7/20/92

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

IN THE MATTER OF THE	**STATEMENT OF NEED**
PROPOSED ADOPTION OF AMENDMENTS TO	**AND**
RULES OF THE	**REASONABLENESS**
DEPARTMENT OF HEALTH	
RELATING TO TESTING, TREATMENT, AND	
REGISTRY OF CASES OF INFANTS WITH	
INBORN METABOLIC ERRORS	

STATUTORY AUTHORITIES

The Minnesota Commissioner of Health (hereinafter "commissioner"), pursuant to Minnesota Statutes, section 14.05 through 14.28 presents facts establishing the need for and reasonableness of the proposed amendments to the following rules relating to Tests of Infants For Inborn Metabolic Errors Causing Mental Retardation: Minnesota Rules, parts 4615.0300, 4615.0400, 4615.0500, 4615.0600, 4615.0700, 4615.0750, 4615.0755, 4615.0760.

The statutory authority of the commissioner to adopt these rules is Minnesota Statutes, section 144.125 and section 144.128 which require the agency to adopt rules to carry-out the purposes of

Minnesota Statutes, sections 144.125, 144.126 and 144.128.

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 Statutes, sections 14.05-14.12) have been complied with by the commissioner. The commissioner has determined that the amendment of the rules in 4615.0300, 4615.0400, 4615.0500, 4615.0600, 4615.0700, 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 this 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. This subject was discussed in meetings of the Ad Hoc Newborn Screening Advisory Committee and it was recommended that the screening program be expanded to add

congenital adrenal hyperplasia and that the relevant rules be amended as appropriate to reflect this expansion. In the State Register issue dated January 21, 1992 the commissioner published a "Notice of Solicitation of Outside Opinion Regarding the Proposed Adoption of Amendments to Rules of the Department of Health Relating to Testing, Treatment, and Registry of Cases of Infants with Inborn Metabolic Errors."

These rules do not duplicate statutory language, in conformance with 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. This is because the same blood sample presently taken for the screening program will be utilized and the test cost will only marginally increase the fee charged for the test. The rules will have no impact on agricultural land. (Minnesota Statutes, section 14.11.) The adoption of these rules will not affect small businesses. (Minnesota Statutes, section 14.115.) This is because the same blood sample presently taken for the screening program will be utilized and the test cost will only marginally increase the fee charged for the test.

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 a 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 the 30-day comment period; c) giving information pertaining to the matter 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 a 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 amendment, 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.

STATEMENT OF NEED

Since the last revision of the rules relating to Tests of Infants for Inborn Metabolic Errors Causing Mental Retardation, there have been changes in the legislation mandating these Rules; Minn. Stat. § 144.125 (1988), and Minn. Stat. § 144.126 and Minn. Stat. § 144.128 (1991). These legislative revisions added "hemoglobinopathy" as a metabolic error for which the Department must screen all newborns, deleted the terminology "metabolic diseases causing mental retardation," and added specific criteria which the commissioner must take into consideration when adding new diseases for which screening must be done.

The first need for the amendments is to change the language of the rules so that it is in agreement with the legislative changes. This has been done.

The second need is to add the metabolic disease "congenital adrenal hyperplasia" to the group of diseases for which the Department now screens, i.e., hemoglobinopathy, phenylketonuria, galactosemia and hypothyroidism.

The need for each specific provision in the amended rules is addressed in the amendment by amendment justification. It is the Department's position that the need for all amendments proposed in this rulemaking is well established.

GENERAL STATEMENT OF REASONABLENESS

The proposed amendments to the rules relating to Testing, Treatment and Registry of Cases of Infants with Inborn Metabolic Errors are intended to 1) have consistent and uniform language in the rules based on legislative changes and 2) add congenital adrenal hyperplasia to the list of diseases for which the Department screens all newborns.

