

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

ATTORNEY GENERAL

August 1, 1988

THOMAS M. McSTEEN
Special Assistant Attorney General
Attorney General Health Division

CHRISTIE B. ELLER
Assistant Attorney General
515 Transportation Building

6-9421

In the Matter of the Adopted Rule Relating to
Cancer Surveillance System

The above-referenced rule has been approved as to its legality by the Attorney General on (date).

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

Also enclosed are any petitions, requests, submissions or comments 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, the agency must establish 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.

CBE:bbl
Enclosures

cc: Maryanne Hruby
Duane Harves

RULE REVIEW CHECKLIST
RESUBMITTED RULE

File No. 1492 Docket No. 050009 1550

RESUBMISSION DATE 7/29/88 ADOPTED W/O HEARING X
DATE DUE _____ EMERGENCY RULE _____

APPROVED 8/1/88 REVISOR APPROVED ✓
DISAPPROVED _____ REVISOR DISAPPROVED _____
WITHDRAWM _____ FILED W/SEC. STATE _____
RETURNED TO AGENCY _____

---

no **Does the revision raise significant new legal issues?**

_____ Review date

✓ Rule as adopted (4 copies)

✓ Supplemental Findings of Fact, Conclusions & Order Adopting

n/a Board's Supplemental Resolution Adopting

n/a Notice of submission to Attorney General

none requested

n/a Affidavit of Mailing Notice to Attorney General

SF-00006-05 (4/86)

STATE OF MINNESOTA

Office Memorandum

DEPARTMENT : ATTORNEY GENERAL - Health

DATE : July 27, 1988

TO : Christie Eller
Assistant Attorney General

FROM : Thomas M. McSteen TMM
Special Assistant
Attorney General

PHONE : 341-7272

SUBJECT : Cancer Surveillance Rules

As we discussed, I have enclosed the Commissioner of Health's Supplemental Findings of Fact, Conclusions, and Order Adopting Rules Without a Public Hearing. I understand that this order meets the requirements of Minn. Rules part 2010.1300.

Please contact me if you have any questions.

TMM:lb

Enclosure

RECEIVED
JUL 29 88
GENERAL'S OFFICE
PORTATION BLDG
ST. PAUL, MN 55155

Department of Health

Adopted Permanent Rules Relating to Cancer Surveillance System

Rules as Adopted

4606.3300 PURPOSE.

The purpose of parts 4606.3300 to 4606.3309 is to establish a process and assign responsibility for:

A. collecting data from pathology laboratory reports and other demographic data on the occurrence of cancer in the state; and

B. investigating the occurrence of cancer.

4606.3301 SCOPE.

Parts 4606.3300 to 4606.3309 apply generally to the diagnosis of, reporting of, and epidemiologic studies of cancer; and scientific research on the treatment and prevention of cancer.

4606.3302 DEFINITIONS.

Subpart 1. **Abstract.** "Abstract" means a form specified by the commissioner on which the information required in part 4606.3304 has been copied.

Subp. 2. **Attending physician.** "Attending physician" means the physician who provides primary clinical care for the cancer case.

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.

Subp. 4. **Case.** "Case" means any Minnesota resident, living or deceased, having a cancer diagnosed by a physician or dentist.

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Subp. 5. **Case report.** "Case report" means a complete report of a diagnosis of cancer, which has been generated as a result of examination of demographic information and a pathology, cytology, hematology, biopsy, surgical, or autopsy specimen. At a minimum, this shall consist of source documents that contain all or as much as is known of the information required in part 4606.3304.

Subp. 6. **Commissioner.** "Commissioner" means the state commissioner of health, or the commissioner's authorized officers, or employees.

Subp. 7. **Demographic form.** "Demographic form" means the front page of a hospital medical record, the hospital business office form, or the pathology specimen submission slip that contains the demographic information required in part 4606.3304 for cases.

Subp. 8. **Dentist.** "Dentist" means any person who is licensed by the Minnesota Board of Dentistry to practice dentistry.

Subp. 9. **Electronic data submission.** "Electronic data submission" means transferring data from a computer used by a reporting entity to a computer specified by the commissioner through the use of a modem, magnetic tape, or magnetic disk.

Subp. 10. **Epidemiologic studies.** "Epidemiologic studies" means the compilation of data on health and disease, its scientific analysis to determine the distribution and causes of health problems in populations, and the application of this study to the control of health problems.

Subp. 11. **Hospital.** "Hospital" means any institution licensed as such by the commissioner under Minnesota Statutes, section 144.50.

Subp. 12. **Medical clinic.** "Medical clinic" means any institution staffed by one or more physicians where diseases of human beings are diagnosed.

Subp. 13. **Medical laboratory or pathology laboratory.** "Medical laboratory" or "pathology laboratory" means any facility that reports the results of examinations of organ

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tissue, cells, or blood specimens from the human body for cancer to physicians who use the reports for purposes of diagnosis or patient care.

Subp. 14. **Minnesota resident.** "Minnesota resident" means a person who provides a permanent address within the borders of the state at the time of cancer diagnosis. In the case of minors, residency shall be determined as that of the parent or legal guardian. This does not mean that Minnesota is the person's legal residence or voting residence.

Subp. 15. **Physician.** "Physician" means a person who is licensed by the Minnesota Board of Medical Examiners to practice medicine.

Subp. 16. **Reporting entity.** "Reporting entity" means the individual or operational unit within an institution such as a medical laboratory, hospital, clinic, or tumor registry, designated by the institution to submit case reports required by parts 4606.3300 to 4606.3309.

Subp. 17. **Source documents.** "Source documents" means copies of the demographic forms and the pathology laboratory reports that contain the information required in part 4606.3304 for cases.

Subp. 18. **Tumor registry.** "Tumor registry" means a collection of cancer data on patients that is maintained as an identified repository of such data for, or within any hospital, medical clinic, or centralized institution.

4606.3303 COMPREHENSIVE REPORTS OF CANCER.

Subpart 1. **Tumor registries.** Tumor registries shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner within 15 working days of the date the patient's tumor registry was completed.

Subp. 2. **Medical laboratories.** Medical laboratories shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner for all cases of cancer within 15 working days of the date of diagnosis.

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Subp. 3. **Hospitals and medical clinics.** Hospitals and medical clinics shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner for all cases of cancer diagnosed in the institution within 15 working days of the date of diagnosis.

Subp. 4. **Physicians and dentists.** Physicians and dentists not working within a hospital, medical clinic, or medical laboratory required to report by this part, who examine specimens of human organ tissue, cells, or blood with findings indicative of the presence of cancer, shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner within 15 working days of the date of diagnosis.

Subp. 5. **Designating a reporting entity.** Alternatively, tumor registries, medical laboratories, hospitals, medical clinics, or any combination of these within or as part of an institution, may notify the commissioner of the identity of a reporting entity to report on behalf of the institution and as such shall meet the requirements of cancer reporting under subparts 1 to 4.

4606.3304 REPORTS.

Subpart 1. **Case information.** Reports of case information that are required in part 4606.3303 must consist of source documents and contain as much of the following information as is known:

A. last name;

B. first name;

C. middle name or initial;

D. address, including house number, street, rural route number, city, state, and zip code;

E. county of residence;

F. date of birth;

G. sex;

H. social security number;

I. attending physician;

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J. other attending physician;

K. diagnostic or treatment facility;

L. case's hospital or clinic medical record number; and

M. cancer diagnostic information:

(1) primary site;

(2) histologic type;

(3) date of diagnosis or date specimen was obtained; and

(4) pathologist's designation of whether the case is newly or previously diagnosed or not known.

Subp. 2. **Abstracts or electronic data submission.** Alternatively, reports of case information that are required in part 4606.3303 may consist of completed abstracts or electronic data submission and must contain the information required in subpart 1.

Subp. 3. **Race, ethnicity, and occupational data.** Hospitals, medical clinics, and physicians shall, upon request of the commissioner, report as much information as is known concerning the race, ethnicity, and occupational history of cancer cases. The commissioner shall by publication in the State Register request reports of such information when the following conditions exist:

A. epidemiologic surveillance and studies based on this information will assist in identifying cancer risks in certain racial, ethnic, or occupational groups; and

B. there is a specific, planned mechanism for the surveillance and epidemiologic study of the cancer related to the racial, ethnic, or occupational group.

4606.3305 DATA SUBMISSION.

Subpart 1. **Completeness.** Every case report shall include, at a minimum, legible source documents, or completed abstracts, or electronic data submission that must contain the data required in part 4606.3304. Abstracts must be legible and submitted on forms provided by the commissioner. Electronic

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data must be submitted in a manner and format that conforms to the state cancer surveillance system computer system.

Subp. 2. **Missing information.** The reporting entity or individual shall, within five working days of notification by the commissioner, supply all missing information, if known, or clarify information submitted in any report required in parts 4606.3303 and 4606.3304.

Subp. 3. **Inspection.** For the purpose of assuring the quality and completeness of individual cancer case reports, each reporting entity or individual shall allow the commissioner to inspect the demographic portions of a patient's medical record or medical records related to the diagnosis of cancer as are necessary to verify the accuracy and completeness of the cancer diagnostic information and demographic data.

4606.3306 PHYSICIAN CONSENT.

Subpart 1. **Attempt to obtain consent.** When undertaking epidemiologic studies, the commissioner shall attempt to locate and obtain the consent of the attending physician as identified in the case report before approaching any case named in a report or a personal representative of a deceased case as defined in Minnesota Statutes, section 13.10, subdivision 1, paragraph (c).

Subp. 2. **Approach without consent.** The commissioner may approach a case named in a report or a personal representative of a deceased case as defined in Minnesota Statutes, section 13.10, subdivision 1, paragraph (c), without the consent of the attending physician as identified in the case report in order to conduct epidemiologic investigations if the attending physician is deceased, is no longer licensed in the state, is no longer practicing, or cannot otherwise be located.

4606.3307 AUTHORIZED RESEARCH.

Subpart 1. **Criteria.** The commissioner of health may enter into contracts to conduct research, using data collected pursuant to parts 4606.3300 to 4606.3309, with public and private research agencies or with individuals who satisfy all of the following criteria:

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by Revisor _____

A. the research proposed to be conducted will assist in improving the diagnosis, treatment, or prevention of cancer and the public health;

B. there is documented evidence that the principal investigator for the research proposed is qualified:

(1) by having attained the degree of medical doctor, doctor of dental surgery, doctor of science, doctor of philosophy, or equivalent degree from an accredited college or university; and

(2) by specific academic graduate level training in epidemiology, biomedical research or biometry, or documented evidence of biomedical or related medical research experience; and

C. there is a written protocol which includes but is not limited to a complete description of:

(1) the proposed scientific research hypotheses;

(2) the purpose of the proposed research;

(3) the specific methodologies, including data required from the commissioner, to be used in conducting the research and testing of scientific hypotheses;

(4) the projected or anticipated result of the research;

(5) the period of time during which the proposed research will be conducted and when a final report will be completed;

(6) the physical facilities to be employed in conducting the research; and

(7) the methods to be used to assure that privacy of data is maintained in accordance with state law, and that access to private, nonpublic data is limited to those authorized by the commissioner to have access.

Subp. 2. **Release of information.** Under no circumstances will researchers be provided access to personal identifiers that would allow contact of a patient without attempting to obtain physician consent as described in part 4606.3306. The following personal identifiers will not be released:

Approved
by Revisor _____

A. last name;

B. first name;

C. middle name or initial;

D. address;

E. county of residence; or

F. social security number.

No researcher operating under contractual agreement with the commissioner as described in subpart 1 shall release any personal identifier, mark, or description obtained during an investigation that could be used for identification of an institution, a physician, or an individual who is or was the subject of a case report required in part 4606.3303.

Subp. 3. **Evaluation of proposals.** The commissioner shall evaluate proposals based upon the criteria in items A to E.

A. The proposed research has social and scientific merit that is directed primarily toward improving the diagnosis, treatment, defining of risks, or prevention of cancer.

B. All co-investigators are qualified to undertake the proposed research by means of specific academic training or demonstrable, related experience in epidemiology, medical, biomedical, or statistical research.

C. The hypotheses to be tested are explicit, and are determined to be researchable and feasible by the scientific peer review committee described in subpart 4.

D. The methods proposed for testing the hypothesis clearly define:

(1) the population or cancers to be studied;

(2) the type and amount of data to be collected;

(3) the source of the data;

(4) the procedures for collecting and maintaining the data; and

(5) the specific measurement techniques to be employed in analysis of data, including discussion of: major variables, statistical methods, methods of testing data reliability and validity, and required levels of accuracy, precision, or completeness of the data to be collected.

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E. The results of this study will be interpreted so that the findings can be used or generalized to other populations and provide a timely, substantive, and important contribution to the understanding of cancer diagnosis, treatment, or prevention in Minnesota.

