

STATE OF MINNESOTA  
OFFICE OF ADMINISTRATIVE HEARINGS  
FOR THE DEPARTMENT OF HEALTH

In the Matter of the Proposed Rules of the  
Department of Health Relating to Medical  
Cannabis

**REPORT OF THE  
ADMINISTRATIVE LAW JUDGE**

This matter came before Administrative Law Judge James E. LaFave for a rulemaking hearing on January 22, 2016. The public hearing was held at 9:00 a.m. in Room B-107 of the Orville Freeman Building, 625 North Robert Street, St. Paul, MN 55155-2538.

The Minnesota Department of Health (Department or Agency) proposes to amend its rules governing medical cannabis.<sup>1</sup> The Department's objectives for this rule revision are to:

- clarify existing requirements and correct editorial issues;
- address inconsistencies within current rules;
- address needs identified after completion of the expedited rules; and
- simplify the requirement, where feasible.<sup>2</sup>

The hearing and this Report are part of a larger rulemaking process conducted under the Minnesota Administrative Procedure Act.<sup>3</sup> The Minnesota legislature has designed this process to ensure that state agencies have met all of the requirements that the state has specified for adopting rules.

The hearing was conducted to permit Agency representatives and the Administrative Law Judge to hear public comment regarding the impact of the proposed rules and what rule changes might be appropriate. The hearing process provided the general public an opportunity to review, discuss, and critique the proposed rules.

The Agency must establish that: 1) the proposed rules are necessary and reasonable; 2) the rules are within the Agency's statutory authority; and 3) any modifications that the Agency may have made after the proposed rules were initially

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<sup>1</sup> See Statement of Need and Reasonableness (SONAR).

<sup>2</sup> *Id.* at 5.

<sup>3</sup> See Minn. Stat. §§ 14.131-.20 (2014).

published in the *State Register* are within the scope of the matter that was originally announced.<sup>4</sup>

The Agency panel at the public hearings included Patricia Winget, Attorney for the Minnesota Department of Health and its Rules Coordinator, and Darin Teske, Policy Analyst for the Minnesota Department of Health's Office of Medical Cannabis.<sup>5</sup>

Approximately 31 people attended the hearing and ten signed the hearing register. The proceedings continued until all interested persons, groups and associations had an opportunity to be heard concerning the proposed rules. Two members of the public made statements or asked questions during the hearing.<sup>6</sup>

After the close of the hearing, the Administrative Law Judge kept the rulemaking record open for another 20 calendar days – until February 11, 2016 – to permit interested persons and the Agency time to submit written comments. Following the initial comment period, the hearing record was held open an additional five business days to permit interested parties and the Agency an opportunity to reply to earlier-submitted comments.<sup>7</sup> The hearing record closed on February 19, 2016.

## **SUMMARY OF CONCLUSIONS**

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

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

## **FINDINGS OF FACT**

### **I. Background to the Proposed Rules**

1. The Department, through its Office of Medical Cannabis (OMC), regulates medical cannabis in Minnesota.<sup>8</sup> On May 29, 2014, Governor Mark Dayton signed the medical cannabis therapeutic use law (the Therapeutic Research Act or Act)<sup>9</sup> into law.<sup>10</sup>

2. The legislature designed this law to enable patients having certain serious medical conditions to use cannabis for therapeutic treatment, while preventing its being misused or diverted from medical purposes.<sup>11</sup> Another objective of this program is to generate and collect data using science-based methods to advance evidence about

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<sup>4</sup> Minn. Stat. §§ 14.05, .131, .23, .25 (2014).

<sup>5</sup> Hearing Transcript (T.) 11, 14 (Jan. 22, 2016).

<sup>6</sup> See Testimony (Test.) of Cassie Traun (T. 27-28); Test. of Kurtis Hanna (T. 29-30).

<sup>7</sup> See Minn. Stat. § 14.15, subd. 1.

<sup>8</sup> SONAR at 4.

<sup>9</sup> See 2014 Minn. Laws, ch. 311 (codified at Minn. Stat. §§ 152.22-.37 (2014)).

<sup>10</sup> SONAR at 4.

<sup>11</sup> *Id.*

cannabis' medical effectiveness from anecdotal accounts to formal public health research.<sup>12</sup>

3. Medical cannabis has the uneasy status of being permissible under state law but prohibited under federal law.<sup>13</sup> Federal law makes no distinction between medical and non-medical cannabis and thus cannabis remains a Schedule I controlled substance under the federal Controlled Substances Act of 1970.<sup>14</sup> The United States Department of Justice has issued guidance to its district attorneys regarding federal enforcement of cannabis law in jurisdictions with state-adopted medical cannabis programs.<sup>15</sup> On August 29, 2013, Deputy Attorney General James Cole issued a guidance memorandum (the Cole Memo)<sup>16</sup> which established eight federal enforcement priorities, as follows:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for trafficking of other illegal drugs or other illegal activity;
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession or use on federal property.<sup>17</sup>

4. The Cole Memo emphasized that its guidance was predicated on its expectation that states which have enacted laws authorizing marijuana-related conduct will implement strong and effective regulatory and enforcement systems.<sup>18</sup> The Cole Memo noted that in jurisdictions that have enacted laws legalizing marijuana in some form and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale, and possession of marijuana,

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<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*; See 21 U.S.C. § 801 *et seq.*

<sup>15</sup> SONAR at 4.

<sup>16</sup> The Cole Memo (Aug. 29, 2013) appears at <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>.

<sup>17</sup> SONAR at 4; the Cole Memo at 1-2.

