January 26, 2011

Legislative Reference Library
645 State Office Building
100 Constitution Avenue
St. Paul, Minnesota 55155

Re: In The Matter of the Proposed Rules of the State Department of Health Governing the Minnesota Cancer Surveillance System, Governor's Tracking #AR 380

Dear Librarian:

The Minnesota Department of Health intends to amend governing the Minnesota Cancer Surveillance System. We plan to publish a Dual Notice of Intent to Adopt Rules without a Public Hearing in the January 31, 2011 State Register.

The Department has prepared a Statement of Need and Reasonableness. As required by Minnesota Statutes, sections 14.131 and 14.23, the Department is sending the Library an electronic copy of the Statement of Need and Reasonableness at the same time we are mailing our Notice of Intent to Adopt Rules.

If you have questions, please contact me at 651-201-5374.

Yours very truly,

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Minnesota Department of Health

STATEMENT OF NEED AND REASONABLENESS

Proposed Amendment to Rules Governing the Minnesota Cancer Surveillance System, Minnesota Rules Chapter 4606

1. BACKGROUND AND INTRODUCTION

The Minnesota Cancer Surveillance System ("MCSS") is an ongoing program within the Section of Chronic Disease and Environmental Epidemiology at the Minnesota Department of Health ("MDH"). The MCSS systematically collects demographic and diagnostic information on all Minnesota residents with newly diagnosed cancers.

The Minnesota Legislature first acknowledged the need for accurate information about the occurrence of cancer in 1981, when legislation was introduced to establish a statewide cancer surveillance system. In 1987, following a six-year process that included consensus building, methods development, and a feasibility study, Minnesota Statutes, sections 144.671 to 144.69 were adopted, creating this cancer surveillance system. Minnesota Statutes, section 144.671 states the purpose of MCSS:

A. Monitor incidence trends of cancer to detect potential public health problems, predict risks, and assist in investigating cancer clusters;

B. More accurately target intervention resources for communities and patients and their families;

C. Inform health professionals and citizens about risks, early detection, and treatment of cancers known to be elevated in their communities; and

D. Promote high quality research to provide better information for cancer control and to address public concerns and questions about cancer.

MCSS began operations on January 1, 1988. The Commissioner of Health adopted Minnesota Rules, Chapter 4606, on September 12, 1988, and a revised version on April 7, 1997.

At present, MCSS intends to amend six parts of Minnesota Rules: 4606.3300, 4606.3302, 4606.3303, 4606.3304, and 4606.3308, which relate to purpose, definitions, and data collection; and 4606.3306, which relates to case-contact procedures.

Briefly stated, the proposed amendments do the following to reflect scientific advances of the last 15 to 20 years and otherwise bring the Department's rule up to date:

1.1. make Minnesota cancer data more compatible with cancer data from other areas of the U.S. and the world by including information on cases that are diagnosed without microscopic confirmation [affects 4606.3300(A); 4606.3302, subparts 5 and 17; and 4606.3303, subpart 4];

1.2. enable Minnesota to comply more quickly with new national standards for data collection by allowing the Commissioner to bring the list of required data items up to date via *State Register* publication without having to amend the affected Minnesota Rules [affects 4606.3304, subparts 1 and 1a];

1.3. make it possible to describe cancer survival in Minnesota and learn more about the late effects of cancer by acquiring available follow-up information on cancer patients [affects 4606.3300 (A); and 4606.3304, subpart 1];

1.4. specify an additional condition under which MDH may approach longer-term cancer survivors without physician consent [affects 4606.3306, Subpart 2];

1.5. clarify that no *in situ* neoplasm of the uterine cervix is defined as "cancer" [affects 4606.3302, subpart 3]; and

1.6. revise obsolete or unclear terminology [affects 4606.3302, subparts 1, 4-9, 16, and 18; 4606.3303, subparts 1 and 5; and 4606.3308, subpart 2].

To draft these amendments, MDH has consulted with the MCSS Advisory Group, reviewed other state cancer registries' reporting rules, and incorporated public responses to the published Request for Comments.

