

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

Our File No. [26]

05.0004.1600

RULE REVIEW CHECKLIST

DATE RULE RECEIVED 4-4-86
DATE FOR REVIEW 4-14-86
DATE DUE 4-18-86

Adopted w/a hearing _____
Adopted w/o hearing ✓
Temporary rule _____

Approved 4/18/86 Disapproved _____ Returned to Agency _____

Resubmitted _____ Due _____
Approved _____ Disapproved _____ Returned to Agency _____

Date filed w/Secretary of State 4-22-86 Revisor approved 4.8.86
disapproved _____

✓ Rule as Adopted

✓ Rule as Proposed

✓ Order Adopting 3.27.86 Date combined w/ FF

✓ Notice of Intent to Solicit Outside Opinion SR. 12.16.85
✓ Committee Notes

✓ Order for rulemaking
N/A date of Hearing

N/A Certificate of Board's Authorizing Resolution

✓ Notice of rulemaking
✓ Sufficiency

✓ Affidavit of Mailing Notice or rulemaking
1.29.86 At least 30 days prior to ~~hearing~~/adoption } combined

✓ Mailing list Certificate

✓ Publication in State Register
3.3.86 At least 30/~~20~~ days prior to ~~hearing~~/adoption

N/A Hearing Examiner's Report

✓ Chief Hearing Examiner's Report(s)
_____ Approving H.E.'s Report
_____ Approving agency action

✓ Agency's Findings of Fact combined with order Adopting

N/A LCRAR Report or agency Affidavit

✓ Certificate of Board's Resolution Adopting Rules

✓ Order Approving Incorporation by Reference

✓ Statement of Need and Reasonableness

N/A Petition for Adoption of a Rule

✓ Record (includes transcript or tape, exhibits, comments received by agency, requests for a hearing, and other relevant materials)

✓ Certificate of Compliance w/Rulemaking Procedures

N/A Affidavit of Mailing Notice of Submission to Attorney General

✓ Notice of Submission to the Attorney General

SF-00006-03

STATE MINNESOTA

DEPARTMENT ATTORNEY GENERAL

Office Memorandum

TO: SR. MARY MADONNA ASHTON, Commissioner
Dept. of Health

ATTN: CATHERINE AVINA
Special Assistant Attorney General

DATE: 4/21/86

FROM: J. MICHAEL MILES
Assistant Attorney General

PHONE: 296-6555

SUBJECT: In the Matter of the Adoption of Rules Relating to Phenylketonuria Testing Program, the Treatment for a Positive Diagnosis, and a Registry of Cases

The above-referenced rule has been approved as to its legality by the Attorney General on April 18, 1986.

Enclosed is the agency's copy of the approved rule. This office has already filed two copies of the approved rule with the Secretary of State, who will forward one copy to the Revisor of Statutes. The fourth copy is being retained by this division of the Attorney General's Office for its records.

Also enclosed are any petitions, requests, submission or comments received by the agency and any extra copies of documents which the agency submitted to the Attorney General.

In order for a permanent rule without a hearing to become effective, your agency must publish a notice of adoption in the State Register in accordance with Minn. Stat. § 14.27. An emergency rule becomes effective five working days after approval by the Attorney General; however, the agency must publish a notice in the State Register in accordance with Minn. Stat. § 14.34.

If you have any questions in this regard, please contact me.

JMM:pmf

Enclosures

cc: Maryanne Hruby
Executive Director
Legislative Commission to Review
Administrative Rules

Duane Harves
Chief Administrative Law Judge
Office of Administrative Hearings

RR1263

AS COPY OF RESUBMITTED RULE

Department of Health

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

Rules as Adopted

4615.0750 PURPOSE AND SCOPE.

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

4615.0755 DEFINITIONS.

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

Subp. 2. **Department.** "Department" means the Minnesota Department of Health.

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

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

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

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

Subp. 7. **Recipient.** "Recipient" means patient.

APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

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

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

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

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

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

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

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

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

APPROVED IN THE
REVISOR OF STATUTES
OFFICE BY:

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

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

A. name of patient;

B. gender;

C. date of birth;

D. place of birth;

E. parents' names;

F. current address of patient;

G. diagnosis;

H. name and address of physician; and

I. other data the commissioner deems necessary for follow-up services.

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

APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

OFFICE OF THE REVISOR OF STATUTES

Certificate of Approval of Adopted Rules

AR0889

Agency: Department of Health

Division:

Agency Contact: Dr. Lee Schacht

Minnesota Rules: Parts 4615.0750 to 4615.0760

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

Type of Rules: Permanent

Incorporations by Reference: None
Rule Number: Material Incorporated:

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
APR 22 1986 2:17 P.M.
Joan Anderson Growe
Secretary of State

Steven C. Cross
Revisor of Statutes

Susan E. Quayle
Assistant Revisor
Phone: 296-0956
Date: April 21, 1986

APPROVED AS TO FORM AND LEGALITY
4/18 1986
HUBERT H. HUMPHREY III
ATTORNEY GENERAL
BY
ASSISTANT ATTORNEY GENERAL

AG copy 1

Department of Health

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

Rules as Adopted

4615.0750 PURPOSE AND SCOPE.

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

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A. name of patient;

B. gender;

C. date of birth;

D. place of birth;

E. ~~parent's~~ parents' names;

F. current address of patient;

G. diagnosis;

H. name and address of physician; and

I. other data the commissioner deems necessary for follow-up services.

Subp. 5. **Classification of data.** The department shall classify all data in the registry as private pursuant to Minnesota Statutes, section 13.38, the Minnesota Government Data Practices Act.

