

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

AVK
12-1-93

RULE REVIEW CHECKLIST

File No. 1974
DATE RECEIVED 11-25-92
REVIEW DATE 12-4-92
DUE DATE 12-9-92
(DIS)APPROVED 12-9-92
WITHDRAWN

Docket No. 050009 1610
ADOPTED W/O HEARING
EMERGENCY RULE
TO REVISOR ON 12/1/93
REVISOR (DIS)APPROVED 12-3-92
FILED W/SEC. OF STATE 12-10-92
RETURNED TO AGENCY 12-11-93

✓ Rule as adopted (4 copies)

Notice to Solicit Outside Information/Opinion (if applicable)
Date published in State Register
Comments

Petition for Adoption of a Rule

Board's Authorizing Resolution
Date adopted

✓ Proposed Rule
~~Revisor~~
Revisor's Certificate

✓ Notice of Intent to Adopt Rule
144.125 144.125 Statutory Authority
no statement Small Business Statement
Expenditure of public money statement
undated Signature

Statement of Need and Reasonableness (if applicable)
✓ Small Business Statement
NA Fees - § 16A.128

✓ Affidavit of Mailing Notice of Intent to Adopt Rule
July 16, 1992 Dated 30/25 days before adoption
✓ Notice attached indicates it is attached
Copy of rule or summary attached

✓ Publication in State Register
July 20, 1992 Date 30/25 days before adoption Sept 14, 1992
Additional 30 days

✓ 180-day deadline from:
Effective date of law requiring rule (14.12) (both rules) amendments don't apply
✓ end of comment period (§ 14.26) (rules without hearing)
effective date of statutory authority (§ 14.29) (emergency rules)

✓ Resolution Adopting
Date adopted

Findings of Fact, Conclusions & Order Adopting
NOV 23, 1992 Date

NA Written Requests, Submissions or Comments

✓ Declaration of Attorney
Mary Christy Name of SAAG representing agency

Notice of Submission to Attorney General (if applicable)

Affidavit of Mailing Notice to Attorney General (if applicable)

STATE OF MINNESOTA

Office of the Attorney General

TO : MALCOLM B. JENKINS, Ph.D.
Department of Health
Human Genetics Unit
Maternal and Child Health Division
717 S.E. Delaware Street
Minneapolis

DATE : December 10, 1992

FROM : AMY V. KVALSETH
Special Assistant
Attorney General

PHONE : 296-9422

SUBJECT : In the Matter of the Adopted Rule Relating to Infants; Newborn Metabolic Error Test

The above-referenced rule has been approved as to its legality by the Attorney General on December 9, 1992.

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

Also enclosed are any petitions, requests, submissions or comments along with any extra copies of documents which you submitted to the Attorney General.

Your next step is to arrange for publication of the Notice of Adoption in the State Register. In a day or two, you should receive from the Revisor's Office three copies of the notice of adoption of your rule. You should submit two copies of the Notice of Adoption to the State Register for publication. A permanent rule without a hearing does not become effective until five days after a notice of adoption is published 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.

Enclosures
cc: Maria C. Christu
William Brown, Chief Judge
MaryAnn Hruby

AVK:jj.rules.be5

Department of Health

Adopted Permanent Rules Relating to Infants; Newborn Metabolic Error Test

Rules as Adopted

TESTS OF INFANTS FOR INBORN METABOLIC ERRORS

4615.0300 PURPOSE AND SCOPE.

Parts 4615.0300 to 4615.0700 describe the responsibilities of the hospitals, physicians, and the Minnesota Department of Health to assure that all newborn infants are screened for hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia.

4615.0400 DEFINITIONS.

[For text of subps 1 to 4, see M.R.]

Subp. 5. **Responsible party.** "Responsible party" means the administrative officer or other person in charge of the hospital where the child is born, and the physician or other person operating under the supervision of a physician in attendance at the birth, or if not so attended, one of the parents.

Subp. 6. **Screen.** "Screen" means to carry out a series of laboratory tests on a dried capillary blood specimen which will identify those newborn infants who may develop hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia.

Subp. 7. **Specimen.** "Specimen" means a specimen of dried blood from the newborn infant collected on a specimen card.

[For text of subp 8, see M.R.]

4615.0500 DUTIES OF RESPONSIBLE PARTIES INVOLVED IN NEWBORN METABOLIC SCREENING PROGRAM.

The responsible party shall do all of the following:

A. Inform the parent(s) or legal guardian that their newborn(s) will be screened for the metabolic diseases hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism,

and congenital adrenal hyperplasia, and explain the reasons for such screening and their right to refuse this screening on the grounds that such tests conflict with their religious tenets and practices.

B. Collect or have collected a specimen for screening no later than the fifth day after the infant's birth, unless the parents lawfully object to such screening. If this specimen is taken prior to 24 hours after birth, the responsible party shall notify the parents or legal guardian verbally and in writing of the necessity of having the phenylketonuria test repeated on their newborn not later than the 14th day of life. If taking a blood sample at the times specified above is medically contraindicated, the sample shall be taken as soon as the infant's condition permits.

[For text of item C, see M.R.]

D. Send the specimen card including all of the required information as indicated on the card to the Minnesota Department of Health laboratory within 24 hours after collection.

[For text of item E, see M.R.]

4615.0600 DUTIES OF DEPARTMENT OF HEALTH.

The Minnesota Department of Health shall do all of the following:

A. develop specimen cards and make them available to the responsible party;

B. maintain a record of all cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia reported to it; and

C. notify the attending physician within 24 hours of obtaining the results, verbally and in writing by deposition in first class mail, of positive screening results and provide consultation on diagnostic and treatment sources available.

4615.0700 DUTIES OF ATTENDING PHYSICIAN.

The attending physician shall do all of the following:

A. Report, in writing, results of diagnostic evaluation of all instances of positive newborn screening

results of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia to: Human Genetics Unit, Minnesota Department of Health, 717 SE Delaware Street, P.O. Box 9441, Minneapolis, MN 55440-9441.

B. However, if the attending physician refers a patient with positive screening results to a medical specialist for diagnosis and/or treatment, the attending physician may delegate the responsibility for reporting a confirmed diagnosis to the medical specialist.

HEMOGLOBINOPATHY, PHENYLKETONURIA, GALACTOSEMIA, HYPOTHYROIDISM, AND CONGENITAL ADRENAL HYPERPLASIA TESTING PROGRAM; TREATMENT FOR POSITIVE DIAGNOSIS; REGISTRY OF CASES

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 hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia will: (1) have access to approved laboratory treatment control tests when available; (2) have necessary financial assistance for treatment of diagnosed cases when indicated; and (3) be included in a registry of cases for the purpose of coordinating follow-up services.

4615.0755 DEFINITIONS.

[For text of subps 1 to 3, see M.R.]

Subp. 4. [See repealer.]

Subp. 5. **Patient.** "Patient" means the person who has been diagnosed with hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia or the person's parents or legal guardian.

[For text of subp 6, see M.R.]

Subp. 7. [See repealer.]

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 hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism,

and/or congenital adrenal hyperplasia.

[For text of subps 9 to 11, see M.R.]

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

[For text of subps 1 and 2, see M.R.]

Subp. 3. **Assistance in obtaining treatment.** The department shall make arrangements for the medically indicated treatment of the metabolic defect in diagnosed cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia 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, Children's Health Plan, and Services for Children with Handicaps.

Subp. 4. **Registry of cases.** The department shall maintain a registry of all diagnosed cases of hemoglobinopathy, phenylketonuria, galactosemia, hypothyroidism, and congenital adrenal hyperplasia 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:

[For text of items A to I, see M.R.]

[For text of subp 5, see M.R.]

REPEALER. Minnesota Rules, part 4615.0755, subparts 4 and 7, are repealed.

APPROVED AS TO FORM AND LEGALITY

12-9 19 92

HUBERT H. HUMPHREY, III
ATTORNEY GENERAL

BY Amy V. Kvalseth
SPECIAL ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED

DEC 10 1992 4:05 pm

Joan Anderson Growe
Secretary of State

Stat Authority 144.125 144.128
attached

made a mistake in getting rules
gave an additional 30 days

no signed Notice of Intent - harmless
no proposed rule - O.K. as is.

Department of Health

Proposed Permanent Rules Relating to Infants; Newborn Metabolic Error Test

Rules as Proposed

TESTS OF INFANTS FOR INBORN METABOLIC ERRORS ~~CAUSING MENTAL RETARDATION~~

4615.0300 PURPOSE AND SCOPE.

Parts 4615.0300 to 4615.0700 describe the responsibilities of the hospitals, physicians, and the Minnesota Department of Health to assure that all newborn infants are screened for hemoglobinopathy, phenylketonuria, galactosemia, ~~and~~ hypothyroidism, and congenital adrenal hyperplasia.

