

STATE OF MINNESOTA  
OFFICE OF ADMINISTRATIVE HEARINGS  
FOR THE DEPARTMENT HEALTH

In the Matter of the Proposed  
Amendments to Rules of the  
Department of Health Governing the  
Minnesota Cancer Surveillance System,  
Minnesota Rules, Chapter 4606

**REPORT OF THE  
ADMINISTRATIVE LAW JUDGE**

Administrative Law Judge (ALJ) Manuel J. Cervantes conducted a hearing concerning the above rules on the morning of March 17, 2011, at the Minnesota Department of Health, Freeman Building, 625 Robert Street North, Saint Paul, Minnesota. The hearing continued until all interested persons, groups, and associations had an opportunity to be heard concerning the proposed rules.

The Hearing and this Report are part of a rulemaking process governed by the Minnesota Administrative Procedure Act.<sup>1</sup> The legislature has designed the rulemaking process to ensure that state agencies have met all of the requirements that Minnesota law specifies for adopting rules. Those requirements include assurances that the proposed rules are necessary and reasonable, that they are within the agency's statutory authority, and that any modifications that the agency may have made after the proposed rules were initially published are not impermissible substantial changes.

The rulemaking process includes a hearing when a sufficient number of persons request that a hearing be held. The hearing is intended to allow the agency and the Administrative Law Judge reviewing the proposed rules to hear public comment regarding the impact of the proposed rules and what changes might be appropriate. The Administrative Law Judge is employed by the Office of Administrative Hearings, an agency independent of the Department.

Patricia Winget, Attorney for the Department of Health (Department or Agency), and Dr. Sally Bushhouse, Director of the Department's Minnesota Cancer Surveillance System (MCSS), appeared at the rule hearing on behalf of the Department.

Approximately 14 people signed the hearing register and six interested persons spoke at the hearing. The proceedings continued until all interested persons, groups or associations had an opportunity to be heard concerning the proposed amendments to these rules.

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<sup>1</sup> Minn. Stat. §§ 14.131 through 14.20 (2010).

After the hearing ended, the record remained open until March 24, 2011, to allow interested persons and the Department an opportunity to submit written comments. Following the initial comment period, the record remained open for an additional five working days to allow interested persons and the Department the opportunity to file a written response to the comments submitted. The OAH hearing record closed on March 31, 2011. All of the comments received were read and considered.

## **SUMMARY OF CONCLUSIONS**

The Department has established that it has the statutory authority to adopt the proposed rules and that the proposed rules are necessary and reasonable.

Based on the testimony, exhibits and written comments, the Administrative Law Judge makes the following:

## **FINDINGS OF FACT**

### **Nature of the Proposed Rules**

1. The Minnesota Cancer Surveillance System (MCSS) is a program within the Minnesota Department of Health's Section of Chronic Disease and Environmental Epidemiology that was authorized by the Legislature in 1987.<sup>2</sup> The purpose of the MCSS is to monitor incidence trends of cancer and predict risk to public health; target intervention resources for communities; inform health professionals and citizens about risks, early detection, and treatment of cancers that are occurring in their communities; and promote high quality research.<sup>3</sup>

2. Every state in the United States has a similar law and collects data similar to MCSS. MCSS serves as a resource for education and research. By studying the data in the MCSS, the Department can identify population-based patterns in how and where cancers are appearing in Minnesota.<sup>4</sup>

3. The Department first adopted rules regarding the MCSS in 1988, which are codified in Chapter 4606 of the *Minnesota Rules*.<sup>5</sup> In this rulemaking, the Department seeks to update the rules to reflect the scientific advances that have occurred in the last 15 to 20 years, and proposes modifications in the following areas:

- To make Minnesota cancer data more compatible with cancer data from other areas of the United States and the world by including information on cases that are diagnosed without microscopic confirmation;
- To enable Minnesota to comply with new national standards for data collection by allowing the Commissioner to update the list of required data items via

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<sup>2</sup> Statement of Need and Reasonableness (SONAR) at 1. See, Minn. Stat. § 144.671 to 144.69.

<sup>3</sup> Minn. Stat. § 144.671 (2010).

<sup>4</sup> Tr. at 13-14, 16 (Sally Bushhouse); 22 (James Cerhan).

<sup>5</sup> The Department amended Chapter 4606 in 1997. See, SONAR at 2.

publication in the *State Register* without having to amend Minnesota Rules through a formal rulemaking process;

- To obtain follow-up information on cancer patients to better describe cancer survival and effects of cancer in Minnesota;
- To specify an additional instance when the Department may approach long-term cancer survivors without physician consent (i.e. when a physician is no longer caring for the case and is unable to identify the individual's current attending physician);
- To clarify that no *in situ* neoplasm of the uterine cervix is defined as "cancer;" and
- To revise obsolete or unclear terminology.