Subp. 4. **Scientific peer review committee.** To assist in evaluating the scientific merits of proposals for research, the commissioner may appoint up to seven scientists to conduct scientific peer review who are qualified by having:

A. attained the degree of medical doctor, doctor of science, doctor of philosophy, or equivalent degree from an accredited college or university;

B. specific training in medicine, epidemiology, cancer research, or biometry from an accredited college or university; and

C. two or more years of applied experience in epidemiology, medical research, biomedical research, or biometry.

4606.3308 CONTRACTS FOR DEVELOPMENT, EXTENSION OF SERVICES, AND QUALITY ASSURANCE.

Subpart 1. **Contracts.** The commissioner may, upon receipt of an application described in this section, contract with any institution or reporting entity in compliance with part 4606.3304 for the following purposes:

A. providing more efficient, expedient, and complete cancer registry and reporting systems for those required to report under part 4606.3303;

B. extending the capability and efficiency of the commissioner to meet the mandate established under Minnesota Statutes, sections 144.671 to 144.69; and

C. maintaining and validating the quality, accuracy, and completeness of cancer case data.

Subp. 2. **Notice of availability of funds.** The commissioner shall publish and distribute a notice of availability of funds and request for contract proposals to all hospitals, medical laboratories, tumor registries, and medical

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by Revisor _____

clinics required to report under part 4606.3303.

Subp. 3. **Content of application.** Applications made under this section shall address all of the following information requirements, including:

A. Full corporate or company name, address, and tax identification number of applicant institution, or in the case of multiple institutions, the full corporate or company name, address, and tax identification number of the principal applicant institution, and the full corporate or company names and addresses of other institutions participating in the application.

B. A description of the individual components of the reporting systems to be provided by the applicant. The quality assurance standards in part 4606.3305 shall be incorporated into all applications. For each component to be provided, the application must describe, but not be limited to:

(1) the specific objectives to be achieved during the funding period;

(2) the methods by which each objective will be achieved;

(3) the institutions to be involved in the registry or reporting system;

(4) criteria to be used to evaluate achievement of objectives;

(5) budget and budget justification; and

(6) a summary of the training and experience relevant to the components to be provided by the key personnel.

C. Assurance that services will be provided in accordance with state and federal laws and rules.

D. Assurance that the privacy of all data will be maintained in accordance with law and acceptable medical practice.

Subp. 4. **Priority.** Priority will be given to applications proposing to provide cancer reporting systems addressing one or more of the following criteria:

A. the highest quality and completeness of data;

Approved by Revisor _____

B. services to the greatest number of persons;

C. services to the largest geographic area; and

D. demonstrated capacity to perform on the proposal.

4606.3309 CHARGES FOR DATA.

The commissioner may charge fees for out-of-pocket expenses including hourly employee wages, employee expenses, electronic data processing costs, duplicating, and clerical charges incurred as a result of requests by agencies for summary data compilation or analyses under the following conditions:

A. the agency requesting the summary data is not a community health services agency as defined in Minnesota Statutes, chapter 145;

B. the request requires more than one person hour of time to complete for an employee of the commissioner who is classified as either a programmer/analyst or higher, or an epidemiologist I or higher; and

C. the estimated total out-of-pocket expenses, regardless of person hours needed to satisfy the request, are greater than $50.

REPEALER. Minnesota Rules, part 4605.8000 is repealed.

Approved
by Revisor _____

APPROVED AS TO FORM AND LEGALITY

Aug 1, 1988

HUBERT H. HUMPHREY, III
ATTORNEY GENERAL

BY Christie B Eller
ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED

AUG 1 1988 4:00 PM

Joan Anderson Growe
Secretary of State

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Rules of the Department of Health Relating to Cancer Case Reporting and Uses of Cancer Case Information in the State

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

The above-referenced rules were temporarily withdrawn from review by the Attorney General on June 16, 1988, so that I could consider whether part 4606.3009 concerning "fees" was required to be promulgated according to Minn. Stat. § 16A.128.

Based on the attached two memorandums, namely, a July 14, 1988 memorandum from Thomas M. McSteen to Bruce Redemann, and a July 22, 1988 memorandum from Bruce Redemann to Thomas M. McSteen, I make the following:

FINDING OF FACT

The process for collecting fees as set forth in part 4606.3309 constitutes a procedure for calculating and collecting the actual costs of providing summary data to an agency or an individual that requests such data;

Based upon the foregoing Finding of Fact, I make the following:

CONCLUSION

The "fees" required under part 4606.3309 are based on actual direct costs of a service, and they do not constitute a fee for purposes of Minn. Stat. § 16A.128.

ORDER

Based on the foregoing conclusion, IT IS HEREBY ORDERED:

That the above referenced rules be transmitted immediately to the Attorney General for review and approval.

Dated 7-27-88

S. Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

DEPARTMENT: of Finance

STATE OF MINNESOTA

OFFICE MEMORANDUM

DATE: July 22, 1988



TO: Thomas M. McSteen
Special Assistant Attorney General

FROM: Bruce Reddemann, Director BR.
Budget Operations and Support

PHONE: 296-5188

SUBJECT: Pending Minnesota Cancer Surveillance Rules

I have received your memo of July 14, 1988 requesting clarification on charges for data covered under Finance's fee review authority (M.S.16A.128).

In review of the pending rules, under part 4606.3309, I would agree that the fees are based on actual direct cost of a service.

I agree with the position of the Health Department that the charges for data pursuant to part 4606.3309 of the pending rules are not considered a fee under M.S.16A.128.

If I can be of additional assistance, please give me a call or drop me a line.

C.C. Christie Eller
Brian Roherty
Dave Hovet
Bart Nelson

SF-00006-05 (4/86)

STATE OF MINNESOTA

Office Memorandum

DEPARTMENT : ATTORNEY GENERAL - Health

DATE : July 14, 1988

TO : Bruce Reddemann
Director
Budget Operations and Support

FROM : Thomas M. McSteen TMM
Special Assistant
Attorney General

PHONE : 341-7272

SUBJECT : Minnesota Cancer Surveillance Rules

I have received a copy of your June 29, 1988 memorandum to David Hovet, Director of Financial Management at the Department of Health. I would like to review this situation and request a clarification of your decision concerning the characterization of fees under part 4606.3309 of the above-referenced rules.

The rules were submitted to the Attorney General's Office for approval. Assistant Attorney General Christie Eller has been responsible for receiving these rules. Ms. Eller reported to me her concern that the fee provision of the rules, part 4606.3309, was not promulgated according to Minn. Stat. § 16A.128. (I have enclosed this part for your convenience.) I reviewed with her the Health Department's position that the charges for data pursuant to part 4606.3309 are not to be considered fees under Minn. Stat. § 16A.128. Ms. Eller requested that we consult with the Department of Finance and obtain approval of this interpretation.

As you know, personnel of both the Health and Finance Departments have been working to resolve this issue. I have been informed by Health Department personnel that you agree with the Health Department's position that the charges for data in these rules are not to be considered "fees," and that, therefore, the requirements of Minn. Stat. § 16A.128 do not apply to this rule. Rather, the rule simply specifies the procedure for calculating and collecting the actual costs of providing summary data to an agency or an individual that requests such data. Unfortunately, your memorandum to David Hovet did not specifically affirm this conclusion in writing.

I request that you respond to this memorandum by stating whether you agree with the above interpretation. Please communicate your decision in writing to me directly.

Thank you for your cooperation. Please contact me if you wish to discuss this matter.

TMM:dsc

Enclosure

cc: David Hovet
David Carlson
John Washburn
Al Bender
Mike Moen

CBE

RULE REVIEW CHECKLIST

File No. 1492 Docket No. 05-0009.1550

DATE RECEIVED 6-2-88 ADOPTED W/O HEARING X

REVIEW DATE ~~6-11-88~~ 6/13/88 EMERGENCY RULE

DUE DATE 6-16-88

REVISOR APPROVED

APPROVED REVISOR DISAPPROVED

DISAPPROVED FIELD W/SEC.STATE

WITHDRAWN 6-16-88 RETURNED TO AGENCY

✓ Rule as adopted (4 copies)

✓ Notice to Solicit Outside Information/Opinion

11/3/86 Date published in State Register

Comments

~~Petition for Adoption of a Rule~~

~~Board's Authorizing Resolution~~

✓ Proposed rule

Yes Revisor's Certificate

✓ Notice of Intent to Adopt Rule

144.05, 144.671-144.69 Statutory Authority

Yes Small Business Statement

Yes Expenditure of public money statement

Yes Signature

✓ Statement of Need and Reasonableness

~~Yes~~ Small Business Statement

No Fees - § 16A.128

✓ Affidavit of Mailing Notice of Intent to Adopt Rule

4/7/88 Date (30)/25 days before adoption

✓ Publication in State Register

4/11/88 Date (30)/25 days before adoption

Resolution Adopting

✓ Findings of Fact, Conclusions & Order Adopting

5/31/88 Date

✓ Written requests, submissions or comments (3)

✓ Declaration of attorney

Tom McSteen Name of SAAG representing agency

~~Notice of Submission to Attorney General~~

~~Affidavit of Mailing Notice to Attorney General~~

DEPARTMENT : ATTORNEY GENERAL - Health

STATE OF MINNESOTA

Office Memorandum

DATE : June 1, 1988

TO : Christine Eller
Assistant Attorney General

RECEIVED
JUN 02 88
ATTORNEY GENERAL'S OFFICE
515 TRANSPORTATION BLDG.
ST. PAUL, MN 55155

FROM : Thomas M. McSteen Tom
Special Assistant
Attorney General

PHONE : 341-7272

SUBJECT : In the Matter of the Proposed Adoption of Rules of the Department of Health Relating to Cancer Case Reporting and Uses of Cancer Case Information in the State

Enclosed for your review, pursuant to Minn. Stat. § 14.26 (1986) and Minn. Rules pt. 2010.0300 (1987), are the following documents to support the above-referenced rules:

1. The notice of solicitation of outside information and opinions published in the State Register on November 3, 1986;
2. The proposed rules with a certificate of approval as to form by the Revisor of Statutes attached;
3. Notice of Intent to Adopt Rules Without a Public Hearing as mailed;
4. Statement of Need and Reasonableness;
5. Affidavit of Mailing the Notice of Intent to Adopt Rules Without a Public Hearing;
6. Notice of Intent to Adopt Rules Without a Public Hearing as published in the State Register;
7. Memorandum of John W. Washburn to Tom McSteen, dated May 20, 1988, with all written comments attached;
8. Findings of Fact, Conclusions, and Order Adopting Rules Without a Public Hearing;
9. Rules as adopted (original and three copies);
10. Declaration of Counsel.

TMM:dsc

Enclosures

RECEIVED

ATTORNEY GENERAL'S OFFICE
515 TRANSPORTATION BLDG.
ST. PAUL, MN 55155

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Rules of the Department of Health Relating to Cancer Case Reporting and Uses of Cancer Case Information in the State

ORDER FOR WITHDRAWAL

WHEREAS, an issue has been raised regarding the interpretation of the term "fee" in part 4606.3309 of the above-referenced rules; and

WHEREAS, it is my desire to insure a fair rulemaking process; and

WHEREAS, it is in both the public and the Department of Health's interests to review this issue with all due deliberation.

IT IS HEREBY ORDERED that the above-referenced rules be temporarily withdrawn from review by the Attorney General until such time as all outstanding issues are resolved.

Dated: June 16, 1988

Daniel J. McSweeney for

SISTER MARY MADONNA ASHTON
Commissioner of Health

RECEIVED

JUN 16. 88

ATTORNEY GENERAL'S OFFICE
515 TRANSPORTATION BLDG.
ST. PAUL, MN 55155

SONAR

discusses (4606.3309 - Charges for data) that "a mechanism for charging fees is established in these rules."

But there are no comments re the approval by Finance + ~~Sub~~ committees on house appropriations or senate finance.

16A.128 ?

144.672 subd 1 (5) require fees ~~are~~ to be fixed by rule.

Authority

144.672 ok.

Rule

p 4 line 17 - "may" They have a choice?

ok I think no def of interpretation

p 6 line 17 - "shall attempt" Do they have to take certain steps in each case or whatever steps they feel like taking at the time - some attempts may ~~be~~ include numerous inquisitions while others may not.

may need some modifier

p 6 line 29 "cannot otherwise be located" - although it may be necessary wording, it does sound quite broad.

p 11 ~~line~~ 5 "may" ~~In what cases will they not charge a fee~~? ok

STATEMENT OF NEED AND REASONABLENESS

BEFORE THE MINNESOTA COMMISSIONER OF HEALTH

STATE OF MINNESOTA COUNTY OF HENNEPIN

IN THE MATTER OF PROPOSED RULES RELATING TO CANCER CASE REPORTING AND USES OF CANCER CASE INFORMATION IN THE STATE.

