

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

Our File No. 1180

RULE REVIEW CHECKLIST

DATE RULE RECEIVED 7-2-85
DATE FOR REVIEW 7-11-85
DATE DUE 7-16-85

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

Approved 7-11-85 Disapproved _____ Returned to Agency _____

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

Date filed w/Secretary of State 7-12-85 Revisor approved 7/9/85
disapproved _____

✓ Rule as Adopted

✓ Rule as Proposed

✓ Order Adopting 6.20.85. Date combined with FF

✓ Notice of Intent to Solicit Outside Opinion SR. 4.23.84,

✓ Order for rulemaking
N/A date of Hearing

N/A Certificate of Board's Authorizing Resolution

✓ Notice of rulemaking
✓ Sufficiency

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

✓ Mailing list Certificate Affidavit of Delivery to Legislators

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

N/A Hearing Examiner's Report

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

✓ Agency's Findings of Fact combined with Order Adopting

N/A LCRAR Report or agency Affidavit

✓ Certificate of Board's Resolution Adopting Rules

✓ Order Approving Incorporation by Reference

✓ Statement of Need and Reasonableness

N/A Petition for Adoption of a Rule

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

✓ ~~Certificate of~~ Declaration of Counsel Compliance w/Rulemaking Procedures

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

✓ Notice of Submission to the Attorney General

SF-00006-03

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL - Health

Office Memorandum

TO: J. Michael Miles
Assistant Attorney General
204 Administration Building

DATE: July 1, 1985

FROM: Catherine E. Avina
Special Assistant
Attorney General

PHONE: 341-7272

SUBJECT:

In the Matter of Amendments to a Rule Related to the Duties of Responsible Parties Involved in the Newborn Metabolic Screening Program, Minn. Rules, pt. 4115.0500 (formerly 7 MCAR § 1.172)

Pursuant to Minn. Stat. 14.26, the attached documents in support of the above-referenced rule amendments are submitted to your office for approval as to the legality of the adopted amendments:

1. A photocopy of the Notice of Intent to Solicit Information or Opinions from Nonagency Sources on Rule Revisions, published April 23, 1984, at S.R. 2306.

2. Order for Notice of Intent to Adopt Rules Without Public Hearing, executed April 4, 1985.

3. Notice of Intent to Adopt Rules Without a Public Hearing, executed April 3, 1985.

4. Copy of the proposed amendments approved by the Revisor's office February 28, 1985.

5. A photocopy of the relevant pages of the April 22, 1985, State Register, Volume 9, in which the above Notice and proposed amendments were published.

6. Statement of Need and Reasonableness.
7. Affidavit of Mailing, executed April 17, 1985.
8. Affidavit of Delivery, executed April 18, 1985.
9. Certificate of Agency's Mailing List, executed April 25, 1985.
10. Order Adopting Noncontroversial Rules, executed October 3, 1984.
11. The original and three copies of the amended rule as adopted.
12. Declaration of Counsel.

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

CEA:cs

Attachments

RECEIVED
JUL 02 1985
ATTORNEY GENERAL
ADMINISTRATIVE AGENCIES

SF-00006-03

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL

Office Memorandum

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

DATE: 7-12-85

ATTN: CATHERINE E. AVINA
Special Assistant Attorney General

FROM: J. MICHAEL MILES JMM
Assistant Attorney General

PHONE: 296-6555

SUBJECT: In the Matter of the Amendments To a Rule Related to the Duties of Responsible Parties Involved in the Newborn Metabolic Screening Program, Minnesota Rules Part 4615.0500.

The above-referenced rule has been approved as to its legality by the Attorney General on July 11, 1985.

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

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

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

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

JMM:sz

Enclosures

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

Duane Harves
Chief Administrative Law Judge
Office of Administrative Hearings

AG copy RECEIVED JUN 28 1985 Health Resources Division

Department of Health

Maternal and Child Health

Adopted Rule Relating to Newborn Metabolic Screening Program; Duties of Responsible Parties

Rule as Adopted

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

The responsible party shall do all of the following:

A. [Unchanged.]

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 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.

