

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

Missed 180 - deadline - 14.26
should have meeting - ASAP

RULE REVIEW CHECKLIST

AVK 8-21-82

File No. 1941
DATE RECEIVED 8-18-92
REVIEW DATE
DUE DATE 9-1-92
(DIS)APPROVED 8-27-92
WITHDRAWN

Docket No. 05 0009 1550
ADOPTED W/O HEARING
EMERGENCY RULE
TO REVISOR ON 8-21-92
REVISOR (DIS)APPROVED
FILED W/SEC. OF STATE
RETURNED TO AGENCY

✓ 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's Certificate

Notice of Intent to Adopt Rule
144.05, 144.0742 Statutory Authority 144.12
no statement Small Business Statement
NA Expenditure of public money statement
October 28, 1991 Signature — missing (7)

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

✓ Affidavit of Mailing Notice of Intent to Adopt Rule
December 31, 1991 Dated (30/25 days before adoption
Notice attached indicates it is attached
Copy of rule or summary attached

✓ Publication in State Register
December 30, 1991 Date (30/25 days before adoption

Problem

180-day deadline from:
✓ Effective date of law requiring rule (14.12) (both rules) amendments don't apply
Missed it 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
Feb 25, 1992 Date

✓ Written Requests, Submissions or Comments

✓ Declaration of Attorney
Jerry P. O'Brien 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 : MARLENE E. MARSCHALL, Commissioner
Department of Health

DATE : August 27, 1992

TERRY O'BRIEN
Special Assistant Attorney General

FROM : AMY V. KVALSETH
Special Assistant
Attorney General

PHONE : 296-9422

SUBJECT : **Minnesota Rules Part 4606.3302, Relating to Cancer Case Reporting**

The above-referenced rule has not been approved by the Attorney General, because it was not submitted to the Attorney General within 180 days of the day that the comment period for the rule was over. Minnesota Statutes § 14.26 (1990) provides: "The rule and these materials shall be submitted to the Attorney General within 180 days of the day that the comment period for the rule is over or the rule is automatically withdrawn." Minnesota Laws, 1992, ch. 494, § 6 amended Minn. Stat. § 14.26 by including a provision on harmless error. That provision states:

> The Attorney General shall disregard any error or defect in the proceeding due to the agency's failure to satisfy any procedural requirements imposed by law or rule if the Attorney General finds:
>
> (1) that the failure did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process; or
>
> (2) that the agency has taken corrective action to cure the error or defect so that the failure did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process.

This office does not believe that the harmless error rule can be applied in this situation because of the phrase "automatically withdrawn."

Two major consequences arise from automatic withdrawal. First, automatic withdrawal operates as a failure to adopt the rules. Under Minn. Stat. § 14.26, "the agency shall report its failure to adopt the rules and the reasons for that failure to the legislative commission to review administrative rules, other appropriate legislative committees, and the governor." Thus, the agency will have to make that report to those bodies.

Second, pursuant to Minn. Stat. § 14.05, subd. 3, the agency must publish notice in the State Register that the proposed rule has been withdrawn and then, if the agency wishes to propose it again for adoption, the agency must comply with all the procedures of sections 14.05 to 14.36. Thus, the rule will have to be re-noticed in the State Register and the comment period must be permitted again. See Minn. Stat. §§ 14.05 to 14.36.

In addition to the determinative problem with the 180 day deadline, we note that the notice of intent to amend rules without a public hearing was deficient. The initial notice stated:

> The commissioner has determined that the proposed rule amendment will be noncontroversial in nature and has elected to follow the provisions of Minnesota statutes section 14.05 and 14.21-14.28 (1990). M.S. section 14.21-14.28 provide an expedited process for the adoption of noncontroversial and administrative rule changes without the holding of a public hearing.

The language used there follows Minn. Stat. § 14.21, but that section was repealed in 1984 by 1984 Minn. Laws ch. 640, § 33. The current preferred notice is found in Minnesota Rules part 2010.9915. The form given there states in the first paragraph:

> Notice is hereby given that the [agency name] intends to adopt the above-entitled rule without a public hearing following the procedures set forth in the administrative procedure act for adopting rules without a public hearing in Minnesota statutes, sections 14.22 to 14.28.