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 the above rules adoption and amendment.

In order to adopt the proposed rules, the commissioner must demonstrate compliance 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.

STATEMENT OF NEED AND REASONABLENESS

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1. STATUTORY AUTHORITY

The Statutory authority of the commissioner to adopt these rules is briefly noted below. The specific statutory authority for each rule is discussed in detail as part of the rule-by-rule justification.

- Minnesota Statute 144.05 provides the commissioner with the authority and 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 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 programming efforts in the state.

- Minnesota Statute 144.0742 authorizes the commissioner to enter into contractual agreements with any public or private entity for provision of statutorily prescribed public health services by the Department of Health.

- Minnesota Statute 144.671 through 144.69 (Supp. 1987) mandates:

  a) That 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 in the 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

In 1935, Connecticut became the first state to authorize formation of a statewide cancer registry. The majority of statewide, county or city cancer registries have been established since the early 1950's. This increase in cancer registries is due primarily to mounting concern about chronic diseases as major public health problems. Methods for studying infectious diseases are inadequate for chronic diseases such as cancer, and newer, innovative strategies for surveillance and control are being developed. Many cancers have long induction periods requiring regional registries for historical evaluation of cancer trends and hypotheses. Most existing regional cancer registries are very good and generate high quality data; however, they also tend to be very costly. The MCSS method of surveillance, based upon pathology laboratory reports, reduces costs while maintaining high quality data.

In 1981, the legislature (Minnesota Session Laws, 1981, Chapter 340) mandated that the commissioner conduct a feasibility study of a statewide population-based cancer surveillance system to address the feasibility of an accurate and cost-effective pathology-based system. Under the sponsorship of the Minnesota Cancer Council and with funds provided by The Bush Foundation, with supplemental support from the American Cancer Society - Minnesota Affiliate, the Minnesota Department of Health conducted a three-year feasibility study and published a report of its findings in early 1986 (Minnesota Department of Health: Feasibility Study of a Statewide Pathology-Based Cancer Surveillance System. Final Report, Minneapolis, Minnesota. Minnesota Department of Health, 1986). This report, which is over 250 pages in length, covers in detail the investigations into the accuracy, reliability, and cost effectiveness of a surveillance system which collects pathology laboratory reports and basic patient demographic information on all cases of cancer among Minnesotans. Based upon this evidence, during the 1987 legislative session amendments were made to M.S. 144.66 - 144.69 which dealt with cancer reporting in order to mandate the establishment of the Minnesota Cancer Surveillance System now cited as M.S. 144.671 - 144.69 (Supp. 1987).

The need for a statewide cancer surveillance system is justified as part of a coordinated cancer control program. Based upon American Cancer Society data, there were more than 16,000 new cancers diagnosed in Minnesotans during 1987. Vital statistics records indicate that more than 7,500 Minnesotans died of cancer in 1987. Cancer is second only to heart disease as a cause of death. Using the standard text, *Cancer Epidemiology and Prevention* (Schottenfeld D, Fraumeni JF Jr, [Eds]: Cancer Epidemiology and Prevention. Philadelphia, WB Saunders Company, 1982), the costs of diagnosis and treatment of cancer are estimated to conservatively represent a one-half billion dollar annual burden on the State. The social costs of the human tragedy that cancer represents adds to this burden. Specifically, the Minnesota Cancer Surveillance System is needed in order to: 1) **Monitor public concerns and questions** about cancer; 2) **Monitor incidence trends** of cancer to enable the State, as well as other users, to detect potential problems that may have public health significance, to describe and predict the risk of developing cancer, and assist in the investigation of cancer clusters; 3) **Promote high quality research** by enabling population based studies to be conducted to provide better information for cancer prevention and control; 4) **Develop and accurately target resources** that will benefit cancer patients and their families; and 5) **Educate health professionals and citizens** regarding specific health risks, early detection, and treatment for cancers known to be elevated in their communities.

STATEMENT OF NEED AND REASONABLENESS

As society has become more sensitized to environmental problems, many people have fixed on cancer as the health end point of their concern about environmental contaminations. The concern over health effects of the DC powerline in west central Minnesota, drinking water contaminated with carcinogens in Duluth, St. Louis Park, New Brighton, Rosemount, and approximately fifty other smaller communities, leukemia among our State highway maintenance workers, increased incidence of leukemia in our dairy regions and concern over the possibility of generalized contaminations of the Iron Range environment with asbestos, are examples of issues that the State must be able to respond to with up-to-date cancer occurrence information.

Each year, there are more than fifty reports to the Minnesota Department of Health of increased incidence of cancer in a workplace, school, neighborhood, or community, observed by health professionals, civic leaders, or individual citizens. Without the establishment of the Minnesota Cancer Surveillance System, Minnesota has no systematic method for monitoring the occurrence of cancer. Therefore, the Minnesota Department of Health cannot readily respond to the reports of citizens, physicians, and other scientists and health professionals about possible excesses in the number of cancers in an area.

The need for each specific provision in the proposed rules is addressed in the rule-by-rule justification. It is the Minnesota Department of Health's position that the need for all rules related to the cancer surveillance system mandated by the 1987 legislature is obvious and well established.

3. COMPLIANCE WITH PROCEDURAL RULEMAKING REQUIREMENTS

Minnesota Statutes Sections 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 Section 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 Minnesota Rules 4606.3300 - 4606.3310 is non-controversial and has elected to follow procedures set forth in Minnesota Statutes Sections 14.21 - 14.28 which provide for an expedited process for the adoption of non-controversial administrative rules without holding a public hearing.

Procedural Rulemaking Requirements of the Administrative Procedures Act

Minnesota Statutes Section 14.10 requires an agency that seeks information or opinions 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 (11 S.R. 780-1) of Monday, November 3, 1986, pp. 780-781, the commissioner published a Notice of Intent to Solicit Outside Information and Opinions Concerning Revision of Minnesota Rules: 4605.3000---"Cancer Statistical Research Service" (rules currently renumbered as 4605.8000 [1987]).

These rules do not incorporate by reference text from any other law or rule (Minnesota Statute Section 14.07 Subd. 4), or duplicate statutory language (Minnesota Statute Section 14.07 Subd. 5).

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

Pursuant to Minnesota Statute Section 14.23, the commissioner has prepared this statement of need and reasonableness which is available to the public. The commissioner will publish notice of intention to adopt the rules without public hearing in the State Register and mail copies of the notice and proposed rules to persons registered with the Minnesota Department of Health pursuant to Minnesota Statute Section 14.14 Subd. 1. The notice will include the 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; and
d) that the rule may be modified if modifications are supported by data and the views submitted.

STATEMENT OF NEED AND REASONABLENESS

If 25 or more persons submit to the Minnesota Department of Health a written request for a hearing of the proposed rules, the agency shall proceed under the provisions of Minnesota Statute Section 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 rules and notice as published, the rules 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.

These rules shall become effective upon publication of a notice of adoption in the State Register.

4. GENERAL STATEMENT OF REASONABLENESS

In addition to the procedural requirements of the Administrative Procedures Act, there are three other non-mandatory actions which the commissioner has taken to ensure the reasonableness of these rules:

First, Minnesota Session Laws, 1981, Chapter 340, mandated that the commissioner conduct a pilot study to test the feasibility of a statewide, population-based cancer surveillance system. No funds were appropriated for this purpose; however, the Minnesota Department of Health and a Technical Advisory Committee of eight prominent physicians and scientists, with the sponsorship of the Minnesota Cancer Council, obtained a grant from The Bush Foundation with supplemental support from the American Cancer Society - Minnesota Affiliate for $400,000 to conduct the study. Over 250 persons representing government, hospitals, laboratories, volunteer and non-profit agencies spent an estimated 32,000 hours developing and contributing to the feasibility study upon which these statutes and these proposed rules are based.

Second, 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, Veteran's 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, SD), and North Central Regional Pathology Laboratory.

Third, the commissioner has conducted informational meetings for representatives from all the hospitals in Minnesota concerning the cancer surveillance system and these rules. The commissioner intends to notify others who have not registered with the agency for receiving notices of rulemaking hearings. The notice of intent and copies of the proposed rules 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.

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

STATEMENT OF NEED AND REASONABLENESS

These rules provide a framework within which the commissioner can conduct a complete, highly accurate and cost-effective statewide cancer surveillance system. The following recommendations which were made in 1981 by the Technical Advisory Committee and published in the journal of the Minnesota Medical Association (Bender AP: *Development of a Feasibility Study for a Statewide Cancer Surveillance System in Minnesota.* Minnesota Medicine 1982; 65:571-573) have served as the principal guidelines in drafting these rules:

1. The cancer surveillance system must be population-based. That is, complete ascertainment of all new cancer diagnoses must be obtained from a population of known size and demographic characteristics.
2. The surveillance system must be based primarily upon diagnoses that have been microscopically confirmed as cancer.
3. The surveillance system must provide for prompt identification of all new cancer diagnoses and rapid computer processing of incoming information.
4. The core data of the surveillance system should contain only the information required for the calculation of rates (for example, by county, age, and sex) and to direct researchers to hospital records for more detailed data. 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.
5. The surveillance system must be designed for close collaboration with the research programs of many institutions. It is through surveillance/research collaboration that effective knowledge for the prevention of cancer will be developed.
6. The design of the surveillance system should be flexible enough to facilitate modifications and extensions that address newly identified needs of health professionals, cancer patients and researchers.
7. The cancer surveillance system must provide strict confidentiality for cancer patients and their surveillance records.
8. Information in existing hospital-based cancer registries should be used whenever possible to maximize the efficiency of operation of the surveillance system. The function of hospital-based registries in collecting clinical information and providing patient follow-up should not be supplanted by a statewide system.

Overall, the purpose of these rules is to coordinate statewide cancer control activities through systematic collection of data on individual cancer patients in order to:

- Monitor the occurrence of cancer;
- Develop and target resources;
- Facilitate new research;
- Respond to public concerns; and
- Inform and educate

The commissioner asserts that the rules proposed here are reasonable. The rules have a rational basis in law, medicine, and public health; do not represent arbitrary or capricious policies; and meet every procedural and substantive requirement for adoption.

5. RULE-BY-RULE JUSTIFICATION

4606.3300 and 4606.3301 PURPOSE AND SCOPE.

As stated in the proposed rules, the purpose is to establish a process and assign responsibility for reporting and investigating cancers in the State. The purpose is generally based upon the provisions of Minnesota Statutes 144.05 and 144.12 and specifically upon Minnesota Statutes 144.671-144.69.

4606.3302 DEFINITIONS.

Terms used for these rules are defined to make the provisions of these rules clear and understandable in order to provide a basis for consistent data. They are derived from the usual and customary usage of cancer epidemiology terms and concepts. Basic to any epidemiologic study is a need to define **who**, **what**, **when**, and **where**. As defined in these proposed rules, there is a clear definition of **what** will be considered disease (in these rules "Cancer"), and **who** will be considered a "Case." The definition of cancer provided in these rules is not an all inclusive definition. For the purposes of efficiency of reporting required in these rules, certain types of cancer (e.g., most skin cancers) are intentionally excluded because the routine reporting of them would not yield useful, reliable data or because the personnel and resources necessary to collect the reports would be too costly. Cases of cancer are restricted to "Minnesota residents" diagnosed as having cancer by a licensed "Physician" or "Dentist," since this is the population upon which all data analysis and further studies will be based.

Using the definitions of what cancer is and who are cases, the next definitions involved **what** defines a "Case report." Since these rules cover a pathology-based system, diagnoses of cases are best collected from the "Medical laboratories", "Hospitals" and "Medical clinics" **where** they are made or from "Tumor registries" **where** the data required by these rules has already been collected for clinical care and patient follow-up purposes. The case report definition includes for reporting all laboratory information for diagnosing cancer found on the pathology report, as well as requiring the minimum of demographic information ("Demographic form") containing the information necessary for analyzing reports by the basic epidemiologic parameters of time, place, and person.

4606.3303 COMPREHENSIVE REPORTS OF CANCER.

This rule is based upon Minnesota Statutes 144.05 (a) and 144.68 which requires detailed reports to the commissioner of cancers from persons practicing the healing arts and hospitals, tumor registries, and other institutions for the diagnosis and treatment of cancers.

Based upon the results of the three year *Feasibility Study of a Statewide, Pathology-Based Cancer Surveillance System* (MDH, 1986), and recommendations of the Working Group which developed these rules, a mechanical framework is proposed for reporting which allows for maximum flexibility for the various institutions and individuals required to report to develop a reporting method which is least cumbersome and intrusive for them. Receiving completed reports from registries is preferred as the most complete, accurate, and least intrusive method, followed by laboratory/hospital and clinic reports and finally individual physicians, if the cases are not otherwise reported. Any combination of these can be used to meet the reporting requirement in the most convenient way for the institution.