4. The proposed amendments have received written support from the Minnesota Medical Association, the Mayo Clinic Cancer Registry, the Masonic Cancer Center of the University of Minnesota, and the Executive Committee of the Minnesota Cancer Registrars Association.<sup>6</sup>

### **Rulemaking Legal Standards**

5. Under Minn. Stat. § 14.14, subd. 2, and Minn. Rule 1400.2100, a determination must be made in a rulemaking proceeding as to whether the agency has established the need for and reasonableness of the proposed rule by an affirmative presentation of facts. In support of a rule, an agency may rely upon legislative facts, namely general facts concerning questions of law, policy and discretion, or it may simply rely upon interpretation of a statute, or stated policy preferences.<sup>7</sup> The Department prepared a Statement of Need and Reasonableness (SONAR) in support of the proposed rules. At the hearing, the Department primarily relied upon the SONAR as its affirmative presentation of need and reasonableness for the proposed rule. The SONAR was supplemented by comments made by Department representatives at the public hearing and in written post-hearing submissions.

6. The question of whether a rule has been shown to be reasonable focuses on whether it has been shown to have a rational basis, or whether it is arbitrary, based upon the rulemaking record. Minnesota case law has equated an unreasonable rule with an arbitrary rule.<sup>8</sup> Arbitrary or unreasonable agency action is action without consideration and in disregard of the facts and circumstances of the case.<sup>9</sup> A rule is

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<sup>6</sup> Ex. 11b.

<sup>7</sup> *Mammenga v. Department of Human Services*, 442 N.W.2d 786 (Minn. 1989); *Manufactured Housing Institute v. Petterson*, 347 N.W.2d 238, 244 (Minn. 1984).

<sup>8</sup> *In re Hanson*, 275 N.W.2d 790 (Minn. 1978); *Hurley v. Chaffee*, 231 Minn. 362, 367, 43 N.W.2d 281, 284 (1950).

<sup>9</sup> *Greenhill v. Bailey*, 519 F.2d 5, 19 (8<sup>th</sup> Cir. 1975).

generally found to be reasonable if it is rationally related to the end sought to be achieved by the governing statute.<sup>10</sup>

7. The Minnesota Supreme Court has further defined an agency's burden in adopting rules by requiring it to "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken."<sup>11</sup> An agency is entitled to make choices between possible approaches as long as the choice made is rational. Generally, it is not the proper role of the Administrative Law Judge to determine which policy alternative presents the "best" approach since this would invade the policy-making discretion of the agency. The question is rather whether the choice made by the agency is one that a rational person could have made.<sup>12</sup>

8. In addition to need and reasonableness, the Administrative Law Judge must also assess whether the rule adoption procedure was complied with, whether the rule grants undue discretion, whether the Agency has statutory authority to adopt the rule, whether the rule is unconstitutional or illegal, whether the rule constitutes an undue delegation of authority to another entity, or whether the proposed language is not a rule.<sup>13</sup>

#### **Procedural Requirements of Chapter 14**

9. On September 7, 2010, the Department published in the *State Register* a Request for Comments on the proposed rules. The Request for Comments was published at 35 S.R. 396.<sup>14</sup>

10. By letter dated January 20, 2011, the Department asked the Commissioner of Minnesota Management and Budget (MMB) to evaluate the fiscal impact and benefit of the proposed rules on local units of government.<sup>15</sup> The Department received no response from MMB.

11. By letter dated January 5, 2011, the Department requested that the Office of Administrative Hearings schedule a hearing on the proposed rules and assign an Administrative Law Judge. Along with the letter, the Agency filed a proposed Dual Notice, a copy of the proposed rules, and a draft of the Statement of Need and Reasonableness (SONAR). The agency also requested that the Office of Administrative Hearings give prior approval of its Additional Notice Plan.

12. Administrative Law Judge Manuel J. Cervantes was assigned to the rule hearing. In a letter dated January 12, 2011, Judge Cervantes approved the Department's Dual Notice, as modified, and Additional Notice Plan.

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<sup>10</sup> *Mammenga*, 442 N.W.2d at 789-90; *Broen Memorial Home v. Department of Human Services*, 364 N.W.2d 436, 444 (Minn. Ct. App. 1985).

<sup>11</sup> *Manufactured Housing Institute*, 347 N.W.2d at 244.

<sup>12</sup> *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, 233 (1943).

<sup>13</sup> Minn. R. 1400.2100.

<sup>14</sup> Ex. 1.

<sup>15</sup> Ex. 11a; Minn. Stat. § 14.131.

13. On January 24, 2011, the Department mailed copies of the Dual Notice and proposed rules to the Chairs of the Senate Health and Human Services Budget Committee, House Health Care and Human Services Reform Committee, and the House Health Care and Human Services Finance Committee. On the same date, the Department also mailed copies of the Dual Notice and proposed rules to the Director of the Legislative Coordinating Commission and Chairs of several other legislative committees.<sup>16</sup>

14. On January 24, 2011, the Department mailed a copy of the Dual Notice and the proposed rules to all interested parties on its rulemaking mailing list.<sup>17</sup>

15. Between January 24 and 26, 2011, the Department mailed via U.S. mail or electronic mail a copy of the Dual Notice and proposed rules to all persons identified in the Additional Notice Plan.<sup>18</sup>

16. On January 26, 2011, the Department electronically mailed a copy of the SONAR to the Legislative Reference Library as required by law.<sup>19</sup>

17. On January 31, 2011, a copy of the Dual Notice and proposed rules was published in the *State Register* at 35 S.R. 1156.<sup>20</sup>