2. ALTERNATIVE FORMAT

Upon request, MDH will make this Statement of Need and Reasonableness available in an alternative format such as large print, Braille, or cassette tape. To make a request, please contact the MCSS at 651-201-5900. Deaf, hard of hearing, or speech-disabled persons may call Minnesota Relay Service (MRS) at 7-1-1.

3. DEPARTMENT'S STATUTORY AUTHORITY

The Department's statutory authority to adopt or amend rules for the MCSS appears in Minnesota Statutes, section 144.672 (2008), which requires the Commissioner to adopt rules to administer the MCSS, collect information, and distribute data.

Under this statute, the Department has the necessary statutory authority to adopt the proposed rules. This rulemaking is an amendment of rules for which the Legislature has not changed the statutory authority since 1995 and so Minnesota Statutes, section 14.125, does not apply.

4. REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, requires that an agency, through reasonable efforts, include information about several regulatory factors. The required factors are listed below with MCSS's respective response.

4.1. ***A description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.***

Under current rule, Minnesota laboratories, hospitals, and physicians report microscopically confirmed cancer cases. The proposed amendments expand reporting to cases that are diagnosed solely by clinical or radiologic means, which likely represent approximately four percent*, overall, of cancer cases in the state – about 1,000 cases per year, based on data from 2007 and 2008. The percent varies by cancer type, from less than one percent for skin melanomas to 17 percent for pancreatic cancer, to nearly 30% for cancers of the brain and eye. The type of data collected is also expanded to include available follow-up information. The existing rules reflect the 1981 Technical Advisory Committee's recommendation, "The surveillance system must be based primarily upon diagnoses that have been microscopically confirmed as cancer." The 1981 committee emphasized efficiency and considered non-microscopically confirmed cancer diagnoses as doubtful. Although some doubt remains with respect to the accuracy of cancer diagnoses made without tissue confirmation, the ability to diagnose certain cancers using only radiologic and clinical pathology methods has advanced since the early 1980's.

Hospitals that do not have a cancer registry would be affected because they will need to submit electronic files containing discharge diagnoses or uniform billing data to MDH. Physicians who diagnose and treat cancer patients outside of hospital settings would also be affected because they will need to initiate cancer reports when no diagnostic specimen was submitted to a laboratory that reports to MCSS. Hospitals that have a cancer registry would be affected because they will need to report cancer cases diagnosed without microscopic confirmation and include follow-up information on all their reported cases (the registries already collect these data for their own purposes).

* Based on data from SEER system, 2003-2007 data

Since the State would improve its ability to monitor cancer, all Minnesotans will indirectly benefit from this rule change. Persons who, because of economic, cultural, or other reasons, forego physician visits until their cancer is too advanced to treat, are more likely to receive a clinically or radiologically based diagnosis. The proposed rule change would benefit them because MDH could describe treatment disparities and target cancer control programs more accurately. In addition, the changes would make MDH's cancer registry data more directly comparable with cancer data collected by all other cancer registries in the United States (and the world). Thus Minnesotans would better know how the state's cancer rates and survival compare with those of other areas.

4.2. ***The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.***

The proposed change to the case report definition would increase costs to the Minnesota Department of Health by expanding the sorts of cancer diagnoses that the Department will track. MCSS has estimated that the additional, ongoing work to collect non-microscopically confirmed cancers will require approximately 1.25 FTE's ($80,000 per year). The Department has secured federal funds, through the Centers for Disease Control and Prevention's National Program of Cancer Registries (CDC's NPCR), to support this activity. MCSS will need to develop software to manage the receipt and linkage of discharge data, as well as methods to identify possible new cases for follow-up by MCSS Field Operations staff. The existing MCSS development team will absorb the software-development costs.

Changing the method by which the Commissioner notifies reporting entities of the required data items will reduce costs to MDH because it is less expensive to publish a notice in the *State Register* than it is to modify rules.

All other proposed changes will not affect the agency's costs for running the Minnesota

Cancer Surveillance System. None of the proposed changes will affect costs to other agencies, and none of the changes will have any effect on state revenues.