? cannot classify data by rule.

anyway, even with this section, it seems the data is classified by 13.38. There is no need for this sectio

Department of Health

Proposed Rules Relating to Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases.

Rules as Proposed (all new material)

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APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

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APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

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A. name of patient;

B. gender;

C. date of birth;

D. place of birth;

E. parent's names;

F. current address of patient;

G. diagnosis;

H. name and address of physician; and

I. other data the commissioner deems necessary for follow-up services.

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APPROVED IN THE REVISOR OF STATUTES BY:

OFFICE OF THE REVISOR OF STATUTES

Proposed Rule

RD889

Agency: Department of Health

Division:

Agency Contact: Dr. Lee Schacht

Minnesota Rules: Parts 4615.0750 to 4615.0760

Title: Proposed Rules Relating to Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases

Type of Rules: Permanent

Incorporations by Reference: None
Rule Number: Material Incorporated:

Steven C. Cross
Revisor of Statutes

Susan E. Quayle
Assistant Revisor
Phone: 296-0956

Date: January 7, 1986

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 Cases

FINDINGS OF FACT
CONCLUSIONS, AND
ORDER ADOPTING RULE
WITHOUT PUBLIC HEARING

Notice of the Commissioner's proposed adoption of the above-entitled rule was published in the State Register on February 3, 1986 and was sent by United States mail to all persons on the list maintained by the agency pursuant to Minnesota Statutes, sections 14.14, subdivision 1, paragraph (a) and 14.22 on January 29, 1986.

All persons were given the opportunity to submit comment on the rule for 30 days after publication of the notice of the proposed rulemaking without a public hearing. No requests for hearing or requests for notice of submission to the attorney general were received by the agency.

Based on the comments and evidence in the record before the agency, I find the above-captioned rule is needed and reasonable.

NOW, THEREFORE, IT IS ORDERED that the rule identified as Rules Relating to Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases is adopted this 27th day of March, 1986, pursuant to authority vested in me by Minnesota Statutes, section 144.128 (1985 Supp.).

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

Sr Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

City of Winona MN Energy & Economic Development Authority	Schuler Chocolates, Inc. Advertising Unlimited, Inc.	9 8	1,450,000.00 1,000,000.00
City of Rosemount	Koch Refining Company No. 5 Sulfur Plant	8	20,000,000.00
Washington Co. HRA	Nelle, Inc.	8	5,000,000.00
Washington Co. HRA	Washington Square Dvlpt., Inc.	8	2,500,000.00
City of Chanhassen	M. A. Gedney Co. Expansion	7	1,300,000.00
City of Lakeville	Mills Fleet Farm	6	3,500,000.00
City of New Brighton	Cohasset Investments	6	5,200,000.00
City of Plainview	Lakeside Packing Company	6	4,000,000.00
City of Woodbury	Parkwood Place	6	300,000.00
City of Elk River	Hardware Store-Morrell and Plaistad Partnership	5	304,260.00
Total Allocations Awarded:			$48,954,260.00
Amount of Issuance Authority Available as of December 5, 1985:			$ 0.53

Department of Health

Outside Opinion Sought on Proposed Rules Relating to a Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases

Notice is hereby given that the Minnesota Department of Health is seeking information or opinions from sources outside the agency in preparing to propose the adoption of rules governing a phenylketonuria testing program, the treatment for positive diagnosis, and a registry of cases. The adoption of the rules is authorized by Minnesota Statutes, section 144.128, which requires the agency to adopt rules to carry out the purposes of Minnesota Statutes, sections 144.126 and 144.128 (Supp. 1985).

The Minnesota Department of Health requests information and comments concerning the subject matter of the rules. Interested or affected persons or groups may submit data or views on the subject matter of concern orally or in writing. Written statements should be addressed to: Lee Schacht, PhD, Supervisor, Human Genetics Unit, Maternal and Child Health Technical Services, Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440. Oral statements will be received during regular business hours over the telephone at (612) 623-5269 and in person at the above address.

All statements of information and comment shall be accepted until January 10, 1986. Any written material received by the Minnesota Department of Health shall become part of the rulemaking record in the event that the rule is adopted.

December 4, 1985

Sister Mary Madonna Ashton
Commissioner of Health

Department of Health
Health Resources Division

Outside Opinion Sought Regarding Proposed Rules Governing Nursing Staff Hour Requirements in Nursing Homes

Notice is hereby given that the State Department of Health is seeking information or opinions from sources outside the agency in preparing to amend Minn. Rules 4655.5600 regarding nursing staff hours in licensed nursing homes. The amendment of this rule is authorized by Minnesota Statutes, sections 144A.02 to .08.