4606.3304 REPORTS.

Basic diagnostic and demographic data are necessary for the commissioner to carry out the mandate of M.S. 144.671- 69 (supp. 1987) and provide summary data on the occurrence and types of cancer in the State. The required data elements in these rules were developed from a minimum list of diagnostic and demographic items determined necessary from the *Feasibility Study of a Statewide, Pathology-Based Cancer Surveillance System* (MDH, 1986) for operating the Minnesota Cancer Surveillance System. This minimum data set consisting of patient demographic information and specific cancer diagnostic information was developed from concordance testing of study data elements and recommendations of the Working Group which developed these rules.

Collection of racial/ethnic and occupational information for epidemiologic studies is limited by the completeness and accuracy of hospital and clinic data as shown in a number of studies including one done as part of the *Feasibility Study of a Statewide, Pathology-Based Cancer Surveillance System* (MDH, 1986). Also, cancer case data concerning race, ethnicity, and occupation are not routinely collected by all hospitals and medical clinics and when collected, are not always sufficiently accurate or detailed enough to be useful in epidemiologic studies. In certain instances, however, race, ethnicity, and occupation may be related to an individual's risk of developing cancer and collection of such data pursuant to these rules and pursuant to other such legislatively mandated authorities is necessary. This rule is based upon Minnesota Statutes 144.672 and 144.68.

4606.3305 DATA SUBMISSION.

This rule, based upon Minnesota Statutes 144. 05 (a) and 144. 68, addresses the need for complete submission of cancer data for all residents and for all data elements; following up to obtain all missing data elements; and validating the quality and completeness of the data elements which are required to produce a valid and reliable population-based cancer surveillance system.

All institutions and individuals required to report must provide the minimum "Source documents" defined in these rules. Three general methods of submission have been developed in order to allow institutions the flexibility to select the most cost-effective and efficient means of submission for their operation. The database developed from these reports will be used for:

1) routine assessment of cancer rates (by time, place, demographic characteristics of patients or cancer type) to evaluate the existence of public health problems;
2) response to reports of citizens, physicians, and other scientists and health professionals about possible excesses in the number of cancers in an area; and
3) monitoring the effects of exposure to known carcinogens.

4606.3306 PHYSICIAN CONSENT

This rule formalizes the Department of Health's standing policy of obtaining physician consent prior to contacting a case. It also establishes a procedure if the physician's consent cannot be obtained with reasonable effort. The commissioner needs to obtain physician consent for two major purposes:

1. The physician caring for an individual patient needs to know about any interactions between that patient and public health authorities in order to ensure continuity of care; and
2. Public health authorities need to know any information a physician caring for an individual has which might influence the way a patient or a personal representative of the patient is approached for epidemiologic research data.

This rule is based upon Minnesota Statutes 144.69.

4606.3307 AUTHORIZED RESEARCH.

In order to conduct collaborative research and coordinate cancer prevention and control activities, a method is needed to allow persons other than surveillance system and Health Department staff to use the database without jeopardizing patient data privacy. This rule which is based upon Minnesota Statutes 144.0472, and 144. 672 Subd. 1, paragraph 4, establishes a mechanism by which the commissioner may contract with research groups to undertake a variety of cancer research activities for the purpose of promoting the public health, which would not be possible for the Minnesota Department of Health to conduct due to limited resources. The purpose of this rule is to allow qualified researchers with legitimate research interests access to certain elements of the data collected in order to conduct further studies. The procedures proposed in this rule parallel the procedures used for considering research proposals at the National Institutes of Health and National Cancer Institute. (These procedures are described in the U.S. Department of Health and Human Services, Public Health Service, Grant Application Form PHS 398, and the Public Health Service statutory authorities for awarding grants contained in Sections 301(a) and 487 of the PHS Act, as amended [42 USC 241a and 42 USC 288].)

4606.3308 CONTRACTS FOR DEVELOPMENT, EXTENSION OF SERVICES, AND QUALITY ASSURANCE.

This rule establishes a mechanism whereby the commissioner can support and facilitate the development of and improve systems for reporting of cancer cases more accurately and easily.

The greatest potential burden of reporting appears to fall upon the tumor registries and larger hospitals and laboratories which are not part of tumor registries. All of those required to report will have access to support for development of methods of reporting which will be both accurate and easily accomplished. This rule is based upon Minnesota Statutes 144.0472, and 144. 672 Subd. 1, paragraph 3.

In order to do this, the commissioner must have a set of criteria upon which the credentials of the applicants for contracts can be evaluated and against which the scientific merits of proposals can be evaluated. These criteria are intended to match, as closely as reasonably and legally possible, the federal grant evaluation criteria in order to provide consistency for applications. This rule is based upon Minnesota Statutes 144.0472, and 144. 672 Subd. 1, paragraph 3.

4606.3309 CHARGES FOR DATA.

Complex data analyses and lengthy retrievals of summary data from the system represent a necessary, but potentially considerable burden on the resources allotted to the cancer surveillance system. The Minnesota Cancer Surveillance System needs to be able to recoup some of the resources which are used for analyses and data retrieval for studies conducted by researchers outside of the Minnesota Department of Health. A mechanism for charging fees is established in these rules. Under Minnesota Statutes, Sections 13.03, subdivision 3, and 144.672, subdivision 1, paragraph (5), the commissioner may charge fees for all actual costs and out-of-pocket expenses. This section establishes a method by which the commissioner can recover the expenses of preparing or undertaking complex statistical analyses or particularly large summary reports on cancer data from the system. The charges will be only for actual expenses incurred and not for monetary profit or otherwise supporting the system.

Minnesota Environmental Quality Board
Power Plant Siting Program

Notice of Annual Hearing 9:00 am, Saturday, November 22, 1986

Conference Room A
Capitol Square Building
550 Cedar Street
St. Paul, MN 55101

The Minnesota Environmental Quality Board will hold the annual public hearing on the Power Plant Siting and Transmission Line Routing Program, as required by the Power Plant Siting Act, Minnesota Statutes § 116.58 and Rule 6 MCAR § 3.081, at 9:00 am, Saturday, November 22, 1986, in Conference Room A of the Capitol Square Building, in St. Paul, Minnesota.

The annual hearing is intended to afford interested persons an opportunity to be heard regarding any aspects of the Board's activities, duties, or policies pursuant to the Power Plant Siting Act.

All persons will be afforded the opportunity to be heard through the presentation of oral or written statements. Written statements marked for the annual hearing record may also be submitted for inclusion in the annual hearing by delivery to the Board's offices at 100 Capitol Square by the close of business December 1, 1986.

Direct all inquiries to:

John P. Hynes
Power Plant Siting Program
Minnesota Environmental Quality Board
100 Capitol Square Building
550 Cedar Street
St. Paul, MN 55101
(612) 296-2871

Department of Finance

Maximum Interest Rate for Municipal Obligations in November

Pursuant to Minnesota Statutes, Section 475.55, Subdivision 4, Commissioner of Finance, Jay Kiedrowski, announced today that the maximum interest rate for municipal obligations in the month of November would be nine (9) percent per annum. Obligations which are payable wholly or in part from the proceeds of special assessments or which are not secured by General Obligations of the municipality may bear an interest rate of up to ten (10) percent per annum.

Dated: 21 October 1986

Peter Sausen, Assistant Commissioner
Cash and Debt Management
(612) 296-8372

Department of Health
Disease Prevention and Health Promotion Division

Notice of Intent to Solicit Outside Information and Opinions Concerning Revision of Minnesota Rules: 4605.3000—"Cancer Statistical Research Service"

Notice is hereby given that the Minnesota Department of Health is considering revising Minnesota Rules 4605.3300—"Cancer Statistical Research Service".

The rules are promulgated pursuant to Minnesota Statutes 144.05; 144.12; and 144.66-69, which allow the Commissioner of Health to conduct studies and investigations, to plan for and organize services for the prevention and control of illness and to enforce health standards for the protection and promotion of the public's health including the reporting of disease. Regarding Cancer, the Commissioner of Health is specifically authorized to make and amend rules and furnish forms for collecting transcribing, compiling and preserving the information received.

The type of revisions which are being considered include, but are not limited to, determining the provisions to be included to: improve methods for reporting cancer and monitoring of the incidence trends of cancer in order to detect public health problems and predict risks; more accurately target cancer intervention resources for communities, patients and their families; inform health professionals and citizens about risks, early detection and treatment; promote high quality research to provide better information for cancer control; and address public concerns and questions about cancer. The revisions will specifically consider the types of data to be reported; standards for reporting specific types of data; methods for reimbursements allowed to hospitals, pathologists and registry systems participating in cancer reporting; and criteria for determining access to data collected pursuant to these rules.

All interested or affected persons or groups may submit information on the subject. Written or oral information and comment should be addressed to:

John Washburn
Chronic Disease and Environmental Epidemiology Section
Disease Prevention and Health Promotion Division
Minnesota Department of Health
717 Delaware Street S.E.
Minneapolis, Minnesota 55440

Department of Health

Life Support Transportation Service Licensure Application

As of November 3, 1986 a complete application for a Scheduled Advanced Life Support Transportation Service was received from MedPlus Transportation Services, Inc., 186 Forbes Avenue, St. Paul, Minnesota.

Minnesota Statutes, Section 144.802, requires in part that the Commissioner of Health publish the notice at the applicant's expense in the *State Register*.

Each municipality, county, community health service agency, or interested person has the opportunity to comment on this application by submitting written comments to the Health Systems Agency in the area of service, (Metropolitan Health Board), 300 Metro Square Bldg., 7th and Robert, St. Paul, Minnesota 55101. The comments must reach the Health Systems Agency on or before December 3, 1986 or be submitted at the public hearing.

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 the applicant.

Department of Natural Resources

Notice of Sale of State Copper, Nickel, and Associated Minerals Leases

Notice is hereby given that a sale of leases to prospect for, mine and remove copper, nickel, and associated minerals in trust fund lands, lands and minerals forfeited for nonpayment of taxes, lands and minerals otherwise acquired, and other state-owned land under the jurisdiction of the Commissioner of Natural Resources, and located in portions of Beltrami, Carlton, Itasca, Koochiching, Lake, Lake of the Woods, Marshall, Norman, Pine, Roseau and St. Louis Counties, will be held before the State Executive Council at their regularly scheduled meeting at 8:00 o'clock a.m. on December 11, 1986. At the time of the issuance of this notice, the meeting is scheduled to be held in Room 118 of the State Capitol, St. Paul, Minnesota. No land or water areas within the Boundary Waters Canoe Area Wilderness or Voyageurs National Park are included in this lease sale.

Prior to the time of sale, the Commissioner of Natural Resources, Box 45, 500 Lafayette Road, St. Paul, Minnesota 55155-4045, will receive sealed bids and applications for leases covering minerals in state lands, in accordance with Minnesota Rules, parts 6125.0100 through 6125.0700, the copper, nickel, and associated minerals rules, issued under the authority of Minnesota Statutes Sections 93.08-93.12 and 93.25.

Each application and bid, together with a certified check, cashier's check, or bank money order, payable to the State Treasurer in the sum of $50.00, must be submitted in a bid envelope obtained from the Commissioner.

At the time specified, the Commissioner, together with the State Executive Council, will publicly open the bids and announce the amount of each bid separately. Leases will be awarded by the Commissioner, with the approval of the State Executive Council, to the highest bidder for the respective mining units, but no bids will be accepted that do not equal or exceed the base royalty

Department of Health

Proposed Permanent Rules Relating to Cancer Surveillance System

Rules as Proposed (all new material)

4606.3300 PURPOSE.

The purpose of parts 4606.3300 to 4606.3309 is to establish a process and assign responsibility for:

A. collecting data from pathology laboratory reports and other demographic data on the occurrence of cancer in the state; and

B. investigating the occurrence of cancer.

4606.3301 SCOPE.

Parts 4606.3300 to 4606.3309 apply generally to the diagnosis of, reporting of, and epidemiologic studies of cancer; and scientific research on the treatment and prevention of cancer.

4606.3302 DEFINITIONS.

Subpart 1. **Abstract.** "Abstract" means a form specified by the commissioner on which the information required in part 4606.3304 has been copied.

Subp. 2. **Attending physician.** "Attending physician" means the physician who provides primary clinical care for the cancer case.

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.

Subp. 4. **Case.** "Case" means any Minnesota resident, living or deceased, having a cancer diagnosed by a physician or dentist.

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Subp. 5. **Case report.** "Case report" means a complete report of a diagnosis of cancer, which has been generated as a result of examination of demographic information and a pathology, cytology, hematology, biopsy, surgical, or autopsy specimen. At a minimum, this shall consist of source documents that contain all or as much as is known of the information required in part 4606.3304.