4.3. ***A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.***

Case report definition: The MCSS could theoretically collect just those clinically diagnosed cancers that are either identified by death certificate review or reported by hospital-based registries. This would reduce the costs of collecting the information. The purpose of the proposed rule, however, would not be achieved because the resulting information would not be representative of all Minnesotans with a non-microscopically confirmed cancer diagnosis.

Specify required data items by publication in State Register: Because the proposed rule enables the Commissioner to keep the list of required data items more consistent with those of the national standard setters, the proposed change is the least-cost alternative. Requiring the registries to continue to comply with outdated standards, and continuing to enforce rules not in accord with changing national standards would be more costly because these practices waste resources.

Follow-up information: Because the rule does not require facilities to report information they do not have, and because hospital-based cancer registries already collect this information as required by their certifying entity (ACoS), no less costly alternative would accomplish the purpose of facilitating survival analyses and contact of long-term cancer survivors.

Additional conditions under which cases may be approached without physician consent: The less costly way to contact patients would be not to require physician consent at all. This, however, would be contrary to Minnesota Statutes, section 144.69, and potentially more troublesome to some of the patients who might be affronted at this intrusion on their privacy.

Cease collection of all in situ *neoplasms of uterine cervix:* By no longer collecting this

information, we are eliminating all possible costs and intrusions.

Update terminology: Since this is a no-cost change, there is no less costly method.

4.4. ***A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.***

There simply are not very many ways to accomplish the needed changes. For each of the proposed changes, the only alternative method seriously considered was to forego changing the rules at all. If the rules are left without change, then MDH will not be able to run an effective program and will be out of compliance with national standards.

4.5. ***The probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals.***

Hospitals that do not have their own cancer registry will bear some costs associated with the collection of non-microscopically confirmed cancers. The implementation plan, however, should minimize those costs. MCSS plans to screen electronic billing or discharge data files submitted by these hospitals for diagnosis codes that indicate cancer. MCSS would then electronically link those records with reports received from pathology laboratories and hospital registries. For the possible cancer diagnoses not reported by some other source, MDH staff would request and review medical records at the hospital to verify the diagnosis and collect the required data items. Non-registry hospitals, therefore, would need to create and submit files that contain patient identifiers and diagnosis codes. Their computer systems most likely already create these types of files, which will function for this purpose either "as is" or after a few modifications. The cost for modifications, if needed, would depend on the level of in-house computer support and might be as much as $5,000. The other proposed changes would not affect

the costs of non-registry hospitals because facilities are not required to report information they do not have, such as follow-up information.

Physicians who diagnose or treat a clinically diagnosed cancer patient not seen in a hospital will also bear a portion of the costs of implementation. Their costs would be the time required to complete a 1- or 2-page reporting form (either on paper or on-line) and submit it to MCSS. If one assumes a physician's time costs $125 to $175 per hour and that the form would take 20 minutes to an hour to complete, the cost would be $42 to $175 per non-microscopically confirmed case. Physicians would need to initiate these reports only for patients who are not being seen at a hospital and for whom no diagnostic pathology report has been submitted to MCSS. The total cost for any given physician, which would be in the form of non-revenue producing work, will depend on the volume of such cases he or she sees. With the proposed additional condition under which MDH could contact cancer patients without physician consent, MDH might collaborate in more research on cancer outcomes, so some physicians might receive more requests for permission to contact a patient. The physicians' cost would depend on how many of their patients were eligible for a study, and how long it took the physicians to decide whether each patient should be contacted or deduce that the patient has transferred care to another physician. The cost would be mainly in the form of unbillable time.

Hospitals that have their own cancer registry would most likely experience very little change in costs for complying with the revised cancer reporting rules. Costs might decrease for complying with more up-to-date rules, since registrars would not need to apply two sets of standards (the outmoded MDH standard and the national ones) to each cancer case. Costs might decrease proportionate with the number of *in situ* cervical neoplasms currently reported to MDH, but since MCSS has stopped enforcing that portion of the rule, the number would be very small. If a hospital registry increases its diligence in identifying and abstracting non-microscopically

confirmed cancers because of the proposed rule change, its costs would increase concomitant with the increased number of cases abstracted (approximately $130 per case[†]). Hospital registries already collect follow-up information and would incur costs *only* if their registry software vendor required payment to begin including that information in the submissions to MDH. This is unlikely because all vendors with clients in Minnesota provide updates needed to meet state reporting standards as part of their maintenance agreements, and none of those vendors are located in Minnesota.