The State Department of Health requests information and comments concerning the subject matter of this rule. Interested or affected persons or groups may submit statements of information or comment orally or in writing. Written statements should be addressed to: Robert Eelkema, 717 Delaware Street Southeast—P.O. Box 9441, Minneapolis, Minnesota 55440.

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 Cases

NOTICE OF SOLICITATION
OF OUTSIDE INFORMATION
OR OPINIONS

Notice is hereby given that the Minnesota Department of Health is seeking information or opinions from sources outside the agency in preparing to propose the adoption of rules governing a phenylketonuria testing program, the treatment for positive diagnosis, and a registry of cases. The adoption of the rules is authorized by Minnesota Statutes, section 144.128, which requires the agency to adopt rules to carry out the purposes of Minnesota Statutes, sections 144.126 and 144.128 (Supp. 1985).

The Minnesota Department of Health requests information and comments concerning the subject matter of the rules. Interested or affected persons or groups may submit data or views on the subject matter of concern orally or in writing. Written statements should be addressed to: Lee Schacht, PhD, Supervisor, Human Genetics Unit, Maternal and Child Health Technical Services, Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440. Oral statements will be received during regular business hours over the telephone at (612) 623-5269 and in person at the above address.

All statements of information and comment shall be accepted until January 10, 1986. Any written material received by the Minnesota Department of Health shall become part of the rulemaking record in the event that the rule is adopted.

Dated: December 4, 1985

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

S. Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

December 23, 1985

M E M O R A N D U M

TO: Members, Ad Hoc Technical Advisory Committee on Newborn Metabolic Screening

FROM: Lee E. Schacht, Ph.D., Supervisor
Human Genetics Unit

SUBJECT: Summary of Discussion from the Committee Meeting of December 18, 1985.

Members Present

Virginia Michals, M.D.
Joseph Sockalosky, M.D.
John Fangman, M.D.
Elving Anderson, Ph.D.
Rolf Engel, M.D.
Susan Berry, M.D.

MDH Members Present

Valentine O'Malley, M.D.
Ronald Campbell, M.D.
Duane Morse, D.P.H.
Michael Foley
Robert Siem, Ph.D.
Malcolm Jenkins, Ph.D
Lee E. Schacht, Ph.D.

A summary of the discussions regarding the new Minnesota Department of Health rule on metabolic screening follow-up is attached, as is a copy of the revised draft of the rule incorporating many of your comments and suggests.

If you have any further questions or comments please contact me at (612) 623-5267.

LES:sjj

Attachments

Ad Hoc Technical Advisory Committee on Newborn Metabolic Screening

Meeting of December 18, 1985

Review and comment on proposed new Rules regarding Minnesota Statutes 144.126 and 144.128 (12-11-85 version)

4615.0750 Purpose and Scope of Rule.

Some concern was expressed over the term "treatment control test" - comments were deferred to discussion of this under Definitions

4615.0755 Definitions.

1. No comment
2. Some discussion concerning "appropriate treatment" especially with reference to qualifications of all physicians to treat these diseases. Consensus was no change.
3. No comment
4. No comment
5. No comment
6. No comment
7. "Registry" It was suggested that there be some statement with regard to limiting the registry to Minnesota - concern with the Department trying to track patients who have moved out-of-state during their life time. Committee had no specific recommendation. Staff would recommend no change and handle the problem by making referral to the state to which the patient has moved, keep the patient name in the registry on an "inactive" basis and not track them.
8. "Treatment control test" Committee thought that this was an inaccurate term for what was intended to be a monitoring service/function provided by the Department. Staff would

suggest the following revision:
"Treatment control test" means a laboratory test to monitor medical treatment in diagnosed patients to assist in the medical management of the patient's metabolic disease.

9. No comment
10. No comment

4615.0760 The Department shall do all of the following:

1. The Committee was concerned that there might be a few parents who might abuse this provision and want to monitor their children on a daily or weekly basis when this was medically of no value in adjusting the treatment program. Staff would suggest the following revision:

1. Develop and make available treatment control test specimen kits to physicians and patients as medically indicated to effectively monitor treatment. Provide the treatment control test specimen kit and the laboratory evaluation of the treatment control test specimen at no cost to the patient.

2. No comment

3. The Committee was concerned about the Department being obligated, at least potentially, to pay for all medical treatment of these patients over the patient's life time - even when those medical problems were only secondary to the primary cause of the disease or are not even disease related. Concern was also expressed that SCH dollars might be used to pay for medical care of adult patients.

Staff would suggest several options for consideration:

Section 3:

a) Make arrangements for the treatment of the metabolic defect (causing mental retardation) in diagnosed cases of phenylketonuria and other metabolic diseases causing mental retardation when the treatment is medically indicated and the patient is uninsured or is unable to pay because of a lack of available income. The patient's ability to pay for medical treatment and cost share shall be determined as prescribed in Minnesota Rules, 4705.0600, regardless of the patient's age.

b) Make arrangements, through the Department's Services for Children with Handicaps Program, for the treatment of the metabolic defect (causing mental retardation) in diagnosed cases of phenylketonuria and other metabolic diseases causing mental retardation when the treatment is medically indicated and the patient is uninsured or is unable to pay because of a lack of available income. If the patient is over 21 years of age, the cost share for medcial treatment prescribed in Minnesota Rules, 4705.0600 shall be applied in determining the patient's ability to pay for medical treatment.

c) Make arrangements for the medically indicated treatment of the metabolic defect (causing mental retardation) in diagnosed cases of phenylketonuria and other metabolic diseases causing mental retardation when the patient is ininsured or is unable to pay the cost of treatment because of a lack of available income.