Subp. 6. **Commissioner.** "Commissioner" means the state commissioner of health, or the commissioner's authorized officers, or employees.

Subp. 7. **Demographic form.** "Demographic form" means the front page of a hospital medical record, the hospital business office form, or the pathology specimen submission slip that contains the demographic information required in part 4606.3304 for cases.

Subp. 8. **Dentist.** "Dentist" means any person who is licensed by the Minnesota Board of Dentistry to practice dentistry.

Subp. 9. **Electronic data submission.** "Electronic data submission" means transferring data from a computer used by a reporting entity to a computer specified by the commissioner through the use of a modem, magnetic tape, or magnetic disk.

Subp. 10. **Epidemiologic studies.** "Epidemiologic studies" means the compilation of data on health and disease, its scientific analysis to determine the distribution and causes of health problems in populations, and the application of this study to the control of health problems.

Subp. 11. **Hospital.** "Hospital" means any institution licensed as such by the commissioner under Minnesota Statutes, section 144.50.

Subp. 12. **Medical clinic.** "Medical clinic" means any institution staffed by one or more physicians where diseases of human beings are diagnosed.

Subp. 13. **Medical laboratory or pathology laboratory.** "Medical laboratory" or "pathology laboratory" means any facility that reports the results of examinations of organ

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tissue, cells, or blood specimens from the human body for cancer to physicians who use the reports for purposes of diagnosis or patient care.

Subp. 14. **Minnesota resident.** "Minnesota resident" means a person who provides a permanent address within the borders of the state at the time of cancer diagnosis. In the case of minors, residency shall be determined as that of the parent or legal guardian. This does not mean that Minnesota is the person's legal residence or voting residence.

Subp. 15. **Physician.** "Physician" means a person who is licensed by the Minnesota Board of Medical Examiners to practice medicine.

Subp. 16. **Reporting entity.** "Reporting entity" means the individual or operational unit within an institution such as a medical laboratory, hospital, clinic, or tumor registry, designated by the institution to submit case reports required by parts 4606.3300 to 4606.3309.

Subp. 17. **Source documents.** "Source documents" means copies of the demographic forms and the pathology laboratory reports that contain the information required in part 4606.3304 for cases.

Subp. 18. **Tumor registry.** "Tumor registry" means a collection of cancer data on patients that is maintained as an identified repository of such data for, or within any hospital, medical clinic, or centralized institution.

4606.3303 COMPREHENSIVE REPORTS OF CANCER.

Subpart 1. **Tumor registries.** Tumor registries shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner within 15 working days of the date the patient's tumor registry was completed.

Subp. 2. **Medical laboratories.** Medical laboratories shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner for all cases of cancer within 15 working days of the date of diagnosis.

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Subp. 3. **Hospitals and medical clinics.** Hospitals and medical clinics shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner for all cases of cancer diagnosed in the institution within 15 working days of the date of diagnosis.

Subp. 4. **Physicians and dentists.** Physicians and dentists not working within a hospital, medical clinic, or medical laboratory required to report by this part, who examine specimens of human organ tissue, cells, or blood with findings indicative of the presence of cancer, shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner within 15 working days of the date of diagnosis.

Subp. 5. **Designating a reporting entity.** Alternatively, tumor registries, medical laboratories, hospitals, medical clinics, or any combination of these within or as part of an institution, may notify the commissioner of the identity of a reporting entity to report on behalf of the institution and as such shall meet the requirements of cancer reporting under subparts 1 to 4.

4606.3304 REPORTS.

Subpart 1. **Case information.** Reports of case information that are required in part 4606.3303 must consist of source documents and contain as much of the following information as is known:

A. last name;

B. first name;

C. middle name or initial;

D. address, including house number, street, rural route number, city, state, and zip code;

E. county of residence;

F. date of birth;

G. sex;

H. social security number;

I. attending physician;

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J. other attending physician;

K. diagnostic or treatment facility;

L. case's hospital or clinic medical record number; and

M. cancer diagnostic information:

(1) primary site;

(2) histologic type;

(3) date of diagnosis or date specimen was obtained; and

(4) pathologist's designation of whether the case is newly or previously diagnosed or not known.

Subp. 2. **Abstracts or electronic data submission.** Alternatively, reports of case information that are required in part 4606.3303 may consist of completed abstracts or electronic data submission and must contain the information required in subpart 1.

Subp. 3. **Race, ethnicity, and occupational data.** Hospitals, medical clinics, and physicians shall, upon request of the commissioner, report as much information as is known concerning the race, ethnicity, and occupational history of cancer cases. The commissioner shall by publication in the State Register request reports of such information when the following conditions exist:

A. epidemiologic surveillance and studies based on this information will assist in identifying cancer risks in certain racial, ethnic, or occupational groups; and

B. there is a specific, planned mechanism for the surveillance and epidemiologic study of the cancer related to the racial, ethnic, or occupational group.

4606.3305 DATA SUBMISSION.

Subpart 1. **Completeness.** Every case report shall include, at a minimum, legible source documents, or completed abstracts, or electronic data submission that must contain the data required in part 4606.3304. Abstracts must be legible and submitted on forms provided by the commissioner. Electronic

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data must be submitted in a manner and format that conforms to the state cancer surveillance system computer system.

Subp. 2. **Missing information.** The reporting entity or individual shall, within five working days of notification by the commissioner, supply all missing information, if known, or clarify information submitted in any report required in parts 4606.3303 and 4606.3304.

Subp. 3. **Inspection.** For the purpose of assuring the quality and completeness of individual cancer case reports, each reporting entity or individual shall allow the commissioner to inspect the demographic portions of a patient's medical record or medical records related to the diagnosis of cancer as are necessary to verify the accuracy and completeness of the cancer diagnostic information and demographic data.

4606.3306 PHYSICIAN CONSENT.

Subpart 1. **Attempt to obtain consent.** When undertaking epidemiologic studies, the commissioner shall attempt to locate and obtain the consent of the attending physician as identified in the case report before approaching any case named in a report or a personal representative of a deceased case as defined in Minnesota Statutes, section 13.10, subdivision 1, paragraph (c).

Subp. 2. **Approach without consent.** The commissioner may approach a case named in a report or a personal representative of a deceased case as defined in Minnesota Statutes, section 13.10, subdivision 1, paragraph (c), without the consent of the attending physician as identified in the case report in order to conduct epidemiologic investigations if the attending physician is deceased, is no longer licensed in the state, is no longer practicing, or cannot otherwise be located.

4606.3307 AUTHORIZED RESEARCH.

Subpart 1. **Criteria.** The commissioner of health may enter into contracts to conduct research, using data collected pursuant to parts 4606.3300 to 4606.3309, with public and private research agencies or with individuals who satisfy all of the following criteria:

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A. the research proposed to be conducted will assist in improving the diagnosis, treatment, or prevention of cancer and the public health;

B. there is documented evidence that the principal investigator for the research proposed is qualified:

(1) by having attained the degree of medical doctor, doctor of science, doctor of philosophy, or equivalent degree from an accredited college or university; and

(2) by specific academic graduate level training in epidemiology, biomedical research or biometry, or documented evidence of biomedical or related medical research experience; and

C. there is a written protocol which includes but is not limited to a complete description of:

(1) the proposed scientific research hypotheses;

(2) the purpose of the proposed research;

(3) the specific methodologies, including data required from the commissioner, to be used in conducting the research and testing of scientific hypotheses;

(4) the projected or anticipated result of the research;

(5) the period of time during which the proposed research will be conducted and when a final report will be completed;

(6) the physical facilities to be employed in conducting the research; and

(7) the methods to be used to assure that privacy of data is maintained in accordance with state law, and that access to private, nonpublic data is limited to those authorized by the commissioner to have access.

Subp. 2. **Release of information.** Under no circumstances will researchers be provided access to personal identifiers that would allow contact of a patient without attempting to obtain physician consent as described in part 4606.3306. The following personal identifiers will not be released:

A. last name;

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B. first name;

C. middle name or initial;

D. address;

E. county of residence; or

F. social security number.

No researcher operating under contractual agreement with the commissioner as described in subpart 1 shall release any personal identifier, mark, or description obtained during an investigation that could be used for identification of an institution, a physician, or an individual who is or was the subject of a case report required in part 4606.3303.

Subp. 3. **Evaluation of proposals.** The commissioner shall evaluate proposals based upon the criteria in items A to E.

A. The proposed research has social and scientific merit that is directed primarily toward improving the diagnosis, treatment, defining of risks, or prevention of cancer.

B. All co-investigators are qualified to undertake the proposed research by means of specific academic training or demonstrable, related experience in epidemiology, medical, biomedical, or statistical research.

C. The hypotheses to be tested are explicit, and are determined to be researchable and feasible by the scientific peer review committee described in subpart 4.

D. The methods proposed for testing the hypothesis clearly define:

(1) the population or cancers to be studied;

(2) the type and amount of data to be collected;

(3) the source of the data;

(4) the procedures for collecting and maintaining the data; and

(5) the specific measurement techniques to be employed in analysis of data, including discussion of: major variables, statistical methods, methods of testing data reliability and validity, and required levels of accuracy, precision, or completeness of the data to be collected.

E. The results of this study will be interpreted so

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that the findings can be used or generalized to other populations and provide a timely, substantive, and important contribution to the understanding of cancer diagnosis, treatment, or prevention in Minnesota.

Subp. 4. **Scientific peer review committee.** To assist in evaluating the scientific merits of proposals for research, the commissioner may appoint up to seven scientists to conduct scientific peer review who are qualified by having:

A. attained the degree of medical doctor, doctor of science, doctor of philosophy, or equivalent degree from an accredited college or university;

B. specific training in medicine, epidemiology, cancer research, or biometry from an accredited college or university; and

C. two or more years of applied experience in epidemiology, medical research, biomedical research, or biometry.

4606.3308 CONTRACTS FOR DEVELOPMENT, EXTENSION OF SERVICES, AND QUALITY ASSURANCE.

Subpart 1. **Contracts.** The commissioner may, upon receipt of an application described in this section, contract with any institution or reporting entity in compliance with part 4606.3304 for the following purposes:

A. providing more efficient, expedient, and complete cancer registry and reporting systems for those required to report under part 4606.3303;

B. extending the capability and efficiency of the commissioner to meet the mandate established under Minnesota Statutes, sections 144.671 to 144.69; and

C. maintaining and validating the quality, accuracy, and completeness of cancer case data.

Subp. 2. **Notice of availability of funds.** The commissioner shall publish and distribute a notice of availability of funds and request for contract proposals to all hospitals, medical laboratories, tumor registries, and medical clinics required to report under part 4606.3303.

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Subp. 3. **Content of application.** Applications made under this section shall address all of the following information requirements, including:

A. Full corporate or company name, address, and tax identification number of applicant institution, or in the case of multiple institutions, the full corporate or company name, address, and tax identification number of the principal applicant institution, and the full corporate or company names and addresses of other institutions participating in the application.

B. A description of the individual components of the reporting systems to be provided by the applicant. The quality assurance standards in part 4606.3305 shall be incorporated into all applications. For each component to be provided, the application must describe, but not be limited to:

(1) the specific objectives to be achieved during the funding period;

(2) the methods by which each objective will be achieved;

(3) the institutions to be involved in the registry or reporting system;

(4) criteria to be used to evaluate achievement of objectives;

(5) budget and budget justification; and

(6) a summary of the training and experience relevant to the components to be provided by the key personnel.

C. Assurance that services will be provided in accordance with state and federal laws and rules.

D. Assurance that the privacy of all data will be maintained in accordance with law and acceptable medical practice.

Subp. 4. **Priority.** Priority will be given to applications proposing to provide cancer reporting systems addressing one or more of the following criteria:

A. the highest quality and completeness of data;

B. services to the greatest number of persons;

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C. services to the largest geographic area; and

D. demonstrated capacity to perform on the proposal.

4606.3309 CHARGES FOR DATA.

The commissioner may charge fees for out-of-pocket expenses including hourly employee wages, employee expenses, electronic data processing costs, duplicating, and clerical charges incurred as a result of requests by agencies for summary data compilation or analyses under the following conditions:

A. the agency requesting the summary data is not a community health services agency as defined in Minnesota Statutes, chapter 145;

B. the request requires more than one person hour of time to complete for an employee of the commissioner who is classified as either a programmer/analyst or higher, or an epidemiologist I or higher; and

C. the estimated total out-of-pocket expenses, regardless of person hours needed to satisfy the request, are greater than $50.