C. [Unchanged.]

D. Send the specimen and the following information 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.

E. [Unchanged.]

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
JUL 12 1985
Joan Anderson Growe
Secretary of State 9:30 AM

APPROVED AS TO FORM AND EXECUTION
7/11 19 85
HUBERT H. HUMPHREY, III
ATTORNEY GENERAL
BY _____
ASSISTANT ATTORNEY GENERAL

Rule as Proposed

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

The responsible party shall do all of the following:

A. [Unchanged.]

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 the third day of life or~~ prior to 24 hours after ~~beginning breast or milk formula feeding~~ birth, the responsible party shall notify the parents or legal guardian verbally and in writing of the necessity of having the PKU 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.

C. [Unchanged.]

D. Send the specimen and the following information 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) ~~premature (yes or no)~~ birth weight or gestational age; and

(11) bottle, breast, both.

E. [Unchanged.]

APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

OFFICE OF THE REVISOR OF STATUTES

Proposed Rule

RD736

Agency: Department of Health

Division: Maternal and Child Health

Agency Contact: Edward Hendricks

Minnesota Rules: Part 4615.0500

Title: Proposed Rule Relating to Newborn Metabolic Screening Program; Duties of Responsible Parties

Type of Rules: Permanent

Steven C. Cross
Revisor of Statutes

Susan M. Lentsch
Assistant Revisor
Phone: 296-0956
Date: February 28, 1985

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the Amendments
To a Rule Related to the
Duties of Responsible Parties
Involved in the Newborn
Metabolic Screening Program,
Minnesota Rules Part 4615.0500

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

Notice of the Commissioner's proposed adoption of the above-entitled rule was published in the State Register on April 22, 1985 and was sent by United States mail to all persons on the list maintained by the agency pursuant to Minnesota Statutes, sections 14.14, subdivision 1, paragraph (a) and 14.22 on April 17, 1985.

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

Based on the record before the agency, I find the following: the above-captioned rule is needed and reasonable.

NOW, THEREFORE, IT IS ORDERED that the rule identified as Duties of Responsible Parties Involved in the Newborn Metabolic Screening Program is adopted this 20th day of June, 1985 pursuant to authority vested in me by Minnesota Statutes, section 144.125.

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

Sr Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

Department of Corrections

Outside Opinion Sought Regarding Proposed Changes in Rules Governing Group Foster Homes

Notice is hereby given that the Department of Corrections is seeking information or opinions from sources outside the agency in preparing to make changes in the promulgated rules Governing Group Foster Homes. The existing rules are identified Minnesota Rules 2925.0100.

The Minnesota Department of Corrections requests information and comments concerning the subject matter of these rules. Interested and affected persons or groups may submit statements of information or comments orally or in writing. Written statements should be addressed to:

John McLagan
430 Metro Square Building
7th & Robert Streets
St. Paul, Minnesota 55101

Oral statements will be received during regular business hours over the telephone at (612) 296-1312 and in person at the above address.

All statements of information and comments shall be accepted until May 18, 1984. Any written material received by the Department of Corrections shall become part of the record in the event that changes in the rules are promulgated.

Orville B. Pung
Commissioner of Corrections

Department of Health

Outside Opinion Sought Regarding: 1) Rules Governing Administration of the Special Supplemental Food Program for Women, Infants and Children (WIC); 2) Rules Governing Administration of the Maternal and Child Health (MCH) Grant Programs; 3) an Amendment to a Rule Governing Metabolic Screening, 7 MCAR § 1.172; 4) an Amendment to a Rule Governing Family Planning Special Projects, 7 MCAR § 1.457; 5) Repeal of a Rule Governing Private Baby Homes and Infant Homes, MDH 171; and 6) Amendments to Rules Relating to Services for Children with Handicaps and Adults with Cystic Fibrosis and Hemophilia for Eligibility, Cost Sharing and Reimbursement, 7 MCAR §§ 1.651-1.657

