



November 6, 2015

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Re: Proposed Amendments to Rules Governing Medical Cannabis, Minnesota Rules Chapter 4770; Revisor's ID Number RD04275

Dear Librarian:

The Minnesota Department of Health (MDH) intends to amend rules governing medical cannabis. MDH plans to publish a Dual Notice of Intent to Adopt Rules in the November 16, 2015 issue of the *Minnesota State Register*.

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

If you have questions, please contact me at (651) 539-3004.

Sincerely,

A handwritten signature in black ink, appearing to read "Darin Teske", with a large, sweeping flourish extending to the left.

Darin Teske, Policy Analyst
Office of Medical Cannabis
Minnesota Department of Health
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St Paul, MN 55164-0882

Enclosure: Statement of Need and Reasonableness

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Minnesota Department of Health
Office of Medical Cannabis

In the Matter of the Proposed Rules of the Minnesota Department of Health
Relating to Medical Cannabis,
Minnesota Rules, Chapter 4770.
Revisor's ID Number: 04275

Statement of Need and Reasonableness

November 2015

November 4, 2015



Edward Ehlinger, M.D., M.S.P.H.
Commissioner
Minnesota Department of Health
P.O. Box 64975
Saint Paul, MN 55164

ABOUT THIS DOCUMENT

This Statement of Need and Reasonableness (SONAR) supports the Minnesota Department of Health's revision of its rules on the Medical Cannabis program. The proposed rules are available at:

<http://www.health.state.mn.us/topics/cannabis/rulemaking/index.html>

For questions or concerns regarding this document, please contact Darin Teske at darin.teske@state.mn.us or, call (651) 539-3004.

The Minnesota Department of Health (MDH) will publish the proposed rules in the Minnesota's *State Register* at a later time. For Minnesota's statutory procedure for adopting administrative rules, see Minnesota Statutes, section 14.001 et seq., and in particular section 14.22.

Upon request, MDH can make this SONAR available in an alternative format. Contact Darin Teske to make a request at the Minnesota Department of Health, Office of Medical Cannabis, P.O. Box 64882, Saint Paul, MN 55164-0882, phone (651) 539-3004, or email darin.teske@state.mn.us.

**MINNESOTA DEPARTMENT OF HEALTH
STATEMENT OF NEED AND REASONABLENESS
Proposed Amendments to the Rules on Medical Cannabis
(Minnesota Rules, chapter 4770)**

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I. INTRODUCTION

The Minnesota Department of Health (MDH or the department) through its Office of Medical Cannabis (OMC) regulates medical cannabis in Minnesota. Governor Mark Dayton signed the medical cannabis therapeutic use law, 2014 Minnesota Laws, chapter 311 (codified at Minnesota Statutes, sections 152.22 to 152.37), into law on May 29, 2014. The legislature designed this act to enable patients having certain serious medical conditions to use cannabis for therapeutic treatment, while preventing its being misused or diverted from its medical purpose. Another objective of the program is to generate and collect data using science-based methods to advance evidence about cannabis' medical effectiveness from anecdotal accounts to formal public health research. This Statement of Need and Reasonableness (SONAR) supports MDH's revision of its Permanent Rules Relating to Medical Cannabis (the rules). The revised rules are available at: <http://www.health.state.mn.us/topics/cannabis/rulemaking/index.html>.

Medical cannabis has the uneasy status of being permissible under state law, but prohibited under federal law. 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 (21 U.S.C. §801 et seq.). The U.S. Department of Justice has issued guidance documents to its District Attorneys regarding federal enforcement of cannabis law in jurisdictions with state-adopted medical cannabis programs. Most applicable, Deputy James Cole issued a guidance memorandum (the Cole memo) in August 2013, which established eight federal enforcement priorities to prevent:

- distribution to minors,
- criminal enterprise, gang, and cartel involvement,
- diversion to other states,
- use of state-authorized activity as a cover for other illegal activity,
- violence and the use of firearms,
- drugged driving and other adverse public health issues,
- marijuana grows on public lands, and
- possession or use on federal property

In addition, the Cole memo emphasizes the need for states with medical cannabis programs to establish strong and effective state regulatory systems.¹

Minnesota Laws 2014, Chapter 311, charged the department with implementing a medical cannabis patient registry program within tight statutory timelines. The statutory structure given the program includes two vertically integrated medical cannabis manufacturers, a patient registry, and a research element. The statutes required the manufacturers to be registered by December 1, 2014 (*see* Minnesota Statutes, section 152.25, subdivision 1) and distribution of medical cannabis to registered patients to begin by July 1, 2015 (*see* Minnesota Statutes, sections 152.25, subdivision 1(b)(1) and 152.29, subdivision 1). To launch the program by July 1, 2015,

¹ The Cole memo appears at <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>

MDH adopted two sets of rules using the expedited rulemaking process (see section II. B. below).

Medical cannabis is a dynamic policy field and is developing rapidly. The department's objectives for this rules revision are to:

- clarify existing requirements and correct editorial issues,
- address inconsistencies within the current rules,
- address needs identified after completion of the expedited rules, and
- simplify the requirements, where feasible.

These changes maintain standards necessary to promote and protect the health and safety of the public.

MDH appointed an advisory committee to advise the department on the new rules and rule amendments. This committee considered current rules, 2015 legislative changes, and stakeholder interests in the program. Groups represented on the committee included patients, health care providers, health care institutions, law enforcement, and manufacturers. This committee met five times for two hours each time to develop its recommendations and provide feedback to the department.

The department also regularly testifies before and receives feedback from the Task Force on Medical Cannabis Therapeutic Research (task force) that was established by Minnesota Statutes 152.36. This task force is composed of 23 members, appointed by the Governor and legislative leadership. Its membership represents the following interests: legislature, state agencies, patients, health care providers, law enforcement, and substance-use treatment providers. This group was tasked with assessing and analyzing:

- program design and implementation,
- impact on the health care provider community,
- patient experiences,
- impact on the incidence of substance abuse,
- access to and quality of medical cannabis and medical cannabis products,
- impact on law enforcement and prosecutions,
- public awareness and perception, and
- any unintended consequences.

In identifying these topics for the task force, the legislature established them as policy priorities.