<sup>18</sup> SONAR at 4; the Cole Memo at 2.

conduct in compliance with those laws and regulations is less likely to threaten the federal priorities set forth above.<sup>19</sup>

5. The Therapeutic Research Act charged the Department with implementing a medical cannabis patient registry program within tight statutory timelines.<sup>20</sup> The program's statutory structure includes two vertically integrated medical cannabis manufacturers, a patient registry, and a research element.<sup>21</sup> To launch the program by July 1, 2015, the Department adopted two sets of rules using the expedited rulemaking process.<sup>22</sup>

6. The Therapeutic Research Act gave the Department the authority to adopt and implement administrative rules necessary for medical cannabis manufacturers to begin distributing medical cannabis to patients by July 1, 2015, by using the expedited rulemaking process under Minn. Stat. § 14.389 (2014).<sup>23</sup> The Department adopted two sets of rules using the expedited process: one set applying to the manufacturers; and one set applying to the patients, their caregivers, and participating health care practitioners.<sup>24</sup>

7. The Department published proposed expedited rules that apply to medical cannabis manufacturers in the *State Register* on October 6, 2014.<sup>25</sup> The expedited rules prescribe the manufacturers' operation.<sup>26</sup> They spell out restrictions on producing medical cannabis starting with planting, growing, and harvesting cannabis plants through processing them into medical cannabis.<sup>27</sup> These rules also specify how the manufacturers must handle the medical cannabis until it is dispensed and also the disposal of waste plant material.<sup>28</sup> The expedited rules were reviewed and approved by Administrative Law Judge Barbara Case on December 9, 2014.<sup>29</sup>

8. The manufacturers' requirements in the rules address:

- packaging and labeling medical cannabis for patients;
- site security;
- transportation and its corresponding security;
- advertising and marketing manufactured cannabis;
- disposing of cannabis plant material and waste medical cannabis;

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<sup>19</sup> The Cole Memo at 3.

<sup>20</sup> SONAR at 4.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.* at 4-5.

<sup>23</sup> *Id.* at 6.

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

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

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

<sup>27</sup> *Id.* at 6-7.

<sup>28</sup> *Id.* at 7.

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

- quality assurance of the medical cannabis produced; and
- recordkeeping.<sup>30</sup>

9. In addition to the manufacturers' operation requirements, the current rules describe how the Department administers the following oversight functions:

- manufacturer registration;
- facility inspection;
- testing labs approval;
- registration revocation; and
- voluntary facility closure.<sup>31</sup>

10. The Department published a second set of proposed expedited rules that apply to patients and health care practitioners in the *State Register* on December 15, 2014.<sup>32</sup> Administrative Law Judge LauraSue Schlatter approved the rules on May 4, 2015.<sup>33</sup> The rules were published in the *State Register* and became effective on June 29, 2015.<sup>34</sup>

11. The Therapeutic Research Act requires patients to be Minnesota residents and be diagnosed with at least one of the qualifying medical conditions set forth in statute.<sup>35</sup> The existence of a qualifying medical condition must be certified by a health care practitioner.<sup>36</sup>

12. "Health care practitioner" is defined as a Minnesota-licensed doctor of medicine, a Minnesota-licensed physician assistant acting within the scope of their practice, or a Minnesota-licensed advanced practice registered nurse with the primary responsibility for care and treatment of the underlying medical condition.<sup>37</sup>

13. The patient's certifying health care practitioner is also responsible for certifying a patient's need for a designated caregiver, if applicable, to acquire or administer medical cannabis.<sup>38</sup> If the health care practitioner certifies that the patient needs a caregiver to either access or administer the medication, the patient may "invite" a caregiver to register with the program.<sup>39</sup> The process of registering the designated caregiver requires a criminal background check before enrolling the caregiver in the

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<sup>30</sup> SONAR at 7.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

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

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* See Minn. Stat. § 152.22, subd. 4.

<sup>38</sup> SONAR at 7.

<sup>39</sup> *Id.* at 7-8.

registry.<sup>40</sup> Parents and legal guardians may act as caregivers without having to register as a caregiver or undergo a criminal history check.<sup>41</sup>

14. The patient registry requirements describe:

- application qualifications and procedures for patients, designated caregivers, and health care practitioners;
- procedures for health care practitioners providing written certification of a patient's qualifying medical condition;
- prohibitions for health care practitioners;
- revocation or suspension of a qualifying patient or designated caregiver registration;
- recordkeeping and reporting requirements for health care practitioners; and
- disposal of unused medical cannabis by persons authorized to possess it.<sup>42</sup>

15. In addition to the operational requirements of the patient registry, the rules which became effective in June of 2015 describe the following functions:

- procedures for requesting a medical condition or delivery method be added to the list of qualifying medical conditions;
- procedures for requesting a delivery method be added to the list of approved delivery methods (excluding smoking);
- medical cannabis point-of-distribution requirements, including dosage calculation and purchasing limits; and
- reporting requirements for serious health effects and unauthorized possession incidents.<sup>43</sup>

## II. Rulemaking Authority

16. The Therapeutic Research Act established the Minnesota medical cannabis patient registry program and directed the Department to implement the law. Minn. Stat. § 152.26 provides that “[t]he commissioner [of health] may adopt rules to implement sections 152.22 to 152.37.”