The proposed rule change would not affect the costs of pathology laboratories because they provide narrative information to the MCSS, which MCSS staff subsequently code.

4.6. ***The probable costs or consequences of not adopting the proposed rules, including those borne by identifiable categories of affected parties.***

If these proposed rules are not adopted, the continued exclusion of non-microscopically confirmed cancer cases would perpetuate anomalies in the data caused by their exclusion. For example, the data would continue to show that more people die of pancreatic cancer than develop it. MDH would still not be able to respond to citizens' concerns about cancer types, such as many brain tumors, that are often diagnosed by radiology alone. Furthermore, because the federal funding agency requires collection of non-microscopically confirmed cancer cases, MDH runs the risk losing its funding.

Without the proposed rules, MDH's ability to describe cancer survival in Minnesotans will still be limited. MDH will not be able to give Minnesotans an opportunity to participate in cancer survivorship studies. MDH would continue to operate far less effectively than it should. Reporting entities would waste time and effort supplying data that would not produce useful results. Thus, the waste of resources, both public and private, in having outdated reporting

[†] Based on budget and caseload information received in 1995 from 5 Minnesota registries, adjusted to 2010 dollars

requirements is self-evident.

4.7. ***An assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.***

There are no existing federal regulations that govern cancer reporting. There are federal standards, however, that are required for states receiving federal funds for cancer registration. In all instances, the proposed rule brings Minnesota's practice into conformance with these required federal standards.

5. PERFORMANCE-BASED RULES

When developing rules, Minnesota Statutes, section 14.002 requires an agency to emphasize superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals. Minnesota Statutes, section 14.131 requires an agency to describe in its Statement of Need and Reasonableness how it considered and implemented the policy in section 14.002.

The proposed rule, by specifying national standards as a reference for cancer reporting, emphasizes superior achievement in meeting the agency's objective of having complete, timely, and high quality data on cancer. Flexibility for the regulated party is provided as follows: First, MDH accepts reports on a variety of media. Second, reporting facilities are not required to submit information they do not have. Finally, MCSS will work with hospitals without a cancer registry to identify the least difficult method by which they can submit their files of identifiers and diagnosis codes.

6. ADDITIONAL NOTICE

In addition to the notice in the *State Register*, MDH will send a letter with a copy of the

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(44.2% inflation).

proposed rules and instructions on how to obtain a copy of this SONAR to the following groups:

6.1. By first-class mail –

6.1.1. designated contact persons at each facility that submits reports to the MCSS

6.1.2. associations representing professionals likely to be affected by the proposed changes:

6.1.2.1. Minnesota Medical Society

6.1.2.2. Minnesota Cancer Registrars Association

6.1.2.3. Minnesota Society of Pathologists

6.1.2.4. Minnesota Health Information Management Association

6.1.2.5. Minnesota Hospital Association

6.1.3. physicians to whom MCSS has, within the past year, sent a letter asking for more information about a specific cancer patient

6.1.4. individuals who replied to the Request for Comments by first-class mail

6.1.5. everyone who has registered to be on the Department's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a

6.1.6. the Legislature per Minnesota Statutes, section 14.116

6.2. By email –

6.2.1. pathologists, via the listserve of the Minnesota Society for Pathology (MSP)

6.2.2. physicians who are members of the Minnesota Medical Association (MMA), via the MMA's listserve

6.2.3. cancer registrars, via the Minnesota Cancer Registrars Association (MCRA) listserve

6.2.4. MDH staff in cancer control

6.2.5. members of the MCSS Advisory Group and MCSS Peer Review Committee

6.2.6. cancer epidemiology faculty at the University of Minnesota and Mayo Clinic

6.2.7. individuals who replied to the Request for Comments by email

6.3. Our Notice Plan does not include notifying the Commissioner of Agriculture because the rules do not affect farming operations per Minnesota Statutes, section 14.111.