4. Committee raised the question of inclusion in the registry of children diagnosed as hyperphenylalaninemia (persistent elevation of the phenylalanine level without a diagnosis of PKU). The concern is over what the long range impact of this condition would be on women patients in the reproductive years. There is no clear answer at this time. Staff suggested that the Department could establish a policy that such patients (e.g., persistent phenylalanine levels over 10 mg%) would be included in the registry until it is determined what, if any, medical implications these patients represent. The Committee felt that this was acceptable.

5. No comment (the A.G's office may have resolved this issue)

minnesota department of health
717 s.e. delaware st. p.o. box 9441 minneapolis 55440
(612) 623-5000

DEC 16 1985
RECEIVED
DEC 19 1985
MCH Technical Services
Minnesota Dept of Health

December 16, 1985

M E M O R A N D U M

12/18 R Nelson MD

Please see attached comments

TO: Member, Ad Hoc Technical Advisory Committee on Newborn Metabolic Screening

FROM: Lee E. Schacht, Ph.D, Supervisor
Human Genetics Unit

SUBJECT: December 18, Meeting

Attached is the most recent draft of the new rules to implement Minnesota Statutes 144.126. and 144.128. This draft constitutes the basic agenda for the meeting.

LES:sjj

Attachment

Rules relating to treatment control testing for phenylketonuria and other metabolic diseases causing mental retardation, treatment for cases with positive diagnosis, and registry of cases.

4615.0750 Purpose and Scope of Rule. This rule describes the responsibilities of the Minnesota Department of Health to assure that persons diagnosed as having phenylketonuria and other metabolic diseases causing mental retardation will have access to treatment control tests and necessary financial assistance for treatment of diagnosed cases when indicated, and will be included in a registry of cases for the purpose of coordinating follow-up services.

4615.0755 Definitions. For the purpose of the rule, the follwing terms have the meaning given them:

1. "Department" means the Minnesota Department of Health.
2. "Follow-up services" means assisting the patient in accessing appropriate treatment and other services.
3. "Other metabolic diseases causing mental retardation" means those diseases identified in Minnesota Rules, part 4615.0500.
4. "Patient" means the person who has been diagnosed with phenylketonuria or other metabolic disease causing mental retardation or the person's parents or legal guardian.
5. "Physician" means the medical doctor licensed under Minnesota Statutes, Chapter 147, who is supervising the ongoing treatment of the patient. The patient may identify more than one such physician.
6. "Recipient" means patient.

7. "Registry" means a permanent recond maintained by the Department on each patient diagnosed by a physician and reported to the Department as having phenylketonuria or other metabolic dieseases causing mental retardation.
8. "Treatment control test" means a laboratory test to evaluate a treatment contol test specimen to assist in the management of a patient's metabolic disease.
9. "Treatment control test specimen" means a specimen of blood or other body fluid collected from a patient.
10. "Treatment control test specimen kit" means a kit containing suitable containers and other materials provided by the Department and used to collect and transport a treatment control test specimen.

4615.0760 The Department shall do all of the following:

1. Develop and distribute, upon request, treatment control test specimen kits to physicians and patients, and evaluate the treatment control test specimen at no cost to the recipient.
2. Report the laboratory results of the treatment control tests to the physician or patient submitting the treatment control test specimen. If the treatment control test specimen is submitted directly by the patient, the spatient shall identify a physician who shall receive a copy of the laboratory results.
3. Arrange for the treatment of diagnosed cases of phenylketonuria and other metabolic diseases causing mental retardation when diagnosis-related treatment is medically indicated and the patient is uninsured or is unable to pay the cost of treatment because of a lack of available income through referral to Services for Children with Handicaps (SCH), regardless of the patient's age. Financial eligibilty for SCH reimbursed care will be dittermined according to the program's rule

4. Maintain a registry of all diagnosed cases of phenylketonuria and other metabolic diseases causing mental retardation which are reported to the Department. The registry shall be updated no more frequently than annually by means of direct contract with the patient to determine their address and their need for medical treatment services, educational materials and counseling related to their metabolic disease. The registry shall include the following minimum data on each patient:
   a. Name
   b. Gender
   c. Date of birth
   d. Place of birth
   e. Parents' names
   f. Current address
   g. Diagnosis
   h. Name and address of physician
   i. Other data the Commissioner deems necessary for follow-up services
5. Classify all data in the regisry as "medical" under the Minnesota government data practices act.

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 Cases

ORDER FOR NOTICE
OF PROPOSED ADOPTION
OF RULES WITHOUT A
PUBLIC HEARING

IT IS ORDERED this 16th day of January, 1986, that a Notice of Proposed Adoption and Amendment of Rules Without a Public Hearing in the above-entitled matter be given to all persons who have registered their names with the Minnesota Department of Health for that purpose and be published in the State Register.