The newer type of notice is preferred because it encourages people to comment, and if they so desire, to request a public hearing.

In addition to correcting the initial notice paragraph, the notice must also contain a statement that "if a public hearing is required, the agency will proceed pursuant to Minnesota statutes sections 14.131 to 14.20." Minn. Rules pt. 2010.9915 provides an example of the format that is preferred for the published notice.

Finally, in your findings of fact, a statement is required regarding how many people requested a hearing.

Assuming you will want to adopt this rule, please correct the notice and findings of fact during the next rulemaking process.

We regret not being able to approve these rules due to the problem with the 180 day deadline. If you have any questions regarding this memo, please contact me at the above telephone number.

cc: MARYANNE HRUBY, Executive Director
Legislative Commission to Review Administrative Rules
WILLIAM BROWN, Chief Administrative Law Judge
Office of Administrative Hearings
PAUL MARINAC, Assistant Deputy Revisor for Rules
Revisor of Statutes Office

AVK:cr.kval.ae8

Department of Health

Adopted Permanent Rules Relating to Cancer Case Reporting

Rules as Adopted

4606.3302 DEFINITIONS.

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

Subp. 3. **Cancer.** "Cancer" means:

A. malignant and in situ neoplasms of all sites, except basal and squamous cell carcinomas of the skin;

B. basal and squamous cell carcinomas of the genitalia; and

C. all brain and central nervous system neoplasms regardless of malignancy.

[For text of subps 4 to 18, see M.R.]

Office of the Revisor of Statutes

Administrative Rules

TITLE: Adopted Permanent Rules Relating to Cancer Case Reporting

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4606

The attached rules are approved for filing with the Secretary of State

Janet M. Rahm
Senior Assistant Revisor

Department of Health

Adopted Permanent Rules Relating to Cancer Case Reporting

Rules as Adopted

4606.3302 DEFINITIONS.

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

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[For text of subps 4 to 18, see M.R.]

Office of the Revisor of Statutes

Administrative Rules

TITLE: Adopted Permanent Rules Relating to Cancer Case Reporting

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4606

The attached rules are approved for
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Janet M. Rahm
Senior Assistant Revisor

need to have a meeting on this ASAP

MN Stat 144.05,
General duties of the Commissioner etc

144.0742 - Contracts for Provision of Public Health Services.

The commissioner of health is authorized to enter into contractual agreements with any public or private entity . . .

144.12 Rules

The commissioner may adopt reasonable rules pursuant to Chapter 14 for the preservation of the public health.

Notice of Intent - different - ~~was~~ ~~assume~~ assume there is going to be no hearing missing point 2010.0300 E (7)
use the word "expedited" process in the notice

199 days after mailed notice 200 days after published notice

missed 180 day deadline - 14.26
end of Comment period - Dec 31, 1991 — Jan 30, 1991
maybe Harmless error — Jan - Feb - August 19 —
but must write the letters per 14.26 - Feb - 29 March 31 April 30 May 31 June 30 July 31 August 19
14.26 has consequence ____ days

DEPARTMENT : ATTORNEY GENERAL

STATE OF MINNESOTA
Office Memorandum

DATE : March 11, 1992

loc
8-19-92

TO : CHRISTIE B. ELLER
Assistant Attorney General

FROM : TERRY P. O'BRIEN
Special Assistant
Attorney General

out until Sept 14

PHONE : 297-5930

SUBJECT : Rules Amendment Materials Regarding Minnesota Rules § 4606.3302

Attached is the record to support the amendment to the above-referenced rule. I am enclosing for your review the following documents:

1. Four stripped copies of the amended rule as adopted.

2. A certificate of approval as to form by the revisor of statutes.

3. The signed Notice of Intent to Adopt a Rule Without a Public Hearing as mailed.

4. The Statement of Need and Reasonableness in support of the proposed rule.

5. The affidavit of mailing of the Notice of Intent to Adopt a Rule Without a Public Hearing.

6. A copy of the Notice of Intent to Adopt the Rule Without a Public Hearing as published in the State Register on Monday, December 30, 1991.