4615.0400 DEFINITIONS.

[For text of subps 1 to 4, see M.R.]

Subp. 5. **Responsible party.** "Responsible party" means the administrative officer or other person in charge of ~~each~~ the hospital where the child is born, and the physician or other person operating under the supervision of a physician in attendance at the birth, or if not so attended, one of the parents.

Subp. 6. **Screen.** "Screen" means to carry out a series of laboratory tests on a dried capillary blood specimen which will identify those newborn infants who may develop hemoglobinopathy, phenylketonuria, galactosemia, ~~and/or~~ hypothyroidism, and/or congenital adrenal hyperplasia.

Subp. 7. **Specimen.** "Specimen" means a specimen of dried ~~capillary~~ blood from the newborn infant collected on a specimen card.

[For text of subp 8, see M.R.]

4615.0500 DUTIES OF RESPONSIBLE PARTIES INVOLVED IN ~~THE~~ NEWBORN METABOLIC SCREENING PROGRAM.

The responsible party shall do all of the following:

Approved by Revisor MEO

A. Inform the parent(s) or legal guardian that their newborn(s) will be screened for the metabolic diseases hemoglobinopathy, phenylketonuria, galactosemia, ~~and~~ hypothyroidism, and congenital adrenal hyperplasia, and explain the reasons for such screening and their right to refuse this screening on the grounds that such tests conflict with their religious tenets and practices.

B. Collect or have collected a specimen for screening no later than the fifth day after the infant's birth, unless the parents lawfully object to such screening. If this specimen is taken prior to 24 hours after birth, the responsible party shall notify the parents or legal guardian verbally and in writing of the necessity of having the ~~PKU~~ phenylketonuria test repeated on their newborn not later than the 14th day of life. If taking a blood sample at the times specified above is medically contraindicated, the sample shall be taken as soon as the infant's condition permits.

[For text of item C, see M.R.]

D. Send the specimen ~~and-the-following-information~~ card including all of the required information as indicated on the card to the Minnesota Department of Health laboratory within 24 hours after collection~~:~~.

~~(1)-newborn-infant's-name;~~

~~(2)-sex;~~

~~(3)-mother's-name;~~

~~(4)-home-address;~~

~~(5)-date-of-birth;~~

~~(6)-date-of-first-feeding;~~

~~(7)-date-specimen-collected;~~

~~(8)-name-and-address-of-attending-physician-and hospital-submitting-specimen;~~

~~(9)-county;~~

~~(10)-birth-weight-or-gestational-age;-and~~

~~(11)-bottle;-breast;-both.~~

[For text of item E, see M.R.]

Approved by Revisor _____

4615.0600 DUTIES OF ~~THE~~ DEPARTMENT OF HEALTH.

The Minnesota Department of Health shall do all of the following:

A. develop specimen cards and make them available ~~at no-charge~~ to the responsible party;

B. maintain a record of all cases of hemoglobinopathy, phenylketonuria, galactosemia, ~~and~~ hypothyroidism, and congenital adrenal hyperplasia reported to it; and

C. notify the attending physician within 24 hours of obtaining the results, verbally and in writing by deposition in first class mail, of positive screening results and provide consultation on diagnostic and treatment sources available.

4615.0700 DUTIES OF ~~THE~~ ATTENDING PHYSICIAN.

The attending physician shall do all of the following:

A. Report, in writing, ~~all-confirmed-diagnoses~~ results of diagnostic evaluation of all instances of positive newborn screening results of hemoglobinopathy, phenylketonuria, galactosemia, ~~and~~ hypothyroidism, and congenital adrenal hyperplasia to: Human Genetics Unit, Minnesota Department of Health, 717 SE Delaware Street, P.O. Box 9441, Minneapolis, MN ~~55440~~ 55440-9441.

B. However, if ~~he~~ the attending physician refers a patient with positive screening results to a medical specialist for diagnosis and/or treatment, ~~he~~ the attending physician may delegate the responsibility for reporting a confirmed diagnosis to the medical specialist.

HEMOGLOBINOPATHY, PHENYLKETONURIA, GALACTOSEMIA, HYPOTHYROIDISM, AND CONGENITAL ADRENAL HYPERPLASIA TESTING~~;~~ PROGRAM; TREATMENT FOR POSITIVE DIAGNOSIS; REGISTRY OF CASES

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 hemoglobinopathy, phenylketonuria ~~and-other-metabolic-diseases~~

Approved by Revisor _____

~~causing-mental-retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia will: (1) have access to approved laboratory treatment control tests ~~and~~ when available; (2) have necessary financial assistance for treatment of diagnosed cases when indicated~~,~~; and ~~will~~ (3) be included in a registry of cases for the purpose of coordinating follow-up services.

4615.0755 DEFINITIONS.

[For text of subps 1 to 3, see M.R.]

Subp. 4. [See repealer.]

Subp. 5. **Patient.** "Patient" means the person who has been diagnosed with hemoglobinopathy, phenylketonuria ~~or other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia or the person's parents or legal guardian.

[For text of subp 6, see M.R.]

Subp. 7. [See repealer.]

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 hemoglobinopathy, phenylketonuria ~~or other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia.

[For text of subps 9 to 11, see M.R.]

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

[For text of subps 1 and 2, see M.R.]

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 hemoglobinopathy, phenylketonuria ~~and other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia 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

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by Revisor _____

to pay for medically indicated treatment such as private health insurance companies, medical assistance, Children's Health Plan, and Services for Children with Handicaps.

Subp. 4. **Registry of cases.** The department shall maintain a registry of all diagnosed cases of hemoglobinopathy, phenylketonuria ~~and other metabolic diseases causing mental retardation~~, galactosemia, hypothyroidism, and congenital adrenal hyperplasia 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:

[For text of items A to I, see M.R.]

[For text of subp 5, see M.R.]

REPEALER. Minnesota Rules, part 4615.0755, subparts 4 and 7, are repealed.

Approved
by Revisor _____

RECEIVED

NOV 25 1992

Office at the Attorney Genera
Government Services Section
apitol Office Bldg., Suite 5
525 Park Street
Paul, MN 5510

Office of the Revisor of Statutes

Administrative Rules

TITLE: Proposed Permanent Rules Relating to Infants; Newborn Metabolic Error Test

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4615

The attached rules are approved for publication in the State Register

Marie O'Neill

Marie E. O'Neill
Assistant Revisor

rule, reduced fees for permits, licenses, registrations, and certifications when the application therefor is submitted during the last three months of the permit, license, registration, or certification period. Fees proposed to be prescribed in the rules shall be first approved by the department of finance. All fees proposed to be prescribed in rules shall be reasonable. The fees shall be in an amount so that the total fees collected by the commissioner will, where practical, approximate the cost to the commissioner in administering the program. All fees collected shall be deposited in the state treasury and credited to the general fund unless otherwise specifically appropriated by law for specific purposes.

(b) The commissioner may charge a fee for voluntary certification of medical laboratories and environmental laboratories, and for environmental and medical laboratory services provided by the department, without complying with paragraph (a) or chapter 14. Fees charged for environment and medical laboratory services provided by the department must be approximately equal to the costs of providing the services.

(c) The commissioner may develop a schedule of fees for diagnostic evaluations conducted at clinics held by the services for children with handicaps program. All receipts generated by the program are annually appropriated to the commissioner for use in the maternal and child health program.

History: *1974 c 471 s 1; 1975 c 310 s 36; 1977 c 305 s 45; 1985 c 248 s 70; 1986 c 444; 1987 c 403 art 2 s 7; 1989 c 209 art 1 s 14; 1989 c 282 art 1 s 16*

144.123 FEES FOR DIAGNOSTIC LABORATORY SERVICES; EXCEPTIONS.

Subdivision 1. **Who must pay.** Except for the limitation contained in this section, the commissioner of health shall charge a handling fee for each specimen submitted to the department of health for analysis for diagnostic purposes by any hospital, private laboratory, private clinic, or physician. No fee shall be charged to any entity which receives direct or indirect financial assistance from state or federal funds administered by the department of health, including any public health department, nonprofit community clinic, venereal disease clinic, family planning clinic, or similar entity. The commissioner of health may establish by rule other exceptions to the handling fee as may be necessary to gather information for epidemiologic purposes. All fees collected pursuant to this section shall be deposited in the state treasury and credited to the general fund.

Subd. 2. **Rules for fee amounts.** The commissioner of health shall promulgate rules, in accordance with chapter 14, which shall specify the amount of the handling fee prescribed in subdivision 1. The fee shall approximate the costs to the department of handling specimens including reporting, postage, specimen kit preparation, and overhead costs. The fee prescribed in subdivision 1 shall be $5 per specimen until the commissioner promulgates rules pursuant to this subdivision.