Dated: January 16, 1986

STATE OF MINNESOTA

COMMISSIONER OF HEALTH

Sr. Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

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 Cases

NOTICE OF PROPOSED
ADOPTION OF RULES
WITHOUT A
PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the Minnesota Commissioner of Health proposes to adopt Minn. Rules pts. 4615.0750, 4615.0755, and 4615.0760 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. The Commissioner proposes to adopt the above rules without a public hearing and is following the procedures set forth in Minnesota Statutes, sections 14.22 to 14.28. The specific statutory authority to adopt the rules is contained in Minnesota Statutes, section 144.128.

Persons interested in these rules shall have 30 days in which to submit comment in support of or in opposition to the proposed rules or any part or subpart of the rules, and comment is encouraged. Each comment should identify the portion of the proposed rules addressed, the reason for the comment, and any proposed change.

Any person may make a written request for a public hearing on the rules within the 30-day comment period. If 25 or more persons submit to the agency during the 30-day comment period a written request for a public hearing on the proposed rules, a public hearing will be held unless a sufficient number withdraw their request. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed rule addressed, the reason for the request, and any

proposed change. If a public hearing is required, the agency will proceed pursuant to Minnesota Statutes, sections 14.131 to 14.20.

Persons who wish to submit comments or a written request for a public hearing must submit such comments or request to:

Lee Schacht, PhD
Human Genetics Unit
Maternal and Child Health Division
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440
Telephone: (612) 623-5269

The proposed rules may be modified if the modifications are supported by the data and views submitted and do not result in a substantial change in the proposed rules as noticed.

A copy of the proposed rules is attached to this notice.

A Statement of Need and Reasonableness has been prepared and is available upon request from Dr. Schacht at the above phone number and address. The statement describes the need for and reasonableness of each provision of the proposed rules and identifies the data and information relied upon to support the proposed rule and amendments.

The proposed rules will not affect small businesses as they are defined in Minn. Stat. § 14.115, subd. 1, nor will they require the expenditure of public monies by local public bodies.

If no hearing is required, upon adoption of the rule, the rule and the required supporting documents will be delivered to the Attorney General for review as to legality and form. Any person may request notification of the date of submission to the Attorney General. Persons who wish to be advised of the submission of this material to the

Attorney General, or who wish to receive a copy of the adopted rule and amendments, must submit a written request to Dr. Schacht at the above address.

Dated: January 16, 1986

STATE OF MINNESOTA

COMMISSIONER OF HEALTH

Sr. Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

Department of Health

Proposed Rules Relating to Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases.

Rules as Proposed (all new material)

4615.0750 PURPOSE AND SCOPE.

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

4615.0755 DEFINITIONS.

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

Subp. 2. **Department.** "Department" means the Minnesota Department of Health.

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

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

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

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

Subp. 7. **Recipient.** "Recipient" means patient.

APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

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

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

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

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

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

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

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

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

APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

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

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

A. name of patient;

B. gender;

C. date of birth;

D. place of birth;

E. parent's names;

F. current address of patient;

G. diagnosis;

H. name and address of physician; and

I. other data the commissioner deems necessary for follow-up services.

Subp. 5. **Classification of data.** The department shall classify all data in the registry as private pursuant to Minnesota Statutes, section 13.38, the Minnesota Government Data Practices Act.

APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

OFFICE OF THE REVISOR OF STATUTES

Proposed Rule

RD889

Agency: Department of Health

Division:

Agency Contact: Dr. Lee Schacht

Minnesota Rules: Parts 4615.0750 to 4615.0760

Title: Proposed Rules Relating to Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases

Type of Rules: Permanent

Incorporations by Reference: None
Rule Number: Material Incorporated:

Steven C. Cross
Revisor of Statutes

Susan E. Quayle
Assistant Revisor
Phone: 296-0956
Date: January 7, 1986

Department of Health

Proposed Rules Relating to Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases.

Rules as Proposed (all new material)

4615.0750 PURPOSE AND SCOPE.

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

4615.0755 DEFINITIONS.

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

Subp. 2. **Department.** "Department" means the Minnesota Department of Health.

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

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

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

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

Subp. 7. **Recipient.** "Recipient" means patient.

APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

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

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

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

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

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

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

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

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

APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

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

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

A. name of patient;

B. gender;

C. date of birth;

D. place of birth;

E. parent's names;

F. current address of patient;

G. diagnosis;

H. name and address of physician; and

I. other data the commissioner deems necessary for follow-up services.

Subp. 5. **Classification of data.** The department shall classify all data in the registry as private pursuant to Minnesota Statutes, section 13.38, the Minnesota Government Data Practices Act.

APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

OFFICE OF THE REVISOR OF STATUTES

Proposed Rule

RD889

Agency: Department of Health

Division:

Agency Contact: Dr. Lee Schacht

Minnesota Rules: Parts 4615.0750 to 4615.0760

Title: Proposed Rules Relating to Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases

Type of Rules: Permanent

Incorporations by Reference: None
Rule Number: Material Incorporated:

Steven C. Cross
Revisor of Statutes

Susan E. Quayle
Assistant Revisor
Phone: 296-0956
Date: January 7, 1986

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 Cases

AFFIDAVIT OF MAILING
AND CERTIFICATE OF
MAILING LIST

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

Lee Schacht, being first duly sworn deposes and says:

I hereby certify that the attached list of persons, associations, and other interested groups who have requested, pursuant to Minnesota Statutes, sections 14.14, subdivision 1, paragraph (a), and 14.22, that their names be placed on the Minnesota Department of Health rulemaking mailing list is accurate and complete as of ____.m., this 28th day of Jan., 1986.

That on the 29th day of January, 1986, at the City of Minneapolis, County of Hennepin, State of Minnesota, I mailed the attached Notice of Proposed Adoption of Rules Without a Public Hearing together with the proposed rules by depositing in the United States mail, through the mail room at the Minnesota Department of Health Building, a copy thereof with postage prepaid, to all persons, associations, and interested groups on the aforementioned mailing list.

Lee E Schacht

Subscribed and sworn to before me

this 29 day of Jan., 1986.

Louise Kaniuk

LOUISE KANIUK
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
MY COMMISSION EXPIRES FEBRUARY 22, 1991

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 Cases

NOTICE OF PROPOSED
ADOPTION OF RULES
WITHOUT A
PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the Minnesota Commissioner of Health proposes to adopt Minn. Rules pts. 4615.0750, 4615.0755, and 4615.0760 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. The Commissioner proposes to adopt the above rules without a public hearing and is following the procedures set forth in Minnesota Statutes, sections 14.22 to 14.28. The specific statutory authority to adopt the rules is contained in Minnesota Statutes, section 144.128.

Persons interested in these rules shall have 30 days in which to submit comment in support of or in opposition to the proposed rules or any part or subpart of the rules, and comment is encouraged. Each comment should identify the portion of the proposed rules addressed, the reason for the comment, and any proposed change.

Any person may make a written request for a public hearing on the rules within the 30-day comment period. If 25 or more persons submit to the agency during the 30-day comment period a written request for a public hearing on the proposed rules, a public hearing will be held unless a sufficient number withdraw their request. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed rule addressed, the reason for the request, and any

proposed change. If a public hearing is required, the agency will proceed pursuant to Minnesota Statutes, sections 14.131 to 14.20.

Persons who wish to submit comments or a written request for a public hearing must submit such comments or request to:

Lee Schacht, PhD
Human Genetics Unit
Maternal and Child Health Division
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440
Telephone: (612) 623-5269

The proposed rules may be modified if the modifications are supported by the data and views submitted and do not result in a substantial change in the proposed rules as noticed.

A copy of the proposed rules is attached to this notice.

A Statement of Need and Reasonableness has been prepared and is available upon request from Dr. Schacht at the above phone number and address. The statement describes the need for and reasonableness of each provision of the proposed rules and identifies the data and information relied upon to support the proposed rule and amendments.

The proposed rules will not affect small businesses as they are defined in Minn. Stat. § 14.115, subd. 1, nor will they require the expenditure of public monies by local public bodies.

If no hearing is required, upon adoption of the rule, the rule and the required supporting documents will be delivered to the Attorney General for review as to legality and form. Any person may request notification of the date of submission to the Attorney General. Persons who wish to be advised of the submission of this material to the

Attorney General, or who wish to receive a copy of the adopted rule and amendments, must submit a written request to Dr. Schacht at the above address.

Dated: January 16, 1986

STATE OF MINNESOTA

COMMISSIONER OF HEALTH

Sr Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

Department of Health

Proposed Rules Relating to Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases.

Rules as Proposed (all new material)

4615.0750 PURPOSE AND SCOPE.

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

4615.0755 DEFINITIONS.

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

Subp. 2. **Department.** "Department" means the Minnesota Department of Health.

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

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

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

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

Subp. 7. **Recipient.** "Recipient" means patient.

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

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

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

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

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

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

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

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

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

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

A. name of patient;

B. gender;

C. date of birth;

D. place of birth;

E. parent's names;

F. current address of patient;

G. diagnosis;

H. name and address of physician; and

I. other data the commissioner deems necessary for follow-up services.

Subp. 5. **Classification of data.** The department shall classify all data in the registry as private pursuant to Minnesota Statutes, section 13.38, the Minnesota Government Data Practices Act.

OFFICE OF THE REVISOR OF STATUTES

Proposed Rule

RD889

Agency: Department of Health

Division:

Agency Contact: Dr. Lee Schacht

Minnesota Rules: Parts 4615.0750 to 4615.0760

Title: Proposed Rules Relating to Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases

Type of Rules: Permanent

Incorporations by Reference: None
Rule Number: Material Incorporated:

Steven C. Cross
Revisor of Statutes

Susan E. Quayle
Assistant Revisor
Phone: 296-0956
Date: January 7, 1986

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1200 Pillsbury Center
Minneapolis, MN 55402

Alpha Homes, Inc.
P.O. Box 487
Spicer, MN 56288

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Dakota County Community Health Services
Human Services Building
1600 Highway 55
Hastings, MN 55033