6.4. These rules affect all Minnesotans equally, and therefore, do not have a primary affect on Chicano/Latino people. Thus, Minnesota Statutes, section 3.9223 does not apply.

7. CONSULTATION WITH MMB ON LOCAL GOVERNMENT IMPACT

As required by Minnesota Statutes, section 14.131, the Department will consult with the Minnesota Management and Budget (MMB). We will do this by sending the MMB copies of the documents that we send to the Governor's Office for review and approval on the same day we send them to the Governor's office. We will do this before the Department's publishing the Notice of Intent to Adopt. The documents will include: the Governor's Office Proposed Rule and SONAR Form; the proposed rules; and the SONAR. The Department will submit a copy of the cover correspondence and any response received from Minnesota Management and Budget to OAH at the hearing or with the documents it submits for ALJ review.

8. DETERMINATION ABOUT RULES REQUIRING LOCAL IMPLEMENTATION

The Department has considered the requirements of Minnesota Statutes, section 14.128, which requires that "an agency must determine if a local government will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule," Subdivision 1. These rules amend MDH's specific public health program that supports research. All data collection functions are performed within the Department of Health and do not require local government enforcement.

Furthermore, the affected parties are hospitals, clinics, and physicians. These parties are

almost exclusively either individuals or privately owned entities. While there are or could be publicly owned hospitals and clinics who might report cancer data to MDH, local units of government do not have an active role in this system. During the rulemaking process, the Department received no comments that suggested that the rule would affect local governments so that they would be required to adopt or amend any ordinance or other regulation.

9. COST OF COMPLYING FOR SMALL BUSINESS OR CITY

The Department has also considered the requirements of Minnesota Statutes, section 14.127, which requires an "agency to determine if the cost of complying with proposed rules in the first year after the rules take effect will exceed $25,000 for any small business or small city." Small cities will have no costs for complying with the proposed rules because none of them owns a hospital or pathology laboratory. Small businesses affected by the proposed rule would most likely be independent clinics with one or two physicians or dentists. Their first-year costs would exceed $25,000 only if the practice diagnosed at least 625 cancer cases without microscopic confirmation, an extremely unlikely occurrence.

10. OTHER REQUIRED INFORMATION

Minnesota Rules, Pat 1400.2070, subpart 2, item B, states that the SONAR must include information required by any other law or rule . . . or which the agency is required by law or rule to consider in adopting a rule. The MCSS submits that no other information is required in support of the proposed amendments to the MCSS Rules.

11. LIST OF WITNESSES

If a hearing is held, MCSS anticipates calling the following witnesses:

Sally Bushhouse, D.V.M., M.P.H., Ph.D., MCSS Director

James Cerhan, M.D., Ph.D., Mayo Clinic

12. RULE-BY-RULE ANALYSIS

MCSS justified its need for rules when it adopted them in 1988. MCSS, in its twenty-second year of operation, is meeting its objectives of:

(1) Responding to public concerns and questions about cancer;

(2) Monitoring incidence trends;

(3) Promoting high quality research;

(4) Developing and targeting cancer control resources; and

(5) Educating health professionals and citizens.

These amendments accomplish four objectives, all of which are explained more fully below:

(1) Broadening surveillance by requiring the reporting of cancers diagnosed in ways other than by microscopic confirmation;

(2) Reflecting terminology and technology changes that have occurred since the MCSS rules were written in 1988;

(3) Adding a mechanism so that the MCSS can modify its data collection to keep pace with the national standard setters by simply publishing changes in the *State Register* and on the MCSS web site; and

(4) Adding a condition that allows MCSS to contact a cancer survivor without obtaining consent from the person's physician when the person becomes eligible for a study.