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<sup>40</sup> SONAR at 8.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

17. Minn. Stat. § 152.261 directs the Department to adopt rules that establish reporting requirements for incidents of unauthorized possession and incidents of overdose.<sup>44</sup>

18. Governor Mark Dayton signed the Therapeutic Research Act into law on May 29, 2014, and it became effective the day following final enactment.<sup>45</sup>

19. Notice of intent to adopt rules must be published within 18 months of the effective date of the legislative authorization.<sup>46</sup>

### **III. Procedural Requirements of Chapter 14 (2014)**

#### **A. Publications**

20. On Monday, July 28, 2014, to comply with the Act the Department published in the *State Register* a Request for Comments seeking comments on its possible rules governing the medical cannabis registry program.<sup>47</sup>

21. On October 22, 2015, the Department requested approval of its Notice of Intent to Adopt Rules With or Without a Hearing (Dual Notice) and Additional Notice Plan.<sup>48</sup>

22. On October 29, 2015, Administrative Law Judge James E. LaFave issued an Order that approved the Department's Dual Notice and Additional Notice Plan.<sup>49</sup>

23. The Dual Notice, published in the November 16, 2015 *State Register*, set December 16, 2015 as the deadline for submitting comments or to request a hearing.<sup>50</sup>

24. The Department failed to demonstrate either at the hearing, during the initial comment period, or during the rebuttal period that it mailed a copy of the Dual Notice to all persons and associations who had registered their names with the Department for the purpose of receiving such notice, and to all persons and associations identified in the Additional Notice Plan.

25. On November 5, 2015, the Department sent a copy of the Dual Notice and the Statement of Need and Reasonableness (SONAR) to certain legislators and the Legislative Coordinating Commission, either by depositing them in the United States

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<sup>44</sup> See Minn. Stat. § 152.261; SONAR at 6.

<sup>45</sup> SONAR at 6.

<sup>46</sup> See Minn. Stat. § 14.125 (2014).

<sup>47</sup> 39 *State Register* 126 (July 28, 2014).

<sup>48</sup> Letter from Darin Teske, Policy Analyst, Office of Medical Cannabis, to The Honorable Tammy L. Pust, Chief Administrative Law Judge (Oct. 22, 2015).

<sup>49</sup> Order on Review of Additional Notice Plan and Dual Notice (Oct. 29, 2015).

<sup>50</sup> Ex. 5.

mail with postage prepaid or by sending an electronic copy via e-mail in an effort to comply with Minn. Stat. § 14.116.<sup>51</sup>

26. On November 9, 2015, the Department sent by email a copy of the SONAR to the Legislative Reference Library to meet the requirement set forth in Minn. Stat. §§ 14.131, .23.<sup>52</sup>

27. The Notice of Hearing identified the date and location of the hearing in this matter.<sup>53</sup>

28. At the hearing on January 22, 2016, the Department filed copies of the following documents as required by Minn. R. 1400.2220 (2015):

- a. Agency's Request for Comments as published in the *State Register* on July 24, 2014;<sup>54</sup>
- b. Proposed rules dated January 21, 2015, including the Revisor's approval;<sup>55</sup>
- c. Agency's Statement of Need and Reasonableness;<sup>56</sup>
- d. Certificate of Mailing the SONAR to the Legislative Reference Library on November 9, 2015;<sup>57</sup>
- e. Dual Notice as mailed and as published in the *State Register* on November 16, 2015;<sup>58</sup>
- f. Certificate Mailing Notice of Hearing to Those Who Requested a Hearing on December 18, 2015 and the Certificate of Accuracy of the list of persons and associations who requested a hearing;<sup>59</sup>
- g. Certificate of Giving Additional Notice Pursuant to the Additional Notice Plan;<sup>60</sup>
- h. Written comments on the proposed rules that the Agency received during the comment period that followed the Dual Notice;<sup>61</sup>

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<sup>51</sup> Ex. 9.

<sup>52</sup> Ex. 4.

<sup>53</sup> Ex. 5.

<sup>54</sup> Ex. 1.

<sup>55</sup> Ex. 2.

<sup>56</sup> Ex. 3.

<sup>57</sup> Ex. 4.

<sup>58</sup> Ex. 5.

<sup>59</sup> Ex. 6.

<sup>60</sup> Ex. 7.

<sup>61</sup> Ex. 8.

- i. Certificate of Sending the Dual Notice and the Statement of Need and Reasonableness to Legislators on November 5, 2015;<sup>62</sup>
- j. December 30, 2015 memorandum from Minnesota Management and Budget;<sup>63</sup> and
- k. Post-publication modifications to Rule 4770.4003.<sup>64</sup>

29. The Department did not file or offer at the hearing, during the initial comment period, or during the rebuttal period, the Certificate of Mailing to the Department's rulemaking mailing list.<sup>65</sup>

30. The Department's filed Certificate of Giving Additional Notice Pursuant to the Additional Notice Plan, failed to document when the Department gave the additional notice set forth in the Additional Notice Plan.

31. On February 26, 2016, the Department filed the Certificate of Mailing the Dual Notice to the Rulemaking Mailing List and Certificate of Accuracy of the Mailing List.<sup>66</sup>

32. On February 26, 2016, the Department also filed the Certificate of Giving Additional Notice Under the Additional Notice Plan.<sup>67</sup>

## **B. Additional Notice Requirements**

33. Minn. Stat. §§ 14.131, .23 requires that an agency include in its SONAR a description of its efforts to provide additional notification to persons or classes of persons who may be affected by the proposed rule; or alternatively, the agency must detail why these notification efforts were not made.

34. Pursuant to the Additional Notice Plan approved by the Office of Administrative Hearings on October 29, 2015, the Department used the following methods to deliver notification to persons or classes of person who may be affected by the proposed rules:

- Office of Medical Cannabis Staff Speaking Engagements;
- Rules Advisory Committee;
- Department's OMC Website;
- Call Center Operation and Email Box;

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<sup>62</sup> Ex. 9.

<sup>63</sup> Ex. 10.

<sup>64</sup> Ex. 11.

<sup>65</sup> See Minn. R. 1400.2220, subp. 1(G).