II. BACKGROUND

A. STATUTORY AUTHORITY

Minnesota Laws 2014, chapter 311, established the Minnesota medical cannabis patient registry program and directed the department to implement the law. This law was codified at Minnesota

Statutes, sections 152.22 to 152.37. Section 6 of the law (codified at section 152.26) provides that: “[t]he commissioner [of health] may adopt rules to implement sections 152.22 to 152.37.”

Section 19 (codified at section 152.261) requires MDH to adopt rules that establish reporting requirements for incidents of unauthorized possession and incidents of overdose.

Governor Mark Dayton signed Minnesota Laws 2014, chapter 311, into law on May 29, 2014, and it became effective the day following final enactment. Notice of intent to adopt rules must be published within 18 months of the effective date of the legislative authorization. *See* Minnesota Statutes, section 14.125.

B. PRIOR RULEMAKING

The Department was given the authority to adopt and implement administrative rules necessary for medical cannabis manufacturers to begin distributing medical cannabis to patients by July 1, 2015 using the expedited rulemaking process under Minnesota Statutes, section 14.389. Section 5, subdivision 3 of 2014 Minnesota Laws, chapter 311 (codified at Minnesota Statutes, section 152.25, subdivision 3(a)), provides:

The commissioner shall adopt rules necessary for the manufacturer to begin distribution of medical cannabis to patients under the registry program by July 1, 2015, and have notice of proposed rules published in the State Register before January 1, 2015.

And 2014 Minnesota Laws, chapter 311, section 6 (codified at Minnesota Statutes, section 152.26), provides:

The commissioner may adopt rules to implement sections 152.22 to 152.37. Rules for which notice is published in the State Register before January 1, 2015, may be adopted using the process in section 14.389.

The department adopted two sets of rules using the expedited process: one set applying to the manufacturers and one set applying primarily to the patients, their caregivers, and participating health care practitioners.

(1) Manufacturer Rules. MDH published proposed expedited rules that apply to medical cannabis manufacturers in the *State Register* on October 6, 2014 (Revisor’s ID Number 4272). Administrative Law Judge Barbara Case approved these rule by Order on Review of Rules dated December 9, 2014. These rules were effective on publication in the *State Register* on January 20, 2015. The vertically integrated manufacturers are responsible for cultivating, producing, and distributing all medical cannabis to patients enrolled in Minnesota’s medical cannabis registry program. Minnesota Statutes, sections 152.25, subdivision 1 and 152.29. These expedited manufacturer rules were circulated and posted on the department’s medical cannabis website during the medical cannabis manufacturer application process during the fall of 2014 and can be found at Minnesota Rules parts 4770.0100–4770.2700.

The expedited rules prescribe the manufacturers’ operation. They spell out restrictions for producing medical cannabis starting with planting, growing, and harvesting cannabis plants

through processing them into medical cannabis. These rules also specify how the manufacturers must handle the medical cannabis until it is dispensed and also the disposal of the waste plant material. The manufacturers' requirements address:

- packaging and labeling the medical cannabis for patients,
- site security,
- transportation and its corresponding security,
- advertising and marketing the manufactured medical cannabis,
- disposing cannabis plant material and waste medical cannabis,
- quality assurance of the medical cannabis produced, and
- record keeping.

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.

(2) Patient and Health Care Practitioner Rules. MDH published a second set of proposed expedited rules that apply to patients and health care practitioners in the *State Register* on December 15, 2014 (Revisor's ID Number 4301). Administrative Law Judge Laura Sue Schlatter approved these rules by Order on Review of Rules dated May 4, 2015. These rules were published in the *State Register* and became effective on June 29, 2015. Minnesota Rules, parts 4770.4000 through 4770.4018 apply primarily to the patients, and their parents or legal guardians, their designated caregivers, and health care practitioners who are taking part in the registry program. In her May 4 order (ALJ Schlatter's May 4 Order), Judge Schlatter made recommendations for MDH's consideration.² MDH proposes to incorporate some of the recommendations in these amendments.

The statutes require patients to be Minnesota residents and be diagnosed with at least one of the qualifying medical conditions. The existence of a qualifying medical condition must be certified by a health care practitioner. "Health care practitioner" is defined in statute 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 of care and treatment of the underlying qualifying medical condition. Minnesota Statutes, section 152.22, subdivision 4.

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. If the health

² (<http://mn.gov/oah/images/0900-32442MedicalCannabisExpeditedRuleReport.pdf>)

care practitioner certifies the patient needs a caregiver to either access or administer the medication, the patient may then “invite” a caregiver to register with the program. Part of registering the designated caregiver is a state-level criminal history check before enrolling the caregiver in the registry. Parents and legal guardians can act as caregivers without having to register as a caregivers or undergo a criminal history check.

The patient registry requirements describe:

- application qualifications and procedures for patients, designated caregivers, and health care practitioners;
- procedure for health care practitioners providing a 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;
- record keeping and reporting requirements for health care practitioners; and
- disposal of unused medical cannabis by persons authorized to possess it.

In addition to the operational requirements of the patient registry, these rules adopted in June 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.

III. PROPOSED RULES

The department proposes to revise the following rule parts:

- Minnesota Rules, part 4770.0200
- Minnesota Rules, part 4770.0850
- Minnesota Rules, part 4770.1100
- Minnesota Rules, part 4770.1300
- Minnesota Rules, part 4770.1400
- Minnesota Rules, part 4770.1700
- Minnesota Rules, part 4770.2000
- Minnesota Rules, part 4770.4002
- Minnesota Rules, part 4770.4003
- Minnesota Rules, part 4770.4004
- Minnesota Rules, part 4770.4009
- Minnesota Rules, part 4770.4010

Minnesota Rules, part 4770.4011
Minnesota Rules, part 4770.4014
Minnesota Rules, part 4770.4017

The department proposes to add the following rule parts:

Minnesota Rules, part 4770.1460
Minnesota Rules, part 4770.1850
Minnesota Rules, part 4770.4030

The department proposes to renumber the following rule part:

Minnesota Rules, part 4770.4011, as part 4770.1750

IV. RULE-BY-RULE ANALYSIS

This section discusses each proposed change. Some rule parts are self-explanatory and thus necessary and reasonable on their face and, therefore, only explained briefly, while others are explained in more detail for future rule interpretation.