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by Revisor _____

Office of the Revisor of Statutes

Administrative Rules

TITLE: Proposed Permanent Rules Relating to Cancer Surveillance System

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4606

The attached rules are approved for publication in the State Register

Janet C. Rahm
Senior Assistant Revisor

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the
Proposed Adoption of
Rules of the Department
of Health Relating to
Cancer Case Reporting
and Uses of Cancer Case
Information in the State

NOTICE OF INTENT TO
ADOPT RULES WITHOUT
A PUBLIC HEARING

Notice is hereby given that the Minnesota Department of Health (hereinafter "Department") intends to adopt the above-entitled rules without a public hearing following the procedures set forth in the Administrative Procedure Act for adopting rules without a public hearing in Minn. Stat. §§ 14.22 to 14.28 (1986). The statutory authority to adopt the rules is Minn. Stat. §§ 144.05 (1986) and 144.671 to 144.69 (Supp. 1987).

All persons have 30 days in which to submit comment in support of or in opposition to the proposed rules or any part or subpart of the rules. 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 30-day comment period. If 25 or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held unless a sufficient number withdraw their request in writing. 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 Department will proceed pursuant to Minn. Stat. §§ 14.131 to 14.20 (1986).

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

Mr. John Washburn
Disease Prevention and Control Division
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440
Telephone: (612) 623-5636

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

A copy of the proposed rules 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 rules has been prepared and is available from John Washburn upon request. The Statement of Need and Reasonableness addresses, among other matters, the methods within the proposed rules to reduce their impact on small businesses pursuant to Minn. Stat. § 14.115 (1986).

Implementation of the proposed rules will not result in expenditures by local governments falling within the provisions of Minn. Stat. § 14.11 (1986).

If no hearing is required, upon adoption of the rules, the rules and the required supporting documents will be submitted to the Attorney General for review as to legality and form to the extent the 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 adopted rules must submit the written request to John Washburn.

Dated: March 28, 1988

Sr. Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of the Rules of the Department of Health Relating to Cancer Case Reporting and Uses of Cancer Case Information in the State

AFFIDAVIT OF MAILING THE NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING AND CERTIFICATE OF MAILING LIST

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

John W. Washburn, being duly sworn says:

I hereby certify that the list of persons and associations who have requested, pursuant to Minn. Stat. §§ 14.14, subd. la, and 14.22 or 14.30, that their names be placed on the Department of Health rulemaking mailing list is accurate, complete, and current as of this 7th day of April, 1988.

That on the 7th day of April, 1988, at the City of Minneapolis, County of Hennepin, State of Minnesota, I mailed the attached Notice of Intent to Adopt Rules Without a Public Hearing by depositing in the State of Minnesota Central Mail System for United States mailing, a copy thereof, with postage prepaid, to all persons and associations on the aforementioned mailing list.

John W. Washburn

JOHN W. WASHBURN, Administrator
Minnesota Cancer Surveillance System

Subscribed and sworn to before me this
7th day of April, 1988.

Martin Kvidera

MARTIN KVIDERA
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
MY COMMISSION EXPIRES DECEMBER 31, 1991

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MINNESOTA STATE SENATE

Senate Members — 1988 Session

PARTY	PHONE	SENATOR	ROOM*	DIST.
DFL	296-5981	Adkins, Betty A.	235 Cap	22
IR	6455	Anderson, Don	153 SOB	12
DFL	5713	Beckman, Tracy L.	G-10 Cap.	29
IR	5975	Belanger, William V., Jr.	107 SOB	41
IR	3903	Benson, Duane D.	147 SOB	32
DFL	5094	Berg, Charles A.	328 Cap.	11
DFL	4261	Berglin, Linda	G-29 Cap.	60
IR	4131	Bernhagen, John	113 SOB	21
DFL	2084	Bertram, Joe Sr.	323 Cap.	16
DFL	4837	Brandl, John E.	306 Cap.	62
IR	4848	Brataas, Nancy	139 SOB	33
DFL	4182	Chmielewski, Florian	325 Cap.	14
DFL	5931	Cohen, Richard J.	G-27 Cap.	64
DFL	5003	Dahl, Gregory L.	111 Cap.	50
DFL	2302	Davis, Charles R.	G-24 Cap.	18
IR	0415	Decker, Bob	151SOB	4
DFL	6820	DeCramer, Gary M.	303 Cap.	27
DFL	2859	Dicklich, Ronald R.	235 Cap.	5
DFL	8298	Diessner, A.W. "Bill"	326 Cap.	56
DFL	2877	Frank, Don	G-10 Cap.	51
IR	4123	Frederick, Mel	119 SOB	30
DFL	5640	Frederickson, David J.	G-24 Cap.	20
IR	8138	Frederickson, Dennis R.	143 SOB	23
DFL	9307	Freeman, Michael O.	122 Cap.	40
IR	4314	Gustafson, Jim	115 SOB	8
DFL	4183	Hughes, Jerome M.	328 Cap.	54
IR	3826	Johnson, Dean E.	105 SOB	15
DFL	8881	Johnson, Douglas J.	205 Cap.	6
DFL	4248	Jude, Tad	G-28 Cap.	48
IR	1253	Knaak, Fritz	149 SOB	53
IR	4120	Knutson, Howard A.	121 SOB	38
DFL	4302	Kroening, Carl W.	124 Cap.	57
IR	4351	Laidig, Gary W.	141 SOB	55
DFL	3205	Langseth, Keith	G-24 Cap.	9
DFL	8017	Lantry, Marilyn M.	328 Cap.	67
IR	5655	Larson, Cal	145 SOB	10
DFL	296-4136	Lessard, Bob	111 Cap.	3
DFL	8869	Luther, William P.	205 Cap.	47
DFL	5645	Marty, John J.	235 Cap.	63
IR	1279	McQuaid, Phyllis W.	135 SOB	44
IR	8075	Mehrkens, Lyle G.	127 SOB	26
DFL	4154	Merriam, Gene	122 Cap.	49
DFL	4370	Metzen, James	303 Cap.	39
DFL	4264	Moe, Donald M.	309 Cap.	65
DFL	2577	Moe, Roger D.	208 Cap.	2
DFL	5649	Morse, Steven	G-24 Cap.	34
DFL	4334	Novak, Steven G.	301 Cap.	52
IR	1282	Olson, Gen	133 SOB	43
DFL	4241	Pehler, James C.	G-9 Cap.	17
DFL	4274	Peterson, Donna C.	G-24 Cap.	61
DFL	8018	Peterson, Randolph W.	G-9 Cap.	19
DFL	9248	Piper, Pat	325 Cap.	31
DFL	7809	Pogemiller, Lawrence J.	306 Cap.	58
DFL	4167	Purfeerst, Clarence M.	303 Cap.	25
IR	9251	Ramstad, Jim	123 SOB	45
DFL	2889	Reichgott, Ember D.	G-9 Cap.	46
IR	4125	Renneke, Earl W.	117 SOB	35
DFL	4875	Samuelson, Don	124 Cap.	13
DFL	7157	Schmitz, Robert J.	235 Cap.	36
DFL	4188	Solon, Sam G.	303 Cap.	7
DFL	4191	Spear, Allan H.	G-27 Cap.	59
IR	6238	Storm, Donald A.	125 SOB	42
DFL	8660	Stumpf, LeRoy A.	306 Cap.	1
IR	9457	Taylor, Glen	103 SOB	24
DFL	5650	Vickerman, Jim M.	G-29 Cap.	28
DFL	3809	Waldorf, Gene	124 Cap.	66
DFL	8091	Wegscheid, Darril	309 Cap.	37

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33B	Bishop, David T. (IR)	357	0573
41B	Blatz, Kathleen A. (IR)	259	4218
8B	Boo, Ben (IR)	311	2228
11A	Brown, Chuck (DFL)	569	4929
43A	Burger, John (IR)	225	9188
14B	Carlson, Douglas W. (IR)	203	4308
46B	Carlson, Lyndon R. (DFL)	379	4255
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21A	Dille, Stephen E. (IR)	227	4344
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42B	Forsythe, Mary (IR)	245	4363
24B	Frederick, Marcel "Sal" (IR)	303	5513
32A	Frerichs, Don L. (IR)	389	4378
61A	Greenfield, Lee (DFL)	375	0173
17B	Gruenes, David B. (IR)	201	6316
33A	Gutknecht, Gil (IR)	309	9249
30A	Hartle, Dean P. (IR)	233	5368
31A	Haukoos, M. R. "Bob" (IR)	279	8216
45B	Heap, Jim (IR)	281	7026
41A	Himle, John (IR)	247	7803
29A	Hugoson, Gene (IR)	221	3240
49B	Jacobs, Joel (DFL)	485	4231
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4A	Johnson, Bob A. (DFL)	413	5516
34A	Johnson, Virgil J. (IR)	207	1069
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12B	Krueger, Rick (DFL)	433	3201
50A	Larsen, Ernest A. (DFL)	575	5369
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55B	McPherson, Harriet A. (IR)	211	5511
39B	Milbert, Bob P. (DFL)	579	4192
20B	Miller, Howard G. (IR)	353	5066
5B	Minne, Lona A. (DFL)	439	0172
38A	Morrison, Connie (IR)	387	4212
7A	Munger, Willard (DFL)	479	4282
8A	Murphy, Mary (DFL)	557	2676
11B	Nelson, Clair L. (DFL)	515	4317
49A	Nelson, Darby (DFL)	501	1729
62A	Nelson, Ken (DFL)	367	4244
3A	Neuenschwander, Bob (DFL)	337	1188
66B	O'Connor, Richard "Rich" (DFL)	593	7807
14A	Ogren, Paul Anders (DFL)	417	7808
44A	Olsen, Sally (IR)	255	3964
2B	Olson, Edgar L. (DFL)	529	4265
28B	Olson, Katy (DFL)	523	5373
16A	Omann, Bernie (IR)	229	6612
22B	Onnen, Tony D. (IR)	277	1534
64B	Orenstein, Howard R. (DFL)	521	4199
66A	Osthoff, Tom (DFL)	591	4224
59B	Otis, Todd H. (DFL)	403	9281
37B	Ozment, Dennis D. (IR)	287	4306
65B	Pappas, Sandra L. (DFL)	327	9714
42A	Pauly, Sidney J. (IR)	291	7449
34B	Pelowski, Gene P. (DFL)	531	8637
18A	Peterson, Jerome "J. P." (DFL)	597	6746
10A	Poppenhagen, Dennis J. (IR)	301	5387
56A	Price, Leonard "Len" (DFL)	507	3018
50B	Quinn, Joseph (DFL)	545	2439
23B	Quist, Allen J. (IR)	213	7065
32B	Redalen, Elton R. (IR)	251	9278
31B	Reding, Leo J. (DFL)	537	4193
46A	Rest, Ann H. (DFL)	429	4176
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12A	Richter, Don H. (IR)	223	4293
40B	Riveness, Phillip J. (DFL)	445	7158
25B	Rodosovich, Peter (DFL)	451	8237
63A	Rose, John T. (IR)	209	4342
5A	Rukavina, Tom (DFL)	473	0170
58A	Sarna, John (DFL)	563	4219
35A	Schafer, Gary L. (IR)	215	8634
47A	Scheid, Linda J. (DFL)	583	3751
48B	Schreiber, William H. "Bill" (IR)	267	4128
38B	Seaberg, Arthur W. (IR)	393	3533
44B	Segal, Gloria M. (DFL)	415	9889
45A	Shaver, Craig H. (IR)	243	9934
51B	Simoneau, Wayne (DFL)	335	4331
61B	Skoglund, Wes (DFL)	409	4330
3B	Solberg, Loren A. (DFL)	571	2365
1B	Sparby, Wally A. (DFL)	351	9918
53B	Stanius, Brad G. (IR)	315	5363
27B	Steensma, Andy (DFL)	471	4336
26A	Sviggum, Steve A. (IR)	237	2273
55A	Swenson, Douglas G. (IR)	321	4124
13A	Thiede, Paul M. (IR)	217	4333
40A	Tjornhom, Chris M. (IR)	239	5375
37A	Tompkins, Eileen J. (IR)	231	5506
67B	Trimble, Steve (DFL)	491	4201
1A	Tunheim, Jim (DFL)	525	9635
15A	Uphus, Sylvester B. (IR)	253	5185
54A	Valento, Don J. (IR)	359	7153
25A	Vanasek, Robert E. (DFL)	463	4229
64A	Vellenga, Kathleen O. (DFL)	549	8799
52A	Voss, Gordon O. (DFL)	443	4226
62B	Wagenius, Jean D. (DFL)	551	4200
26B	Waltman, Bob (IR)	289	9236
15B	Welle, Alan W. (DFL)	503	6206
13B	Wenzel, Steve (DFL)	487	4247
28A	Winter, Theodore "Ted" (DFL)	411	5505
63B	Wynia, Ann (DFL)	459	3824

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Revised Nov. 25, 1987

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F. possible consequences of denial or reparations.