7. The Findings of Fact, Conclusions, and Order adopting the rule.

8. The declaration of the attorney in the Attorney General's Office who represents the agency.

I hope you find everything in order, please let me know if you have any questions.

JC:mr
cc: Patty Nolte
Enclosures

Findings of Fact
- no statement on how many requested a hearing (5) - again the way the Notice was written they already assumed there would be no hearing

Also - in notice - no statement that if hearing req'd proceed accdg to 14.131 & 14.20



State of Minnesota
OFFICE MEMORANDUM

Department of Health

Date: October 22, 1991

To: Marlene E. Marschall
Commissioner

From: John Washburn, Assistant Section Chief
Chronic Disease & Environmental Epidemiology

Through: Michael Moen, M.P.H., Director
Disease Prevention & Control

Phone: 5636

Subject: Notice of Intent to Amend Minnesota Rule § 4606.3302 - Definition of Reportable Cancers Without a Public Hearing

Attached for your signature is a notice of intent to amend Minnesota Rule § 4606.3302 without a public hearing. The amendment is very straightforward. We propose that three words, "lip, eyelid, or" be eliminated from Minnesota Rules § 4606.3302, Subp. 3B., the definition of "Cancer."

The justification for this change is covered in the Statement of Need and Reasonableness also attached. Essentially, collection of data on basal cell carcinomas of the lip and eyelid is very labor intensive and only marginally useful to the Minnesota Cancer Surveillance System (MCSS). This change will make it easier for the hospitals, laboratories, and tumor registries to report.

We have discussed this change with Terry O'Brien. If you have any questions or concerns please call me.

JWW/MEM/pp
attachments
cc: Beverly Krogseng
Terry O'Brien
Sally Bushhouse
Alan Bender

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH

In the matter of a Proposed Amendment
Relating to Cancer Case Reporting
Pursuant to Minnesota Rule § 4606.3302

NOTICE OF INTENT TO
AMEND RULES WITHOUT
A PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the Commissioner of Health (hereinafter "Commissioner") proposed to amend the following rule: M.R. § 4606.3302.

The Commissioner has determined that the proposed rule amendment will be noncontroversial in nature and has elected to follow the provisions of Minnesota Statutes §14.05 and 14.21 - 14.28 (1990). M.S. § 14.21-14.28 provide for an expedited process for the adoption of noncontroversial administrative rule changes without the holding of a public hearing.

THE PUBLIC IS HEREBY ADVISED that:

1. There is a 30-day period in which to submit comment in support of or in opposition to the proposed rule amendment and repealer, and comment is encouraged;

2. Each comment should identify the proposed rule amendment, the reason for the comment, and any change proposed;

3. 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;

4. All comments and any written requests for a public hearing shall be submitted to Dr. Sally Bushhouse, Supervisor, Minnesota Cancer Surveillance System, Minnesota Department of Health, 717 Delaware Street Southeast, P.O. Box 9441, Minneapolis, Minnesota 55441;

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 rule amendment, the reason for the request, and any change proposed;

6. The proposed rule amendment 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, the department must submit any action on its rules to the attorney general for review of the form and legality of the rule change. If a hearing is not required, notice of the date of submission of the proposed rule amendment 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. Bushhouse at the above address;

Part 1

8. Authority to amend Minnesota Rule § 4606.3302 is contained in Minnesota Statutes § 144.05, 144.0742, and 144.12 (1990). Additionally, a Statement of Need and Reasonableness that describes the need for and reasonableness of each provision of the proposed rule amendment and the repealer has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Dr. Bushhouse at the above address;

STATE OF MINNESOTA
COUNTY OF HENNEPIN

NOTICE OF INTENT TO
AMEND RULES WITHOUT
A PUBLIC HEARING

(4)

9. If 25 or more persons request a public hearing on this matter, notice of any such hearing will be published in the State Register;

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

Dated: October 28, 1991

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

Marlene E. Marschall

MARLENE E. MARSCHALL
Commissioner of Health

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH

In the matter of a Proposed Amendment Relating to Cancer Case Reporting Pursuant to Minnesota Rule § 4606.3302 In the State

AFFIDAVIT OF MAILING

Sally Bushhouse, being first duly sworn, deposes and says:

That on the 31st day of December, 1991, at the City of Minneapolis, County of Hennepin, State of Minnesota, she served the attached Notice of Intent to Amend Rules Without a Public Hearing by depositing in the United States mail through the mailroom 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 rule amendment by the Commissioner of Health.