18. On the day of the hearing the Department placed the following documents in the record:

- The Request for Comments on Possible Amendment to Rules Governing the Minnesota Cancer Surveillance System, published in the *State Register* on September 7, 2010, at 35 SR 396. (Ex. 1);
- A copy of the proposed rules with Revisor's approval, dated August 5, 2010 (Ex. 3);
- The Statement of Need and Reasonableness (SONAR) (Ex. 4);
- A copy of the transmittal letter and a Certificate of Mailing the SONAR to the Legislative Reference Library on January 26, 2011 (Ex. 5);
- A copy of the Dual Notice as mailed and as published in the *State Register* 35 S.R. 1156 (Ex. 6a and 6b);
- Certificate of Mailing the Dual Notice to the Rulemaking Mailing List on January 24, 2011, and Certificate of Accuracy of the Mailing List (Ex. 7a and 7b);

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<sup>16</sup> Ex. 11d. See Minn. Stat. § 14.116.

<sup>17</sup> Ex. 7a.

<sup>18</sup> Ex. 8.

<sup>19</sup> Ex. 5.

<sup>20</sup> Ex. 6b.

- Certificate of Mailing the Dual Notice to individuals and organizations pursuant to the Additional Notice Plan between January 24 and 26, 2011 (Ex. 8);<sup>21</sup>
- Written public comments in support of and in opposition to the proposed rules received during the public comment period (Ex. 9a and 9b);
- Letter to MMB dated January 20, 2011, regarding fiscal impact of proposed rules (Ex. 11a);
- Letters in support of proposed rules from the Minnesota Medical Association, the Mayo Clinic Cancer Registry, the University of Minnesota Masonic Cancer Center, and the Minnesota Cancer Registrars Association (Ex. 11b);
- Email sent to those who requested a hearing, stating that the hearing would take place as scheduled in the Dual Notice (Ex. 11c); and
- Certificate of Mailing the Dual Notice and the SONAR to Legislators on January 24, 2011 (Ex. 11d).<sup>22</sup>

19. The Agency's responses and written comments from Citizens Council for Health Freedom (CCHF), received after the hearing, were also placed in the record.

20. Under Minn. Stat. § 14.116, an agency is required to give notice of proposed rules to both the chairs *and* the ranking minority members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules. Here, the Department certified that it provided proper notice to the chairs of those committees, but did not provide any evidence that it gave notice to the ranking minority members. The Department's failure to provide notice of the proposed rules to the ranking minority members constitutes a procedural defect in these rules.

21. The ALJ requested an extension to complete his report so that the Department could cure the procedural defect. The Chief ALJ granted the request by Order dated May 2, 2011. The Order required the Department to provide the Dual Notice, proposed rules, and SONAR to the ranking minority members of the appropriate committees, and re-open a 30-day comment period for these legislators. The Order further required the Department to provide to the ALJ, by June 7, 2011, evidence that it complied with the notice requirement, copies of any comment received from the legislators, and any responses made by the Department to those legislators.

22. A procedural defect can be considered a harmless error under Minn. Stat. § 14.15, subd. 5, if: "(1) the failure did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process; or (2) the agency has taken

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<sup>21</sup> This document was erroneously entitled "Certificate of Mailing the Request for Comments."

<sup>22</sup> This rulemaking was not initiated in response to a Petition for Rulemaking (Ex. 2), and the Department did not seek permission to omit the text of the proposed rules from publication in the *State Register* (Ex. 10).

corrective action to cure the error or defect so that the failure did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process.”

23. Under the circumstances, the Administrative Law Judge concludes that the Department has taken corrective action to cure the defect. Accordingly, this error is harmless under Minn. Stat. § 14.15, subd. 5 (2).

### **Additional Notice**

24. Minnesota Statutes §§ 14.131 and 14.23, require that the SONAR contain a description of the Agency’s efforts to provide additional notice to persons who may be affected by the proposed rules. The Agency submitted an additional notice plan to the Office of Administrative Hearings, which reviewed and approved it by letter dated January 12, 2011. In addition to notifying those persons on the Agency’s rulemaking mailing list for these proposed rules, the Agency represented that it would mail or electronically mail the Dual Notice to:

- Designated contact persons at each facility that submits reports to the MCSS;
- Minnesota Medical Society;
- Minnesota Cancer Registrars Association;
- Minnesota Society of Pathologists;
- Minnesota Health Information Management Association;
- Minnesota Hospital Association;
- Physicians to whom MCSS has, within the past year, sent a letter asking for more information about a specific cancer patient;
- Individuals who replied to the Request for Comments;
- Pathologists, via the listserve of the Minnesota Society for Pathology (MSP);
- Physicians who are members of the Minnesota Medical Association (MMA), via the MMA’s listserve;
- Cancer registrars, via the Minnesota Cancer Registrars Association (MCRA) listserve;
- Department staff in cancer control;
- Members of the MCSS Advisory Group and MCSS Peer Review Committee; and
- Cancer epidemiology faculty at the University of Minnesota and Mayo Clinic.

25. A copy of the proposed rules, SONAR, the Dual Notice, and a Q&A regarding the proposed rules were also posted on the Department’s rulemaking webpage.