Subp. 2. **Utilization review.** Where the board is unable, due to multiple caregivers or complex treatment issues, to determine reasonableness, it may use the services of outside experts to assist in a determination. This review shall include, but is not limited to:

A. review of clinical records;

B. submission of a questionnaire to the claimant to elicit specific information; and

C. interview or examination of the claimant.

7505.2900 CONTRIBUTORY MISCONDUCT.

The board shall reduce, by a minimum of 25 percent, any claim submitted by or on behalf of a person who the board finds has engaged in any of the following acts or behavior that contributed to the injury for which the claim is filed:

A. used fighting words, obscene or threatening gestures, or other provocation;

B. knowingly and willingly been in a vehicle operated by a person who is under the influence of alcohol or a controlled substance;

C. consumed alcohol or other mood-altering substances; or

D. failed to retreat or withdraw from a situation where an option to do so was readily available.

Any of these provisions may be waived in cases of domestic abuse or sexual assault.

7505.3000 CLAIMS PRORATING.

Subpart 1. **Designation of monthly allotment.** Total annual appropriations, grants, and other funds designated for the payment of claims, excluding an annually determined set-aside for emergency funds, must be equally divided among each month of the fiscal year. The resulting amount is designated the "monthly reparations allotment."

Subp. 2. **Requests in excess of monthly allotment.** If the monthly reparations allotment minus any awards granted on an emergency basis during the 30 days preceding the month in question is less than the total dollar amount of reparations claims eligible for payment in that month, the board shall pay only a portion of each claim approved that month.

Subp. 3. **Payment ratio.** The payment ratio shall equal the monthly reparations allotment minus any emergency awards granted in the preceding month divided by the total dollar amount of reparations awards eligible for payment in that month.

Subp. 4. **Excess allotment.** Where the amount of reparations awarded during a specific month equals less than the monthly allotment, any excess will be carried forward to the next month and added to the monthly allotment for that period.

Subp. 5. **Claim filing.** The payment ratio of the month in which the claim or supplementary claim is approved is the payment ratio which governs the claim or supplementary claim.

REPEALER. *Minnesota Rules*, parts 7505.0500; 7505.0800; 7505.0900; 7505.1000; 7505.1100; 7505.1200; 7505.1300; 7505.1400; 7505.1500; 7505.1600; 7505.1700; 7505.1800; 7505.2000; 7505.2100; 7505.2200; 7505.2300; 7505.2400; and 7505.2500, are repealed.

Department of Health

Proposed Permanent Rules Relating to Cancer Surveillance System

Notice of Intent to Adopt Rules Without a Public Hearing

Notice is hereby given that the Minnesota Department of Health (hereinafter "Department") intends to adopt the above-entitled rules 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 (1986). The statutory authority to adopt the rules is *Minnesota Statutes*, §§ 144.05 (1986) and 144.671 to 144.69 (Supp. 1987).

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.

All persons have 30 days in which to submit comment in support of or in opposition to the proposed rules or any part or subpart of the rules. 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 30-day comment period. If 25 or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held unless a sufficient number withdraw their request in writing. 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 Department will proceed pursuant to *Minnesota Statutes* §§ 14.131 to 14.20 (1986).

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

Mr. John Washburn
Disease Prevention and Control Division
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440
Telephone: (612) 623-5636

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

A copy of the proposed rules 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 rules has been prepared and is available from John Washburn upon request. The Statement of Need and Reasonableness addresses, among other matters, the methods within the proposed rules to reduce their impact on small businesses pursuant to *Minnesota Statutes* § 14.115 (1986).

Implementation of the proposed rules will not result in expenditures by local governments falling within the provisions of *Minnesota Statutes* § 14.11 (1986).

If no hearing is required, upon adoption of the rules, the rules and the required supporting documents will be submitted to the Attorney General for review as to legality and form to the extent the 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 adopted rules must submit the written request to John Washburn.

Dated: 28 March 1988

Sister Mary Madonna Ashton
Commissioner of Health

Rules as Proposed (all new material)

4606.3300 PURPOSE.

The purpose of parts 4606.3300 to 4606.3309 is to establish a process and assign responsibility for:

A. collecting data from pathology laboratory reports and other demographic data on the occurrence of cancer in the state; and

B. investigating the occurrence of cancer.

4606.3301 SCOPE.

Parts 4606.3300 to 4606.3309 apply generally to the diagnosis of, reporting of, and epidemiologic studies of cancer; and scientific research on the treatment and prevention of cancer.

4606.3302 DEFINITIONS.

Subpart 1. **Abstract.** "Abstract" means a form specified by the commissioner on which the information required in part 4606.3304 has been copied.

Subp. 2. **Attending physician.** "Attending physician" means the physician who provides primary clinical care for the cancer case.

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.

Subp. 4. **Case.** "Case" means any Minnesota resident, living or deceased, having a cancer diagnosed by a physician or dentist.

Subp. 5. **Case report.** "Case report" means a complete report of a diagnosis of cancer, which has been generated as a result of examination of demographic information and a pathology, cytology, hematology, biopsy, surgical, or autopsy specimen. At a minimum, this shall consist of source documents that contain all or as much as is known of the information required in part 4606.3304.

Subp. 6. **Commissioner.** "Commissioner" means the state commissioner of health, or the commissioner's authorized officers, or employees.

Subp. 7. **Demographic form.** "Demographic form" means the front page of a hospital medical record, the hospital business office form, or the pathology specimen submission slip that contains the demographic information required in part 4606.3304 for cases.

Subp. 8. **Dentist.** "Dentist" means any person who is licensed by the Minnesota Board of Dentistry to practice dentistry.

Subp. 9. **Electronic data submission.** "Electronic data submission" means transferring data from a computer used by a reporting entity to a computer specified by the commissioner through the use of a modem, magnetic tape, or magnetic disk.

Subp. 10. **Epidemiologic studies.** "Epidemiologic studies" means the compilation of data on health and disease, its scientific analysis to determine the distribution and causes of health problems in populations, and the application of this study to the control of health problems.

Subp. 11. **Hospital.** "Hospital" means any institution licensed as such by the commissioner under *Minnesota Statutes*, section 144.50.

Subp. 12. **Medical clinic.** "Medical clinic" means any institution staffed by one or more physicians where diseases of human beings are diagnosed.

Subp. 13. **Medical laboratory or pathology laboratory.** "Medical laboratory" or "pathology laboratory" means any facility that reports the results of examinations of organ tissue, cells, or blood specimens from the human body for cancer to physicians who use the reports for purposes of diagnosis or patient care.

Subp. 14. **Minnesota resident.** "Minnesota resident" means a person who provides a permanent address within the borders of the state at the time of cancer diagnosis. In the case of minors, residency shall be determined as that of the parent or legal guardian. This does not mean that Minnesota is the person's legal residence or voting residence.

Subp. 15. **Physician.** "Physician" means a person who is licensed by the Minnesota Board of Medical Examiners to practice medicine.

Subp. 16. **Reporting entity.** "Reporting entity" means the individual or operational unit within an institution such as a medical laboratory, hospital, clinic, or tumor registry, designated by the institution to submit case reports required by parts 4606.3300 to 4606.3309.

Subp. 17. **Source documents.** "Source documents" means copies of the demographic forms and the pathology laboratory reports that contain the information required in part 4606.3304 for cases.

Subp. 18. **Tumor registry.** "Tumor registry" means a collection of cancer data on patients that is maintained as an identified repository of such data for, or within any hospital, medical clinic, or centralized institution.

4606.3303 COMPREHENSIVE REPORTS OF CANCER.

Subpart 1. **Tumor registries.** Tumor registries shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner within 15 working days of the date the patient's tumor registry was completed.

Subp. 2. **Medical laboratories.** Medical laboratories shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner for all cases of cancer within 15 working days of the date of diagnosis.

Subp. 3. **Hospitals and medical clinics.** Hospitals and medical clinics shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner for all cases of cancer diagnosed in the institution within 15 working days of the date of diagnosis.

Subp. 4. **Physicians and dentists.** Physicians and dentists not working within a hospital, medical clinic, or medical laboratory required to report by this part, who examine specimens of human organ tissue, cells, or blood with findings indicative of the presence

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of cancer, shall forward by first class mail, by messenger, or via electronic data submission, case reports to the commissioner within 15 working days of the date of diagnosis.

Subp. 5. **Designating a reporting entity.** Alternatively, tumor registries, medical laboratories, hospitals, medical clinics, or any combination of these within or as part of an institution, may notify the commissioner of the identity of a reporting entity to report on behalf of the institution and as such shall meet the requirements of cancer reporting under subparts 1 to 4.

4606.3304 REPORTS.

Subpart 1. **Case information.** Reports of case information that are required in part 4606.3303 must consist of source documents and contain as much of the following information as is known:

A. last name;

B. first name;

C. middle name or initial;

D. address, including house number, street, rural route number, city, state, and zip code;

E. county of residence;

F. date of birth;

G. sex;

H. social security number;

I. attending physician;

J. other attending physician;

K. diagnostic or treatment facility;

L. case's hospital or clinic medical record number; and

M. cancer diagnostic information:

(1) primary site;

(2) histologic type;

(3) date of diagnosis or date specimen was obtained; and

(4) pathologist's designation of whether the case is newly or previously diagnosed or not known.

Subp. 2. **Abstracts or electronic data submission.** Alternatively, reports of case information that are required in part 4606.3303 may consist of completed abstracts or electronic data submission and must contain the information required in subpart 1.

Subp. 3. **Race, ethnicity, and occupational data.** Hospitals, medical clinics, and physicians shall, upon request of the commissioner, report as much information as is known concerning the race, ethnicity, and occupational history of cancer cases. The commissioner shall by publication in the *State Register* request reports of such information when the following conditions exist:

A. epidemiologic surveillance and studies based on this information will assist in identifying cancer risks in certain racial, ethnic, or occupational groups; and

B. there is a specific, planned mechanism for the surveillance and epidemiologic study of the cancer related to the racial, ethnic, or occupational group.

4606.3305 DATA SUBMISSION.

Subpart 1. **Completeness.** Every case report shall include, at a minimum, legible source documents, or completed abstracts, or electronic data submission that must contain the data required in part 4606.3304. Abstracts must be legible and submitted on forms provided by the commissioner. Electronic data must be submitted in a manner and format that conforms to the state cancer surveillance system computer system.

Subp. 2. **Missing information.** The reporting entity or individual shall, within five working days of notification by the commissioner, supply all missing information, if known, or clarify information submitted in any report required in parts 4606.3303 and 4606.3304.

Subp. 3. **Inspection.** For the purpose of assuring the quality and completeness of individual cancer case reports, each reporting entity or individual shall allow the commissioner to inspect the demographic portions of a patient's medical record or medical records related to the diagnosis of cancer as are necessary to verify the accuracy and completeness of the cancer diagnostic information and demographic data.

4606.3306 PHYSICIAN CONSENT.

Subpart 1. **Attempt to obtain consent.** When undertaking epidemiologic studies, the commissioner shall attempt to locate and obtain the consent of the attending physician as identified in the case report before approaching any case named in a report or a personal representative of a deceased case as defined in *Minnesota Statutes*, section 13.10, subdivision 1, paragraph (c).

Subp. 2. **Approach without consent.** The commissioner may approach a case named in a report or a personal representative of a deceased case as defined in *Minnesota Statutes*, section 13.10, subdivision 1, paragraph (c), without the consent of the attending physician as identified in the case report in order to conduct epidemiologic investigations if the attending physician is deceased, is no longer licensed in the state, is no longer practicing, or cannot otherwise be located.

4606.3307 AUTHORIZED RESEARCH.

Subpart 1. **Criteria.** The commissioner of health may enter into contracts to conduct research, using data collected pursuant to parts 4606.3300 to 4606.3309, with public and private research agencies or with individuals who satisfy all of the following criteria:

A. the research proposed to be conducted will assist in improving the diagnosis, treatment, or prevention of cancer and the public health;

B. there is documented evidence that the principal investigator for the research proposed is qualified:

(1) by having attained the degree of medical doctor, doctor of science, doctor of philosophy, or equivalent degree from an accredited college or university; and

(2) by specific academic graduate level training in epidemiology, biomedical research or biometry, or documented evidence of biomedical or related medical research experience; and

C. there is a written protocol which includes but is not limited to a complete description of:

(1) the proposed scientific research hypotheses;

(2) the purpose of the proposed research;

(3) the specific methodologies, including data required from the commissioner, to be used in conducting the research and testing of scientific hypotheses;

(4) the projected or anticipated result of the research;

(5) the period of time during which the proposed research will be conducted and when a final report will be completed;

(6) the physical facilities to be employed in conducting the research; and

(7) the methods to be used to assure that privacy of data is maintained in accordance with state law, and that access to private, nonpublic data is limited to those authorized by the commissioner to have access.