Part 4770.0200 DEFINITIONS

Minnesota Rules, part 4770.0200 defines the terms used throughout parts 4770.0100–4770.2700. Defining words used in this rule ensures that regulated and other affected parties clearly understand the terms used in the requirements. Definitions provide consistency, clarity, and understanding when reading and interpreting the proposed rules.

Subpart 13. Distribution facility. The department proposes to add “and medical cannabis products” to the definition of “distribution facility” to make it more consistent with the statutory language. Minnesota Statutes, section 152.29, subdivisions 1(a) and 3(b) explicitly authorize a distribution facility to dispense medical cannabis products.

Subpart 25. Manufacturer facility. The department proposes to amend the definition of manufacturer facility to conform the language to the statutory authority language, which will avoid potential confusion from using different terms to describe the same facility.

Part 4770.0850, PACKAGING AND LABELING

Subpart 1. The department proposes to insert a missing “or” in item C for so that the phrase “business name or logo” makes sense. This change is not substantive.

Part 4770.1100 TRANSPORTATION OF MEDICAL CANNABIS

Subpart 2. Manifest. The department proposes to insert a new item A into this subpart that would require each manufacturer itself to develop a transportation manifest system. This manufacturer-developed manifest would be required to include minimum requirements, subject to the commissioner's approval.

The current rule requires the commissioner to develop a manifest for the manufacturers to use. The manufacturers informed MDH that allowing them to develop their own manifest system, subject to department approval, would allow them to design it to better integrate with their tracking software. This change will allow the manufacturer more flexibility to fit the manifest into their software system without compromising MDH's ability to ensure the public health and safety is protected by requirements being met.

MDH also proposes to renumber subpart 2(A) and 2(B) to 2(B) and 2(C) and to modify both sub-items to include each destination to which medical cannabis may legally be transported. The change would add laboratories and waste-to-energy facilities as transport destinations. The resulting requirement would still require that a manufacturer send a transport manifest to the destination and have it signed upon receipt of the medical cannabis. This change makes the list of authorized destinations complete and corrects an oversight in the current rule by including destinations mistakenly not included.

Subpart 3. Transportation of medical cannabis; vehicle requirements. To reduce the risk of diversion, medical cannabis packaged in tamper-evident containers must be placed in larger, tamper-evident containers for transport. But the current rule is unclear. The department proposes to modify item (A)(1)(a) by inserting the word "bulk" after "tamper-evident" and before "containers" to clarify that containers used for transporting medical cannabis must be tamper-evident themselves and must contain tamper-evident packages of medical cannabis. Diverting from a large number of small tamper-evident packages is easier than from a small number of large tamper-evident containers.

Item E is amended to allow a single employee of the medical cannabis manufacturer in a vehicle to transport medical cannabis to the testing laboratories. The current rule requires all manufacturer transports of medical cannabis to be staffed by at least two employees. The two state-registered medical cannabis manufacturers jointly proposed the modification to respond to the amount of medical cannabis being transported between the manufacturers and the labs. The rules advisory committee considered the proposal and agreed that since the amount of medical cannabis being transported to the lab is nominal, the risk of diversion is low. Thus there was consensus to support this rule change.

Part 4770.1300 MANDATORY SIGNAGE

Item B. MDH proposes to clarify the requirement in item B by changing "premises" to "manufacturing facility and each distribution facility" to more precisely identify the premises to which the requirement applies. The resulting rule would clearly require each

manufacturing site and each distribution facility to post a sign reading “THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE.”

Part 4770.1400 PERSONNEL IDENTIFICATION SYSTEM

Subpart 4. The department proposes to simplify this subpart to clarify that manufacturer employees must keep their employee badges visible whenever they are transporting medical cannabis. The current rule requires that they have their badges visible only when transporting to a distribution facility. The requirement was intended to apply whenever medical cannabis is being transported. The proposed modification remedies this defect in the current rule and is both necessary and reasonable.

NEW Part 4770.1460 RENEWAL OF REGISTRATION

The department proposes to add this requirement that a manufacturer apply to renew its registration with the state at least six months before its current registration agreement expires. This would allow the department and manufacturer to plan and manage the registration renewal process, reducing administration costs and uncertainty for both parties.

Minnesota Rules part 4770.1500 requires a manufacturer to notify the department at least six months before ceasing operations. However, there is no corresponding requirement that the manufacturer notify the department it intends to continue operations as its registration agreement winds down. Such notice became more relevant with the passage of Minnesota Laws 2015, chapter 74, amending Minnesota Statutes, section 152.25, subdivision 1, which extended the term of registration of a manufacturer from one year to two.

Part 4770.1700 MEDICAL CANNABIS MANUFACTURER; PRODUCTION REQUIREMENTS

Subpart 3. General sanitation requirements. The department proposes to modify item J to delete redundant language. It is reasonable and necessary to remove potentially confusing, duplicative wording so the requirements of the rule can be understood.

Subpart 4. Storage. The department’s proposed modification to item B would add the word “during,” which is needed to state when the provision applies. It was inadvertently omitted from current rule.

NEW Part 4770.1750 MEDICAL CANNABIS DISTRIBUTION

The department proposes to renumber current Minnesota Rules, part 4770.4011 as part 4770.1750. This proposed move puts the requirement, which applies to the manufacturer’s medical cannabis distribution to patients, closer to other manufacturer requirements.

In addition, the department proposes to modify subpart 2(D) to insert “a review of” before “any changes” to clarify the nature of the consultation that the rule requires and to provide parallel sentence structure. This modification is technical and not substantive.

NEW Part 4770.1850 RECALL PROCEDURE

This new rule part would formalize and standardize a recall procedure that the manufacturers would be required to use. The purpose of the rule is to protect patient safety and ensure the reliability of the medical cannabis available in Minnesota.

Having a reliable supply of medical cannabis and protecting patient safety implies a need to recall medical cannabis known or suspected of presenting a risk of harm to the patients. Likewise, Minnesota Rules, part 4770.0500 requires manufacturers to have a quality control program, maintain reserve samples of their medical cannabis, and conduct retesting of their samples if required by MDH, but at present there is no explicit requirement to have a written recall procedure if a batch of medical cannabis fails to meet standards. This proposed rule remedies that.

The department has determined that patient safety will be better protected by having this requirement in addressed by rule. In their registration agreements with the state, both manufacturers agreed to be bound by the terms of their applications, which had recall requirements. Given this, the new rule would not impose a significant new burden on the manufacturers.