26. The Administrative Law Judge finds that the Department fulfilled its additional notice requirement.

## Statutory Authorization

27. Minn. Stat. § 144.672 gives the Department general authority to collect “cancer incidence information, analyze the information, and conduct special studies designed to determine the potential public health significance of an increase in cancer incidence.”

28. Minn. Stat. § 144.672 directs the Commissioner to adopt rules “to administer the system, collect information, and distribute data.” The rules must include, among other things, the type of data to be reported, the standards for reporting specific types of data, and criteria for contracts made with outside entities to conduct studies using the data collected by MCSS.

29. The Administrative Law Judge finds that the Department has the statutory authority to adopt the proposed rules. The issue of whether the proposed rules are consistent with the governing statutes is addressed in the part-by-part analysis below.

## Regulatory Analysis in the SONAR

30. The Administrative Procedure Act requires an agency adopting rules to consider seven factors in its Statement of Need and Reasonableness. The first factor requires:

**(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.**

The proposed rule amendments will affect hospitals that do not have a cancer registry because they will need to submit electronic files containing discharge diagnoses or uniform billing data to the Department. Also affected will be physicians who diagnose and treat cancer patients outside of hospital settings. They will need to initiate cancer reports when no diagnostic specimen was submitted to a laboratory that reports to the MCSS. Hospitals with a cancer registry will be affected in that they will need to report cancer cases diagnosed without microscopic confirmation.<sup>23</sup>

According to the Department, all Minnesotans will indirectly benefit from this rule change because the Department will be able to describe treatment disparities and target cancer control programs more accurately. The Department suggests that broadening the data collected to non-microscopically diagnosed cancer will pull in information from economic and cultural classes whose data are not currently represented in the MCSS. Minnesotans will better understand how the cancer rates and survival in Minnesota compare with other states.<sup>24</sup>

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<sup>23</sup> SONAR at 4.

<sup>24</sup> *Id.* at 5.

**(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 Department states that its costs related to the implementation and enforcement of this rule will increase because it is expanding the types of cancer diagnoses that it will track. Specifically, the Department estimates that the additional, ongoing work to collect non-microscopically confirmed cancers will require approximately 1.25 full-time employees at a rate of about \$80,000 per year. The Department has secured federal funding to support this activity. The MCSS software will need to be updated to receive this new information, but the Department projects that the software costs will be absorbed by the existing MCSS development team.<sup>25</sup>

Additionally, the Department asserts that changing the method by which it notifies reporting entities of the required data items will reduce costs to the Department because it is less expensive to publish a notice in the *State Register* that it is to modify the rules.<sup>26</sup>

According to the Department, the balance of the proposed rules will not affect the Department's costs of running the MCSS; nor will they affect costs to other agencies or state revenues.<sup>27</sup>

**(3) The determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.**

The Department addressed this issue by subject matter.

*Case report definition:* If the Department continued to collect data on only clinically-diagnosed cancers identified by death certificate review or reported by hospital-based registries, it would save money. But the current approach does not achieve the goal of broadening the data in the MCSS and the resulting research.<sup>28</sup>

*Specify required data items by publication in State Register:* The Department asserts that the proposed rules are the least-cost alternative because the rules enable the Commissioner to keep the list of required data items consistent with national standards as those standards are updated. Further, these proposed changes allow the Department to publish the changes in the *State Register* without going through the formal lengthy rulemaking process.

*Follow-up information:* According to the Department there is no less costly alternative to collecting information regarding survival rates and outcomes because the

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<sup>25</sup> *Id.* at 5.

<sup>26</sup> *Id.* at 5.

<sup>27</sup> SONAR at 5-6.

<sup>28</sup> *Id.* at 6.

proposed changes do not require facilities to report information that they do not have or that they do not already collect as required by other law.<sup>29</sup>

*Additional conditions under which cases may be approached without physician consent:* The Department states that the least costly way to contact patients would be to not require physician consent at all. The Department acknowledges, however, that this method would be contrary to Minn. Stat. § 144.69, and an intrusion on patient privacy.<sup>30</sup>

*Cease collection of all in situ neoplasms of uterine cervix:* The Department is eliminating all possible costs and intrusions because they are proposing to no longer collect this information.<sup>31</sup>

*Update terminology:* There is no cost involved with these proposed changes.

**(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.**

The Department states that there are limited ways to accomplish the necessary changes. The only alternative seriously considered by the Department was to forego making the changes to the rules. The Department declined to pursue that alternative because it would not be able to run an effective MCSS program if it was out of compliance with national standards.<sup>32</sup>

**(5) The probable costs of complying with the proposed rules, 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.**

As stated under Item (1) above, the proposed rules affect hospitals without cancer registries, physicians who diagnose or treat a clinically diagnosed cancer patient, and hospitals with cancer registries.

*Hospitals without cancer registries:* These hospitals will bear some costs associated with the collection of non-microscopically confirmed cancers. The Department believes that its plan to screen electronic billing or discharge data files submitted by these hospitals for cancer diagnosis codes should minimize the costs to these hospitals. Non-registry hospitals may need to make some modifications to existing computer software and in-house support, which could cost up to \$5,000.<sup>33</sup>

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<sup>29</sup> *Id.* at 6.

<sup>30</sup> *Id.* at 6.

<sup>31</sup> *Id.* at 6-7.