<sup>66</sup> The Certificate of Mailing the Dual Notice to the Rulemaking Mailing List and Certificate of Accuracy of the Mailing List was received and marked as "Ex. 12."

<sup>67</sup> The Certificate of Giving Additional Notice Under the Additional Notice Plan was received and marked as "Ex. 13."

- GovDelivery Email Notices;
- Tweeting on Social Media; and
- Statutory Task Force.

## **C. Notice Practice**

### **1. Notice to Stakeholders**

35. On November 5, 2015, the Agency provided a copy of the Notice of Hearing to its official rulemaking list maintained under Minn. Stat. § 14.14, and to stakeholders identified in its Additional Notice Plan.<sup>68</sup>

36. The hearing on the proposed rules was held on January 22, 2016.<sup>69</sup>

37. There are 78 days between November 5, 2015, and January 22, 2016.

38. The Administrative Law Judge concludes that the Agency fulfilled its responsibility to mail the Notice of Hearing “at least 33 days before the ... start of the hearing.”<sup>70</sup>

### **2. Notice to Legislators**

39. On November 5, 2015, the Agency sent a copy of the Notice of Hearing and the SONAR to legislators and the Legislative Coordinating Commission as required by Minn. Stat. § 14.116.<sup>71</sup>

40. Minn. Stat. § 14.116 requires the Agency to send a copy of the Notice of Hearing and the SONAR to certain legislators on the same date that it mails its Notice of Hearing to persons on its rulemaking list and pursuant to its additional notice plan.

41. The Administrative Law Judge concludes that the Department fulfilled its responsibilities to mail the Notice of Hearing “at least 33 days before the . . . start of the hearing.”<sup>72</sup>

### **3. Notice to the Legislative Reference Library**

42. On November 9, 2015, the Department emailed a copy of the SONAR to the Legislative Reference Library.<sup>73</sup>

43. Minn. Stat. § 14.23 requires the agency to send a copy of the SONAR to the Legislative Reference Library when the Notice of Intent to Adopt is mailed.

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<sup>68</sup> Ex. 12.

<sup>69</sup> Ex. 5.

<sup>70</sup> Minn. R. 1400.2080, subp. 6 (2015).

<sup>71</sup> Ex. 9.

<sup>72</sup> Minn. R. 1400.2080, subp. 6.

<sup>73</sup> Ex. 4.

44. The Administrative Law Judge concludes that the Agency fulfilled its responsibilities to “send a copy of the SONAR to the Legislative Reference Library when the Notice of Intent to Adopt [was] mailed.”

#### **4. Assessment of Agency’s Notice Practice**

45. Minn. Stat. § 14.15, subd. 5, requires an administrative law judge to disregard an error or defect in the proceeding due to an “agency’s failure to satisfy any procedural requirement” if the administrative law judge finds “that the failure did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process . . . .”

46. An agency must place into the hearing record “any other document or evidence to show compliance with any other law or rule which the agency is required to follow in adopting this rule.”<sup>74</sup>

47. The Agency did not file at the hearing, during the initial comment period or the initial rebuttal period, any document or evidence to show it provided a copy of the Notice of Hearing to its official rulemaking list maintained under Minn. Stat. § 14.14, or when and how it provided the additional notice under the Additional Notice Plan.<sup>75</sup>

48. On February 26, 2016, the Agency made a supplemental filing of the Certificate of Mailing the Dual Notice to the Rulemaking List and Certificate of Accuracy of the Mailing List,<sup>76</sup> along with the Certificate of Giving Additional Notice Under the Additional Notice Plan.<sup>77</sup>

49. The Certificate of Mailing the Dual Notice to the Rulemaking List documented that on November 5, 2015, the Agency provided a copy of the Notice of Hearing to its official rulemaking list maintained under Minn. Stat. § 14.14, and to stakeholders identified in its Additional Notice Plan.<sup>78</sup>

50. The Agency timely provided a copy of the Notice of Hearing to its official rulemaking list maintained under Minn. Stat. § 14.14, and to stakeholders identified in its Additional Notice Plan as required by law.

51. The Certificate of Giving Additional Notice Under the Additional Notice Plan documented that the Agency timely complied with the Additional Notice Plan as required by law.

52. The Administrative Law Judge concludes that the Agency’s failure to file evidence that it timely provided a copy of the Notice of Hearing to its official rulemaking

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<sup>74</sup> Minn. R. 1400.2220, subp. 1(K).

<sup>75</sup> See Minn. Stat. §§ 14.14, subd. 1a, .131, .23.

<sup>76</sup> See Ex. 12.

<sup>77</sup> See Ex. 13.

<sup>78</sup> Ex. 12.

list maintained under Minn. Stat. § 14.14, and to stakeholders identified in its Additional Notice Plan during the hearing or the initial comment period did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process. For those reasons, the procedural errors constituted harmless error under Minn. Stat. § 14.15, subd. 5(1).

#### **D. Impact of Farming Operations**

53. Minn. Stat. § 14.111 imposes additional notice requirements when the proposed rules affect farming operations. The statute requires that an agency provide a copy of any such changes to the Commissioner of Agriculture at least 30 days prior to publishing the proposed rules in the *State Register*.

54. The proposed rules do not impose restrictions or have an impact on farming operations. The Administrative Law Judge finds that the Agency was not required to notify the Commissioner of Agriculture.

#### **E. Statutory Requirements for the SONAR**

55. The Administrative Procedure Act obliges an agency adopting rules to address certain factors in its SONAR.<sup>79</sup> Those factors are:

- a. 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;
- b. 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;
- c. a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;
- d. 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;
- e. 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;

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<sup>79</sup> Minn. Stat. § 14.131.

- f. the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals;
- g. 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; and
- h. an assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.