History: *1979 c 49 s 1; 1982 c 424 s 130; 1987 c 403 art 2 s 8*

144.125 TESTS OF INFANTS FOR INBORN METABOLIC ERRORS.

It is the duty of (1) the administrative officer or other person in charge of each institution caring for infants 28 days or less of age and (2) the person required in pursuance of the provisions of section 144.215, to register the birth of a child, to cause to have administered to every infant or child in its care tests for hemoglobinopathy, phenylketonuria, and other inborn errors of metabolism in accordance with rules prescribed by the state commissioner of health. In determining which tests must be administered, the commissioner shall take into consideration the adequacy of laboratory methods to detect the inborn metabolic error, the ability to treat or prevent medical conditions caused by the inborn metabolic error, and the severity of the medical conditions caused by the inborn metabolic error. Testing and the recording and reporting of the results of the tests shall be performed at the times and in the manner prescribed by the commissioner of health. This section does not apply to an infant whose parents object on the grounds that the tests and treatment conflict with their religious tenets and practices.

The commissioner shall charge laboratory service fees for conducting the tests of infants for inborn metabolic errors so that the total of fees collected will approximate the costs of conducting the tests. Costs associated with capital expenditures and the development of new procedures may be prorated over a three-year period when calculating the amount of the fees.

History: *1965 c 205 s 1; 1977 c 305 s 45; 1Sp1981 c 4 art 1 s 75; 1985 c 248 s 70; 1986 c 444; 1988 c 689 art 2 s 31*

144.126 PHENYLKETONURIA TESTING PROGRAM.

The commissioner shall provide on a statewide basis without charge to the recipient, treatment control tests for which approved laboratory procedures are available for phenylketonuria and other metabolic diseases causing mental retardation.

History: *1Sp1985 c 9 art 2 s 9*

144.128 TREATMENT FOR POSITIVE DIAGNOSIS, REGISTRY OF CASES.

The commissioner shall:

(1) make arrangements for the necessary treatment of diagnosed cases of phenylketonuria and other metabolic diseases when treatment is indicated and the family is uninsured and, because of a lack of available income, is unable to pay the cost of the treatment;

(2) maintain a registry of cases of phenylketonuria and other metabolic diseases for the purpose of follow-up services to prevent mental retardation; and

(3) adopt rules to carry out section 144.126 and this section.

History: *1Sp1985 c 9 art 2 s 10*

144.13 RULES, NOTICE PUBLISHED.

Three weeks published notice of such rules, if of general application throughout the state, shall be given at the seat of government; if of local application only, as near such locality as practicable. Special rules applicable to particular cases shall be sufficiently noticed when posted in a conspicuous place upon or near the premises affected. Fines collected for violations of rules adopted by the commissioner shall be paid into the state treasury; and of local boards and officers, into the county treasury.

History: *(5346) RL s 2132; 1977 c 305 s 45; 1985 c 248 s 70*

144.14 QUARANTINE OF INTERSTATE CARRIERS.

When necessary the commissioner may establish and enforce a system of quarantine against the introduction into the state of any plague or other communicable disease by common carriers doing business across its borders. Its members, officers, and agents may board any conveyance used by such carriers to inspect the same and, if such conveyance be found infected, may detain the same and isolate and quarantine any or all persons found thereon, with their luggage, until all danger of communication of disease therefrom is removed.

History: *(5347) RL s 2133; 1977 c 305 s 45*

144.145 FLUORIDATION OF MUNICIPAL WATER SUPPLIES.

For the purpose of promoting public health through prevention of tooth decay, the person, firm, corporation, or municipality having jurisdiction over a municipal water supply, whether publicly or privately owned or operated, shall control the quantities of fluoride in the water so as to maintain a fluoride content prescribed by the state commissioner of health. In the manner provided by law, the state commissioner of health shall promulgate rules relating to the fluoridation of public water supplies which shall include, but not be limited to the following: (1) The means by which fluoride is controlled; (2) the methods of testing the fluoride content; and (3) the records to be kept relating to fluoridation. The state commissioner of health shall enforce the provisions

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NOV 25 1992

Office of the Attorney General
Government Services Section
Capitol Office Bldg., Suite 500
525 Park Street
St. Paul, MN 55101

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Amendments to Parts 4615.0300 to 4615.0760 Relating to Infants; Newborn Metabolic Error Test

FINDINGS OF FACT, CONCLUSIONS, AND ORDER ADOPTING RULES

The Department of Health (hereinafter "Department") initiated the above-captioned rulemaking proceeding to adopt rules without a public hearing pursuant to Minn. Stat. sections 14.22 to 14.28 as well as all other provisions of Minn. Stat. ch. 14 applicable to this rulemaking proceeding. The comment period has closed without 25 or more persons requesting that a hearing be held on these rule amendments. Accordingly, the Commissioner of Health (hereinafter "Commissioner") having fully and thoroughly reviewed and considered the record in this matter, and based thereon, makes the following

FINDINGS:

1. The Department's Notice of Intent to adopt the above-entitled rules without a public hearing was published in the State Register on July 20, 1992 and was sent by United States mail to all persons on the list maintained by the Department pursuant to Minn. Stat. sections 14.14, subd. 1a and 14.22 on July 16, 1992.

2. The Statement of Need and Reasonableness was prepared before the Notice of Intent to Adopt Rules Without a Public Hearing was mailed to all persons on the rulemaking mailing list and published in the State Register and was available to the public.

(4) 3. All persons were given the opportunity to submit comment on the rules for 30 days after the notice of proposed rulemaking was published and mailed.

4. All persons were given an additional 30 days to submit comment after it was learned that there was an error in the July 16 mailing to all persons on the list maintained by the Department. The notice of this extension of the comment period was published in the State Register on September 14, 1992 and was sent by United States mail to all persons on the list maintained by the Department pursuant to Minn. Stat. sections 14.14, subd. 1a and 14.22 on September 9, 1992.

(5) 5. The Department received no requests for a public hearing on the rules.

6. The Department received no comments on the proposed rule changes.

(7) 7. The Department received no requests to be notified when the rulemaking record is submitted to the Office of the Attorney General.

(8) 8. The Commissioner incorporates herein as findings, the statement of need and reasonableness.

Based upon the above findings, the Commissioner with respect to the above-captioned rules makes the following **CONCLUSIONS:**

1. That all substantive and procedural requirements have been complied with;

2. That the rules are statutorily authorized; and

3. That the rules are both needed and reasonable. **NOW, THEREFORE, IT IS HEREBY ORDERED** that the rules identified as In the Matter of the Proposed Adoption of Amendments to Parts 4615.0300 to 4615.0760 Relating to Infants; Newborn Metabolic Error Test are adopted this 23rd day of November, 1992, pursuant to authority vested in the Commissioner by Minn. Stat. sections 144.125 and 144.128 (1990).

Marlene E. Marschall
Commissioner of Health

RECEIVED

NOV 25 1992

Office of the Attorney General
Government Services Section
Capitol Office Bldg., Suite 500
525 Park Street
St. Paul, MN 55101

STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of the Rules of the Minnesota Department of Health Governing Proposed Permanent Rules Relating to Infants; Newborn Metabolic Error Test Parts 4615.0300 to 4615.0700

NOTICE OF INTENT TO ADOPT A RULE WITHOUT A PUBLIC HEARING

(1) Notice is hereby given that the Minnesota Department of Health intends to adopt the above-entitled rule without a public hearing following the procedures set forth in the Administrative Procedures Act for adopting rules without a public hearing in Minnesota Statutes, sections 14.22 to 14.28. The statutory authority to adopt the rule is Minnesota Statutes, section 144.125 and section 144.128.

(2) All persons have 30 days or until 4:30 p.m. on August 19, 1992 in which to submit comment in support of or in opposition to the proposed rule or any part or subpart of the rule. Comment is encouraged. (3) Each comment should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed.

Any person may make a written request for a public hearing on the rule within the 30-day comment period or until 4:30 p.m. on August 19, 1992. (4) If 25 or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held unless a sufficient number withdraw their request in writing. (6) 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 change proposed. (7) If a public hearing is required, the agency will proceed pursuant to Minnesota Statutes, sections 14.131 to 14.20.

(5) Comments or written requests for a public hearing must be submitted to: Malcolm B. Jenkins, Ph.D., Human Genetics Unit, Maternal and Child Health Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268.

(8) The proposed rule may be modified if the modifications are supported by data and views submitted to the Department and do not result in a substantial change in the proposed rule as noticed.

The proposed changes will add hemoglobinopathy and congenital adrenal hyperplasia to the Minnesota Department of Health newborn screening program.