The rules advisory committee, after discussing the need for a recall rule, reached consensus that manufacturers must have a reliable and effective recall plan and procedure in place before one is needed. The committee briefly discussed a prescriptive recall process modelled on the US FDA’s approach but determined that to be too costly and cumbersome for the state program. It decided instead that the best approach was to allow the manufacturer some flexibility but to require departmental approval to ensure the process is complete and patient safety is protected.

It is necessary for the manufacturers to have an established recall procedure in place before the need for a recall arises and it is reasonable for MDH, as the regulatory body, to have final approval over that procedure.

Part 4770.2000 MEDICAL CANNABIS LABORATORY APPROVAL; APPLICATION AND APPROVAL

Subpart 2. Application requirements; commissioner’s evaluation. The department proposes to insert item C, which adds an explicit requirement that no board member, officer, manager, owner, partner, principal stakeholder, or member of a medical cannabis manufacturer may have an interest or voting rights in an independent laboratory. Minnesota Statutes, section 152.29, subdivision 1(b) requires manufacturers to contract with an

approved laboratory to test the medical cannabis produced for content, contamination, and consistency. Moreover, Minnesota Statutes, section 152.25, subdivision 1(d) provides it must be an independent laboratory. This proposed rule requirement is necessary and reasonable to maintain the independence of the laboratories from the manufacturers.

Part 4770.4002 DEFINITIONS

Minnesota Rules, part 4770.4002 defines the terms used in parts 4770.4001–4770.4018. Defining words used in this rule ensures that regulated and other affected parties clearly understand the terms being used in the requirements. Definitions provide consistency, clarity, and understanding when reading and interpreting the proposed rules.

Subpart 1a. Adverse incident. Department rule makers propose this definition be used for adverse incident reporting purposes proposed in rule part 4770.4004. Minnesota Statutes, section 152.162 requires reporting adverse incidents but expressly leaves the details to rulemaking. Because this program is designed to study evidence of the effects of medical cannabis, the department needs to know how patients who take medical cannabis are affected. Thus we need to gather as much information as possible, with special attention to responses that show harm. This subpart broadly describes the events that trigger reporting as any negative medical occurrence in a patient after using medical cannabis. These occurrences can be physical or psychological. Encompassing harmful reactions, symptoms, or disease is reasonable to carry out our statutory mandate.

Subpart 4a. Diversion involving adverse incidents. The department proposes this definition be used for adverse incident reporting purposes proposed in rule part 4770.4004. This definition simply dovetails with the definition of diversion involving adverse incidents for the reasons discussed for subpart 1a, above.

Subpart 15a. Patient Advocate. The department proposes this definition of “patient advocate.” The term is used in Minnesota Rules, part 4770.4003. MDH is following up on ALJ Schlatter’s May 4 Order with this definition. The rules advisory committee reviewed the proposed definition and support it.

Subpart 15b. Peace Officer. “Peace officer” has the meaning given in Minnesota Statutes, section 626.84, subdivision 1, paragraph c.

Subpart 22a. Serious adverse incident. The department proposes this definition be used for adverse incident reporting purposes proposed in rule part 4770.4004. Minnesota Statutes, section 152.162 is written in terms of reporting “overdose” events but, as mentioned above, expressly leaves the details to rulemaking. The department proposes this definition of serious adverse incidents to give meaning to the requirement since there is not a reliable body of scientific evidence to turn to about overdoses. The department therefore offers this definition that encompasses situations of severe harm, disability, or death to differentiate the adverse incidents that require immediate scrutiny or treatment.

Part 4770.4003 PROCESS FOR ADDING A QUALIFYING MEDICAL CONDITION

Minnesota Statutes section 152.27, subdivision 2(b) authorizes the commissioner to add a qualifying delivery method or a qualifying medical condition upon notifying the legislative policy committees and allowing for legislative response. Approved qualifying medical conditions are then effective the following August 1 under this same statute. Minnesota Rules, part 4770.4003 outlines the process for a person to request the administrative addition of a medical condition or delivery method to the list of qualifying medical conditions or the list of approved delivery methods.

The department proposes to make several grammatical changes in this subpart recommended by ALJ Schlatter's May 4 Order. These changes make the rule clearer, more readable, and easier to understand. There are several proposed modifications, some technical in nature and some substantive. They are broken out below.

Subpart 2. Requests for adding a condition. The department proposes to modify the language in the first paragraph of this subpart to add details that we did not previously have. The schedule show that the commissioner would accept requests to add a qualifying medical condition beginning June 1, 2016. This change was recommended in ALJ Schlatter's May 4 Order. This change will eliminate potential confusion about whether the June 1, 2016 date applies to the forms becoming available or to the requests being accepted.

The department also proposes a specified procedure for those requesting conditions to be added that they file them only during a two-month-long window each June and July, with the commissioner's review ending each December 1 when the commissioner must post his or her decision. This allows the commissioner sufficient time to notify the legislature as required by statute. As noted above, approved qualifying medical conditions are then effective the following August 1 under Minnesota Statutes, section 152.27, subdivision 2(b). The department surveyed processes that other state medical cannabis programs use to review their requests for adding qualifying medical conditions. MDH developed this proposed modification as a result. MDH determined that limiting requests to one submission window would allow greater administrative ability to manage the process with limited resources, ability to schedule resources, and increased predictability for members of advisory panel. MDH staff will supplement the public requests by supplying its objective review of scientific literature about the efficacy of cannabis in treating the proposed medical condition. And the predictability of one submission window will enable MDH to better schedule staff time to meet the rule requirements.

In addition, the department proposes to limit each request to a single medical condition. Requests that contain multiple conditions are potentially confusing and can be difficult to interpret. It is reasonable and administratively necessary to limit the requests to single topics.

Subpart 4. Advisory panel meetings. The department proposes to change the minimum number of meetings of the advisory panel per year from three to one, to correspond with the one submission window proposed in subpart 2. A minimum of one meeting following the submission window is reasonable and, if circumstances require, MDH could call the panel together more frequently.

Part 4770.4004 ~~SERIOUS HEALTH EFFECT~~ ADVERSE INCIDENT REPORTING

Minnesota Statutes, section 152.261 requires the department to adopt rules that govern how law enforcement officials and health care professionals report incidents of overdose. Likewise, data collected through the adverse incident reports may be used by the Task Force on Medical Cannabis Therapeutic Research to evaluate the policy topics they are charged to review. These topics include the impact of medical cannabis on patient experiences and the quality of medical cannabis available (*see* Minnesota Statutes, section 152.36, subdivision 2).