## 1. The Agency's Regulatory Analysis

- (a) **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.**

56. The Department believes that, because the rules pertain to medical cannabis production and distribution in Minnesota, the proposed amendments could affect a variety of people.<sup>80</sup> Most immediately, the proposed rules would affect registry-eligible patients, their caregivers, health care practitioners, and registered manufacturers.<sup>81</sup> Others affected include law enforcement and health care facilities.<sup>82</sup> In addition, those affected include potential patients and advocates who support adding qualifying medical conditions to the list.<sup>83</sup>

57. The following stakeholders would be potentially affected by the proposed rules:

- Manufacturers would be affected by new requirements for producing a transportation manifest and vehicle staffing (part 4770.1100), registration renewal (part 4770.1460), and recall procedures (part 4770.1850).<sup>84</sup>
- Health care practitioners would be affected by a proposed modification of the adverse incident reporting rule (part 4770.4004) that is more stringent than the current rule. They would also be affected by a proposed modification of the unauthorized possession reporting rule (part 4770.4010) (removing them from the list of mandatory reporters).<sup>85</sup>

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<sup>80</sup> SONAR at 20.

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

- Patients and their caregivers would be affected by a proposed change to the adverse incident rule (part 4770.4004) that is more stringent than the current rule.<sup>86</sup>
- Law enforcement officials would be affected by the changes proposed for reporting requirements found in Minnesota Rules parts 4770.4004 (adverse incidents) and 4770.4010 (unauthorized possession).<sup>87</sup>
- Health care facilities would be affected by the proposed new rule relating to storage of medical cannabis in health care facilities (part 4770.4030).<sup>88</sup>
- Persons and advocacy groups who support medical cannabis use for medical conditions not now included on the list of qualifying medical conditions in Minnesota Statutes section 152.22, subdivision 14, would be affected by proposed changes to part 4770.4003.<sup>89</sup>

**(b) 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.**

58. The Department anticipates there will be no additional costs to it or any other agency to implement or enforce the proposed rule revision. The Department has staff in place to enforce the existing rules and the Department will require no additional revenues to implement and enforce the proposed rules. The Department asserts the proposed rules will not affect state revenues because the Department already administers the medical cannabis program.<sup>90</sup>

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

59. The Department does not believe there are less costly methods or less intrusive methods of achieving the purpose of the proposed rules. It reviewed other state medical cannabis programs and regulations of botanical supplements and pharmaceutical products. The Department carefully considered the costs and potential burdens of the proposed rules. It solicited stakeholder involvement and input to produce the least costly and intrusive methods.<sup>91</sup>

60. With respect to the required efforts of health care practitioners, the Department evaluated the time it would take to comply with each certification, medical history review, and availability requirement. It discarded requirements that would

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<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at 21.

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

impose a burden without adding a benefit to the research component of the program. The Department crafted requirements to minimize the amount of time required for recordkeeping and other administrative tasks.<sup>92</sup>

61. As a result of the Department's efforts, it was better able to identify groups required to report adverse health incidents (part 4770.4004) and unauthorized possession (part 4770.4010). In addition, the Department responded to the manufacturers' requests for flexibility and eliminated unnecessary requirements (parts 4770.110 and 4770.1850). For patients, the Department composed the patient registry of only elements minimally necessary to effectively deliver the medical cannabis program.<sup>93</sup>

**(d) 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.**

62. The medical cannabis program has only been fully operating for three months. The primary focus of the proposed rule changes was to adjust or refine the current rules of the program; as a result neither the Department nor the stakeholders explored alternatives that warranted serious changes in direction.<sup>94</sup>

63. The Department did, however, consider alternative methods for post-market surveillance. "Post-market surveillance" is the practice of monitoring drug safety after the drug has been released on the market. The Department monitors adverse incident reports and patient self-reports, which ultimately leads to determinations about efficacy and side effects.<sup>95</sup>

64. Under the current rules, the Department receives mandated reports of "serious health effects" related to medical cannabis. The Department considered adding a call center to collect these reports, but the Department chose to expand the manufacturers' responsibilities instead. It chose to have the manufacturers operate the call center, receive the reports, carry out product recalls, and notify the Department. The Department determined that the manufacturers would be better suited to operate the call centers than the Department because:

- Manufacturers would be more responsive to questions about their own medical cannabis formulations and need for potential recalls;
- Manufacturers are responsible for the centralized system costs because they pay them up front or the Department bills costs back to them under Minn. Stat. § 152.35(c);

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<sup>92</sup> *Id.*

<sup>93</sup> *Id.*

<sup>94</sup> *Id.* at 22.

<sup>95</sup> *Id.*

- Manufacturers have more flexibility to integrate the adverse incident system with their own IT systems; and
- Manufacturers have already developed existing relationships with companies currently performing post-market surveillance and research.<sup>96</sup>

**(e) 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.**

65. The manufacturers of medical cannabis will incur certain costs in complying with the proposed rules. For example, the manufacturers will bear the costs of operating the required call center and FDA-compliant database. The manufacturers agreed to assume those obligations in their registration agreement with the state of Minnesota, and thus these responsibilities are contractual obligations.<sup>97</sup>

66. Other than the manufacturers of medical cannabis, the Department does not expect other affected parties to incur cost increases related to complying with the proposed rules.<sup>98</sup>

**(f) 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.**

67. The consequences of not adopting the proposed rules are:

- A reduced ability of the Department to successfully manage and implement the medical cannabis program, and to take advantage of the experience gained while rolling out this new program;
- Inadequate protection of the health and safety of patients and the general public;
- Lack of clarity of the rules, in that several of the proposed changes simplify or clarify an existing rule;
- Unnecessary regulatory burdens on interested parties would be left in place, given that some proposed rules reduce the burden on interested parties of complying with the rules; and

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<sup>96</sup> *Id.*

<sup>97</sup> *Id.* at 22, 23.