<sup>32</sup> SONAR at 7.

<sup>33</sup> *Id.* at 7-8.

*Physicians who diagnose or treat clinically diagnosed cancer patients:* The cost to these physicians would be the time required to complete a 1-2-page reporting form and submit it to MCSS. The Department estimates that each form can be completed in 20-60 minutes, or approximately \$42 to \$175 per non-microscopically confirmed case. These reports are only required for patients who are not being seen at a hospital and for whom no diagnostic pathology report has been submitted to MCSS. These physicians may also be contacted by the Department slightly more frequently regarding patient eligibility for research studies since MCSS will be receiving data on more patients under the proposed rules.<sup>34</sup>

*Hospitals with cancer registries:* These hospitals should experience very little change in costs for complying with the revised reporting rules. In fact, the Department suggests that hospitals with cancer registries may notice a decrease in costs due to updated rules and more consistent standards. Hospital registries already collect follow-up information and would incur costs only if their registry vendor required payment to begin including new information in the submission to the MCSS. According to the Department, most registry vendors provide updates to meet state reporting standards as part of their maintenance agreements.<sup>35</sup>

**(6) The probable costs or consequences of not adopting the proposed rule, including those costs borne by individual categories of affected parties, such as separate classes of governmental units, businesses, or individuals.**

According to the Department, if the proposed rule amendments are not adopted, the continued exclusion of non-microscopically confirmed cancer cases would perpetuate anomalies in Minnesota cancer data. Additionally, the Department asserts that it runs the risk of losing federal funds if the MCSS does not collect non-microscopically confirmed cancers. Without the proposed rule changes, the Department argues that it will not be able to give Minnesotans an opportunity to participate in cancer survivorship studies.<sup>36</sup>

**(7) An assessment of any differences between the proposed rules and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.**

The Department reports that there are no existing federal regulations that govern cancer reporting. To receive federal funds for cancer registration, however, the Department must conform to federal standards.<sup>37</sup>

The Administrative Law Judge finds that the Agency has adequately considered the cost of its proposed amendments and it has adequately considered the other factors in the regulatory analysis required by Minn. Stat. § 14.131.

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<sup>34</sup> *Id.* at 8.

<sup>35</sup> *Id.* at 8-9.

<sup>36</sup> SONAR at 9-10.

<sup>37</sup> *Id.* at 10.

## **Performance-Based Rules**

31. The Administrative Procedure Act<sup>38</sup> also requires an agency to describe in its SONAR how it has considered and implemented the legislative policy supporting performance based regulatory systems. A performance-based rule is one that emphasizes superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals.<sup>39</sup>

32. The Department states that the proposed rules emphasize superior achievement in meeting its agency goals by specifying national standards for cancer reporting. The proposed rules afford the regulated entities flexibility in that the MCSS accepts reports in a variety of media. Physicians and registries are also not required to report information that they do not have, and the Department will work with non-registry hospitals to ease the transition to the new reporting requirements.<sup>40</sup>

33. The Administrative Law Judge finds that the Agency has met the requirements set forth in Minn. Stat. § 14.131 for assessing the impact of the proposed rules, including consideration and implementation of the legislative policy supporting performance-based regulatory systems.

## **Consultation with the Commissioner of Finance**

34. Under Minn. Stat. § 14.131, the Agency is also required to "consult with the commissioner of management and budget to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government."

35. The Department consulted with MMB by letter dated January 20, 2011.<sup>41</sup> MMB did not respond to the Department's submission.

36. The Administrative Law Judge finds that the Department has met the requirements set forth in Minn. Stat. § 14.131.

## **Compliance Costs to Small Businesses and Cities**

37. Under Minn. Stat. § 14.127, state agencies must "determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed \$25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees."<sup>42</sup> Although this determination is not required to be included in the SONAR, the agency must make this determination before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.<sup>43</sup>

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<sup>38</sup> Minn. Stat. § 14.131.

<sup>39</sup> Minn. Stat. § 14.002.

<sup>40</sup> SONAR at 10.

<sup>41</sup> Ex. 11a.

<sup>42</sup> Minn. Stat. § 14.127, subd. 1.

<sup>43</sup> Minn. Stat. § 14.127, subd. 2.

38. In the SONAR, the Department states that it has determined that the cost of complying with the proposed rule amendments in the first year after the rules take effect will not exceed \$25,000 for any one small business or small city. The Department asserts that small cities will have no costs associated with the proposed rules because none of them owns a hospital or pathology laboratory. As for small businesses, such as independent clinics with one or two physicians or dentists, the Department claims that their costs would exceed \$25,000 only if the practice diagnosed at least 625 cancer cases in the first year. According to the Department, this is extremely unlikely.<sup>44</sup>

39. The Administrative Law Judge concludes that the Department has met the requirements set forth in Minn. Stat. § 14.127 for determining whether the cost of complying with the proposed rules in the first year after the rules take effect, will exceed \$25,000 for any small business or small city. The ALJ approves that determination.