Sally Bushhouse
SALLY BUSHHOUSE, Supervisor
Minnesota Cancer Surveillance System

Subscribed and sworn to me before
this 31st day of December, 1991.

Joan M. Osell

JOAN M. OSELL
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
MY COMMISSION EXPIRES MARCH 6, 1997

Office of the Revisor of Statutes

Administrative Rules

Janet M. Rahm
Senior Assistant Revisor
296-0952

700 State Office Building
100 Constitution Avenue
St. Paul, MN 55155-1297

December 30, 1991

John Washburn
Department of Health
717 South East Delaware Street
P.O. Box 9441
St. Paul, MN 55440

RE: File No. 1970

Dear Mr. Washburn:

Enclosed are stripped copies of your proposed rules as published in the State Register. The copy shows the text of the rules as you proposed them with the stricken text deleted and the underscoring removed.

If your emergency rules or rules adopted without public hearing are adopted without modification, please submit the required number of copies of this document to the Attorney General for final approval. If these rules are to be modified, please use this copy to indicate the modifications you wish to make. Our office will then input the changes, approve the document as to form, and provide you with copies to submit to the Attorney General.

If your rules are adopted after public hearing without modification, please submit one copy of this document to our office for final approval as to form. If these rules are to be modified, please use this copy to indicate the modifications you wish to make. Our office will input the changes, approve the document as to form, and provide you with copies.

Very truly yours,

Janet M. Rahm

Department of Health

Adopted Permanent Rules Relating to Cancer Case Reporting

Rules as Adopted

4606.3302 DEFINITIONS.

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

Subp. 3. **Cancer.** "Cancer" means:

A. malignant and in situ neoplasms of all sites, except basal and squamous cell carcinomas of the skin;

B. basal and squamous cell carcinomas of the genitalia; and

C. all brain and central nervous system neoplasms regardless of malignancy.

[For text of subps 4 to 18, see M.R.]

Department of Health

Adopted Permanent Rules Relating to Cancer Case Reporting

Rules as Adopted

4606.3302 DEFINITIONS.

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

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A. malignant and in situ neoplasms of all sites, except basal and squamous cell carcinomas of the skin;

B. basal and squamous cell carcinomas of the genitalia; and

C. all brain and central nervous system neoplasms regardless of malignancy.

[For text of subps 4 to 18, see M.R.]

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 Cancer Case Reporting

Notice of Intent to Amend Rules Without a Public Hearing

NOTICE IS HEREBY GIVEN that the Commissioner of Health (hereinafter "Commissioner") proposed to amend the following rule: M.R. § 4606.3302.

The Commissioner has determined that the proposed rule amendment will be noncontroversial in nature and has elected to follow the provisions of *Minnesota Statutes* § 14.05 and 14.21-14.28 (1990). M.S. § 14.21-14.28 provide for an expedited process for the adoption of noncontroversial administrative rule changes without the holding of a public hearing.

THE PUBLIC IS HEREBY ADVISED that:

1. There is a 30-day period in which to submit comment in support of or in opposition to the proposed rule amendment and repealer, and comment is encouraged;

2. Each comment should identify the proposed rule amendment, the reason for the comment, and any change proposed;

3. 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;

4. All comments and any written requests for a public hearing shall be submitted to Dr. Sally Bushhouse, Supervisor, Minnesota Cancer Surveillance System, Minnesota Department of Health, 717 Delaware Street Southeast, P.O. Box 9441, Minneapolis, Minnesota 55441;

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 rule amendment, the reason for the request, and any change proposed;

6. The proposed rule amendment 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, the department must submit any action on its rules to the attorney general for review of the form and legality of the rule change. If a hearing is not required, notice of the date of submission of the proposed rule amendment 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. Bushhouse at the above address;

8. Authority to amend *Minnesota Rule* § 4606.3302 is contained in *Minnesota Statute* § 144.05, 144.0742, and 144.12 (1990). Additionally, a Statement of Need and Reasonableness that describes the need for and reasonableness of each provision of the proposed rule amendment and the repealer has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Dr. Bushhouse at the above address;

9. If 25 or more persons request a public hearing on this matter, notice of any such hearing will be published in the *State Register;*

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.