<sup>98</sup> *Id.* at 22.

- Reduced flexibility for stakeholders in that many proposals increase flexibility and compliance options while reducing administrative costs by regulated manufacturers.

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

68. All forms of cannabis are prohibited on the federal level. Cannabis' placement on Schedule I of the federal Controlled Substances Act of 1970 presupposes there is no medical use for cannabis. As a result, there are no federal regulations allowing for the use of medical cannabis.<sup>99</sup>

69. The Minnesota legislature passed 2014 Minn. Laws, ch. 311 to enable patients suffering from certain severe conditions to use medical cannabis while preventing its being misused or diverted from its medical purpose. This conflicts with the federal prohibition.

**(h) Assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.**

70. The Department asserts there are no other state or federal regulations related to the specific purposes of the proposed rules.<sup>100</sup>

## **2. Performance-Based Regulation**

71. The Administrative Procedure Act<sup>101</sup> requires an agency to describe 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>102</sup>

72. To fulfill these requirements the Department asked its advisory committee and interested stakeholders for input on performance-based standards. While acknowledging that developing and making medical cannabis necessarily required strict controls, the Department opted for performance-based standards for health care facilities and manufacturers. Manufacturers must determine their own recall procedures and transport manifest systems. Also, health care facilities may set their own storage policies.

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<sup>99</sup> *Id.* at 24.

<sup>100</sup> *Id.*

<sup>101</sup> Minn. Stat. § 14.131.

<sup>102</sup> Minn. Stat. § 14.002.

### **3. Consultation with the Commissioner of Minnesota Management and Budget (MMB)**

73. As required by Minn. Stat. § 14.131, and by means of the Office Memorandum dated December 30, 2015, the Commissioner of MMB responded to a request by the Department to evaluate the fiscal impact and benefit of the proposed rules on local units of government. MMB reviewed the Agency's proposed rules and concluded that: "the proposed amendments to Minnesota Rules, Chapter 4770, are unlikely to have a fiscal impact and fiscal benefits on units of local government."<sup>103</sup>

74. 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, and the fiscal impact on units of local government.

### **4. Cost to Small Businesses and Cities under Minn. Stat. § 14.127**

75. Minn. Stat. § 14.127 requires the Agency to "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." 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>104</sup>

76. The Department determined that the two registered manufacturers of medical cannabis have fewer than 50 full-time employees and could incur costs of more than \$25,000 in complying with the proposed rules in the first year.<sup>105</sup> This is consistent with the probable costs of compliance with the proposed rule described in the Regulatory Analysis of the SONAR.<sup>106</sup>

77. The proposed rules require the registered manufacturers of medical cannabis to operate a call center and to have an FDA-compliant database.<sup>107</sup> The manufacturers will have choices in fulfilling those obligations. If the operation of the call center is contracted out, the price would include a one-time set-up fee, an annual fee, and a sliding fee based on the number of calls received. Two confidential estimates received for these services fall between \$25,000 and \$30,000 for the first year, but could be higher if call volumes are high. Alternatively, the registered manufacturers could keep the call center function in-house. According to the U.S. Bureau of Occupational Employment Statistics' May 2014 National Occupation Employment and Wage Estimates, the annual mean wage of a pharmacist (occupation code 29-1051) in

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<sup>103</sup> Ex. 10.

<sup>104</sup> Minn. Stat. § 14.127, subds. 1, 2.

<sup>105</sup> SONAR at 27.

<sup>106</sup> See *id.* at 22-23.

<sup>107</sup> *Id.*

the United States is \$118,470. If a manufacturer elects to keep the call center function in-house and is required to hire even one more half-time pharmacist, that pharmacist's salary would exceed the \$25,000 threshold.<sup>108</sup>

78. While there were no estimates of the costs to the manufacturers of having an FDA-compliant database, the Administrative Law Judge finds that the Department has made the determinations required by Minn. Stat. § 14.127 and approves those determinations.

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

79. 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>109</sup>

80. The Department notes the Commissioner of the Department of Health (Commissioner) has the sole authority to implement the program and enforce the rules for medical cannabis in Minn. Stat. § 152.27, subd. 2, and that the Commissioner has not delegated this responsibility to any local public health agencies or any other local units of government. Hence, the Department concluded no local government will need to adopt or amend an ordinance or other regulation to comply with the proposed rules.<sup>110</sup>

81. The Administrative Law Judge finds that the Department has made the determination required by Minn. Stat. § 14.128 and approves that determination.

## **IV. Rulemaking Legal Standards**

82. The Administrative Law Judge must inquire as to whether: (1) the Agency has statutory authority to adopt the rule; (2) the rule is unconstitutional or otherwise illegal; (3) the Agency has complied with the rule adoption procedures; (4) the proposed rule grants undue discretion to government officials; (5) the rule constitutes an undue delegation of authority to another entity; and (6) the proposed language meets the definition of a rule.<sup>111</sup>

83. Under Minn. Stat. § 14.14, subd. 2, and Minn. R. 1400.2100, an agency must establish the need for, and reasonableness of, a proposed rule by an affirmative presentation of facts. In support of a rule, an agency may rely upon: materials

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<sup>108</sup> *Id.* at 27-28.

<sup>109</sup> Minn. Stat. § 14.128, subd. 1. Moreover, a determination that the proposed rules require adoption or amendment of an ordinance may modify the effective date of the rule, subject to some exceptions. Minn. Stat. § 14.128, subsd. 2, 3.

<sup>110</sup> SONAR at 27.