Notice is hereby given that the Department of Health is seeking information or opinions from persons outside the agency in preparing to promulgate new rules governing administration of the special supplemental food program for Women, Infants and Children (WIC) as authorized by Minn. Stat. §§ 144.110 and 144.11; rules governing administration of the MCH grant programs as authorized by Minn. Stat. § 145.882 (1982) as amended by Minnesota Laws 1983, ch. 312, art. 4, § 2; an amendment to a rule governing metabolic screening as authorized by Minn. Stat. § 144.125; an amendment to a rule governing family planning special projects as authorized by Minn. Stat. § 145.925, subd. 5; repeal of a rule governing private baby homes and infant homes as authorized by Minn. Stat. § 144.12, subd. 1 (4); and amendments to rules relating to services for children with handicaps and adults with cystic fibrosis and hemophilia for eligibility, cost sharing and reimbursement as authorized by Minn. Stat. § 144.12, as amended by Minnesota Laws 1983, ch. 359, § 9, and Minn. Stat. §§ 144.05, 144.06, 144.07, 144.09, 144.10, and 144.11 (1982). Further authority is vested in the Commissioner of Health (hereinafter "Commissioner") through Minnesota Department of Administration Reorganization Order No. 101 issued pursuant to Minn. Stat. § 16.125 (1982) (hereinafter "Reorganization Order 101"). Reorganization Order 101 vests the Commissioner with the authority to implement Minn. Stat. § 256.01, subd. 2(3) and (5), as amended by Minnesota Laws 1983, ch. 7, § 3; ch. 243, § 5, subd. 3; and ch. 312, art. 5, § 3. Reorganization Order 101 also vests the Commissioner with authority to implement Minn. Stat. §§ 256.011, 257.175, 250.05 (1982) as amended by Minnesota Laws 1983, ch. 305, § 22, and Minn. Stat. § 260.35 (1982) insofar as these statutes concern Services for Children with Handicaps. Further legal authority is found in Minn. Stat. §§ 14.05, subds. 1 to 3; 14.07 subd. 5 (Supp. 1983) and 14.06 (1982).

Outside opinion is also being solicited as to how these rules will affect small businesses as defined by Minnesota Laws 1983, ch. 188, codified as Minn. Stat. § 14.115, subd. 1.

The Department of Health requests information and comments concerning the subject matter of these rules. Interested or affected persons or groups may submit statements of information or comment in writing to: Mr. Gary Goetzke, Minnesota Department of Health, Maternal and Child Health Division, 717 Delaware Street, S.E., Minneapolis, MN 55440, (612) 623-5119.

All statements of information and comment will be accepted until May 31, 1984. Any written material received by the Department of Health will become part of the record in the event that the rules are promulgated.

Sister Mary Madonna Ashton
Commissioner of Health

Department of Health
Emergency Medical Services Section

Emergency Medical Services Licensure Application for Burnsville MN

As of April 23, 1984, a complete application for advanced life support transportation service was submitted by the City of Burnsville (i.e., Burnsville Fire Department), to operate a base of operation at 14011 Burnhaven Drive, Burnsville, Minnesota.

This notice is given pursuant to Minnesota Statutes 1979, Section 144.802, which requires in part that the Commissioner of Health shall publish the notice in the *State Register* at the applicant's expense; and in a newspaper in the municipality in which the service will be provided.

Each municipality, county, community health services agency, and any other interested person wishing to comment on this application may submit comments to the Metropolitan Health Board, 300 Metro Square Building, 7th and Robert, St. Paul, MN 55101, Attn: Tom Chapel, 612/291-6357. The comments mu: reach the Health Systems Agency before May 23, 1984, or be submitted at the public hearing which will be held in Burnsville.

After a public hearing has been held, the Health Systems Agency shall recommend that the Commissioner of Health grant or deny a license or recommend that a modified license be granted. The Health Systems Agency shall make the recommendations and reasons available to any individual requesting them.

Within 30 days of receipt of the recommendation to the Commissioner of Health, the Commissioner shall grant or deny the license to this applicant.

Department of Public Welfare
Mental Health Bureau

Nominations Sought for Individuals to Serve as Reviewers for a Proposed Rule Governing the Provision of Home and Community-Based Waiver Services for Mentally Retarded Persons

Notice is hereby given that the Department of Public Welfare is seeking nominations of individuals to serve as reviewers of a proposed temporary rule which governs the provision of services as specified in the Home and Community-Based Services Waiver Request. Notice is hereby given that the Minnesota Department of Public Welfare is considering a draft temporary rule, Home and Community-Based Services Standards. This proposed temporary rule will provide standards for Home and Community-Based Services to those eligible mentally retarded individuals as specified in the Home and Community-Based Service Waiver.

