments, 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

	<u>Page</u>
1. Statutory Authority	3
2. Statement of Need	4
3. Compliance with Procedural Rulemaking Requirements.	5
4. General Statement of Reasonableness	8
5. Justification	9

1. STATUTORY AUTHORITY.

The statutory authority of the commissioner to adopt an amendment to the rule related to the duties of responsible parties involved in the newborn metabolic screening program is found in Minnesota Statutes, section 144.125.

2. STATEMENT OF NEED.

The commissioner of health has been authorized by state statute to prescribe the times and the manner of the testing and the recording and reporting of the results of tests of newborn infants for phenylketonuria (PKU) and other inborn errors of metabolism causing mental retardation.

The rule which was adopted and which has been in place since 1978 no longer reflects the current trend of hospital care nor the recommendations of the Committee of Genetics of the American Academy of Pediatrics regarding PKU screening. Also, current testing policies require unnecessary second testing in some situations, resulting in an added burden to the responsible parties involved in the newborn metabolic screening program.

Therefore, it is necessary to amend the metabolic screening rule. The need for each specific amendment to the rule is discussed in greater detail in the justification section of this document.

3. COMPLIANCE WITH PROCEDURAL RULEMAKING REQUIREMENTS.

The commissioner has determined that the amendment of part 4615.0500 is non-controversial and has elected to follow the procedures set forth in Minnesota Statutes, section 14.05 through 14.12 and 14.22 through 14.28 which provide for an expedited process for the adoption of non-controversial administrative rule changes without the holding of a public hearing.

Procedural Rulemaking Requirements of the Administrative Procedure Act

Minnesota Statutes, 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, April 23, 1984, at page 2306, the commissioner published a notice entitled "Outside Opinion Sought Regarding: 1) Rules Governing Administration of the Special Supplemental Food Program for Women, Infants and Children (WIC); 2) Rules Governing Administration of the Maternal and Child Health (MCH) Grant Programs; 3) an Amendment to a Rule Governing Metabolic Screening, 7 MCAR § 1.172 [now 4615.0300 to 4615.0700]; 4) an Amendment to a Rule Governing Family Planning Special Projects, 7 MCAR § 1.457 [now 4700.1900 to 4700.2500]; 5) Repeal of a Rule Governing Private Baby Homes and Infant Homes, MDH 171 [now 4615.0200]; and 6) Amendments

to Rules Relating to Services for Children with Handicaps and Adults with Cystic Fibrosis and Hemophilia for Eligibility, Cost Sharing and Reimbursement, 7 MCAR §§ 1.651-1.657 [now 4705.0100 to 4705.1400]."

These rules minimize the duplication of statutory language. See Minnesota Statutes, section 14.07, subdivision 3 (1). The implementation 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 their adoption, nor do the rules have any impact on agricultural land. See Minnesota Statutes, section 14.11. The adoption of these rules will not affect small businesses. See Minnesota Statutes, section 14.115, subd. 7 (c).

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 Statutes, section 14.14, subdivision 1 (a). The notice will include the following statements: a) that the public have 30 days in which to submit comments on the proposed rules; b) that no public hearing will be held unless 25 or more persons make a written request for a hearing within the 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 25 or more persons submit to the Minnesota Department of Health a written request for hearing on the proposed rule, the agency shall proceed under the provisions of Minnesota Statutes, sections 14.131 through 14.20 and notice of the 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 as to their legality and form to the extent that it relates to legality.

These rules shall become effective 5 working days after publication of a notice of adoption in the State Register.

4. GENERAL STATEMENT OF REASONABLENESS.

The several amendments that have been proposed regarding the rule related to the duties of responsible parties involved in the newborn metabolic screening program have been designed to promote a more efficient and less burdensome approach to metabolic screening. The proposed amendments have a basis in medical science, as well as in sound administrative policies. Because the amendments will make the screening program less burdensome, this approach will be more reasonable for those persons who are responsible for the testing and the recording and reporting of PKU test results. Also, the parents of newborns will find this approach more reasonable.

The reasonableness of the specific amendments is discussed in greater detail in the justification section of this document. It is the department's position that the reasonableness of these amendments is obvious and well established.

5. JUSTIFICATION

Part 4615.0500 establishes the duties of responsible parties involved in the metabolic screening program.

Item B has been amended to require a second PKU test only if the first test is taken prior to 24 hours from birth.

This amendment has been made for several reasons.

First, the amendment reflects the current trend in pediatric care, which is to release newborn infants from the hospital at an earlier point in time, often prior to the third day of life. Under the current rule, these infants are required to undergo a second and likely unnecessary test. This amendment will eliminate a second test requirement for most of these infants.

Second, the rule amendment is intended to avoid an excess or unreasonable number of second tests for PKU. Because of the reliability of PKU tests on infants over 24 hours of age, there is no need to retest when the initial test is properly conducted. The rule will require a second PKU test only when the initial test was administered prior to 24 hours of life, at a time when reliability is more of a factor.

Third, the amendment coincides with the recommendation of the Committee on Genetics of the American Academy of Pediatrics. (Pediatrics, Vol. 69, No. 1, January 1982, pp. 104-106.) The policy statements and recommendations for child health care issued by the American Academy of Pediatrics are generally and widely accepted.

The commissioner has been granted the authority to prescribe procedures for the testing and the recording and reporting of the results of tests for inborn metabolic errors at such time and in such manner as the commissioner chooses. Therefore, amending the timing of the second test requirement of Item B is a discretionary power which is within the scope of the commissioner's authority to regulate in the area of metabolic screening of newborns.

Item D, subitem (10) has been amended by substituting "birthweight or gestational age" for "prematurity (yes or no)." Prematurity can be described in terms of gestational age or birth weight. Therefore, the department is interested in collecting either one of these statistics as an indicator of prematurity. In order to specifically allow for either measurement, this item has been amended.



Edward L. Hendricks, MD, MPH

2/20/85