The department proposes to rewrite the current rule to correspond with requirements established by the University of Mississippi for the medical cannabis post-market surveillance demonstration program. The University of Mississippi developed the proposed rule after their department became the first state program to take part in a medical cannabis post-market surveillance demonstration program run through the University of Mississippi's National Center for Natural Product Research. The University of Mississippi contracts with the National Institute of Health's National Institute on Drug Abuse (NIDA) to grow and supply cannabis to NIDA's Drug Supply Program, which is the primary source of federally-supplied cannabis available to medical researchers. Thus, the University of Mississippi holds the rare authority to grow and study medical cannabis scientifically.

Participation in the demonstration program would further MDH's research goals by gathering information relating to the safety and unintended effect of medical cannabis, in addition to satisfying the requirements of Minnesota Statutes, section 152.261.

Subdivision 1. Reporting requirements. This proposed subdivision identifies those who are required to report adverse incidents experienced by the patients. The patients themselves, their registered caregivers, and their certifying health care practitioners are the first group who are required to report. This group must report adverse incidents to the manufacturer where the medical cannabis was dispensed within 15 days unless it is a "serious" adverse incident, which must instead be made within five days. Serious adverse incidents must be reported more quickly to possibly prevent additional serious incidents caused by medical cannabis that should be recalled.

The second group required to report are peace officers, as defined in Minnesota Statutes, section 626.84, subdivision 1(c). They must report adverse incidents of overdose and diversion to the department within 15 business days unless the incident is part of an on-going investigation, which must instead be reported within 72 hours of the investigation's

conclusion. Law enforcement representatives on the advisory committee requested delayed reporting if the incident is part of an on-going investigation to prevent compromising the investigation. The department agrees.

Subpart 2. Manufacturer requirements. The department proposes to require manufacturers to maintain a toll-free telephone line, staffed by trained professionals, to handle adverse incident calls. Manufacturers must also make an on-line reporting option available. As discussed below, the proposed rule also specifies how the data collected will be documented, classified, and stored. These requirements will allow data generated by Minnesota's medical cannabis program to integrate with the University of Mississippi's demonstration program. In addition, data will be uniform, giving researchers a larger and more informative data set. Failure to collect, classify, and store data consistently and uniformly would frustrate one of the goals of the program: to allow for better research into medical cannabis effectiveness and safety.

The proposed structure for adverse incident reporting would allow the data to integrate with the University of Mississippi's demonstration program. Further, the proposed rule requires the adverse incidents reported be classified consistent with the Medical Dictionary for Regulatory Activities (MedDRA). MedDRA is a set of highly specific standard medical terms developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, an international group of regulators and pharmaceutical industry representatives. MedDRA's standard terms are used for regulating the full spectrum of pharmaceutical production, from pre-marketing to post-marketing activities, and for data entry, retrieval, evaluation, and presentation. The US FDA uses MedDRA as guidance. Requiring use of MedDRA classification for Minnesota's post-market medical cannabis surveillance is thus reasonable.

Likewise, requiring manufacturers to use a database that also complies with FDA regulations (Title 21 CFR Part 11) furthers consistency within the industry. Minnesota's manufacturers would also comply with requirements established for the National Center for Natural Product Research. This too allows datasets to be combined more readily, which increases data usefulness. Although Minnesota's medical cannabis manufacturers are not FDA-regulated, the FDA developed its rules for storing and maintaining information securely, and these rules are available to and accepted by industry. For all these reasons requiring the manufacturers to maintain an adverse incident database that is consistent with FDA regulations allows the manufacturers' collected data to be maintained securely and easily integrated into a larger national demonstration program.

Subpart 3. Manufacturer reports. This subpart requires manufacturers to compile and file aggregated monthly adverse incident reports with the department. The manufacturers would also be required to file an annual compilation with the department.

It further requires manufacturers to file expedited reports with the department if there is a serious adverse event, an adverse event that might have been serious without medical intervention, or diversion resulting in an adverse incident. These reports must be filed

within 10 business days. An expedited report allows the department to take corrective action to avoid potential further harm to patients.

Part 4770.4009 CAREGIVERS

The department proposes to modify the current rule to make it consistent with the recommendation in ALJ Schlatter's May 4 Order. It adds the qualifying language "where applicable" following the phrase "together with the patient's designated caregiver," to recognize that not all patients will have registered designated caregivers in the medical cannabis patient registry.

Part 4770.4010 UNAUTHORIZED POSSESSION OF MEDICAL CANNABIS REPORTING

Minnesota Statutes, section 152.261 requires reporting rules for law enforcement officials and health care professionals to report incidents of unauthorized possession of medical cannabis. Moreover, Minnesota Statutes, section 152.36, subdivision 2 instructs the Task Force on Medical Cannabis Therapeutic Research to evaluate the impact of medical cannabis on law enforcement,

This modification to current rule would remove firefighters, paramedics, and emergency medical technicians from those required to report unauthorized possession. These groups would focus their attention on the immediate safety and health of the injured person. As a result, the rules advisory committee decided that those groups would refer the matter to law enforcement to determine whether the possession was authorized. Removing these professions from the list of those required to report for these reasons is necessary and reasonable to conserve public resources, while leaving ample protections for the public.

Under the proposed rule, a peace officer must report to the department when evidence establishes a reasonable suspicion of unauthorized possession. The current rule does not communicate a clear standard for when officers must make the report. Establishing a reporting threshold standard is necessary so that affected groups know when they must report. The department selected the reasonable-suspicion standard because it is the criminal law standard that justifies a search. This standard requires a belief that is based on articulated facts and circumstances while not being as high a standard as that required to make an arrest (probable cause).

The department proposes that the report be made within 72 hours, but if the suspicion of unauthorized possession arises during an investigation, the reporting requirement can be delayed until the investigation concludes. The rules advisory committee agreed with its law enforcement members that the reporting requirement should not compromise the integrity of an on-going investigation.