<sup>111</sup> See Minn. R. 1400.2100 (2015).

developed for the hearing record”<sup>112</sup> “legislative facts” including general and well-established principles that are not related to the specifics of a particular case but which guide the development of law and policy,<sup>113</sup> and the agency’s interpretation of related statutes.<sup>114</sup>

84. A proposed rule is reasonable if the agency can “explain on what evidence it is relying and how the evidence connects rationally with the agency’s choice of action to be taken.”<sup>115</sup> By contrast, a proposed rule will be deemed arbitrary and capricious where the agency’s choice is based upon whim, devoid of articulated reasons or “represents its will and not its judgment.”<sup>116</sup>

85. An important corollary to these standards is that when proposing new rules an agency is entitled to make choices between different possible regulatory approaches, so long as the alternative that is selected by the agency is a rational one.<sup>117</sup> Thus, while reasonable minds might differ as to whether one or another particular approach represents “the best alternative,” the agency’s selection will be approved if it is one that a rational person could have made.<sup>118</sup>

86. Because the Department suggested changes to the proposed rule language after the date it was originally published in the *State Register*, it is also necessary for the Administrative Law Judge to determine if this new language is substantially different from that which was originally proposed. The standards to determine whether any changes to proposed rules create a substantially different rule are found in Minn. Stat. § 14.05, subd. 2. The statute specifies that a modification does not make a proposed rule substantially different if:

- the differences are within the scope of the matter announced . . . in the notice of hearing and are in character with the issues raised in that notice;
- the differences are a logical outgrowth of the contents of the . . . notice of hearing, and the comments submitted in response to the notice; and
- the . . . notice of hearing provided fair warning that the outcome of that rulemaking proceeding could be the rule in question.

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<sup>112</sup> See *Manufactured Hous. Inst. v. Pettersen*, 347 N.W.2d 238, 240 (Minn. 1984); *Minn. Chamber of Commerce v. Minn. Pollution Control Agency*, 469 N.W.2d 100, 103 (Minn. Ct. App. 1991).

<sup>113</sup> Cf. *United States v. Gould*, 536 F.2d 216, 220 (8th Cir. 1976).

<sup>114</sup> See *Mammenga v. Dep’t of Human Servs.*, 442 N.W.2d 786, 789-92 (Minn. 1989); *Manufactured Hous.*, 347 N.W.2d at 244.

<sup>115</sup> *Manufactured Hous. Inst.*, 347 N.W.2d at 244.

<sup>116</sup> See *Mammenga*, 442 N.W.2d at 789; *St. Paul Area Chamber of Commerce v. Minn. Pub. Serv. Comm’n*; 312 Minn. 250, 260-61, 251 N.W.2d 350, 357-58 (1977).

<sup>117</sup> *Peterson v. Minn. Dep’t of Labor & Indus.*, 591 N.W.2d 76, 78 (Minn. Ct. App. 1999).

<sup>118</sup> *Minn. Chamber of Commerce v. Minnesota Pollution Control Agency*, 469 N.W.2d at 103.

87. In reaching a determination regarding whether modifications result in a rule that is substantially different, the Administrative Law Judge is to consider whether:

- persons who will be affected by the rule should have understood that the rulemaking proceeding . . . could affect their interests’;
- the ‘subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the . . . notice of hearing’; and
- ‘the effects of the rule differ from the effects of the proposed rule contained in the . . . notice of hearing.’

## **V. Rule by Rule Analysis**

88. With a few minor exceptions, 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. Rather, the discussion that follows below focuses on those portions of the proposed rules which prompted a genuine dispute as to the reasonableness of the Agency’s regulatory choice or otherwise require closer examination.

89. The Administrative Law Judge finds that the Agency has demonstrated by an affirmative presentation of facts the need for and reasonableness of all rule provisions that are not specifically addressed in this Report.

90. Further, the Administrative Law Judge finds that all provisions that are not specifically addressed in this Report are authorized by statute and that there are no other defects that would bar the adoption of those rules.

### **A. Additional actions urges by stakeholders and the Agency modification**

91. The Department received 36 comments on the proposed rules.<sup>119</sup> Thirty-four of the 36 comments were substantially the same (Collective Comment).<sup>120</sup> No public comments were received after the January 22, 2016 public hearing on the proposed rules governing medical cannabis.<sup>121</sup>

92. Deborah Anderson of Poison Control and Kristen Bluhm of Allina Health Systems submitted comments seeking to clarify the definition of “adverse health effect” and “serious adverse health effect” in Minnesota Rules, part 4770.4002, subpart 1a.<sup>122</sup>

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<sup>119</sup> See Ex. 8.

<sup>120</sup> Letter from Michelle Larson, Director Office of Medical Cannabis to The Honorable James E. LaFave at 2 (Feb. 1, 2016).

<sup>121</sup> *Id.* at 1.

<sup>122</sup> *Id.* at 5.

The Department, in post-hearing changes, modified the definition of “adverse incident” to replace “patient” with “person” because the intent of the rule is to collect information about adverse incidents regardless of whether they occur in registered patients or others.<sup>123</sup>

93. The Collective Comment expressed concern with the potential length of time between the petition to add a new qualifying medical condition or delivery method and the Commissioner’s decision.<sup>124</sup> It also expressed concern that the medical cannabis manufacturers’ compliance costs for the new adverse health incident reporting requirements will be passed through and result in higher costs to patients.<sup>125</sup>

94. There were other comments that addressed specific provisions of the rule. The Department considered them all and adopted the changes listed below. The Department rejected some of the proposed revisions to the rule. In each instance, the Department’s rationale for declining to make the proposed change was well grounded in the record and was reasonable.