12.1. *Proposed Amendments to Minnesota Rules Parts 4606.3300(A); 4606.3302, subparts 5 and 17; and 4606.3303, subpart 4*

Current rule limits data collection to those cancers diagnosed by examining tissue. The proposed amendments would require the reporting of cancers diagnosed by other means. To accomplish this objective, the Department has deleted text limiting data collection to that from

pathology reports. In 4606.3300(A), the phrase, "pathology laboratory reports and other demographic data" is deleted. In 4606.3302, subp.5, the definition of a "Case report" is changed to "a complete report of a diagnosis of cancer *made by a physician or dentist*," instead of "... generated as a result of examination of ... *a pathology, cytology, hematology, biopsy, surgical, or autopsy specimen*." In 4606.3302, subp. 17, the definition of "Source documents" is changed to specify the "portion(s) of a medical record, including pathology reports," instead of just "pathology reports...." Finally, 4606.3303, subp. 4 is split into two parts; Part A requires all physicians and dentists, not just those who examine tissue specimens, to report the cancers they diagnose. Part B exempts physicians and dentists from the requirement to report cancers that they know have been reported to MCSS through another mechanism.

At present, Minnesota's cancer registry is the only one in the world that does not collect clinically diagnosed cancers. Consequently, the state is unable to address possible clusters of cancer types that are often or usually diagnosed without microscopic confirmation. (For example, recently MDH could not accurately assess the occurrence of a certain type of pediatric brain tumor because those tumors are usually diagnosed using radiology alone). The increasing accuracy of radiology for cancer diagnosis means that MCSS must accept these diagnoses to fulfill its mission. Furthermore, without these additional diagnoses, Minnesota cancer data are also not truly comparable to the data collected by any other cancer registry, producing cancer rates that might appear falsely lower than those of other areas. Furthermore, if a person's culture, age, income, or insurance status decreases the likelihood that a biopsy is taken, some individuals will be excluded from the state's cancer statistics, making it more difficult to identify demographic disparities. Finally, the NPCR requires its funded states, including Minnesota, to collect information on all cancers, regardless of the diagnosis method. For all these reasons, collecting data on clinically diagnosed cancers is imperative.

The consequences of collecting clinically-diagnosed-cancer data, however, are added costs for searching additional data sources to identify all reportable cancers. Fortunately, the CDC, through an NPCR cooperative agreement, has funded additional MCSS positions to do this extra work. MDH designed MCSS' implementation plan to be flexible and impose minimal additional costs on facilities for complying with the new requirement. In most instances, hospitals, physicians, and dentists will not need to submit paper documents because one of three events will occur: another facility will report the case with microscopic confirmation, the physician will complete an on-line form, or an MCSS staff member will visit the hospital to complete the information.

12.2. ***Proposed Amendment to Minnesota Rules 4606, Part 3302, Subpart 3.A (2)***

At present, the rules include collecting data on *in situ* neoplasms of the uterine cervix when the *in situ* cells are not of the type, "squamous cell carcinoma." A 1997 rule amendment eliminated collection of the latter type of *in situ* neoplasm. The current rule amendment reflects the fact that MCSS no longer collects the remaining cell types because the nomenclature used to describe these lesions has changed over time, making analysis of the data not meaningful. This is consistent with the requirements of the national standard setters (NPCR; the American College of Surgeons' Commission on Cancer; the National Cancer Institute's Surveillance, Epidemiology, and End Results [SEER] system; and the North American Association of Central Cancer Registries [NAACCR]). Since the requirement is obsolete, the term "cancer" now excludes all *in situ* neoplasms of the uterine cervix.

12.3. ***Proposed Amendment to Minnesota Rules Part 4606.3302, Subparts 1, 4-9, 16, and 18; 4606.3303, Subparts 1 and 5; and 4606.3308, Subpart 2***

MCSS rules were written in 1988, when most transactions were paper-based, electronic data transmission was new, and cancer registries were referred to as "tumor registries." At

present, the term, "electronic data" is in such common usage that it no longer needs a specific definition, and stating that the patient's *record*, not the patient, is contained in a cancer registry is more accurate. Obviously, terminology and technology have evolved since 1988 and making these changes is self-explanatory.