Also, the department proposes to insert an item B, adding a requirement that a peace officer must report to MDH if someone authorized to possess cannabis has violated the statutory limitations on medical cannabis use and possession. Minnesota Statutes, section 152.23 limits the protections and immunities for registry participants. The protections and immunities do not cover:

- (1) undertaking any task under the influence of medical cannabis that would constitute negligence or professional malpractice;
- (2) possessing or engaging in the use of medical cannabis:
 - (i) on a school bus or van;
 - (ii) on the grounds of any preschool or primary or secondary school;
 - (iii) in any correctional facility; or
 - (iv) on the grounds of any child care facility or home daycare;
- (3) vaporizing medical cannabis pursuant to section 152.22, subdivision 6:
 - (i) on any form of public transportation;
 - (ii) where the vapor would be inhaled by a nonpatient minor child; or
 - (iii) in any public place, including any indoor or outdoor area used by or open to the general public or a place of employment as defined under section 144.413, subdivision 1b; and
- (4) operating, navigating, or being in actual physical control of any motor vehicle, aircraft, train, or motorboat, or working on transportation property, equipment, or facilities while under the influence of medical cannabis.

Under Minnesota Statutes, section 152.27, subdivision 3(c)(2), the department may refuse to re-enroll a patient who fails to meet the requirements of sections 152.22 to 152.37. This proposed reporting requirement is the most likely way the department can discover a registrant has been violating the law. Without it many violations could go undetected.

Part 4770.4014, subp. 2C

This item explicitly authorizes health care practitioners to communicate with subspecialists who are treating the patient. This provision emphasizes that while health care practitioners must rely on their professional judgment when certifying a patient's medical condition and being available to continue treatment of the patient's medical condition, he or she has permission to collaborate with others treating the patient, lessening the professional responsibility for treating the patient.

Health care providers on the rules advisory committee opined that one reading of current rules could be that a health care practitioner who certifies a patient's qualifying medical condition is solely responsible for treating that medical condition. Health care providers introduced the proposed change at both the June and August rules advisory committee meetings. Committee members agreed that the proposed language was necessary to clarify that health care practitioners are not *solely* responsible for treating their patient's medical condition but they can consult with other subspecialists, consistent with appropriate standards of medical care.

Part 4770.4017 RECORDS MAINTAINED BY THE CERTIFYING HEALTH CARE PRACTITIONER

This proposed rule part modification would correct mistakes in current rule. By replacing the word "recommended" with "certified" and striking out extraneous language, the department would make the health requirements consistent with their actual health care practitioner duties. Health care practitioners are not required to "recommend" medical cannabis under Minnesota Statutes sections 152.22 through 152.37. Instead health care practitioners certify that a patient's qualifying medical condition exists and the patient's need for a caregiver to access or administer the medical cannabis. Practitioners must also be available for continuing treatment of the qualifying medical condition and to annually recertify the patient's qualifying medical condition (*see* Minnesota Statutes 152.28, subdivision 1). The practitioner must also allow access to medical records if requested by MDH. The proposed change to the language would eliminate any confusion caused by the word "recommended" when only the practitioner's certification of a qualifying medical condition is required.

NEW Part 4770.4030 HEALTH CARE FACILITIES STORING MEDICAL CANNABIS

The proposed new rule part allows, but does not require, a health care facility, defined under Minnesota Statutes, section 152.34(a) to adopt a storage policy that either takes control of their patient's medical cannabis or leaves the medical cannabis in the patient's control. This approach will allow facilities maximum flexibility when determining the nature of their facility-specific medical cannabis policies. Laws 2015, chapter 74, made changes to section 152.34 that expanded responsibilities, protections, and immunities to health care facilities and their agents and employees. These changes prompted an industry request to revise this rule.

The rules advisory committee discussed this change at its August meeting. The group consensus preferred to give health care facilities discretion and flexibility for crafting their policies rather than prescribe facilities' policy content. The rules advisory committee proposed this new rule part and the department rule makers accepted it.

Establishing this flexible requirement gives health care facilities latitude when developing their storage policies for their patients' medical cannabis. Having the policies is necessary and granting them flexibility, especially given the federal-state conflict with the laws, is reasonable.

IV. REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, sets out eight factors for a regulatory analysis that agencies must include in the SONAR. This section discusses each of these factors.

(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

These rules pertain to medical cannabis production and distribution of in Minnesota. As a result, the proposed amendment could affect a variety of people. Most immediately, the proposed rule would affect registry-eligible patients, their caregivers, health care practitioners, and registered manufacturers. Other groups affected include those represented on the task force, such as law enforcement. Other groups affected include health care facilities and also potential patients and advocates who support adding qualifying medical conditions to the list.

Many proposed rule changes modify existing requirements by clarifying provisions, adding definitions, improving consistency, filling in gaps, and correcting errors. These changes will benefit all affected parties and do not have a direct cost to anyone. They were discussed in more detail in the rule-by-rule analysis above.

The following changes are more specific to certain stakeholders:

- 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).
- 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).
- 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.
- Law enforcement officials would be affected by changes proposed for reporting requirements found in Minnesota Rules, parts 4770.4004 (adverse incidents) and 4770.4010 (unauthorized possession).

- Health care facilities would be affected by the proposed new rule relating to storage of medical cannabis in health care facilities (part 4770.4030).
- 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.

(2) the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues

The proposed rules would not affect state revenues. MDH does not expect significant positive or negative direct impacts for state revenues since MDH already administers the medical cannabis program. There are no additional costs to MDH or to any other agency to implement or enforce the proposed rule revision. MDH has staff in place to enforce the existing rules and the department will require no additional revenues to implement and enforce these rules. There are no fees associated with the rules.

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

The department carefully considered the cost and potential burden of the proposed rule. MDH solicited stakeholder involvement and input to produce the least costly and intrusive methods to achieve the purposes of the proposed rule. The department's proposed changes foster efficiency for complying thus reducing costs.

For the health care practitioners we evaluated the time it would take to comply with each certification, medical history review, and availability requirement. We discarded requirements that would impose a burden without adding benefit to the research component of the program. We crafted these requirements to minimize the amount of time required for record keeping and other administrative tasks.

As described above, we better identified groups required to report adverse health incidents (part 4770.4004) and unauthorized possession (part 4770.4010).

In addition, we responded to the manufacturers' requests for flexibility and eliminated unnecessary requirements (parts 4770.1100 and 4770.1850).

For patients, we composed the patient registry of only the elements minimally necessary to effectively deliver the medical cannabis program.