### **Adoption or Amendment of Local Ordinances**

40. Under Minn. Stat. § 14.128, the 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. The agency must make this determination before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.<sup>45</sup>

41. The Department concludes that the proposed rules do not necessitate local government action because the rules contain no provisions that would affect the law or regulations of a town, home rule charter or statutory city. The affected groups are hospitals, clinics, and physicians, the majority of which are individuals or privately-owned entities. To the extent that hospitals and clinics are publicly-owned, local governments do not have a role in the reporting of data to the MCSS. All data collection functions are performed within the Department. Accordingly, the Department asserts that the proposed rules would not require a county to adopt or amend an ordinance to comply with the rules.<sup>46</sup>

42. The Administrative Law Judge finds that the agency has made the determination required by Minn. Stat. § 14.128, and approves that determination.

### **Analysis of the Proposed Rules**

#### **General**

43. This Report is limited to discussion of the portions of the proposed rules that received significant comment or otherwise required close examination. Several sections of the proposed rules were not opposed by any member of the public and were adequately supported by the SONAR. Accordingly, this Report will not address each comment or rule part. When rules are adequately supported by the SONAR or the

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<sup>44</sup> SONAR at 13.

<sup>45</sup> Minn. Stat. § 14.128, subd. 1.

<sup>46</sup> SONAR at 12-13.

agency's oral or written comments, a detailed discussion of the proposed rules is unnecessary.

44. The Administrative Law Judge finds that the Agency has demonstrated the need for and reasonableness of all rule provisions not specifically discussed in this report by an affirmative presentation of facts. Further, the Administrative Law Judge finds that all provisions not specifically discussed are authorized by statute and there are no other problems that would prevent the adoption of the rules.

## **Discussion of Proposed Rules**

### **Part by Part Analysis**

#### **Part 4606.3300 Purpose**

45. The Department proposes the following changes to this rule part:

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 and outcomes of cancer in the state; and
- B. investigating the occurrence of cancer.

46. The current rule limits data collection to cancers diagnosed by examining tissue. The Department, however, wishes to collect data for cancers that are diagnosed clinically (i.e. by means other than looking at cells through a microscope).<sup>47</sup> Accordingly, the Department proposes to delete the language regarding pathology lab reports and other demographic data. This additional information updates the MCSS so that it is collecting the same types of information collected by other cancer registries around the world.<sup>48</sup>

47. The Department also seeks to amend this rule part to include cancer patient outcome data in the MCSS. According to the Department, reporting entities are already collecting outcome data, and this information would make the information distilled from the MCSS more meaningful. The Department asserts that it does not know how the survival rate in Minnesota compares to the survival rates in the rest of the nation because the Department has not had the data necessary to calculate valid survival statistics. Because of this lack of information, the Department argues that it has been forced to decline participation in long-term cancer survivor studies.<sup>49</sup>

48. Dr. James Cerhan, Chair of the Mayo Clinic's Epidemiology Division and the Associate Director of the Mayo Cancer Registry, supported both amendments to

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<sup>47</sup> Transcript (Tr.), at 16.

<sup>48</sup> SONAR, at 14-15.

<sup>49</sup> SONAR at 17-18.

part 4606.3300. Dr. Cerhan explained that oncology is constantly changing and that more cancers are being diagnosed through imaging. According to Dr. Cerhan, failure to include these types of cancer diagnoses will result in skewed population-based estimates and faulty conclusions.<sup>50</sup> Regarding the collection of outcome data, Dr. Cerhan asserts that it is important to understand how different treatments affect different cancer survivors so that the quality of life of cancer patients can be improved. Dr. Cerhan believes that cancer survivors want to be studied so that future cancer patients can benefit from the data and research.<sup>51</sup>

49. Twila Brase, on behalf of Citizens' Council for Health Freedom (CCHF), objected to both amendments to rule part 4606.3300. CCHF questions the Department's motives in collecting clinically diagnosed cancers because often these diagnoses do not turn out to be cancer. CCHF is concerned that the Department readily admits that cancer diagnoses without tissue confirmation are not always accurate. CCHF believes the MCSS has no authority to collect data on people who do not have cancer.<sup>52</sup>

50. As to the outcomes data collection issue, CCHF asserts that the Department is not authorized by statute to collect outcome data, only cancer incidence data. CCHF is concerned that the MCSS will be allowed to collect data on cancer patients "in perpetuity," and that some of those cancer patients may object to this governmental intrusion into their privacy.<sup>53</sup>

51. Donald Lee expressed concern about imposing new reporting requirements on already overburdened doctors, nurses, and health care staff.<sup>54</sup>

52. The Department's response to CCHF's concerns about collecting data on clinically diagnosed cancers is that Minn. Stat. § 144.672 gives the Department broad rulemaking authority to collect and analyze cancer incidence information, and to determine the potential public health significance of an increase in cancer. The Department argues that the MCSS was originally limited to pathology-based diagnoses of cancers because that was the most efficient way to identify the majority of cancers in 1988. As science has progressed and other states have begun collecting clinically diagnosed cancer data, the Department is seeking to keep the MCSS current and viable. The Department argues that it must be able to collect cancer data regardless of the diagnostic method used and claims that its rulemaking authority is broad enough to encompass all of those methods.<sup>55</sup>

53. The Department's response to CCHF's concerns about collecting outcome data, in addition to incidence data, is that Minn. Stat. §§ 144.671 and 144.672 must be

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<sup>50</sup> Tr. at 23.

<sup>51</sup> Tr. at 25.

