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.

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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) <u>The commissioner shall adopt rules to administer the system</u>.

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.

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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.

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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.

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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.