The changes in language of Minnesota Statutes Sections 144.125, 144.126, and 144.128 are such that the Rules require amendment. In each of these Statutes "hemoglobinopathy" has been added as a disease for which the Minnesota Department of Health is required to screen all newborns. The legislature determined that there was sufficient evidence that certain hemoglobinopathies may cause severe disability or death if not detected early in the infants life and medical treatment initiated. The Statutes also removed the phrase "metabolic disease causing mental retardation." This was done so that new diseases which may cause serious health problems or death could be added to the list of diseases for which all newborns must be screened, even if they do not cause mental retardation.

With regard to the second need for amendment, Minnesota Statutes Section 144.125 specifically states those criteria which must be met if the commissioner decides to add a new disease to the list

of diseases for which all newborns must be screened. They are:

1) the adequacy of laboratory methods to detect the inborn metabolic error,

2) the ability to treat or prevent medical conditions caused by the inborn metabolic error, and

3) the severity of the medical conditions caused by the inborn metabolic error.

The commissioner intends to add the disease "congenital adrenal hyperplasia" to the list of diseases for which all newborns are currently screened. This disease produces severe metabolic effects in the newborn which, if not detected early and appropriate medical treatment initiated, may result in acute illness, death, and/or incorrect sex identification in female infants.

The commissioner has determined that the inborn metabolic error of congenital adrenal hyperplasia meets the legislative determinants for inclusion in the list of those diseases for which the Department requires newborn metabolic screening.

The commissioner believes that the amendments to 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.

AMENDMENT BY AMENDMENT JUSTIFICATION

Title changes the title of the first portion of the rules so that it is consistent with Minn. Stat. § 144.125 (1988) by eliminating the phrase "causing mental retardation." This change is necessary to be consistent with the statute and reasonable because some screened diseases are not characterized by mental retardation.

4615.0300 deletes "the" for grammatical reasons. It adds the inborn metabolic error "hemoglobinopathy" as required in Minn. Stat. § 144.125 (1988). The inborn metabolic error "congenital adrenal hyperplasia" is added by the commissioner based on her determination that this disease meets the criteria for inclusion in the newborn metabolic screen program as set forth in section 144.125.

The criteria and the commissioner's justification for including "congenital adrenal hyperplasia" are as follows:

1. The adequacy of laboratory methods to detect the inborn metabolic error. The laboratory procedure which the Department proposes to screen for congenital adrenal hyperplasia measures levels of 17-hydroxy progesterone as an indicator of the existence of this disease. This is a procedure that is nationally recognized as highly accurate and appropriate for screening for this disease and its cost is comparable to that of the other screening tests currently being done by the Department. The laboratory procedure is similar to one which the Department has been using successfully

for the past several years to detect hypothyroidism.

2. The ability to treat or prevent medical conditions caused by the inborn metabolic error. The severe metabolic effects of congenital adrenal hyperplasia are readily controlled with oral hormone therapy under the supervision of a physician. Many other screening programs have included adrenal hyperplasia and demonstrated successful results.

3. The severity of the medical conditions caused by the inborn metabolic error. Congenital adrenal hyperplasia usually causes a profound hormonal imbalance in newborns leading to metabolic difficulties which may cause acute illness or death in affected infants. In addition, affected female infants may have ambiguous genitalia which can lead to incorrect sex identification. The inclusion of congenital adrenal hyperplasia is necessary because of the potential severity of undiagnosed cases. It is reasonable because severe illness and death may be prevented by newborn screening.

4615.0400, Subp. 5. Changes the word "each" to "the" for grammatical reasons.

4615.0400, Subp. 6. The words "hemoglobinopathy" and "congenital adrenal hyperplasia" have been added. These amendments have been justified in the discussion relating to Part 4615.0300.

4615.0400, Subp. 7. The word "capillary" has been deleted because

it is possible and reasonable to obtain the blood specimen from a capillary or a venous source. The source is left to the discretion of the responsible party.

4615.0500, A. The words "hemoglobinopathy" and "congenital adrenal hyperplasia" have been added. These amendments have been justified in the discussion relating to Part 4615.0300.