<sup>52</sup> Tr. at 27-28; *see also*, CCHF's Rebuttal Comments (CCHF Rebuttal), dated March 31, 2011, at 1.

<sup>53</sup> Tr. at 26-27; *see also*, CCHF Rebuttal, at 1-2.

<sup>54</sup> Tr. at 44-45.

<sup>55</sup> Department's Post-hearing Response to Comments (Department's Response), dated March 24, 2011, at 1-2.

read together. The purpose of the MCSS is to “more accurately target intervention resources for communities and patients and their families” and to “promote high quality research to provide better information for cancer control.”<sup>56</sup> The Department also cites the U.S. National Cancer Institute’s position regarding cancer surveillance. “The core functions of cancer surveillance are the measurement of cancer incidence, morbidity, survival, and mortality for persons with cancer. . . . It also includes the assessment of genetic predisposition, environmental and behavioral risk factors, screening practices, and the quality of care from prevention through palliation.”<sup>57</sup> The Department asserts that it would be remiss in not collecting and studying cancer outcomes.

54. The Administrative Law Judge finds the proposed amendments to part 4606.3300 to be needed and reasonable. The decision to collect data on clinically diagnosed cancers and data on cancer patient outcomes is a rational choice by the Department that is supported by their statutory authority.

#### **Part 4606.3304, subpart 1a      Reports – Data items**

55. Rule part 4606.3304 details the information that must be included in the case reports to the MCSS. The current rule, at subpart 1, contains a detailed listing of required case information, which changes on a regular basis. The Department proposes to pare this information down to seven general categories. Rather than maintain a detailed listing in the rule language, the Department proposes to add a new subpart 1a, as follows:

The commissioner shall, at least once per year and by publication in the State Register and electronic notice on the Minnesota Cancer Surveillance System Web site, provide a list of the data items to be reported under part 4606.3303, subpart 1, and specify the format to be used for electronic reports. The list will be revised according to national cancer reporting standards.

The national cancer reporting standards referred to in the proposed language are incorporated by reference in the proposed language at subpart 1b.

56. According to the Department, the national standard setters (the Centers for Disease Control and Prevention’s National Program of Cancer Registries (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)) modify their data collection standards annually to ensure that the collected data remains useful for assessing progress in cancer diagnosis and treatment.<sup>58</sup> The Department asserts that the proposed language at subpart 1a will add administrative flexibility and efficiency by

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<sup>56</sup> Department’s Response, at 4.

<sup>57</sup> Department’s Response, at 4; see *also*, <http://surveillance.cancer.gov/about/>.

<sup>58</sup> SONAR at 17.

allowing MCSS to bring data submission requirements up to date by publishing changes in the *State Register* and the MCSS website, instead of through formal rulemaking.<sup>59</sup>

57. CCHF is troubled by the Department's proposal to modify the rules without going through the formal rulemaking procedures of Minnesota Statutes, chapter 14 and Minnesota Rules, chapter 1400. CCHF also objects to replacing the list of specific required information in subpart 1, with general categories of data. According to CCHF, these proposed changes give the Commissioner of Health great discretion to modify the types of data collected regarding cancer patients. It also argues that the proposed rule robs the general public of the ability to participate in the revision of the rules and to object to potential action by the Department that might exceed its statutory authority (i.e. data on individuals who do not have cancer). CCHF believes that the Department is superseding the rights of Minnesota citizens in order to follow national cancer standards.<sup>60</sup>

58. In response, the Department asserts that its authority under Minn. Stat. § 144.672, subd. 1 (1) permits it to adopt rules that specify the type of data to be reported. The Department states that the proposed changes were prompted by "MCSS's need for a more flexible structure to keep pace with the modern rate of change in science and medicine."<sup>61</sup> The national standards to which the Department will adhere are incorporated by reference into the rule and readily available to the public. Several of the standards are already incorporated by reference in the current rule. The Department argues that the public is protected from over-reaching by the Department because its statutory authority limits its data collection to cancer-related information. According to the Department, the use of the *State Register* and the MCSS website to announce changes to the information reporting standards allows the Department the flexibility to respond quickly to changes in medicine with no loss of transparency.<sup>62</sup>

59. The Administrative Law Judge finds the Department's proposed amendments to part 4606.3304 are needed and reasonable. The Commissioner's discretion is appropriately contained by the national standards incorporated by reference into the rule, as well as the Department's statutory authority.

#### **Part 4606.3306, subpart 2            Physician Consent - Approach without consent**

60. Part 4606.3306 requires the Commissioner to attempt to locate and obtain the consent of the attending physician or a personal representative before undertaking epidemiologic studies on cancer patients whose information appears in the MCSS. Subpart 2 of this part describes when the Commissioner may go forward with studies on patient data without consent. The Department seeks to add to subpart 2 as follows:

The commissioner may approach a case named in a report or a person representative of a deceased case . . . without the consent of the

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<sup>59</sup> *Id.*

<sup>60</sup> Tr. at 28-30; *see also*, CCHF Rebuttal, at 1.

<sup>61</sup> Department's Response, at 3.

<sup>62</sup> *Id.*

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, or is no longer caring for the case and is unable to identify the case's current attending physician.