These efficiencies assured streamlined measures for all participants and thus we could not determine less costly or less intrusive methods for achieving the purpose of the proposed rule. MDH reviewed other state medical cannabis programs and regulations of botanical supplements, and pharmaceutical products. MDH held several public meetings and advisory committee

meetings to receive advice from affected parties and all interested parties had time and opportunity to make recommendations regarding the rules.

(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

Many of these proposed changes simply adjust or refine the current rules for a program that has only been fully operating for three months. Since our focus has been on revising our current course, neither the department nor the stakeholders devised alternatives that warranted serious changes in direction. Some proposals were rejected because they exceeded MDH's statutory authority and are not included here.

The department, however, considered 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. We do this by monitoring adverse incident reports and patient self-reports, which ultimately leads to determinations about efficacy and side effects.

Under current rules MDH receives mandated reports of "serious health effects" related to medical cannabis. The department considered adding a call center to collect these reports. MDH envisioned that MDH would refer this information back to the manufacturers to handle investigation and potential recalls.

But MDH chose instead to expand manufacturer responsibilities. The manufacturers would instead operate the call center to receive the reports, carry out product recalls under methods they develop themselves, and notify the department. MDH determined that the manufacturers would be better suited to operate an adverse incident reporting system than one hosted by the state because:

- (a) manufacturers would more responsive to questions about their own medical cannabis formulations and need for potential recalls;
- (b) manufacturers are responsible for the centralized system costs because they either pay them up front or MDH would bill costs back to them under Minnesota Statutes, section 152.35(c);
- (c) manufacturers would have more flexibility to the to integrate the adverse incident system with their own IT systems; and
- (d) manufacturers have already developed existing relationships with companies already performing post-market surveillance and research.

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

MDH expects these amendments will incur little or no cost increases for the affected parties complying with these proposed rules, with the exception of medical cannabis manufacturers. Most changes are minor in nature and will have a nominal cost. The most significant changes

affect registered cannabis manufacturers and MDH operations. For example, manufacturers' requirements for operating a call center and an FDA-compliant database will carry costs. These responsibilities, however, were those that each manufacturer agreed to assume in its registration agreement with the state and thus are contractual obligations.

As a result, Minnesota Medical Solutions has agreed to work "with SafetyCall International PLLC to develop substantial medical cannabis adverse event reporting systems . . . [and] to assist in the implementation of standard of care, post market surveillance services associated with the sale, distribution, and use of medical cannabis produced and distributed by MinnMed." (Minnesota Medical Solutions Application (December 1, 2014; see page 505 of 1576 of PDF version).³

Likewise, Leafline Labs agreed to "utilize medical cannabis management software . . . in addition to appropriately designed and approved adverse event reporting systems, to prepare and store documentation relating to any events suspected secondary to the use of medical cannabis." (LeaflineLabs Application (December 1, 2015); see section C.4e at page 313 of 938 of the .pdf file).⁴

Therefore the manufacturers have anticipated these costs to comply with the proposed rule from the beginning.

(6) 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

The consequences of not adopting these proposed rules are:

- (a) the reduced ability of MDH to successfully manage and implement the medical cannabis program, taking advantage of the experience gained while rolling out this new program;
- (b) inadequate protection of health and safety of patients and the general public;
- (c) lack of clarity of the rules; several of the proposed changes simplify or clarify an existing rule;
- (d) unnecessary regulatory burdens on interested parties would be left in place; some proposed rules reduce the burden on interested parties of complying with the rules; and

³ Minnesota Medical Solutions' application is at:
<http://www.health.state.mn.us/topics/cannabis/manufacture/minnmedapp.pdf>

⁴ LeaflineLabs' redacted application is at:
<http://www.health.state.mn.us/topics/cannabis/manufacture/leaflineapp.pdf>.

(e) reduced flexibility for stakeholders; many proposals increase flexibility and compliance options while reducing administrative costs faced by regulated manufacturers.

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

Cannabis, whether medical or otherwise, is prohibited on the federal level and so there are no federal regulations that address medical cannabis beyond the blanket prohibition against all forms of cannabis. Cannabis's placement on Schedule I of the federal Controlled Substances Act of 1970 supposes that there is no medical use for cannabis. Therefore, there are no federal regulations for medical cannabis. The Minnesota legislature passed Laws 2014, Chapter 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.

(8) an assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.

The proposed rules represent the only regulatory results, since as stated in item (7) above, there are no existing other state and federal rules related to the same specific purpose of regulating the Minnesota medical cannabis program.

For these reasons, as the sole regulatory requirements for the affected parties, the cumulative effect of regulation comes only from the application of these standards.

V. ADDITIONAL STATUTORY REQUIREMENTS

A. Performance-Based Rules

Minnesota law (Minnesota Statutes, sections 14.002 and 14.131) requires that the SONAR describe how MDH, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting the department's regulatory objectives and maximum flexibility for both the regulated or affected party and the department in meeting those goals. MDH staff asked its advisory committee and affected and interested stakeholders for input on performance-based standards.

Developing and making medical cannabis available under this regulatory scheme necessarily requires strict controls but MDH chose performance-based standards for manufacturers and health care facilities. Manufacturers are left to determine their own recall procedures and transport manifest systems. Health care facilities may set their own storage policies.

Specific prescriptive rule proposals and considerations are discussed in detail in the rule-by-rule analysis above.

B. Additional Notice

From their inception the medical cannabis legislation and program creation have garnered much public interest and media attention. In the spring of 2014, many people implored the Governor and the Legislature on behalf of their children or themselves to legalize and establish a medical cannabis program. These active citizens engaged in very visible policy discussions. Media attention has remained high. This active participation has carried over into rulemaking, leading to patient- and parent-driven rule development in the public eye that have complemented the department's efforts to provide additional notice. The additional notice plan elements are:

- Office of Medical Cannabis Staff Speaking Engagements
- Rules Advisory Committee
- MDH OMC Web Site
- Call Center Operation and Email Box
- GovDelivery Email Notices
- Tweeting on Social Media
- Statutory Task Force

(1) Office of Medical Cannabis Staff Speaking Engagements In February and March of 2015, after the manufacturers were registered and while rule development for the expedited patient and health care practitioners was underway, the medical cannabis program identified and affirmatively reached out to those who might be interested and wanted to learn more. The program specifically targeted organizations and groups, offering to make presentations to their events. These presentations answered questions about the implementation and described this upcoming third rules development in fifteen months.