All interested or affected persons or groups are invited to participate. Nominations may be addressed to:

Russell Tyler, Ph.D.
Mental Retardation Division
Department of Public Welfare
Centennial Office Building, 4th Floor
658 Cedar Street
St. Paul, MN 55155

Oral nominations will be received during regular business hours over the telephone (612) 297-1241. All nominations must be received by May 16, 1984.

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of Amendments
to a Rule Related to the
Duties of Responsible Parties
Involved in the Newborn
Metabolic Screening Program
Minnesota Rules, part 4615.0500

ORDER FOR NOTICE
OF INTENT TO AMEND
RULES WITHOUT A
PUBLIC HEARING

IT IS ORDERED this 24th day of April, 1985, that a Notice of Intent to Amend Rules Without Public Hearing in the above-entitled matter be given to all persons who have registered their names with the Minnesota Department of Health for that purpose and be published in the State Register.

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

Sr Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of Amendments
to a Rule Related to the
Duties of Responsible Parties
Involved in the Newborn
Metabolic Screening Program
Minnesota Rules, part 4615.0500

AFFIDAVIT OF MAILING

Edward L. Hendricks, MD, MPH, being first sworn, deposes and says:

That on the 17th day of April, 1985, at the City of Minneapolis, County of Hennepin, State of Minnesota, he served the attached Notice of Intent to Amend Rules Without a Public Hearing by depositing in the United States mail though the mail room at the Minnesota Department of Health Building in said City of Minneapolis, true and correct copies thereof, properly enveloped, with postage prepaid, on all persons and associations who have requested that their names be placed on file with the Minnesota Department of Health for the purpose of receiving notice of the proposed adoption of rules by the Commissioner of Health.

Edward L Hendricks

EDWARD L. HENDRICKS, MD, MPH
Director
Maternal and Child Health Division
Minnesota Department of Health

Subscribed and sworn to before me
this 17th day of April, 1985.

Christine Grinsteinner

CHRISTINE GRINSTEINNER
NOTARY PUBLIC-MINNESOTA
DAKOTA COUNTY
MY COMMISSION EXPIRES JANUARY 4, 1989

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of Amendments to a Rule Related to the Duties of Responsible Parties Involved in the Newborn Metabolic Screening Program Minnesota Rules, part 4615.0500

NOTICE OF INTENT TO AMEND RULES WITHOUT A PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the Commissioner of Health (hereinafter "Commissioner") proposes to adopt amendments to Minnesota Rules, part 4615.0500 which relates to the duties of responsible parties involved in the newborn metabolic screening program.

The Commissioner has determined that the proposed amendments will be noncontroversial in nature and has elected to follow the provisions of Minnesota Statutes, sections 14.22 to 14.28 (1984). Sections 14.21 to 14.28 provide for an expedited process for the adoption of administrative rule changes without the holding of a public hearing.

The implementation of these amendments will not require the expenditure of public money by local bodies of greater than $100,000.00 in either of the two years following their adoption, nor do the amendments have any impact on agricultural land. The small business considerations in rulemaking do not apply to these amendments pursuant to Minnesota Statutes, section 14.115, subdivision (7c)(1984).

THE PUBLIC IS HEREBY ADVISED that:

1. They have 30 days in which to submit comment in support of or in opposition to the proposed amendments, and comment is encouraged;

2. Each comment should identify the portion of the proposed amendments addressed, the reason for the comment, and any change proposed;

3. If twenty-five or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held;

4. All comments and any written requests for a public hearing shall be submitted to Edward L. Hendricks, MD, MPH, Director, Maternal and Child Health Division, Minnesota Department of Health, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440;

5. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed amendments addressed, the reason for the request, and any change proposed;

6. The proposed amendments may be modified if modifications are supported by the data and views submitted and do not result in a substantial change in the proposed language;

7. Under this expedited procedure, if a hearing is not required the department must submit any action on its rules to the attorney general for review of the form and legality of the rule change. Notice of the date of submission of the proposed amendments to the attorney general for review will be mailed to any person who requests to receive the notice. Requests to receive notice must be submitted to Dr. Hendricks at the above address;

8. Authority to amend Minnesota Rules part 4615.0500 is contained in Minnesota Statutes, section 144.125 (1984). Additionally, a Statement of Need and Reasonableness that describes the need for and reasonableness of each

provision of the proposed amendment has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Dr. Hendricks at the above address;

9. If twenty-five or more persons request a public hearing on this matter, notice of any such hearing will be published in the State Register;

10. Any amendment made pursuant to this proceeding shall be effective five working days after publication in the State Register of notice of the adoption of the amendment.