Herbert Anderson
418 Eighth Street South
Virginia, MN 55792

James F. Andre, City Manager
City of Roseville
2660 Civic Center Drive
Roseville, MN 55113

Anoka County Health Department
c/o Robert M. Hutchison
Courthouse - Fourth Floor
Anoka, MN 55303

Joan M. Archer
MN Manufactured Housing Association
222 East Little Canada Road
Suite 222
St. Paul, MN 55117

Allyson Ashley
Southwestern Mental Health Center
P.O. Box D
Luverne, MN 56156

Assisi Residences of Faribault County, Inc.
218 South Linton
Blue Earth, MN 56013

Association for Retarded Citizens of Olmsted County
903 West Center
Rochester, MN 55902

Walter A. Baldus
Woodvale Management Services, Inc.
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Irene Holmquist
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Worthington, MN 56187

Jan Cuccia
SEIU Local 113
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Minneapolis, MN 55414

Patricia Cullen/Greenbrier Home
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St. Paul, MN 55106

Nancy Dagg
Anoka County Community Health
and Social Service Department
Anoka County Courthouse - Fourth Floor
Anoka, MN 55303

Dakota County Mental Health Center, Inc.
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South St. Paul, MN 55075

Jean Dawson
Minnesota Government Report
Room B-28, Press Room, State Capitol
St. Paul, MN 55155

Donald A. Dee
MN State Pharmaceutical Association
2221 University Avenue Southeast, #326
Minneapolis, MN 55414

Janice M. Devens
Wright County Human Services
Courthouse
Buffalo, MN 55313

Judith S. Douglas
The Phoenix Residence, Inc.
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St. Paul, MN 55107

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LeFeverre, Lefler, Kennedy,
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2000 First Bank Place West
120 South Sixth Street
Minneapolis, MN 55402

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Minnesota Medicaid
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David Felske
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Cloquet, MN 55720

Bob Fitzgerald, D.C.
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Minneapolis, MN 55408

Friendship Haven, Inc.
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Sherburn, MN 56171

Miller A. Friesen
Range Mental Health Center
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Virginia, MN 55792

Peter X. Fugina
MN Senior Federation
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St. Paul, MN 55103

Kathy Gaalswyk, Executive Director
Region 5 Regional Development Commiss
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Community Living, Inc.
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Victoria, Mn 55386

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Outreach Group Homes, Inc.
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St. Louis Park, MN 55416

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Minnetonka, MN 55343

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Twin Town Treatment Center
1706 University Avenue
St. Paul, MN 55104

Tom Heenan, Supervising Sanitarian
Crystal Health Department
4141 Douglas Drive
Crystal, MN 55422

Beverly Helgeson
Presbyterian Family Foundation
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Willmar, MN 56201

Harold Hietala
St. Louis County Health Department
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Virginia, MN 55792

Charles B. Hoffman
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Duluth, MN 55802

Hope Residence, Inc.
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Waterville, MN 56096

Cathie Hughes, Governmental Affairs
North Memorial Medical Center
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Robbinsdale, MN 55422

Ingleside Engineering and Construction, Inc.
Brian Van Beusekom
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St. Paul, MN 55102

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Department of Recreation, Parks and Leisure Services
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Mankato, MN 56001

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Sharon Kannenberg
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252 West Wabasha Street
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Barbara W. Kaufman, Exec. Dir
MN Assoc. of Voluntary Social Service Agencies
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1821 University Avenue
St. Paul, MN 55104

Bob Kent
Kent Well Drilling
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Raylene Kimball
Heartland Homes, Inc.
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PROPOSED RULES

Pursuant to Minn. Stat. of 1982, §§ 14.22, an agency may propose to adopt, amend, suspend or repeal rules without first holding a public hearing, as long as the agency determines that the rules will be noncontroversial in nature. The agency must first publish a notice of intent to adopt rules without a public hearing, together with the proposed rules, in the *State Register*. The notice must advise the public:

1. that they have 30 days in which to submit comment on the proposed rules;
2. 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;
3. of the manner in which persons shall request a hearing on the proposed rules; and
4. that the rule may be modified if the modifications are supported by the data and views submitted.

If, during the 30-day comment period, 25 or more persons submit to the agency a written request for a hearing of the proposed rules, the agency must proceed under the provisions of §§ 14.14-14.20, which state that if an agency decides to hold a public hearing, it must publish a notice of intent in the *State Register*.

Pursuant to Minn. Stat. §§ 14.29 and 14.30, agencies may propose emergency rules under certain circumstances. Proposed emergency rules are published in the *State Register* and, for at least 25 days thereafter, interested persons may submit data and views in writing to the proposing agency.

Department of Health

Proposed Rules Relating to Phenylketonuria Testing Program, the Treatment for Positive Diagnosis, and a Registry of Cases.

NOTICE IS HEREBY GIVEN that the Minnesota Commissioner of Health proposes to adopt Minn. Rules pts. 4615.0750, 4615.0755, and 4615.0760 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. The Commissioner proposes to adopt the above rules without a public hearing and is following the procedures set forth in Minnesota Statutes, sections 14.22 to 14.28. The specific statutory authority to adopt the rules is contained in Minnesota Statutes, section 144.128.