95. Consistent with input received from stakeholders, the Department intends to make the following changes to the rules approved by the Revisor’s office and published in the *State Register* on November 16, 2015.<sup>126</sup> The changes are:

- The name of the panel that will assist in the process is changed from “advisory panel” to “review panel” to better reflect its role and purpose;
- The panel’s membership is reduced from nine to seven members and more latitude is given regarding the make-up of the panel for ease of administration;
- The panel is not required to make recommendations but will issue a report, which may or may not include recommendations;
- The Commissioner’s option to defer a decision for six months has been removed to avoid unnecessary delays;
- The process for adding a delivery method now more closely mirrors the process for adding a condition, (the only difference is public comment rather than a standing panel will assist the Commissioner’s decision); and
- Other minor, technical changes.<sup>127</sup>

96. The Department does not plan to make further changes.<sup>128</sup>

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<sup>123</sup> *Id.* See *id.* at Attachment (a Revisor’s draft dated Jan. 16, 2016) at lines 6.16-6.18.

<sup>124</sup> Letter from Michelle Larson, Director Office of Medical Cannabis to The Honorable James E. LaFave at 2.

<sup>125</sup> *Id.*

<sup>126</sup> *Id.* at 3.

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

97. Cassie Traun, a member of the Collective Comment group, testified at the public hearing on January 22, 2016 that the Department's modification to the proposed amendment regarding the potential length of the process was "pretty much exactly what we wanted."<sup>129</sup>

98. The Agency states that these changes do not result in a substantially different rule, and are being made to comply with federal and state law or are supported by the views submitted to the Agency.

99. The Agency's action in revising the text is needed and reasonable and would not be a substantial change from the rule as originally proposed.

## **VI. The Administrative Law Judge's Determinations Regarding the Proposed Rules**

100. The proposed rules seek to amend the rules governing medical cannabis in Chapter 4770. Prior to the public hearing on the proposed rules held on January 22, 2016, the Department received 36 comments, 34 of which were substantially the same.<sup>130</sup> No comments were received after the public hearing. This absence of controversy supports approval of the proposed rules.

101. The Administrative Law Judge concludes that the Department has shown there is a rational basis for the proposed rule. In compliance with Minnesota law, the Department considered the advice of members of the public, medical providers, pharmacists, health care facilities, law enforcement, nonprofit advocacy groups, medical cannabis patients, and other medical cannabis manufacturers. As described in the SONAR, the Department engaged in an extensive outreach program. The Department's Office of Medical Cannabis staff made over 60 presentations around the state. The process afforded significant opportunities for input from members of the public, organizations, businesses, and others.

102. The Department's SONAR and post-hearing submissions provide an adequate explanation of the need for and reasonableness of the proposed rule and the rule falls within the broad authority the legislature has given to the Department to create the proposed rule. The Administrative Law Judge concludes that, in accordance with applicable case law,<sup>131</sup> the Department has provided ample explanation of the facts on which it is relying and how those facts connect rationally with the approach it has taken in creating the proposed rule.

103. Accordingly, the Administrative Law Judge finds that the Department has demonstrated that:

- a) the proposed rules are needed and reasonable;

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<sup>129</sup> Test. of C. Traun (T. 27-28).

<sup>130</sup> See Collective Comment.

<sup>131</sup> *Manufactured Hous. Inst.*, 347 N.W.2d at 244.

- b) there are no other impediments to preclude their adoption; and
- c) there are no defects found in the rules as proposed.

Based upon the Findings of Fact and the contents of the rulemaking record, the Administrative Law Judge makes the following:

### **CONCLUSIONS OF LAW**

1. The Minnesota Department of Health gave notice to interested persons in this matter.

2. Except as noted in Findings 23, 28, and 29 the Department has fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule. The Administrative Law Judge concludes that the cited omissions constitute harmless error under Minn. Stat. § 14.15, subd. 5.

3. The Administrative Law Judge concludes that the Department has fulfilled its additional notice requirements.

4. The Department has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, .15, subd. 3, .50(i), (ii).

5. The Notice of Hearing, the proposed rules, and Statement of Need and Reasonableness (SONAR) complied with Minn. R. 1400.2080, subp. 5 (2015).

6. The Department has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, .50.

7. The modifications to the proposed rules suggested by the Department after publication of the proposed rules in the *State Register* are not substantially different from the proposed rules as published in the *State Register*, within the meaning of Minn. Stat. §§ 14.05, subd. 2, .15, subd. 3.

8. As part of the public comment process, a number of stakeholders urged the Department to adopt other revisions to Part 4770. In each instance, the Department's rationale in declining to make the requested revisions to its rules was well grounded in this record and reasonable.

9. A finding or conclusion of need and reasonableness with regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the proposed rules based upon this Report and an examination of the public comments, provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions of Law, the Administrative Law Judge makes the following:

### **RECOMMENDATION**

**IT IS HEREBY RECOMMENDED** that the proposed amended rules be adopted.

Dated: March 25, 2016

  
JAMES E. LAFAVE  
Administrative Law Judge

Reported: 1 Transcript

### **NOTICE**

This Report must be available for review to all affected individuals upon request for at least five working days before the agency takes any further action on the rules. The agency may then adopt the final rules or modify or withdraw its proposed rule. If the agency makes any changes in the rule, it must submit the rule to the Chief Administrative Law Judge for a review of the changes prior to final adoption. Upon adoption of a final rule, the agency must submit a copy of the Order Adopting Rules to the Chief Administrative Law Judge. After the rule's adoption, the OAH will file certified copies of the rules with the Secretary of State. At that time, the agency must give notice to all persons who requested to be informed when the rule is adopted and filed with the Secretary of State.