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

Dated: 28 October 1991

Marlene E. Marschall
Commissioner of Health

Rules as Proposed

4606.3302 DEFINITIONS.

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

Subp. 3. **Cancer.** "Cancer" means:

A. malignant and in situ neoplasms of all sites, except basal and squamous cell carcinomas of the skin;

B. basal and squamous cell carcinomas of the ~~lip, eyelid, or~~ genitalia; and

C. all brain and central nervous system neoplasms regardless of malignancy.

[For text of subps 4 to 18, see M.R.]

Higher Education Coordinating Board

Proposed Permanent Rules Relating to Rural Physician Loan Forgiveness Program

Notice of Intent to Adopt Rules Without a Public Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Higher Education Coordinating Board intends to adopt the above-entitled rule without a public hearing following the procedures set forth in the Administrative Procedure Act for adopting rules without a public hearing in *Minnesota Statutes* 14.22 to 14.28 (1990). The Board's authority to adopt the rule is set forth in *Minnesota Statutes* 136A.04, Subd. 1(9) and 136A.16 (1990).

All persons have 30 days in which to submit comments in support of or in opposition to the proposed rules or any part or subpart of the rules. That date would end on January 29, 1992 at 4:30 p.m. Comment is encouraged. Each comment should identify the portion of the proposed rules addressed, the reason for the comment, and any change proposed.

Any person may make a written request for a public hearing on the rules within the 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 requests 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 rules addressed, the reason for the request, and any change proposed. If a public hearing is required, the Board will proceed pursuant to *Minnesota Statutes* 14.131 to 14.20 (1990).

Comments or written requests for a public hearing must be submitted to:

Mary Lou Dresbach
Minnesota Higher Education Coordinating Board
Capitol Square Building, Suite 400
550 Cedar Street
St. Paul, MN 55101

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

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

A **STATEMENT OF NEED AND REASONABLENESS** that describes the need for and reasonableness of each provision of the proposed rules and identifies the data and information relied upon to support the proposed rule has been prepared and is available from Mary Lou Dresbach upon request.

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 to the extent form relates to legality. 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 rule, must submit the written request to Mary Lou Dresbach.

Dated: 12 December 1991

David R. Powers
Executive Director

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH

In the matter of a Proposed Amendment Relating to Cancer Case Reporting Pursuant to Minnesota Rule § 4606.3302 In the State

CERTIFICATE OF MAILING LIST

I hereby certify that the list of persons, associations, and other interested groups who have requested, pursuant to Minnesota Statute § 14.14, subd. 1.a, that their names be placed on file with and maintained by the Minnesota Department of Health for the purpose of receiving supplement to NOTICE OF INTENT TO AMEND RULES WITHOUT A PUBLIC HEARING by the Commissioner of Health is accurate and complete as of 9:00 AM, this 31st day of December, 1991.

Sally Bushhouse

SALLY BUSHHOUSE, Supervisor
Minnesota Cancer Surveillance System

Subscribed and sworn to me before
this 31st day of December, 1991.

Joan M. Osell

JOAN M. OSELL
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
MY COMMISSION EXPIRES MARCH 6, 1997

BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH

STATE OF MINNESOTA
COUNTY OF HENNEPIN

IN THE MATTER OF A PROPOSED AMENDMENT
RELATING TO CANCER CASE
REPORTING PURSUANT TO M.R. § 4606.3302
IN THE STATE

STATEMENT OF NEED
AND REASONABLENESS

The Minnesota Commissioner of Health (hereinafter "Commissioner"), pursuant to Minnesota Statutes § 14.05 and 14.21 and Minnesota Rules § 1400.0200 - 1400.0900, present facts establishing the need for and reasonableness of the above rules amendment.

In order to amend the proposed rules, the Commissioner must demonstrate compliance with all the procedural and substantive requirements of rulemaking. The requirements are that:

1) There is statutory authority to adopt and amend rules;
2) All necessary procedural steps have been taken;
3) The rule amendment is needed;
4) The rule amendment is reasonable; and
5) Any additional requirements imposed by law have been satisfied.