4615.0500, B. The word "phenylketonuria" has replaced the acronym PKU for clarity and consistency. This change is necessary and reasonable in that it helps avoid confusion over the definition of PKU and also provides terminology consistent with the other diseases.

4615.0500, D. The information requested on the specimen card is used to identify and trace those infants who have positive screening test results, to provide epidemiological information regarding these diseases, and to provide the laboratory with information which is needed to evaluate the quality of the specimen for testing. As these informational items may change, especially when laboratory procedures are altered, it was determined that it was not appropriate to list each informational item in the rules; this would allow for changes in the information requested without the need for revision of the rules. This amendment is reasonable because the required information will be clearly listed on the cards.

4615.0600, A. The words "at no charge" have been deleted. This is needed and reasonable because Section 144.125 now states that the commissioner must charge a fee for these laboratory tests at approximately the cost of conducting the tests.

4615.0600, B. The words "hemoglobinopathy" and "congenital adrenal hyperplasia" have been added. These amendments have been justified in the discussion relating to Part 4615.0300.

4615.0600, C. This amendment, adding the language "of obtaining the results" is needed and reasonable in order to more precisely define and clarify the turnaround time for laboratory results. A timely turnaround is needed so that appropriate diagnostic and treatment procedures may be expeditiously implemented and negative consequences of untreated disease may be avoided.

4615.0700, A. With regard to written reporting the rule has been amended so that the attending physician is required to report both positive and negative diagnostic evaluations. This change is needed to assure that diagnostic evaluations have been completed and to monitor the efficacy of the newborn screening program. It is reasonable because it is the simplest way to report follow up and diagnosis.

The words "hemoglobinopathy" and "congenital adrenal hyperplasia" have been added. These amendments have been justified in the

discussion relating to Part 4615.0300. In addition, the mailing address of the Human Genetics Unit has been revised to reflect U. S. Postal Department recommendations for improved delivery.

4615.0700, B. The term "however" has been added for grammatical reasons. The term "he" has been eliminated because the attending physician may be male or female.

Title 4615.0750, 4615.0755 Subp. 5 and 8, and 4615.0760 Subp. 3 and 4. The addition of "hemoglobinopathy" and "congenital adrenal hyperplasia" in each of these parts has been justified in the discussion relating to Part 4615.0300. The addition of "galactosemia" and "hypothyroidism" is needed to bring these parts of the rules into agreement with the existing Part 4615.0300. This addition makes it clear that screening program components described in Parts 4615.0750, 4615.0755 and 4615.0760 apply to hemoglobinopathy, congenital adrenal hyperplasia, galactosemia and hypothyroidism as well as phenylketonuria. These components are needed to assure ongoing medical management of individuals who are diagnosed as having one of the diseases. These components are reasonable because they are minimally intrusive on the life of the individuals, yet help to limit the number of persons who might be lost to medical management with resulting adverse consequences if needed treatment is discontinued.

The deletion of the language "and other metabolic diseases causing

mental retardation" is needed to bring the rules into compliance with Section 144.125 which eliminates this phrasing. The other amendments, to part 4615.0750, adding the language "approved laboratory", "when available', and "will have" are for the purpose of bringing this part of the rule into agreement with Sections 144.126 and 144.128.

4615.0755, Subp.4. This Subpart is deleted because the phrase "causing mental retardation" was eliminated from Sections 144.125, 144.126, and 144.128, and is being deleted from the rule provisions as part of this rulemaking. As a result, it is no longer necessary to provide a definition of the phrase.

4615.0755, Subp. 7. This Subpart is deleted because the term "recipient" is not used in these amended rules. Its use was deleted in previous amendments, however, the definition was not deleted.

4615.0760, Subp. 3. The term "Children's Health Plan" has been added because it is a resource to pay for medically indicated services. It is reasonable in that it provides another possible source for payment for treatment.

Dated: 7/17/92

Marlene E. Marschall
COMMISSIONER OF HEALTH