Dated: 4/3, 1985

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

Sr Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

OFFICE OF THE REVISOR OF STATUTES

Proposed Rule

RD736

Agency: Department of Health

Division: Maternal and Child Health

Agency Contact: Edward Hendricks

Minnesota Rules: Part 4615.0500

Title: Proposed Rule Relating to Newborn Metabolic Screening Program; Duties of Responsible Parties

Type of Rules: Permanent

Steven C. Cross
Revisor of Statutes

Susan M. Lentsch
Assistant Revisor
Phone: 296-0956

Date: February 28, 1985

Rule as Proposed

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

The responsible party shall do all of the following:

A. [Unchanged.]

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 the third day of life or~~ prior to 24 hours after ~~beginning breast or milk formula feeding~~ birth, the responsible party shall notify the parents or legal guardian verbally and in writing of the necessity of having the PKU 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.

C. [Unchanged.]

D. Send the specimen and the following information 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) ~~premature (yes or no)~~ birth weight or gestational age; and

(11) bottle, breast, both.

E. [Unchanged.]

APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

STATE OF MINNESOTA
COUNTY OF HENNEPIN

In the Matter of Amendments
to a Rule Related to the
Duties of Responsible Parties
Involved in the Newborn
Metabolic Screening Program
Minnesota Rules, part 4615.0500

AFFIDAVIT OF DELIVERY

Gary A. Goetzke, being first duly sworn deposes and says that on the 18th day of April, 1985, he delivered:

1. 67 copies of the attached Notice of Intent to Adopt A Temporary Rule to the Office of the Secretary of the Senate, Room 231, State Capitol, with a label marked: "For Distribution to all Senators."

2. 134 copies of the attached Notice of Intent to Adopt A Temporary Rule to the Post Office in the State Office Building, Room G 50, Ground Floor, State Office Building, with a label marked: "For Distribution to all Representatives."

Gary Goetzke

Subscribed and sworn to before me
this 18th day of April, 1985.

Marie B. Tromiczak

MARIE B. TROMICZAK
NOTARY PUBLIC - MINNESOTA
HENNEPIN COUNTY
My Commission Expires Oct. 23, 1987

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of Amendments to a Rule Related to the Duties of Responsible Parties Involved in the Newborn Metabolic Screening Program Minnesota Rules, part 4615.0500

NOTICE OF INTENT TO AMEND RULES WITHOUT A PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the Commissioner of Health (hereinafter "Commissioner") proposes to adopt amendments to Minnesota Rules, part 4615.0500 which relates to the duties of responsible parties involved in the newborn metabolic screening program.

The Commissioner has determined that the proposed amendments will be noncontroversial in nature and has elected to follow the provisions of Minnesota Statutes, sections 14.22 to 14.28 (1984). Sections 14.21 to 14.28 provide for an expedited process for the adoption of administrative rule changes without the holding of a public hearing.

The implementation of these amendments will not require the expenditure of public money by local bodies of greater than $100,000.00 in either of the two years following their adoption, nor do the amendments have any impact on agricultural land. The small business considerations in rulemaking do not apply to these amendments pursuant to Minnesota Statutes, section 14.115, subdivision (7c)(1984).

THE PUBLIC IS HEREBY ADVISED that:

1. They have 30 days in which to submit comment in support of or in opposition to the proposed amendments, and comment is encouraged;

2. Each comment should identify the portion of the proposed amendments addressed, the reason for the comment, and any change proposed;

3. If twenty-five or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held;

4. All comments and any written requests for a public hearing shall be submitted to Edward L. Hendricks, MD, MPH, Director, Maternal and Child Health Division, Minnesota Department of Health, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440;

5. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed amendments addressed, the reason for the request, and any change proposed;

6. The proposed amendments may be modified if modifications are supported by the data and views submitted and do not result in a substantial change in the proposed language;

7. Under this expedited procedure, if a hearing is not required the department must submit any action on its rules to the attorney general for review of the form and legality of the rule change. Notice of the date of submission of the proposed amendments to the attorney general for review will be mailed to any person who requests to receive the notice. Requests to receive notice must be submitted to Dr. Hendricks at the above address;

8. Authority to amend Minnesota Rules part 4615.0500 is contained in Minnesota Statutes, section 144.125 (1984). Additionally, a Statement of Need and Reasonableness that describes the need for and reasonableness of each

provision of the proposed amendment has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Dr. Hendricks at the above address;

9. If twenty-five or more persons request a public hearing on this matter, notice of any such hearing will be published in the State Register;

10. Any amendment made pursuant to this proceeding shall be effective five working days after publication in the State Register of notice of the adoption of the amendment.