12.4. ***Proposed Amendments to Minnesota Rules Parts 4606.3300 A, and 4606.3304, Subparts 1, 1a, and 1b***

The proposed amendments to 4606.3304 move the information that providers must supply for every case report from the current list of very specific data items to a list of general types of information. The amendments also add administrative flexibility and efficiency by allowing MCSS to bring data submission requirements up to date by publishing changes in the *State Register* and the MCSS web site. Examples of the categories of information are the following: patient identifiers and demographics, provider and facility information, cancer diagnostic information, extent of disease and other prognostic information, first course of cancer-directed treatment, follow-up information, and information necessary for system administration. Furthermore, this amendment and the addition of the text "... and outcomes" to 4606.3300 A (Purpose), would require reporting entities to report the follow-up information that they are already collecting.

The national standard setters (Commission on Cancer, SEER, NPCR, and NAACCR) modify their data collection standards annually to ensure that the collected data remains useful for assessing progress in cancer diagnosis and treatment. Without this proposed flexibility, keeping MDH's list of required data items current would require a formal rule amendment nearly every year.

MCSS has retained the patient's social security number as a required data item because it is the best way to assure the vitally important accuracy needed in de-duplicating cancer reports

so that each cancer case is counted only once in Minnesota incidence data (MCSS receives, on average, approximately 1.7 reports per cancer case). NPCR also requires the collection of the social security number. Subparts 1a and 1b clarify how the commissioner will keep MDH standards in step with national standards and provide the "universe" from which data items will be selected without a formal rule change.

MCSS has existed for over 20 years, but to date, we do not know how cancer survival in Minnesota compares to the nation as a whole because MDH has not had the data necessary to calculate valid survival statistics. These calculations would be much more meaningful with the addition of the follow-up data that hospital registries already collect. Furthermore, MCSS has had to decline participation in studies involving long-term cancer survivors partly because it has not had cases' current contact information. Adding the follow-up data would make MDH's participation in survivorship studies more feasible.

The proposed method for updating the list of required data items matches the practices of many other states. Hospital registries are already required to collect follow-up information by their certifying authority (ACoS), so these changes will not further burden them. Other reporting entities, which do not collect follow-up information, will not be required to report information they do not have. Using national standards reduces the workload both for MDH, because MDH need not develop the entire data dictionary in-house, and for facility-based cancer registries, because they already adhere to most of the national standards. Definitions and standards for the data items specific to pathology laboratories are included in NAACCR Standards, Volume V (4606.3304, Subp. 1b. (A)).

12.5. ***Proposed Amendment to Minnesota Rules Part 4606.3306, Subpart 2***

MDH has not been able to participate in studies involving long-term cancer survivors, partly because of the current constraint of having to acquire their physicians' consent to contact

them. The existing rule does not specify what to do when a person becomes eligible for a study, but the physician named in the report no longer has knowledge about the person's health or cancer status and cannot identify another physician who does. The proposed amendment addresses this need, which becomes more apparent and common as more time elapses. Under the proposed modification, the Commissioner could contact a person, or a relative of a deceased person, directly if the physician named in the case report(s) received around the time of diagnosis is no longer caring for the patient and cannot direct the Commissioner to the patient's current attending physician.

The vast majority of cancer patients welcome the opportunity to participate in studies that will increase knowledge about cancer causes and outcomes, because they want their experience to benefit someone in the future. They realize that their treatments would be much less effective without past cancer patients' willingness to participate in research

13. LIST OF EXHIBITS

In support of the need for and reasonableness of the proposed rule amendments, the Department anticipates receiving statements of support from the following: 1. letter of support from Minnesota Cancer Registrars Association

2. letter of support from the director of the University of Minnesota Comprehensive Cancer Center

3. letter of support from the director of the Mayo Clinic Comprehensive Cancer Center

4. letter of support from the Minnesota Medical Association

14. CONCLUSION

Based on the foregoing, the proposed rule amendments are both needed and reasonable.

1-20-11 Jeanne M. Danaher

Date Jeanne Danaher, Deputy Commissioner of Health