(11) A free copy of the rule is available upon request from Malcolm B. Jenkins, Ph.D., Human Genetics Unit, Maternal and Child Health

Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268.

(12) A Statement of Need and Reasonableness that describes the need for and reasonableness of each provision of the proposed rule and identifies the data and information relied upon to support the proposed rule has been prepared and is available from Malcolm B. Jenkins, Ph.D., Human Genetics Unit, Maternal and Child Health Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268, upon request.

(13) Adoption of these rules will not result in additional spending by local public bodies in excess of $100,000 per year for the first two years following adoption under the requirements of Minnesota Statutes, section 14.11.

(9) If no hearing is required, upon adoption of the rule, the rule and the required supporting documents will be submitted to the Attorney General for review as to legality and form, including the issues of substantial change; whether the Department has the authority to adopt the rules; and whether the record demonstrates a rational basis for the need for and reasonableness of the proposed rules. 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, must submit the written request to Malcolm B. Jenkins, Ph.D., Human Genetics Unit,

Maternal and Child Health Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268. If the proposed rule has been modified, the notice will also state that fact and will state that a free copy of the proposed rule, as modified, will be available on request from the Department.

Date:

Marlene E. Marschall
COMMISSIONER OF HEALTH

RECEIVED

NOV 25 1992

Office of the Attorney General
Government Services Section
Capitol Office Bldg., Suite 5C
525 Park Street
St. Paul, MN 5510

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

IN THE MATTER OF 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

STATEMENT OF NEED AND REASONABLENESS

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

RECEIVED

NOV 25 1992

Office of the Attorney General
Government Services Section
Capitol Office Bldg., Suite 5C
525 Park Street
St. Paul, MN 5510

STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of the Rules of the Minnesota Department of Health Governing Tests of Infants for Inborn Metabolic Errors

AFFIDAVIT OF MAILING THE STATEMENT OF NEED AND REASONABLENESS

Ronald G. Campbell, being sworn, says:

That on the 16th day of July, 1992, in the City of Minneapolis, County of Hennepin, State of Minnesota, I mailed the attached Statement of Need and Reasonableness by depositing in the State of Minnesota Central mail System for interoffice mail, six (6) copies thereof to the Legislative Commission to Review Administrative Rules.

Ronald G. Campbell
(name)

Asst Chief, MCH Tech Serv
(title)

Maternal & Child Health
(division)

Subscribed and sworn to before me
this 19th day of November, 1992.

Sandy J. Fliehs

SANDY J. FLIEHS
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
MY COMMISSION EXPIRES FEBRUARY 29 1996

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

IN THE MATTER OF 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

STATEMENT OF NEED AND REASONABLENESS

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

RECEIVED

NOV 25 1992

Office of the Attorney General
Government Services Section
Capitol Office Bldg., Suite 5
525 Park Street
St. Paul, MN 5510

STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of the Rules of the Minnesota Department of Health Governing Tests of Infants for Inborn Metabolic Errors

AFFIDAVIT OF MAILING THE NOTICE OF INTENT TO ADOPT A RULE WITHOUT A PUBLIC HEARING

Kathleen A. Krook, being sworn, says:

That on the 16th day of July, 1992, in the City of Minneapolis, County of Hennepin, State of Minnesota, I mailed the attached Notice of Intent to Adopt a Rule Without a Public Hearing by depositing in the State of Minnesota Central mail System for United States mailing, a copy thereof, with postage prepaid, to all persons and associations on the attached Department list and discretionary mailing list.

Kathleen A. Krook
(name)

Clerical Unit Supervisor
(title)

Maternal & Child Health
(division)

Subscribed and sworn to before me
this 23rd day of July, 1992.

Sandy J. Fliehs

SANDY J. FLIEHS
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
MY COMMISSION EXPIRES FEBRUARY 20, 1993

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

CERTIFICATION

I hereby certify that the list of persons, associations, and other interested groups who have requested, pursuant to Minnesota Statutes, section 14.14, subdivision 1a, that their names be placed on file with, and maintained by, the Minnesota Department of Health for the purpose of receiving notice of rule hearings, is accurate and complete as of 1:00 p.m., this 14th day of July, 1992.

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STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of the Rules of the Minnesota Department of Health Governing Proposed Permanent Rules Relating to Infants; Newborn Metabolic Error Test Parts 4615.0300 to 4615.0700	NOTICE OF INTENT TO ADOPT A RULE WITHOUT A PUBLIC HEARING

Notice is hereby given that the Minnesota Department of Health intends to adopt the above-entitled rule without a public hearing following the procedures set forth in the Administrative Procedures Act for adopting rules without a public hearing in Minnesota Statutes, sections 14.22 to 14.28. The statutory authority to adopt the rule is Minnesota Statutes, section 144.125 and section 144.128.

All persons have 30 days or until 4:30 p.m. on August 19, 1992 in which to submit comment in support of or in opposition to the proposed rule or any part or subpart of the rule. Comment is encouraged. Each comment should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed.

Any person may make a written request for a public hearing on the rule within the 30-day comment period or until 4:30 p.m. on August 19, 1992. If 25 or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held unless a sufficient number withdraw their request in writing. 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 change proposed. If a public hearing is required, the agency will proceed pursuant to Minnesota Statutes, sections 14.131 to 14.20.

Comments or written requests for a public hearing must be submitted to: Malcolm B. Jenkins, Ph.D., Human Genetics Unit, Maternal and Child Health Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268.

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

The proposed changes will add hemoglobinopathy and congenital adrenal hyperplasia to the Minnesota Department of Health newborn screening program.

A free copy of the rule is available upon request from Malcolm B. Jenkins, Ph.D., Human Genetics Unit, Maternal and Child Health

Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268.

A Statement of Need and Reasonableness that describes the need for and reasonableness of each provision of the proposed rule and identifies the data and information relied upon to support the proposed rule has been prepared and is available from Malcolm B. Jenkins, Ph.D., Human Genetics Unit, Maternal and Child Health Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268, upon request.

Adoption of these rules will not result in additional spending by local public bodies in excess of $100,000 per year for the first two years following adoption under the requirements of Minnesota Statutes, section 14.11.

If no hearing is required, upon adoption of the rule, the rule and the required supporting documents will be submitted to the Attorney General for review as to legality and form, including the issues of substantial change; whether the Department has the authority to adopt the rules; and whether the record demonstrates a rational basis for the need for and reasonableness of the proposed rules. 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, must submit the written request to Malcolm B. Jenkins, Ph.D., Human Genetics Unit,

Maternal and Child Health Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268. If the proposed rule has been modified, the notice will also state that fact and will state that a free copy of the proposed rule, as modified, will be available on request from the Department.

Date:

Marlene E. Marschall
COMMISSIONER OF HEALTH

Proposed Rules

Pursuant to Minn. Stat. §§ 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 Permanent Rules Relating to Infants; Newborn Metabolic Error Test

Notice of Intent to Adopt a Rule Without a Public Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Department of Health intends to adopt the above-entitled rule without a public hearing following the procedures set forth in the Administrative Procedures Act for adopting rules without a public hearing in *Minnesota Statutes*, sections 14.22 to 14.28. The statutory authority to adopt the rule is *Minnesota Statutes*, section 144.125 and section 144.128.

All persons have 30 days or until 4:30 p.m. on August 19, 1992 in which to submit comment in support of or in opposition to the proposed rule or any part or subpart of the rule. Comment is encouraged. Each comment should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed.

Any person may make a written request for a public hearing on the rule within the 30-day comment period or until 4:30 p.m. on August 19, 1992. If 25 or more persons submit a written request for a public hearing within the comment period, a public hearing will be held unless a sufficient number withdraw their request in writing. 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 change proposed. If a public hearing is required, the agency will proceed pursuant to *Minnesota Statutes*, sections 14.131 to 14.20.

Comments or written requests for a public hearing must be submitted to: Malcolm B. Jenkins, Ph.D., Human Genetics Unit, Maternal and Child Health Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268.

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

The proposed changes will add hemoglobinopathy and congenital adrenal hyperplasia to the Minnesota Department of Health newborn screening program.

A free copy of the rule is available upon request from Malcolm B. Jenkins, Ph.D., Human Genetics Unit, Maternal and Child Health Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268.

A Statement of Need and Reasonableness that describes the need for and reasonableness of each provision of the proposed rule and identifies the data and information relied upon to support the proposed rule has been prepared and is available from Malcolm B. Jenkins, Ph.D., Human Genetics Unit, Maternal and Child Health Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268, upon request.

Adoption of these rules will not result in additional spending by local public bodies in excess of $100,000 per year for the first two years following adoption under the requirements of *Minnesota Statutes*, section 14.11.