61. The Department's justification for this change is that it has not been able to participate in studies involving long-term cancer survivors, in part, because of the current constraint of having to acquire physicians' consent to contact the patients. The Department proposes this change to account for the instances where a cancer survivor becomes eligible for a study and a physician can no longer be identified. In that instance, the proposed change gives the Department authority to contact a patient directly, or a personal representative, if the patient is deceased. The Department believes that most cancer survivors welcome the opportunity to participate in studies that will benefit future cancer patients.<sup>63</sup>

62. CCHF objects to this amendment because the group does not believe that the legislature intended to let the government track every cancer patient from diagnosis to death. CCHF does not believe that the proposed rule protects cancer patients and survivors who may not want to be approached by the government over their entire lifetime. CCHF questioned the Department's assertion that the majority of cancer patients welcome the opportunity to participate in cancer studies. Instead, CCHF suggests that some cancer patients may feel coerced by the government to participate in cancer studies. CCHF goes so far as to question whether the Department's requests might be overtly coercive or repetitive, relying on guilt or obligation to make patients participate in the studies. CCHF believes that the doctor provides an important "buffer" between the Department and the patient.<sup>64</sup>

63. The Department responded that it takes seriously its obligation to protect the data on individuals collected by the MCSS. Pursuant to Minn. Stat. § 144.69, any unauthorized disclosure of the data is a misdemeanor. The Department also argues that the privacy of patients participating in studies is protected because all studies that involve patient contact must be approved by an Institutional Review Board (IRB) with a Federal Wide Assurance (FWA) and jurisdiction over the researcher.<sup>65</sup>

64. In addition, Minn. Stat. § 144.69 speaks directly to the issue of obtaining physician consent prior to contacting patients: "*Except as provided by rule, and as part of an epidemiologic investigation, an officer or employee of the commissioner of health may interview patients named in any report, or relatives of any such patient, only after the consent of the attending physician or surgeon is obtained.*" (Emphasis added.)<sup>66</sup>

65. The Administrative Law Judge finds the Department's proposed amendment to part 4606.3306 is needed and reasonable and a rational policy choice.

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<sup>63</sup> SONAR at 18-19.

<sup>64</sup> Tr. at 31-35.

<sup>65</sup> Department's Response, at 5-6.

<sup>66</sup> *Id.* at 5.

Minn. Stat. § 144.69 clearly supports the Department's ability to make rules regarding approaching cancers patients without physician consent.

### **Other concerns**

66. CCHF raised many questions regarding how the MCSS functions. The group requested that the Department place information in the rule record regarding, for example, who decides what type of research will occur, if the Department gives or receives compensation for the data in the MCSS, who at the Department contacts patients or doctors to request participation in research and what process or materials are used in that contact, how many patients refused to participate in research studies, and whether the Department ever waives consent requirements.<sup>67</sup>

67. In response, the Department stated that many of CCHF's questions were outside the scope of the changes proposed in the rules. The Department did, however, give an overview of how MCSS functions and how research is conducted and consent is obtained. The Department emphasized that stringent rules apply to private health data received by MCSS, and that MCSS takes seriously its obligations regarding patient privacy.<sup>68</sup>

68. At the hearing, several individuals expressed fear over potential government rationing of health care, government intrusion into their private lives without their consent, and the manner in which the Department conducts its statistical sampling.<sup>69</sup>

69. The Administrative Law Judge acknowledges these concerns but finds that they are outside the scope of this rulemaking proceeding.

Based on the Findings of Fact, the Administrative Law Judge makes the following:

### **CONCLUSIONS**

1. The Department gave proper notice of the hearing in this matter.
2. The Department has fulfilled the procedural requirements of Minnesota Statutes § 14.14 and all other procedural requirements of law or rule, with one exception. This procedural defect was subsequently found to be harmless error, as noted in Findings 20-24.
3. The Department has demonstrated its statutory authority to adopt the proposed rule and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.15, subd. 3, and 14.50 (i) and (ii).

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<sup>67</sup> CCHF's Post-Hearing Comments, dated March 24, 2011.

<sup>68</sup> Department's Rebuttal Comments (Department's Rebuttal), dated March 31, 2011.

<sup>69</sup> Tr. at 38-40 (Wayne King); 40-41 (Thomas Roman); 41-43 (Martin Kellogg).

4. The Department has documented the need for and reasonableness of its proposed rule with an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2, and 14.50 (iii).

5. Any Findings that might properly be termed Conclusions and any Conclusions that might properly be termed Findings are hereby adopted as such.

Based on the Conclusions, the Administrative Law Judge makes the following:

### **RECOMMENDATION**

**IT IS RECOMMENDED** that the proposed rules be adopted, as finally proposed.

Dated: June \_10\_, 2011

/s/ Manuel J. Cervantes  
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MANUEL J. CERVANTES  
Administrative Law Judge

Transcript Prepared.

### **NOTICE**

The Agency must make this Report available for review by anyone who wishes to review it for at least five working days before the Agency takes any further action to adopt final rules or to modify or withdraw the proposed rules. If the Agency makes changes in the rules, it must submit the rules, along with the complete hearing record, to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

When the rule is filed with the Secretary of State by the Office of Administrative Hearings, the Agency must give notice to all persons who requested that they be informed of the filing.