

**BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH**

**STATE OF MINNESOTA
COUNTY OF HENNEPIN**

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

**STATEMENT OF NEED
AND REASONABLENESS**

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

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

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

This statement demonstrates that the Commissioner has met those requirements.

1. STATUTORY AUTHORITY

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

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

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

Minnesota Statute § 144.671 through 144.69 mandates:

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

2. STATEMENT OF NEED

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

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

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

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

3. COMPLIANCE WITH PROCEDURAL RULEMAKING REQUIREMENTS

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

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

Pursuant of Minnesota Statute § 14.23, the Commissioner has prepared this statement of need and reasonableness which is available to the public. The Commissioner will publish notice of intention to adopt the amended rule without public hearing in the State Register and mail copies of the notice and proposed amended rule to persons registered with the Minnesota Department of Health pursuant to Minnesota Statute § 14.14, Subd. 1. The notice will include the statements:

- a) that the public have 30 days in which to submit comments on the proposed rule;
- b) that no public hearing will be held unless 25 or more persons make a written request for a hearing within the 30 day comment period;
- c) giving information pertaining to the manner in which persons shall request a hearing; and
- d) that the amended rule may be modified if modifications are supported by data and the views submitted.

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

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

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

NonMandatory Actions by the Commissioner

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

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

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

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

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

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

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

4. GENERAL STATEMENT OF REASONABLENESS

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

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

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

5. RULE-BY-RULE JUSTIFICATION

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