If no hearing is required, upon adoption of the rule, the rule and the required supporting documents will be submitted to the Attorney General for review as to legality and form, including the issues of substantial change; whether the Department has the authority to adopt the rules; and whether the record demonstrates a rational basis for the need for and reasonableness of the proposed rules. Any

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.

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 must submit the written request to Malcolm B. Jenkins, Ph.D., Human Genetics Unit, Maternal and Child Health Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441; (612) 623-5268. If the proposed rule has been modified, the notice will also state that fact and will state that a free copy of the proposed rule, as modified, will be available on request from the Department.

Marlene E. Marschall
Commissioner of Health

Rules as Proposed

TESTS OF INFANTS FOR INBORN METABOLIC ERRORS ~~CAUSING MENTAL RETARDATION~~

4615.0300 PURPOSE AND SCOPE.

Parts 4615.0300 to 4615.0700 describe the responsibilities of the hospitals, physicians, and the Minnesota Department of Health to assure that all newborn infants are screened for hemoglobinopathy, phenylketonuria, galactosemia, ~~and~~ hypothyroidism, ~~and~~ congenital adrenal hyperplasia.

4615.0400 DEFINITIONS.

[For text of subps 1 to 4, see M.R.]

Subp. 5. **Responsible party.** "Responsible party" means the administrative officer or other person in charge of ~~each~~ the hospital where the child is born, and the physician or other person operating under the supervision of a physician in attendance at the birth, or if not so attended, one of the parents.

Subp. 6. **Screen.** "Screen" means to carry out a series of laboratory tests on a dried capillary blood specimen which will identify those newborn infants who may develop hemoglobinopathy, phenylketonuria, galactosemia, ~~and/or~~ hypothyroidism, and/or congenital adrenal hyperplasia.

Subp. 7. **Specimen.** "Specimen" means a specimen of dried ~~capillary~~ blood from the newborn infant collected on a specimen card.

[For text of subp 8, see M.R.]

4615.0500 DUTIES OF RESPONSIBLE PARTIES INVOLVED IN ~~THE~~ NEWBORN METABOLIC SCREENING PROGRAM.

The responsible party shall do all of the following:

A. Inform the parent(s) or legal guardian that their newborn(s) will be screened for the metabolic diseases hemoglobinopathy, phenylketonuria, galactosemia, ~~and~~ hypothyroidism, and congenital adrenal hyperplasia, and explain the reasons for such screening and their right to refuse this screening on the grounds that such tests conflict with their religious tenets and practices.

B. Collect or have collected a specimen for screening no later than the fifth day after the infant's birth, unless the parents lawfully object to such screening. If this specimen is taken prior to 24 hours after birth, the responsible party shall notify the parents or legal guardian verbally and in writing of the necessity of having the ~~PKU~~ phenylketonuria test repeated on their newborn not later than the 14th day of life. If taking a blood sample at the times specified above is medically contraindicated, the sample shall be taken as soon as the infant's condition permits.

[For text of item C, see M.R.]

D. Send the specimen ~~and the following information~~ card including all of the required information as indicated on the card to the Minnesota Department of Health laboratory within 24 hours after collection~~:~~.

~~(1) newborn infant's name;~~

~~(2) sex;~~

~~(3) mother's name;~~

~~(4) home address;~~

~~(5) date of birth;~~

~~(6) date of first feeding;~~

~~(7) date specimen collected;~~

~~(8) name and address of attending physician and hospital submitting specimen;~~

~~(9) county;~~

~~(10) birth weight or gestational age; and~~

~~(11) bottle, breast, both.~~

[For text of item E, see M.R.]

4615.0600 DUTIES OF ~~THE~~ DEPARTMENT OF HEALTH.

The Minnesota Department of Health shall do all of the following:

A. develop specimen cards and make them available ~~at no charge~~ to the responsible party;

B. maintain a record of all cases of hemoglobinopathy, phenylketonuria, galactosemia, ~~and~~ hypothyroidism, and congenital adrenal hyperplasia reported to it; and

C. notify the attending physician within 24 hours of obtaining the results, verbally and in writing by deposition in first class mail, of positive screening results and provide consultation on diagnostic and treatment sources available.

4615.0700 DUTIES OF ~~THE~~ ATTENDING PHYSICIAN.

The attending physician shall do all of the following:

A. Report, in writing, ~~all confirmed diagnoses~~ results of diagnostic evaluation of all instances of positive newborn screening results of hemoglobinopathy, phenylketonuria, galactosemia, ~~and~~ hypothyroidism, and congenital adrenal hyperplasia to: Human Genetics Unit, Minnesota Department of Health, 717 SE Delaware Street, P.O. Box 9441, Minneapolis, MN ~~55440~~ 55440-9441.

B. However, if ~~he~~ the attending physician refers a patient with positive screening results to a medical specialist for diagnosis and/or treatment, ~~he~~ the attending physician may delegate the responsibility for reporting a confirmed diagnosis to the medical specialist.

HEMOGLOBINOPATHY, PHENYLKETONURIA, GALACTOSEMIA, HYPOTHYROIDISM, AND CONGENITAL ADRENAL HYPERPLASIA TESTING~~;~~ PROGRAM; TREATMENT FOR POSITIVE DIAGNOSIS; REGISTRY OF CASES

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 hemoglobinopathy, phenylketonuria ~~and other metabolic diseases causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia will: (1) have access to approved laboratory treatment control tests ~~and~~ when available; (2) have necessary financial assistance for treatment of diagnosed cases when indicated~~,~~; and ~~will~~ (3) be included in a registry of cases for the purpose of coordinating follow-up services.

4615.0755 DEFINITIONS.

[For text of subps 1 to 3, see M.R.]

Subp. 4. [See repealer.]

Subp. 5. **Patient.** "Patient" means the person who has been diagnosed with hemoglobinopathy, phenylketonuria ~~or other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia or the person's parents or legal guardian.

[For text of subp 6, see M.R.]

Subp. 7. [See repealer.]

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 hemoglobinopathy, phenylketonuria ~~or other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia.

[For text of subps 9 to 11, see M.R.]

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

[For text of subps 1 and 2, see M.R.]

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 hemoglobinopathy, phenylketonuria ~~and other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia when the patient is uninsured or is

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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, Children's Health Plan, and Services for Children with Handicaps.

Subp. 4. **Registry of cases.** The department shall maintain a registry of all diagnosed cases of hemoglobinopathy, phenylketonuria ~~and other metabolic diseases causing mental retardation~~, galactosemia, hypothyroidism, and congenital adrenal hyperplasia 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:

[For text of items A to I, see M.R.]

[For text of subp 5, see M.R.]

REPEALER. *Minnesota Rules*, part 4615.0755, subparts 4 and 7, are repealed.

Department of Human Services

Proposed Permanent Rules Relating to State Grants for Mental Health Services

Notice of Intent to Adopt Rules Without a Public Hearing and Notice of Intent to Adopt Rules With a Public Hearing if Twenty-five or More Persons Request a Hearing

NOTICE IS HEREBY GIVEN that the State Department of Human Services proposes to adopt the above-entitled rule without a public hearing following the procedures set forth in *Minnesota Statutes*, sections 14.22 to 14.28. The specific statutory authority to adopt the rule is found in *Minnesota Statutes*, sections 245.484, which requires the commissioner to adopt permanent rules "as necessary to carry out" the Minnesota Comprehensive Adult Mental Health Act and the Minnesota Comprehensive Children's Mental Health Act; 245.4886, which requires the commissioner to establish a statewide program to assist counties in providing services to children with severe emotional disturbance and their families; and 256E.12, which requires the commissioner to establish a statewide program to assist counties in providing services to persons with serious and persistent mental illness.

Persons interested in this rule shall have 30 days in which to submit comment in support of or in opposition to the proposed rule or any part or subpart of the rule and comment is encouraged. The 30-day comment period ends at 4:30 p.m. on August 19, 1992. Each comment should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed.

Any person may make a written request for a public hearing on the rule within the 30-day comment period. If 25 or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held unless a sufficient number withdraw their request in writing. The 30-day comment period ends at 4:30 p.m. on August 19, 1992. 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 change proposed. If a public hearing is required, the agency will proceed pursuant to *Minnesota Statutes*, section 14.131 to 14.20. PLEASE NOTE THAT IF TWENTY-FIVE OR MORE PERSONS SUBMIT WRITTEN REQUESTS FOR A PUBLIC HEARING WITHIN THE 30-DAY COMMENT PERIOD, A HEARING WILL BE HELD ON AUGUST 31, 1992, UNLESS A SUFFICIENT NUMBER WITHDRAW THEIR REQUEST, IN ACCORDANCE WITH THE NOTICE OF PUBLIC HEARING ON THESE SAME RULES PUBLISHED IN THIS *STATE REGISTER* AND MAILED TO PERSONS REGISTERED WITH THE DEPARTMENT OF HUMAN SERVICES. To verify whether a hearing will be held, please call the Department of Human Services between August 20, 1992 and August 28, 1992 at (612) 296-7454.