Dated: 4/3, 1985

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

Sr Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

OFFICE OF THE REVISOR OF STATUTES

Proposed Rule

RD736

Agency: Department of Health

Division: Maternal and Child Health

Agency Contact: Edward Hendricks

Minnesota Rules: Part 4615.0500

Title: Proposed Rule Relating to Newborn Metabolic Screening Program; Duties of Responsible Parties

Type of Rules: Permanent

Steven C. Cross
Revisor of Statutes

Susan M. Lentsch
Assistant Revisor
Phone: 296-0956

Date: February 28, 1985

Rule as Proposed

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

The responsible party shall do all of the following:

A. [Unchanged.]

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 the third day of life or~~ prior to 24 hours after ~~beginning breast or milk formula feeding~~ birth, the responsible party shall notify the parents or legal guardian verbally and in writing of the necessity of having the PKU 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.

C. [Unchanged.]

D. Send the specimen and the following information 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) ~~premature (yes or no)~~ birth weight or gestational age; and

(11) bottle, breast, both.

E. [Unchanged.]

APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of Amendments
to a Rule Related to the
Duties of Responsible Parties
Involved in the Newborn
Metabolic Screening Program
Minnesota Rules, part 4615.0500

CERTIFICATE OF
MAILING LIST

I hereby certify that the list of persons, associations, and other interested groups who have requested, pursuant to Minnesota Statutes, section 14.14, subdivision 1, that their names be placed on file with and maintained by the Minnesota Department of Health for the purpose of receiving notice of the proposed adoption of rules by the Commissioner is accurate and complete as of 9:00 A.M., the 17th day of April 1985.

April 25, 1985
Date

Dee H. Woodard

Dee H. Woodard
Minnesota Department of Health

PROPOSED RULES

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

1. that they have 30 days in which to submit comment on the proposed rules;
2. that no public hearing will be held unless 25 or more persons make a written request for a hearing within the 30-day comment period;
3. of the manner in which persons shall request a hearing on the proposed rules; and
4. that the rule may be modified if the modifications are supported by the data and views submitted.

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

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

Department of Health
Maternal and Child Health

Proposed Rule Relating to Newborn Metabolic Screening Program; Duties of Responsible Parties

Notice of Intent to Amend Rules without a Public Hearing

NOTICE IS HEREBY GIVEN that the Commissioner of Health (hereinafter "Commissioner") proposes to adopt amendments to Minnesota Rules, part 4615.0500 which relates to the duties of responsible parties involved in the newborn metabolic screening program.

The Commissioner has determined that the proposed amendments will be noncontroversial in nature and has elected to follow the provisions of Minnesota Statutes, sections 14.22 to 14.28 (1984). Sections 14.21 to 14.28 provide for an expedited process for the adoption of administrative rule changes without the holding of a public hearing.

The implementation of these amendments will not require the expenditure of public money by local bodies of greater than $100,000.00 in either of the two years following their adoption, nor do the amendments have any impact on agricultural land. The small business considerations in rulemaking do not apply to these amendments pursuant to Minnesota Statutes, section 14.115, subdivision (7c)(1984).

THE PUBLIC IS HEREBY ADVISED THAT:

1. They have 30 days in which to submit comment in support of or in opposition to the proposed amendments, and comment is encouraged;

2. Each comment should identify the portion of the proposed amendments addressed, the reason for the comment, and any change proposed;

3. If twenty-five or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held;

4. All comments and any written requests for a public hearing shall be submitted to Edward L. Hendricks, MD, MPH, Director, Maternal and Child Health Division, Minnesota Department of Health, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440;

5. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed amendments addressed, the reason for the request, and any change proposed;

6. The proposed amendments may be modified if modifications are supported by the data and views submitted and do not result in a substantial change in the proposed language;