The targeted organizations representing patients with qualifying medical conditions, include the Epilepsy Foundation of Minnesota, the ALS Association, the Minnesota/Dakota chapter of the Crohn's and Colitis Foundation of America, the Minnesota AIDS Project, and the American Cancer Society. We also reached out to municipalities through League of Minnesota Cities. We contacted the University of Minnesota's Schools of Medicine and Pharmacy. We also contacted long-term care and acute-care advocates: Care Providers of Minnesota, the Minnesota Hospital Association, Minnesota HomeCare Association, the Minnesota Network of Hospice and Palliative Care,. Additional contacts were made to individual health plans, and Poison Control. We spoke to law enforcement and community groups.

We scheduled these presentations, which we continue to do, through an email-based speaker request form that organizations can submit specifying the nature of their interest and identifying a particular speaker. This allows the program to tailor the presentations to address issues most pertinent to the audience. Since Spring 2015, OMC has spoken to more than 60 groups statewide and several state and local governmental agencies. Audiences typically range from 8 to 120 people at these presentation, although those that are webcast or recorded can reach a wider audience. We talked to all who asked us.

(2) Rules Advisory Committee MDH appointed a rules advisory committee, which served in an advisory capacity representing the interests of:

- medical care providers,
- pharmacists,
- law enforcement,
- nonprofit organizations,
- patients, and
- medical cannabis manufacturers.

(3) MDH OMC Web Site MDH maintained an Office of Medical Cannabis (OMC) Web site, which has specific pages for patients, caregivers, health care practitioners, and public safety. Further, this site has a specific page devoted to laws and rules. In September 2015 the laws and rules page received more than 1200 unique hits. The department posted notices of advisory committee meetings, meeting notes, draft rules on this page. MDH will also post the proposed rule with this SONAR on this site. Manufacturers, too, have section on the Web site.

(4) Call Center Operation and Email Box MDH set up and operated a 20-person call to handle all the inquiries about medical cannabis in anticipation of launching distribution. The call center started receiving calls on June 1, 2015. It referred rule-related questions to the Web site or more specific questions to Darin Teske, Policy Analyst. This center received more than 2500 calls. We also monitored an email box to respond to written inquiries. The email box received over 4000 email messages.

(5) GovDelivery Email Notices OMC allows visitors to its website to sign up to receive email notices and updates relating to the Minnesota Medical Cannabis program. Approximately 2,500 people have signed up to receive updates through this system. OMC will intend to inform all subscribers of the proposed rules publication and other related information about these rulemaking developments, with direction to look at the OMC Web site for additional detail.

(6) Tweeting on Social Media The Office of Medical Cannabis has just started tweeting through Twitter and will be tweeting about these rules. Tweet quantity will be driven in part by public interest.

(7) Statutory Task Force Minnesota Statutes, section 152.36 established a task force, composed of stakeholder groups, to advise the department on program implementation and rulemaking. OMC provides program updates to the Task Force and the public. These updates include an update on the rulemaking activities of OMC.

C. Consultation with Minnesota Management and Budget on Local Governmental Impact

The department does not expect the proposed rules to have any impact on local governmental units. As required by Minnesota Statutes, section 14.131, the Department will consult with the Commissioner of Minnesota Management and Budget (MMB) before publishing the Notice of

Intent to Adopt in the State Register. We will do this by sending to the Commissioner of MMB copies of the documents sent to the Governor's Office for review and approval. The documents will include: the Governor's Office Proposed Rule and SONAR form; draft rules; and draft SONAR.

D. Determination about Rules Requiring Local Implementation

As required by Minnesota Statutes, section 14.128, subdivision 1, the department has considered whether these proposed rules will require a local government to adopt or amend any ordinance or other regulation to comply. The department has determined that they do not because the commissioner has the sole authority to implement the program and enforce the rules for medical cannabis in Minnesota Statutes, section 152.27, subdivision 2. The commissioner has not delegated this responsibility to any local public health agencies or any other local units of government. Therefore, local government units need not adopt supporting ordinances.

During the rulemaking process, the department received no comments that suggested that the rule would be affected in such a way that would require local governments to adopt or amend any ordinance or other regulation.

E. Cost of Complying for Small Business or City

As required by Minnesota Statutes, section 14.127, MDH has considered 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. MDH has determined that both registered manufacturers have fewer than 50 employees and could incur more than \$25,000. This determination is consistent with the probable costs of compliance with the proposed rule, as described in the Regulatory Analysis section of this SONAR on pages 22–23, above.

The department has determined that the costs of complying depend on choices not yet made, but the manufacturers have foreseeable options. If this function 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. One manufacturer already contracts for an adverse-health-incident call center system and would not incur new costs (see Minnesota Medical Solutions Application (December 1, 2014, page 1343 of 1576 at <http://www.health.state.mn.us/topics/cannabis/manufacture/minnmedapp.pdf>). The other manufacturer has received two confidential estimates for contracting out: the two estimates fall between \$25,000 and \$30,000 for the first year, but could be higher if call volumes are high. In both cases, there would be on-going annual fees and fees based on call volume. It is unclear whether the manufacturers would be responsible for the costs of a MedDRA subscription which is priced on a sliding scale and would likely cost \$804 or \$5,529 (see <http://www.meddra.org/subscription/subscription-rate>).

Alternatively, the manufacturers could keep this function in-house. According to the U.S. Bureau of Occupational Employment Statistics' May 2014 National Occupational Employment and Wage Estimates, the annual mean wage of a pharmacist (occupation code 29-1051) in the United

States is \$118,470 - http://www.bls.gov/oes/current/oes_nat.htm#29-0000. Salaries in Minnesota are comparable to the national averages (see <http://www.salary.com/MN/Pharmacist-salary.html>). Therefore, if a manufacturer decides to keep the adverse health incident call center function in-house and the decision resulted in the company needing to hire even one more half-time pharmacist, the pharmacist's salary would exceed the \$30,000 threshold.

F. List of Witnesses

MDH does not plan to call nonagency witnesses to testify if these rules were to go to a public hearing. In that event, Darin Teske, Policy Analyst, would testify about the rule amendments' development and content in support of the need for and reasonableness of the rules.

VI. CONCLUSION

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