This statement demonstrates that the Commissioner has met those requirements.

1. STATUTORY AUTHORITY

The statutory authority of the Commissioner to adopt and amend rules is briefly noted below.

Minnesota Statute § 144.05 (1991) provides the Commissioner with the authority and assigns the responsibility for development and maintenance of an organized system of programs and services for protecting, maintaining and improving the health of the citizens. This authority includes:

A) Conducting studies and investigations, collecting and analyzing health data and vital data, and identifying and describing health problems;
B) Coordinating and integrating local, state and federal programs and services affecting the public's health; and
C) Continually assessing and evaluating the effectiveness and efficiency of health service systems and public health programing efforts in the state.

Minnesota Statute § 144.671 through 144.69 mandates:

A) the Commissioner shall establish a statewide population-based cancer surveillance system;
B) persons practicing the healing arts, hospitals and similar institutions shall prepare and forward to the Commissioner detailed records of each case of cancer treated or seen by the person or institution;
C) the Commissioner shall collect information on cancer occurrence, analyze this information and conduct special studies using this information;
D) the Commissioner shall maintain the data collected as private; and
E. the Commissioner shall adopt rules to administer the system.

2. STATEMENT OF NEED

The need for the rules relating to the Minnesota Cancer Surveillance System were documented in the original rulemaking process. Briefly, a statewide cancer surveillance system is part of a coordinated cancer control program. Cancer is an important health problem in Minnesota: In 1988 and 1989 more than 34,000 Minnesotans were diagnosed with cancer, and over 16,000 Minnesotans died of cancer. The MCSS is needed in order to: 1) Respond to public concerns and questions about cancer; 2) Monitor incidence trends; 3) Promote high quality research; 4) Develop and target cancer control resources; and 5) Educate health professionals and citizens. The MCSS, in its fourth year of operation, is already meeting these objectives.

The deletion of basal and squamous cell carcinomas of the lip and eyelid from the definition of "cancer" is needed to increase the efficiency of reporting. It requires over twice as much effort to obtain complete information on basal and squamous cell carcinomas of the lip and eyelid as the other types of cancer that are collected by the MCSS. In view of the marginal utility of the data collected, it is necessary to conserve the resources required to collect it.

The utility of these data is questionable at best. There are not comparison data available for them in the United States, and although the lack of comparison does not render the data useless, it reduces the usefulness. In addition, the definition of a "new" cancer of this type is difficult and far from uniform. For example, a person may have had a basal cell carcinoma of the cheek removed two years ago; now a basal cell carcinoma has been found on the eyelid. Some physicians will consider the eyelid lesion a recurrence of the cheek lesion, and some will consider the eyelid lesion a new cancer. Thus, counts of incident cancers of the skin of the eyelid and lip are not reliable.

Second, an inordinate amount of staff time is required to follow-up on the basal and squamou cell carcinomas of the skin. Nearly 7 percent of the 1989 cases needing follow-up for missing or inconsistent data were basal or squamous cell carcinomas of the skin of the eyelid or lip, even though they represented only 3.7 percent of cancers reported in 1989. Sixty-one percent of the reviews for these skin cancers required contact with a hospital, pathology laboratory, of physician's office, while only 41 percent of reviews for non-skin cancers required contact with an outside data source. Physician's offices are queried for follow-up information only as a last resort, when the information cannot be obtained from a laboratory, hospital, or large clinic. It is more time consuming to contact physicians' offices because the number of cases per office is usually quite small, requiring a personalized letter for each office, education of the physician and office staff about the MCSS, and often several phone calls before the missing data items are finally returned. Seventy-two percent of the skin cancer follow-ups were to physicians' offices, as contrasted with only 16 percent of the non-skin follow-ups.