7. Under this expedited procedure, if a hearing is not required the department must submit any action on its rules to the

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.

attorney general for review of the form and legality of the rule change. Notice of the date of submission of the proposed amendments to the attorney general for review will be mailed to any person who requests to receive the notice. Requests to receive notice must be submitted to Dr. Hendricks at the above address;

8. Authority to amend Minnesota Rules part 4615.0500 is contained in Minnesota Statutes, section 144.125 (1984). Additionally, a Statement of Need and Reasonableness that describes the need for and reasonableness of each provision of the proposed amendment has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Dr. Hendricks at the above address;

9. If twenty-five or more persons request a public hearing on this matter, notice of any such hearing will be published in the *State Register*;

10. Any amendment made pursuant to this proceeding shall be effective five working days after publication in the *State Register* of notice of the adoption of the amendment.

April 3, 1985

Sister Mary Madonna Ashton
Commissioner of Health

Rule as Proposed

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

The responsible party shall do all of the following:

A. [Unchanged.]

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 the third day of life or~~ prior to 24 hours after ~~beginning breast or milk formula feeding~~ birth, the responsible party shall notify the parents or legal guardian verbally and in writing of the necessity of having the PKU 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.

C. [Unchanged.]

D. Send the specimen and the following information 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) ~~premature (yes or no~~ birth weight or gestational age; and

(11) bottle, breast, both.

E. [Unchanged.]

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

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

STATEMENT OF NEED
AND REASONABLENESS

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

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

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1. STATUTORY AUTHORITY.

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

2. STATEMENT OF NEED.

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

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

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

3. COMPLIANCE WITH PROCEDURAL RULEMAKING REQUIREMENTS.

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

Procedural Rulemaking Requirements of the Administrative Procedure Act

Minnesota Statutes, section 14.10 requires an agency which seeks information or opinions in preparation for adoption of rules from sources outside the agency to publish a notice of its action in the State Register and afford all interested persons an opportunity to submit data or comments on the subject. In the State Register issue of Monday, April 23, 1984, at page 2306, the commissioner published a notice entitled "Outside Opinion Sought Regarding: 1) Rules Governing Administration of the Special Supplemental Food Program for Women, Infants and Children (WIC); 2) Rules Governing Administration of the Maternal and Child Health (MCH) Grant Programs; 3) an Amendment to a Rule Governing Metabolic Screening, 7 MCAR § 1.172 [now 4615.0300 to 4615.0700]; 4) an Amendment to a Rule Governing Family Planning Special Projects, 7 MCAR § 1.457 [now 4700.1900 to 4700.2500]; 5) Repeal of a Rule Governing Private Baby Homes and Infant Homes, MDH 171 [now 4615.0200]; and 6) Amendments

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

These rules minimize the duplication of statutory language. See Minnesota Statutes, section 14.07, subdivision 3 (1). The implementation of these rules will not require the expenditure of public money by local public bodies of greater than $100,000 in either of the two years following their adoption, nor do the rules have any impact on agricultural land. See Minnesota Statutes, section 14.11. The adoption of these rules will not affect small businesses. See Minnesota Statutes, section 14.115, subd. 7 (c).

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

and the views submitted; and e) other information required by Minnesota Statutes, section 14.22.

If 25 or more persons submit to the Minnesota Department of Health a written request for hearing on the proposed rule, the agency shall proceed under the provisions of Minnesota Statutes, sections 14.131 through 14.20 and notice of the hearing shall be published in the State Register.

If no hearing is required, the commissioner will submit the proposed rule and notice as published, the rule as proposed for adoption, any written comments which have been received, and this statement of need and reasonableness to the Attorney General for approval as to their legality and form to the extent that it relates to legality.

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

4. GENERAL STATEMENT OF REASONABLENESS.

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

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

5. JUSTIFICATION

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

Item B has been amended to require a second PKU test only if the first test is taken prior to 24 hours from birth. This amendment has been made for several reasons.

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

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

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

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

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

Edward L. Hendricks, MD, MPH

2/20/85

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the Amendments
to A Rule Related to the Duties
of Responsible Parties Involved
in the Metabolic Screening Program,
Minnesota Rules Part 4615.0500

DECLARATION OF COUNSEL

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

Catherine E. Avina

CATHERINE E. AVINA
Special Assistant
Attorney General

Dated: July 1, 1985