Subp. 2. **Release of information.** Under no circumstances will researchers be provided access to personal identifiers that would allow contact of a patient without attempting to obtain physician consent as described in part 4606.3306. The following personal identifiers will not be released:

A. last name;

B. first name;

C. middle name or initial;

D. address;

E. county of residence; or

F. social security number.

No researcher operating under contractual agreement with the commissioner as described in subpart 1 shall release any personal identifier, mark, or description obtained during an investigation that could be used for identification of an institution, a physician, or an individual who is or was the subject of a case report required in part 4606.3303.

Subp. 3. **Evaluation of proposals.** The commissioner shall evaluate proposals based upon the criteria in items A to E.

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.

A. The proposed research has social and scientific merit that is directed primarily toward improving the diagnosis, treatment, defining of risks, or prevention of cancer.

B. All co-investigators are qualified to undertake the proposed research by means of specific academic training or demonstrable, related experience in epidemiology, medical, biomedical, or statistical research.

C. The hypotheses to be tested are explicit, and are determined to be researchable and feasible by the scientific peer review committee described in subpart 4.

D. The methods proposed for testing the hypothesis clearly define:

(1) the population or cancers to be studied;

(2) the type and amount of data to be collected;

(3) the source of the data;

(4) the procedures for collecting and maintaining the data; and

(5) the specific measurement techniques to be employed in analysis of data, including discussion of: major variables, statistical methods, methods of testing data reliability and validity, and required levels of accuracy, precision, or completeness of the data to be collected.

E. The results of this study will be interpreted so that the findings can be used or generalized to other populations and provide a timely, substantive, and important contribution to the understanding of cancer diagnosis, treatment, or prevention in Minnesota.

Subp. 4. **Scientific peer review committee.** To assist in evaluating the scientific merits of proposals for research, the commissioner may appoint up to seven scientists to conduct scientific peer review who are qualified by having:

A. attained the degree of medical doctor, doctor of science, doctor of philosophy, or equivalent degree from an accredited college or university;

B. specific training in medicine, epidemiology, cancer research, or biometry from an accredited college or university; and

C. two or more years of applied experience in epidemiology, medical research, biomedical research, or biometry.

4606.3308 CONTRACTS FOR DEVELOPMENT, EXTENSION OF SERVICES, AND QUALITY ASSURANCE.

Subpart 1. **Contracts.** The commissioner may, upon receipt of an application described in this section, contract with any institution or reporting entity in compliance with part 4606.3304 for the following purposes:

A. providing more efficient, expedient, and complete cancer registry and reporting systems for those required to report under part 4606.3303;

B. extending the capability and efficiency of the commissioner to meet the mandate established under *Minnesota Statutes*, sections 144.671 to 144.69; and

C. maintaining and validating the quality, accuracy, and completeness of cancer case data.

Subp. 2. **Notice of availability of funds.** The commissioner shall publish and distribute a notice of availability of funds and request for contract proposals to all hospitals, medical laboratories, tumor registries, and medical clinics required to report under part 4606.3303.

Subp. 3. **Content of application.** Applications made under this section shall address all of the following information requirements, including:

A. Full corporate or company name, address, and tax identification number of applicant institution, or in the case of multiple institutions, the full corporate or company name, address, and tax identification number of the principal applicant institution, and the full corporate or company names and addresses of other institutions participating in the application.

B. A description of the individual components of the reporting systems to be provided by the applicant. The quality assurance standards in part 4606.3305 shall be incorporated into all applications. For each component to be provided, the application must describe, but not be limited to:

(1) the specific objectives to be achieved during the funding period;

(2) the methods by which each objective will be achieved;

(3) the institutions to be involved in the registry or reporting system;

(4) criteria to be used to evaluate achievement of objectives;

(5) budget and budget justification; and

(6) a summary of the training and experience relevant to the components to be provided by the key personnel.

C. Assurance that services will be provided in accordance with state and federal laws and rules.

D. Assurance that the privacy of all data will be maintained in accordance with law and acceptable medical practice.

Subp. 4. **Priority.** Priority will be given to applications proposing to provide cancer reporting systems addressing one or more of the following criteria:

A. the highest quality and completeness of data;

B. services to the greatest number of persons;

C. services to the largest geographic area; and

D. demonstrated capacity to perform on the proposal.

4606.3309 CHARGES FOR DATA.

The commissioner may charge fees for out-of-pocket expenses including hourly employee wages, employee expenses, electronic data processing costs, duplicating, and clerical charges incurred as a result of requests by agencies for summary data compilation or analyses under the following conditions:

A. the agency requesting the summary data is not a community health services agency as defined in *Minnesota Statutes*, chapter 145;

B. the request requires more than one person hour of time to complete for an employee of the commissioner who is classified as either a programmer/analyst or higher, or an epidemiologist I or higher; and

C. the estimated total out-of-pocket expenses, regardless of person hours needed to satisfy the request, are greater than $50.

Secretary of State

Proposed Permanent Rules Relating to Absentee Ballots; Optical Scan Voting Systems

Notice of Intent to Adopt a Rule Without a Public Hearing

Notice is hereby given that the Secretary of State 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 statutory authority to adopt the rules is *Minnesota Statutes*, sections 203B.09 and 206.57.

All persons have 30 days in which to submit comment in support of or in opposition to the proposed rule or any part or subpart of the rule. Comment is encouraged. Each comment should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed.

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

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

Jeff Sigurdson
Election Division
180 State Office Building
St. Paul, MN 55155
(612) 296-6011

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

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

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Rules of the Department of Health Relating to Cancer Case Reporting and Uses of Cancer Case Information in the State

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

Notice of the Department of Health's (hereinafter "Department") intent to adopt the above-entitled rules was published in the State Register on April 11, 1988, and was sent by United States mail on April 7, 1988 to all persons on the list maintained by the Department pursuant to Minn. Stat. 14.14, subd. 1.a. and 14.22. The statement of need and reasonableness was prepared before the notice of intent to adopt rules without a public hearing was mailed to all persons on the rulemaking mailing list and published in the State Register, and it was available to the public.

All persons were given the opportunity to submit comment on the rules for 30 days after notice of proposed rulemaking. The Department received one written comment and one verbal comment. The Department received no requests for a public hearing. The Department received no requests for notice of submission to the Attorney General.

Based on the comments and evidence in the record before the Department, I make the following:

FINDINGS OF FACT

1. The Department received a written comment, which is a part of the record herein, concerning part 4606.3307, subp. 1.B.(2). The Department's reply which is also a part of the record herein, stated that "related medical research experience" will be interpreted to include nursing research;

2. The Department received a verbal comment concerning part 4606.3307 subp. 1.B(1), requesting that this subpart be modified to include a "Doctor of Dental Surgery." The Department agrees with this proposed modification. The change is both reasonable and consistent with the rules, as dentists will be required to report cancer cases pursuant to part 4606.3303, subp. 4 and likely will have an interest in studying oral cancers;

3. The rules as proposed inadvertently omitted a repealer for Minn. Rules pt. 4605.8000. The adoption of the proposed rules effectively makes Minn. Rules pt. 4605.8000 obsolete. The Department now adopts a repealer, as such a change is logical and insubstantial.

Based upon the foregoing Findings of Fact, I make the following:

CONCLUSIONS

1. That the modifications to the proposed rules made after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. 14.24 (1986) and Minn. Rules pt. 2010.1000;

2. The above captioned rules are both needed and reasonable;

ORDER

Based on the foregoing conclusions, IT IS HEREBY ORDERED:

1. Part 4606.3307, subp. 1.B.(1), is modified to read as follows:

(1) by having attained the degree of medical doctor, <u>doctor of dental surgery</u>, doctor of science, doctor of philosophy, or equivalent degree from an accredited college or university;

2. A repealer is proposed as follows:

<u>Minn. Rules pt. 4605.8000 is hereby repealed.</u>

3. The rules identified as Rules of the Department of Health Relating to Cancer Case Reporting and Uses of Cancer Case Information in the State are adopted this 31st day of May 1988, pursuant to authority vested in the Department by Minn. Stat. 144.05 (1986) and 144.671 to 144.69 (Supp. 1987).

Sr. Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

DEPARTMENT OF HEALTH

STATE OF MINNESOTA

Office Memorandum

DATE: May 20, 1988

TO: Tom McSteen, Special Assistant
Attorney General

FROM: John W. Washburn, Epidemiologist/Administrator
Minnesota Cancer Surveillance System

PHONE: 623-5636

SUBJECT: Comments Received Concerning the Proposed Minnesota Cancer Surveillance System Rules (All New Material) M.R. 4606.3300 - 4606.3309.

As you requested I am forwarding the comments and responses that I have received concerning the proposed Minnesota Cancer Surveillance System Rules M.R. 4606.3300 - 4606.3309.

Briefly, the proposed Rules were published in the State Register (12 S.R. 2241) on Monday, April 11, 1988 (copy attached). At your request, I accepted comments through May 13, 1988. Only one letter was received for comment on the proposed rules. A copy of this letter and my response are attached. The letter, which was from a representative of the Minnesota Nurses Association was to clarify and assure them that nurses would be considered, under these rules, as authorized researchers as qualifying a having related medically related degrees and related medical research experience. The answer to this comment is yes.

Also, Dr. Dan Tolman of the Mayo Clinic and the Minnesota Dental Association asked me verbally about whether under 4606.3307 B. (1) if Doctor of Dental Surgery could also be added to clarify that dentists would clearly qualify under this provision. I believe that Dr. Tolman's request is reasonable from the standpoint that dentists are required to report cancer cases seen and certainly will have an interest in studying oral cancers. From our standpoint I believe the addition of "Doctor of Dental Surgery" would be an insubstantial change.

Last, we need to include the "repealer" for M.R. 4605.8000 (Cancer Statistical Research Service). As we discussed earlier, this repealer represents an inadvertent omission when they were published and a logical, insubstantial change.

No requests for a public hearing were received.

Quite a few people are looking to these rules for reporting and planning various national research grants. On behalf of the Division and Section I would like to encourage expeditious completion of the rules reviews for the earliest promulgation date possible.

Please feel free to call me (623-5636) if you have any questions.

pp
attachment
cc: Michael Moen
Alan Bender
Terry O'Brien

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

May 2, 1988

Mary T. Absolon, R.N., M.S.N.
Staff Specialist, Governmental Affairs
Minnesota Nurses Association
1821 University Avenue, Suite N-377
St. Paul, Minnesota 55104

Dear Ms. Absolon:

I have received your letter of April 27, commenting on the proposed rules for the Minnesota Cancer Surveillance System (MCSS). Clearly, nursing research into cancer treatment, prevention, and control will be considered authorized research, as will research in any other medical field or specialty. Therefore, 4606.3307 "related medical research experience" will be interpreted to include nursing research.

MCSS was conceived and is being implemented with "use" of the data as fundamental to its purpose. The reason for limiting access to the data in the MCSS is to ensure that individual patient privacy is protected and that those who have access to the data are capable of interpreting its significance.

I appreciate your careful review of these proposed rules, and please feel free to share any other comments or questions you might have concerning them.

Sincerely yours,

John W. Washburn, Epidemiologist/Administrator
Minnesota Cancer Surveillance System

/pp
cc: Tom McSteen, Special Assistant Attorney General

an equal opportunity employer

Minnesota Nurses Association
1821 UNIVERSITY AVENUE, SUITE N-377
ST. PAUL, MINNESOTA 55104
(612) 646-4807

April 27, 1988

Mr. John Washburn
Disease Prevention and Control Division
The Minnesota Department of Health
717 Delaware Street, S. E.
Minneapolis, Minnesota 55440

RE: Proposed Permanent Rules Relating to Cancer Surveillance System

Dear Mr. Washburn:

These are the comments of the Minnesota Nurses Association on the cancer surveillance rules. Our concern is merely to assure that nursing research for cancer surveillance be considered authorized research.

In 4606.3307, Authorized Research, Subpart 1 (Criteria), B (2), we request that nursing either be added to this section or that "or related medical research experience" be interpreted to include nursing research.

Please contact us if we can assist you in any way, and thank you for your consideration of our concerns.

Sincerely,

Mary T. Absolon, RN, MSN
Staff Specialist, Governmental Affairs

cc: Sandra Edwardson, PhD, RN
University of Minnesota School of Nursing

MTA:hc

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the
Proposed Adoption of
Rules of the Department
of Health Relating to
Cancer Case Reporting and
Uses of Cancer Case Information
in the State

DECLARATION OF COUNSEL

I, Thomas M. McSteen, Special Assistant Attorney General, do hereby declare that I have examined the above-captioned rules and the supporting rulemaking record and that, based on my examination, the Administrative Procedure Act and Minn. Rules ch. 2010 have been followed. For Attorney General billing purposes, the four-digit docket client code is 1550.

Dated: 6/1, 1988

Thomas M. McSteen

THOMAS M. MCSTEEN
Special Assistant
Attorney General