Persons who wish to submit comments or a written request for a public hearing must be submit such comments or requests to: Eleanor Weber, Minnesota Department of Human Services, Rules and Bulletins Division, 444 Lafayette Road, St. Paul, Minnesota 55155-3816.

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

A free copy of this rule is available upon request for your review from Nancy Bishop at the address and telephone number above.

A copy of the proposed rule may be viewed at any of the county welfare or human service agencies in the State of Minnesota.

Proposed parts 9535.1700 to 9535.1760 establish standards for receipt and distribution of state grants to counties for two types of mental health services: community-based mental health services for children with severe emotional disturbance and their families, and community support and case management services for adults with serious and persistent mental illness. The proposed rule will affect counties and contracting service providers, as well as clients of mental health services.

The proposed rule will establish: eligibility to receive grants; funding criteria for grants; criteria for grant applications, the use of grant funds, and grant distributions; budget requirements for counties; county fiscal reporting requirements; that counties will receive

Official Notices

Pursuant to the provisions of Minnesota Statutes § 14.10, an agency, in preparing proposed rules, may seek information or opinion from sources outside the agency. Notices of intent to solicit outside opinion must be published in the *State Register* and all interested persons afforded the opportunity to submit data or views on the subject, either orally or in writing.

The *State Register* also publishes other official notices of state agencies, notices of meetings, and matters of public interest.

Ethical Practices Board

Advisory Opinion Requests #125 re: Campaign Expenditure Limits

Issued 8-31-92 to Thomas J. Bieter, Esq.—SUMMARY—125. The election year campaign expenditure limit under *Minnesota Statutes* §§ 10A.25 and 10A.255 is applicable to a candidate with a Public Subsidy Agreement pursuant to *Minnesota Statutes* § 10A.322 in effect during the period from January 1 of an election year for the office sought or held and until filings open in that election year for that office. This limit will be applied prospectively only from the date of this opinion.

A candidate who had a Public Subsidy Agreement in effect that expired when filings opened in 1992 and who signs a Public Subsidy Agreement after filings opened that is rescinded before September 1, 1992, has no limit on total campaign expenditures during calendar year 1992.

The full text of the opinion is available upon request from the Ethical Practices Board, 1st Floor South, Centennial Building, 658 Cedar Street, St. Paul, MN 55101-2520; (612) 296-5148.

Department of Health

Proposed Permanent Rules Relating to Infants; Newborn Metabolic Error Test Extended Comment Period

On July 20, 1992, the *State Register* contained a Notice of Intent to Adopt the above referenced Rules. The related direct mailing to interested persons on July 16, contained an error in the caption indicating that the Rules were to be amended to Part 4615.0700. The full parts to be amended are 4615.0300 to 4615.0760.

Accordingly, all persons have an additional 30 days or until 4:30 p.m. on October 15, 1992 in which to submit comment in support of or in opposition to the proposed Rules or any part or subpart of the Rules.

A full set of the proposed Rules and information concerning the process for their adoption was contained in the *State Register* on July 20, 1992.

Minnesota Department of Health

Notice of Meeting

In conjunction with the 1992 health care reform legislation (formerly HealthRight), there will be an initial meeting of the Antitrust Rules Advisory Panel at 8:00 a.m. on Thursday, September 17, 1992. The meeting will be held at the Veteran's Service Building, Room D, 20 West 12th Street, St. Paul, Minnesota 55155.

Department of Health

Notice of Completed Application and Notice of and Order for Hearing In the Matter of the License Application of Stevens County Ambulance Service, Morris, Minnesota

PLEASE TAKE NOTICE that the Commissioner of Health (hereinafter "Commissioner") has received a completed application from Stevens County Ambulance Service, Morris, Minnesota for a Specialized Advanced Ambulance Service.

IT IS HEREBY ORDERED AND NOTICE IS HEREBY GIVEN that, pursuant to *Minnesota Statutes* §§ 14.57-14.69 and *Minnesota Statutes* § 144.802 a public hearing will be held on October 21, 1992 at Stevens County Ambulance Office, 209 South Hwy. 9, Morris.

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.

RECEIVED

NOV 25 1992

Office of the Attorney General
Government Services Section
Capitol Office Bldg. - Suite 500
525 Park Street
St. Paul, MN 55101

STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of the Rules of the Minnesota Department of Health Governing Proposed Permanent Rules Relating to Infants; Newborn Metabolic Error Test Parts 4615.0300 to 4615.0760

EXTENDED COMMENT PERIOD

On July 16, 1992 you were mailed a Notice of Intent to Adopt a Rule Without a Public Hearing which contained an error in the caption indicating that the Rules were to be amended to Part 4615.0700. The full Parts to be amended are 4615.0300 to 4615.0760.

Accordingly, all persons have an additional 30 days, from September 14, 1992 until 4:30 p.m. on October 15, 1992 in which to submit comment in support of or in opposition to the proposed Rules or any part or subpart of the Rules. A copy of the Rules is attached for reference.

Further information concerning the process for adopting these Rules was contained in the July 16 Notice which you previously received. An additional copy is available upon request from Malcolm B. Jenkins, Ph.D., Human Genetics Unit, Maternal and Child Health Division, 717 S.E. Delaware Street, P.O. Box 9441, Minneapolis, Minnesota 55440-9441, (612) 623-5268

Department of Health

Proposed Permanent Rules Relating to Infants: Newborn Metabolic Error Test

Rules as Proposed

TESTS OF INFANTS FOR INBORN METABOLIC ERRORS ~~CAUSING MENTAL RETARDATION~~

4615.0300 PURPOSE AND SCOPE.

Parts 4615.0300 to 4615.0700 describe the responsibilities of the hospitals, physicians, and the Minnesota Department of Health to assure that all newborn infants are screened for hemoglobinopathy, phenylketonuria, galactosemia, and hypothyroidism, and congenital adrenal hyperplasia.

4615.0400 DEFINITIONS.

[For text of subps 1 to 4, see M.R.]

Subp. 5. **Responsible party.** "Responsible party" means the administrative officer or other person in charge of ~~each~~ the hospital where the child is born, and the physician or other person operating under the supervision of a physician in attendance at the birth, or if not so attended, one of the parents.

Subp. 6. **Screen.** "Screen" means to carry out a series of laboratory tests on a dried capillary blood specimen which will identify those newborn infants who may develop hemoglobinopathy, phenylketonuria, galactosemia, ~~and/or~~ hypothyroidism, and/or congenital adrenal hyperplasia.

Subp. 7. **Specimen.** "Specimen" means a specimen of dried ~~capillary~~ blood from the newborn infant collected on a specimen card.

[For text of subp 8, see M.R.]

4615.0500 DUTIES OF RESPONSIBLE PARTIES INVOLVED IN ~~THE~~ NEWBORN METABOLIC SCREENING PROGRAM.

The responsible party shall do all of the following:

Approved by Revisor MEO

A. Inform the parent(s) or legal guardian that their newborn(s) will be screened for the metabolic diseases hemoglobinopathy, phenylketonuria, galactosemia, and hypothyroidism, and congenital adrenal hyperplasia, and explain the reasons for such screening and their right to refuse this screening on the grounds that such tests conflict with their religious tenets and practices.

B. Collect or have collected a specimen for screening no later than the fifth day after the infant's birth, unless the parents lawfully object to such screening. If this specimen is taken prior to 24 hours after birth, the responsible party shall notify the parents or legal guardian verbally and in writing of the necessity of having the ~~PKU~~ phenylketonuria test repeated on their newborn not later than the 14th day of life. If taking a blood sample at the times specified above is medically contraindicated, the sample shall be taken as soon as the infant's condition permits.

[For text of item C, see M.R.]

D. Send the specimen ~~and the following information~~ card including all of the required information as indicated on the card to the Minnesota Department of Health laboratory within 24 hours after collection~~:~~.

~~(1) newborn infant's name;~~

~~(2) sex;~~

~~(3) mother's name;~~

~~(4) home address;~~

~~(5) date of birth;~~

~~(6) date of first feeding;~~

~~(7) date specimen collected;~~

~~(8) name and address of attending physician and hospital submitting specimen;~~

~~(9) county;~~

~~(10) birth weight and gestational age; and~~

~~(11) bottle, breast, both;~~

[For text of item E, see M.R.]