3. COMPLIANCE WITH PROCEDURAL RULEMAKING REQUIREMENTS

Minnesota Statutes § 14.05-14.12 and 14.21-14.28 and rules of the Office of Administrative Hearings specify certain procedures which must be followed when an agency such as the Minnesota Department of Health adopts or amends rules. Procedures applicable to all rules (Minnesota Statute § 14.05-14.15) have been complied with by the Commissioner. The Commissioner has determined that the adoption and amendment of the rules in (proposed 4605.3000-) is non-controversial and has elected to follow procedures set forth in Minnesota Statutes § 14.21-14.28 which provide for an expedited process for the adoption of non-controversial administrative rule adoption without holding a public hearing.

The amendment of this rule will not require expenditure of public money by local public bodies (Minnesota Statute § 14.11, Subd. 12) of greater than $100,000.00 in either of the two years following promulgation, nor does this rule have any impact on agricultural land. The amendment of this rule will not affect small businesses (Minnesota Statute § 14.115).

Pursuant of Minnesota Statute § 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 amended rule without public hearing in the State Register and mail copies of the notice and proposed amended rule to persons registered with the Minnesota Department of Health pursuant to Minnesota Statute § 14.14, Subd. 1. The notice will include the 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 manner in which persons shall request a hearing; and
d) that the amended rule may be modified if modifications are supported by data and the views submitted.

If 25 or more persons submit to the Minnesota Department of Health, a written request for a hearing of the proposed amended rule, the agency shall proceed under the provisions of the Minnesota Statute § 14.13-14.20 and notice of hearing shall be published in the State Register.

If no hearing is required, the Commissioner will submit the proposed amended 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 its legality, and form to the extent that it relates to its legality.

This rule shall become effective upon publication of a notice of adoption in the State Register.

NonMandatory Actions by the Commissioner

No other statute requires the Commissioner to comply with requirements in the promulgation of this amended rule; there are three other actions which the Commissioner has taken which should be addressed:

In 1987, the Commissioner established an Administrative Rules Working Group who made recommendations for development of these rules concerning:

a) Types of data to be reported;
b) Standards for reporting specific types of data;
c) Methods for providing funding support for development, extension of services, and quality control for cancer surveillance; and
d) Criteria for determining access to data collected pursuant to these rules.

The Working Group was composed of representatives from the Minnesota Society of Clinical Pathologists, Veterans Administration Hospital, Mayo Clinic, University of Minnesota-Health Sciences, Minnesota Cancer Council, Minnesota Hospital Association, Minnesota Tumor Registrars Association, Minnesota Medical Records Association, Minnesota Medical Association, The Upper Midwest Oncology Registry System (Methodist

Hospital), Laboratory of Clinical Medicine (Sioux Falls, South Dakota), and North Central Regional Pathology Laboratory. All of the members of the Working Group will be informed of the proposed amendment and asked for comment. The Commissioner also intends to notify others who have not registered with the agency for receiving notices of rulemaking hearings.

Second, notice of intent to adopt the amended rule and copies of the proposed amended rule will be sent to the Minnesota Society of Clinical Pathologists, Minnesota Medical Association, Minnesota Hospital Association, Minnesota Tumor Registrars Association, Minnesota Medical Records Association, and Community Health Services Agencies.

Third, we are writing a personalized letter containing the Notice of Intent to every MCSS contact person at every hospital, laboratory, and clinic required to report pursuant to M.R. § 4606 explaining the proposed amendment, our reasoning, and requesting any comments they would want considered.

4. GENERAL STATEMENT OF REASONABLENESS

In order to amend rules, an agency must demonstrate that the proposed amended rules are reasonable. Rulemaking is a process which primarily involves policy decisions. There are many differing policy perspectives and biases which can, therefore, result in alternative ways to address a subject covered by administrative rules.

The amendment proposed here is intended to improve the efficiency of the statewide cancer surveillance system.

This amendment is reasonable because it is consistent with the original recommendations developed in 1981 by the Technical Advisory Committee: "*4. ... Data requiring patient contact, detailed record abstraction, and data that will be difficult or costly to obtain should not be part of the core surveillance system.*" These cancer surveillance rules were officially adopted in September 1988, after work by a committee consisting of representatives from the Minnesota Society of Clinical Pathologists, Veteran's Administration Hospital, Mayo Clinic, University of Minnesota - Health Sciences, Minnesota Cancer Council, Minnesota Hospital Association, Minnesota Tumor Registrars Association, The Upper Midwest Oncology Registry System (Methodist Hospital), Laboratory of Clinical Medicine (Sioux Falls, South Dakota), and North Central Regional Pathology Laboratory. Nearly four years of experience collecting cancer data in Minnesota have revealed that collection of data on basal and squamous cell carcinomas of the skin of the lip and eyelid is disproportionately expensive.