Persons interested in these rules shall have 30 days in which to submit comment in support of or in opposition to the proposed rules or any part or subpart of the rules, and comment is encouraged. Each comment should identify the portion of the proposed rules addressed, the reason for the comment, and any proposed change.

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." ADOPTED RULES SECTION — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

Any person may make a written request for a public hearing on the rules within the 30-day comment period. If 25 or more persons submit to the agency during the 30-day comment period a written request for a public hearing on the proposed rules, a public hearing will be held unless a sufficient number withdraw their request. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed rule addressed, the reason for the request, and any proposed change. If a public hearing is required, the agency will proceed pursuant to Minnesota Statutes, sections 14.131 to 14.20.

Persons who wish to submit comments or a written request for a public hearing must submit such comments or request to:

Lee Schacht, PhD
Human Genetics Unit
Maternal and Child Health Division
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440
Telephone: (612) 623-5269

The proposed rules may be modified if the modifications are supported by the data and views submitted and do not result in a substantial change in the proposed rules as noticed.

A copy of the proposed rules is attached to this notice.

A Statement of Need and Reasonableness has been prepared and is available upon request from Dr. Schacht at the above phone number and address. The statement describes the need for and reasonableness of each provision of the proposed rules and identifies the data and information relied upon to support the proposed rule and amendments.

The proposed rules will not affect small businesses as they are defined in Minn. Stat. § 14.115, subd. 1, nor will they require the expenditure of public monies by local public bodies.

If no hearing is required, upon adoption of the rule, the rule and the required supporting documents will be delivered to the Attorney General for review as to legality and form. Any person may request notification of the date of submission to the Attorney General. Persons who wish to be advised of the submission of this material to the Attorney General, or who wish to receive a copy of the adopted rule and amendments, must submit a written request to Dr. Schacht at the above address.

January 16, 1986

Sister Mary Madonna Ashton
Commissioner of Health

Rules as Proposed (all new material)

4615.0750 PURPOSE AND SCOPE.

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

4615.0755 DEFINITIONS.

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

Subp. 2. **Department.** "Department" means the Minnesota Department of Health.

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

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

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

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

Subp. 7. **Recipient.** "Recipient" means patient.

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

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

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

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

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

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

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

Subp. 3. **Assistance in obtaining treatment.** The department shall make arrangements for the medically indicated treatment of the metabolic defect causing mental retardation in diagnosed cases of phenylketonuria and other metabolic disease causing mental retardation when the patient is uninsured or is unable to pay the cost of treatment because of a lack of available income. The arrangements include referral to appropriate agencies which have financial resources to pay for medically indicated treatment such as private health insurance companies, medical assistance, and Services for Children with Handicaps.

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

A. name of patient;

B. gender;

C. date of birth;

D. place of birth;

E. parent's names;

F. current address of patient;

G. diagnosis;

H. name and address of physician; and

I. other data the commissioner deems necessary for follow-up services.

Subp. 5. **Classification of data.** The department shall classify all data in the registry as private pursuant to Minnesota Statutes, section 13.38, the Minnesota Government Data Practices Act.

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." ADOPTED RULES SECTION — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

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 REASONABLESNESS

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.

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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 infomed 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.

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 Cases

CERTIFICATE OF
COUNSEL

I, Catherine E. Avina, Special Assistant Attorney General, do hereby declare that I have examined the above-captioned rule, and the rulemaking record, and that, based on my examination, the Administrative Procedure Act and the rules of the Attorney General have been followed.

Dated: March 21, 1986

Catherine E. Avina

CATHERINE E. AVINA
Special Assistant
Attorney General

SF-00006-03

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL - Health

Office Memorandum

TO: J. Michael Miles
Assistant Attorney General
Administration/Finance Division

DATE: April 3, 1986

FROM: Catherine E. Avina
Special Assistant
Attorney General

PHONE: 341-7272

SUBJECT: Adopted Rules Relating to Phenylketonuria Testing

Pursuant to Minn. Stat. § 14.26, the attached documents in support of the above-referenced rules are submitted to your office for approval:

1. Notice of Solicitation of Outside Information or Opinions, executed December 4, 1985, and photocopy of same as published December 16, 1985, at 10 S.R. 1380.

2. Outside opinion and comment received by the agency.

3. Order for Notice of Proposed Adoption of Rules Without a Public Hearing, executed January 16, 1986.

4. Notice of Proposed Adoption of Rules Without a Public Hearing, executed January 16, 1986, with attached copy of the proposed amendments approved by the Revisor's office January 7, 1986.

5. A photocopy of the relevant pages of the February 3, 1986, State Register, at 10 S.R. 1609, in which the Notice and proposed rules referenced in number 4 above were published.

6. Statement of Need and Reasonableness.

7. Affidavit of Mailing and Certificate of Mailing List executed January 29, 1986, with attachments referenced therein.

8. Comments received by the agency.

9. Findings of Fact, Conclusions, and Order Adopting Rules Without a Public Hearing, executed March 27, 1986.

10. The original and three copies of the rule as adopted.

11. Certificate of Counsel.

Please call me if you have any questions concerning the attached documents or the procedures followed by the Department.

CEA:tmr

Attachments