Approved by Revisor _____

4615.0600 DUTIES OF ~~THE~~ DEPARTMENT OF HEALTH.

The Minnesota Department of Health shall do all of the following:

A. develop specimen cards and make them available ~~at no charge~~ to the responsible party;

B. maintain a record of all cases of hemoglobinopathy, phenylketonuria, galactosemia, and hypothyroidism, and congenital adrenal hyperplasia reported to it; and

C. notify the attending physician within 24 hours of obtaining the results, verbally and in writing by deposition in first class mail, of positive screening results and provide consultation on diagnostic and treatment sources available.

4615.0700 DUTIES OF ~~THE~~ ATTENDING PHYSICIAN.

The attending physician shall do all of the following:

A. Report, in writing, ~~all confirmed diagnoses~~ results of diagnostic evaluation of all instances of positive newborn screening results of hemoglobinopathy, phenylketonuria, galactosemia, and hypothyroidism, and congenital adrenal hyperplasia to: Human Genetics Unit, Minnesota Department of Health, 717 SE Delaware Street, P.O. Box 9441, Minneapolis, MN ~~55440~~ 55440-9441.

B. However, if ~~he~~ the attending physician refers a patient with positive screening results to a medical specialist for diagnosis and/or treatment, ~~he~~ the attending physician may delegate the responsibility for reporting a confirmed diagnosis to the medical specialist.

HEMOGLOBINOPATHY, PHENYLKETONURIA, GALACTOSEMIA, HYPOTHYROIDISM, AND CONGENITAL ADRENAL HYPERPLASIA TESTING~~;~~ PROGRAM; TREATMENT FOR POSITIVE DIAGNOSIS; REGISTRY OF CASES

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 hemoglobinopathy, phenylketonuria ~~and other metabolic diseases~~

Approved by Revisor _____

~~sing-mental-retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia will: (1) have access to improved laboratory treatment control tests ~~and~~ when available; 2) have necessary financial assistance for treatment of diagnosed cases when indicated~~;~~ and ~~will~~ (3) be included in a registry of cases for the purpose of coordinating follow-up services.

4615.0755 DEFINITIONS.

[For text of subps 1 to 3, see M.R.]

Subp. 4. [See repealer.]

Subp. Patient. "Patient" means the person who has been diagnosed with hemoglobinopathy, phenylketonuria ~~or other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia or the person's parents or legal guardian.

[For text of subp 6, see M.R.]

Subp. 7. [See repealer.]

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 hemoglobinopathy, phenylketonuria ~~or other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia.

[For text of subps 9 to 11, see M.R.]

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

[For text of subps 1 and 2, see M.R.]

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 hemoglobinopathy, phenylketonuria ~~and other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia 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

Approved by Revisor _____

to pay for medically indicated treatment such as private health insurance companies, medical assistance, Children's Health Plan, and Services for Children with Handicaps.

Subp. 4. **Registry of cases.** The department shall maintain a registry of all diagnosed cases of hemoglobinopathy, phenylketonuria ~~and other metabolic diseases causing mental retardation~~, galactosemia, hypothyroidism, and congenital adrenal hyperplasia 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:

[For text of items A to I, see M.R.]

[For text of subp 5, see M.R.]

REPEALER. Minnesota Rules, part 4615.0755, subparts 4 and 7, are repealed.

Approved
by Revisor _____

Office of the Revisor of Statutes

Administrative Rules

TITLE: Proposed Permanent Rules Relating to Infants; Newborn Metabolic Error Test

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4615

The attached rules are approved for publication in the State Register

Marie O'Neill

Marie E. O'Neill
Assistant Revisor

RECEIVED

NOV 25 1992

Office of the Attorney General
Government Services Section
Capitol Office Bldg. - Suite 500
525 Park Street
St. Paul, MN 55101

STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of the Rules of the Minnesota Department of Health Governing Tests of Infants for Inborn Metabolic Errors

AFFIDAVIT OF MAILING THE NOTICE OF EXTENDED COMMENT PERIOD

Kathleen A. Krook, being sworn, says:

That on the 9th day of September, 1992, in the City of Minneapolis, County of Hennepin, State of Minnesota, I mailed the attached Extended Comment Period notice by depositing in the State of Minnesota Central mail System for United States mailing, a copy thereof, with postage prepaid, to all persons and associations on the attached Department list and discretionary mailing list.

Kathleen A. Krook
(name)

Clerical Unit Supervisor
(title)

Maternal & Child Health
(division)

Subscribed and sworn to before me
this 15th day of September, 1992.

Sandy J. Fliehs

SANDY J. FLIEHS
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
MY COMMISSION EXPIRES FEBRUARY 20, 1993

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

CERTIFICATION

I hereby certify that the list of persons, associations, and other interested groups who have requested, pursuant to Minnesota Statutes, section 14.14, subdivision 1a, that their names be placed on file with, and maintained by, the Minnesota Department of Health for the purpose of receiving notice of rule hearings, is accurate and complete as of 1:00 p.m., this 14th day of July, 1992.

Christine R. Barton

Michael J. Ahern
Moss & Barnett
4800 Norwest Center
90 So. Seventh St.
Minneapolis, MN 55402

Walter A. Baldus
Woodvale Management
Services Inc.
P.O. Box 1047
Austin, MN 55912

Lester Block
School of Public Health
C309 Mayo - 97 UMHC
University of Minnesota
Minneapolis, MN 55455

William E. Bond
Minnesota Pharmacists
Association
2550 University Avenue
West #320N
St. Paul, MN 55114

Marge Scudder Brchan
Morrison County Public
Health Services
200 E. Broadway
Little Falls, MN 56345

Mark J. Brunner
MN Manufactured Housing
Association
555 Park Street, Ste 400
St. Paul, MN 55103

Marcia B. Bryan, Ed. D.
A.R.R.M.
26 E. Exchange St. #503
St. Paul, MN 55101

Wm. R. Carter III
Board of Peace Office
Standards & Training
1600 University Avenue
Suite 200
St. Paul, MN 55104

Rebecca A. Comstock
Dorsey & Whitney
2200 First Bank Place East
Minneapolis, MN 55402

Bill Conley
114 Mackubin Street
St. Paul, MN 55102

D.E.F.F.B.A.M.
P.O. Box 11855
St. Paul, MN 55111

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The Phoenix Residence,
Inc.
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St. Paul, MN 55107

John E. Drawz
Fredrikson & Byron, PA
1100 International Centre
900 Second Avenue South
Mpls, MN 55402-3397

Michael J. Duffy, Dir.
Community Health Board
325 Lake Ave So/Rm.510-B
Duluth, MN 55802

Sandra DuVander
Anoka County Community
Health/Environment Srvcs
325 E. Main - Courthouse
Anoka, MN 55303

Ernest K Lehmann & Assoc.
Attn: Land Department
430 First Avenue North
Suite 790
Mpls., MN 55401-1727

Doug Ewald
Ewald Consulting Group
26 E. Exchange St., #507
St. Paul, MN 55101

Matthew Felker
Scott-Levin Associates
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Newtown, PA 18940

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St. Louis Cty Health Dept
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Duluth, MN 55802-2134

Bob Fitzgerald, D.C.
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Minneapolis, MN 55405

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Supervising Sanitarian
City of Crystal
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Crystal, MN 55422

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Minnesota Alliance for
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5609 Lyndale Avenue South
Minneapolis, MN 55419

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P.O. Box 838
Faribault, MN 55021

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Rochester, MN 55902

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Maple Plain, MN 55359

Charles B. Hoffman
Director-Env. Affairs
Cliffs Mining Svcs Co.
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Duluth, MN 55802-1962

Hope Residence Inc.
Box 63
Waterville, MN 56096

Anoka City Environmental Services
c/o Robert Hutchison
Courthouse - 4th Floor
Anoka, MN 55303

Gaynold Jensen, R.D.
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Minneapolis, MN 55438

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Todd County Public Health
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Long Prairie, MN 56347

Vicki Kunerth
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Minneapolis, MN 55406

Robin Lackner
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Minneapolis, MN 55435

Byron Laher
United Way of Minneapolis Area
404 South Eighth Street
Minneapolis, MN 55404

Wayne Larson
Mount Olivet Rolling Acres
7200 Rolling Acres Road
Excelsior, MN 55331

Kathleen LeMay, Exec Dir
Dakota's Children Inc.
60 East Marie Avenue
West St. Paul, MN 55118

Karen Lenander
Northern States Power Co.
A.S. King Plant
210 North 10th Avenue
Bayport, MN 55003

MBW Company
513 Center Street
New Ulm, MN 56073

Mantyla Well Drilling, Inc.
Attn: Richard A. Thron
P.O. Box 797
Lakeland, MN 55043

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Gray, Plant Law Firm
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Minneapolis, MN 55402

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Board of Examiners - Nursing Home Admin.
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Public Health Service
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Annette Spencer
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20 West 12th Street
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So. Center Manor
508 Park Island
Box 386
Center City, MN 55012