5. RULE-BY-RULE JUSTIFICATION

Deletion of the words "lip, eyelid or" from M.R. 4606.3302, Subpart 3.B will change the definition of cancer and eliminate the requirement to reporting the cancers for which it is the most costly to obtain complete data. It is still necessary to collect information on basal and squamous cell carcinomas of the genitalia so that Minnesota data are comparable to national data.

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
DEPARTMENT OF HEALTH

In the Matter of the Proposed Amendment to Cancer Case Reporting Pursuant to Minnesota Rules § 4606.3302 In the State

FINDINGS OF FACT, CONCLUSIONS, AND ORDER AMENDING RULES WITHOUT A PUBLIC HEARING

Notice of the Department of Health's (hereinafter "Department") intent to amend the above-entitled rule was published in the State Register on December 30, 1991 (165.R.1585), and was sent by United States mail on December 31, 1991 to all persons on the list maintained by the Department pursuant to Minnesota Statutes § 14.14, subd. 1.a., and 14.22. The statement of need and reasonableness was prepared before the notice of intent to amend rules without a public hearing, was mailed to all persons on the Minnesota Cancer Surveillance System (MCSS) mailing list and published in the State Register, and was available to the public. 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 OF FACT

1. All persons were given the opportunity to submit comment on the rule amendment for thirty (30) days after notice of proposed rulemaking.

2. The Department did not receive any written comments on the rule amendment.

3. The Department received two verbal comments concerning the rule amendment. These were requests for clarification of the technical classification aspects of no longer requiring reports of basal and squamous cell carcinomas of the lip or eyelid. These requests were received by phone from contact persons at pathology laboratories who wanted to confirm that cancers of the skin, other than basal and squamous cell carcinomas, were still reportable. The answers were yes, all skin cancers other than basal and squamous cell carcinomas are, and remain, reportable.

4. 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 proposed amendment is both needed and reasonable.

NOW, THEREFORE, IT IS HEREBY ORDERED that the amended rule identified as In (9) the Matter of the Proposed Amendment to Cancer Case Reporting Pursuant to Minnesota Rule § 4606.3302 is adopted this 25th day of February 1992, pursuant to authority vested in the Commissioner by Minnesota Statutes § 144.671 - 144.672 (1990).

Marlene E. Marschall

MARLENE E. MARSCHALL, Commissioner of Health

Department of Health

Proposed Permanent Rules Relating to Cancer Case Reporting

Rules as Proposed

4606.3302 DEFINITIONS.

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

Subp. 3. **Cancer.** "Cancer" means:

A. malignant and in situ neoplasms of all sites, except basal and squamous cell carcinomas of the skin;

B. basal and squamous cell carcinomas of the ~~lip, eyelid, or~~ genitalia; and

C. all brain and central nervous system neoplasms regardless of malignancy.

[For text of subps 4 to 18, see M.R.]

Approved by Revisor _____

Office of the Revisor of Statutes

Administrative Rules

TITLE: Proposed Permanent Rules Relating to Cancer Case Reporting

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4606

The attached rules are approved for publication in the State Register

Janet M. Rahm
Senior Assistant Revisor

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the Proposed Amendment to Cancer Case Reporting Pursuant to Minnesota Rules § 4606.3302 In the State

DECLARATION OF COUNSEL

I, Terry P. O'Brien, Special Assistant Attorney General, do hereby declare that I have examined the above-captioned rule, and the supporting rulemaking reward, and that, based on my examination, the Administrative Procedure Act and Minnesota Rules chapter 2010 have been followed. There are no exceptions. For Attorney General billing purposes, the four-digit docket client code is 1550.

Dated: 18 May 92

HUBERT H. HUMPHREY, III
Attorney General
State of Minnesota

By: _____
TERRY P. O'BRIEN
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Attorney General
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Department of Health