Dominic Sposeto
Dominic Sposeto & Assoc.
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Minneapolis, MN 55408

Steffl Drilling &
Pump Inc.
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Willmar, MN 56201

H. A. Swift
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St. Paul, MN 55404

Jim Temple
Chrestomathy Center
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Minneapolis, MN 55409

Jerry Thelen, Director
Health Planning & Admin.
250 So. 4th Street
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Torgerson Well Co., Inc.
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Rockford, MN 55373

Betsy Walton
Fairview Hospital &
Health Care Services
2312 S. 6th St.
Minneapolis, MN 55454

Eleanor Weber
Rules and Bulletins Div.
Dept. of Human Services
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St. Paul, MN 55108-3816

Eric Wellen
South Central MN EMS
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Mankato, MN 56002

Colleen Wieck
MN DD Council
Department of Admin.
300 Centennial Office 658
Cedar Street
St. Paul, MN 55155

Sue Zuidem
525 Portland Avenue So.
3rd Floor
Minneapolis, MN 55415

STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of the Rules of the Minnesota Department of Health Governing Proposed Permanent Rules Relating to Infants; Newborn Metabolic Error Test Parts 4615.0300 to 4615.0760

EXTENDED COMMENT PERIOD

On July 16, 1992 you were mailed a Notice of Intent to Adopt a Rule Without a Public Hearing which contained an error in the caption indicating that the Rules were to be amended to Part 4615.0700. The full Parts to be amended are 4615.0300 to 4615.0760.

Accordingly, all persons have an additional 30 days, from September 14, 1992 until 4:30 p.m. on October 15, 1992 in which to submit comment in support of or in opposition to the proposed Rules or any part or subpart of the Rules. A copy of the Rules is attached for reference.

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Department of Health

Proposed Permanent Rules Relating to Infants; Newborn Metabolic Error Test

Rules as Proposed

TESTS OF INFANTS FOR INBORN METABOLIC ERRORS ~~CAUSING MENTAL RETARDATION~~

4615.0300 PURPOSE AND SCOPE.

Parts 4615.0300 to 4615.0700 describe the responsibilities of the hospitals, physicians, and the Minnesota Department of Health to assure that all newborn infants are screened for hemoglobinopathy, phenylketonuria, galactosemia, and hypothyroidism, and congenital adrenal hyperplasia.

4615.0400 DEFINITIONS.

[For text of subps 1 to 4, see M.R.]

Subp. 5. **Responsible party.** "Responsible party" means the administrative officer or other person in charge of ~~each~~ the hospital where the child is born, and the physician or other person operating under the supervision of a physician in attendance at the birth, or if not so attended, one of the parents.

Subp. 6. **Screen.** "Screen" means to carry out a series of laboratory tests on a dried capillary blood specimen which will identify those newborn infants who may develop hemoglobinopathy, phenylketonuria, galactosemia, ~~and/or~~ hypothyroidism, and/or congenital adrenal hyperplasia.

Subp. 7. **Specimen.** "Specimen" means a specimen of dried ~~capillary~~ blood from the newborn infant collected on a specimen card.

[For text of subp 8, see M.R.]

4615.0500 DUTIES OF RESPONSIBLE PARTIES INVOLVED IN ~~THE~~ NEWBORN METABOLIC SCREENING PROGRAM.

The responsible party shall do all of the following:

Approved by Revisor MEO

A. Inform the parent(s) or legal guardian that their newborn(s) will be screened for the metabolic diseases hemoglobinopathy, phenylketonuria, galactosemia, and hypothyroidism, and congenital adrenal hyperplasia, and explain the reasons for such screening and their right to refuse this screening on the grounds that such tests conflict with their religious tenets and practices.

B. Collect or have collected a specimen for screening no later than the fifth day after the infant's birth, unless the parents lawfully object to such screening. If this specimen is taken prior to 24 hours after birth, the responsible party shall notify the parents or legal guardian verbally and in writing of the necessity of having the ~~PKU~~ phenylketonuria test repeated on their newborn not later than the 14th day of life. If taking a blood sample at the times specified above is medically contraindicated, the sample shall be taken as soon as the infant's condition permits.

[For text of item C, see M.R.]

D. Send the specimen ~~and the following information~~ card including all of the required information as indicated on the card to the Minnesota Department of Health laboratory within 24 hours after collection~~:~~.

~~(1) newborn infant's name;~~

~~(2) sex;~~

~~(3) mother's name;~~

~~(4) home address;~~

~~(5) date of birth;~~

~~(6) date of first feeding;~~

~~(7) date specimen collected;~~

~~(8) name and address of attending physician and hospital submitting specimen;~~

~~(9) county;~~

~~(10) birth weight and gestational age; and~~

~~(11) bottle, breast, both;~~

[For text of item E, see M.R.]

Approved by Revisor _____

4615.0600 DUTIES OF ~~THE~~ DEPARTMENT OF HEALTH.

The Minnesota Department of Health shall do all of the following:

A. develop specimen cards and make them available ~~at no charge~~ to the responsible party;

B. maintain a record of all cases of hemoglobinopathy, phenylketonuria, galactosemia, ~~and~~ hypothyroidism, and congenital adrenal hyperplasia reported to it; and

C. notify the attending physician within 24 hours of obtaining the results, verbally and in writing by deposition in first class mail, of positive screening results and provide consultation on diagnostic and treatment sources available.

4615.0700 DUTIES OF ~~THE~~ ATTENDING PHYSICIAN.

The attending physician shall do all of the following:

A. Report, in writing, ~~all confirmed diagnoses~~ results of diagnostic evaluation of all instances of positive newborn screening results of hemoglobinopathy, phenylketonuria, galactosemia, ~~and~~ hypothyroidism, and congenital adrenal hyperplasia to: Human Genetics Unit, Minnesota Department of Health, 717 SE Delaware Street, P.O. Box 9441, Minneapolis, MN ~~55440~~ 55440-9441.

B. However, if ~~he~~ the attending physician refers a patient with positive screening results to a medical specialist for diagnosis and/or treatment, ~~he~~ the attending physician may delegate the responsibility for reporting a confirmed diagnosis to the medical specialist.

HEMOGLOBINOPATHY, PHENYLKETONURIA, GALACTOSEMIA, HYPOTHYROIDISM, AND CONGENITAL ADRENAL HYPERPLASIA ~~TESTING~~ PROGRAM; TREATMENT FOR POSITIVE DIAGNOSIS; REGISTRY OF CASES

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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 hemoglobinopathy, phenylketonuria ~~and other metabolic diseases~~

Approved by Revisor _____

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4615.0755 DEFINITIONS.

[For text of subps 1 to 3, see M.R.]

Subp. 4. [See repealer.]

Subp. Patient. "Patient" means the person who has been diagnosed with hemoglobinopathy, phenylketonuria ~~or other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia or the person's parents or legal guardian.

[For text of subp 6, see M.R.]

Subp. 7. [See repealer.]

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 hemoglobinopathy, phenylketonuria ~~or other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia.

[For text of subps 9 to 11, see M.R.]

4615.0760 RESPONSIBILITIES OF DEPARTMENT OF HEALTH.

[For text of subps 1 and 2, see M.R.]

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 hemoglobinopathy, phenylketonuria ~~and other metabolic disease causing mental retardation~~, galactosemia, hypothyroidism, and/or congenital adrenal hyperplasia 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

Approved by Revisor _____

to pay for medically indicated treatment such as private health insurance companies, medical assistance, Children's Health Plan, and Services for Children with Handicaps.

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[For text of items A to I, see M.R.]

[For text of subp 5, see M.R.]

REPEALER. Minnesota Rules, part 4615.0755, subparts 4 and 7, are repealed.

Approved by Revisor _____

Office of the Revisor of Statutes

Administrative Rules

TITLE: Proposed Permanent Rules Relating to Infants; Newborn Metabolic Error Test

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4615

The attached rules are approved for publication in the State Register

Marie O'Neill

Marie E. O'Neill
Assistant Revisor

STATE OF MINNESOTA **BEFORE THE MINNESOTA**

COUNTY OF HENNEPIN **DEPARTMENT OF HEALTH**

In the Matter of the Proposed
Adoption of Amendments to
Parts 4615.0300 to 4615.0760
Relating to Infants; Newborn
Metabolic Error Test

DECLARATION OF COUNSEL

I, Maria C. Christu, Special Assistant Attorney General, do hereby declare that I have examined the above-captioned rules and the supporting rulemaking record and that, based on my examination, the Administrative Procedure Act and Minn. Rules ch. 2010 have been followed. Any exceptions are listed below. For Attorney General billing purposes, the four-digit docket client code is 1610.

Dated: 11/25, 1992.

Maria C. Christu

MARIA C. CHRISTU
Special Assistant Attorney General