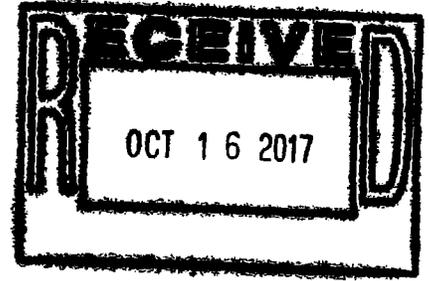


**Minnesota**  
Medical Solutions LLC



October 11, 2017

Dr. Edward Ehlinger  
Commissioner, Minnesota Department of Health

Minnesota Department of Health  
625 Robert St N  
St. Paul, MN 55155-2538

Re: Variance Request – Transportation of Medical Cannabis

Dear Dr. Ehlinger,

I write on behalf of Minnesota Medical Solutions (“MinnMed”) to formally request a variance to Minnesota Reg. 4770.1100, subp. 1A. A summary of the background and rationale for the variance, as required by Minn.Stat. 14.056, subd.1 is set forth below:

1. the name and address of the person or entity for whom a variance is being requested:

Minnesota Medical Solutions  
207 S. 9<sup>th</sup>. St.  
Minneapolis, MN. 55402

2. a description of and, if known, a citation to the specific rule for which a variance is requested:

Minnesota Reg. 4770, subp. 1A. This rule authorizes transportation of medical cannabis by a manufacturer *only* to and from the following locations:

from its manufacturing facility to its distribution facility (dispensary);  
from its manufacturing facility to a laboratory for testing; and  
from its manufacturing facility or distribution facility (dispensary) to a waste-to-energy facility.

3. the variance requested, including the scope and duration of the variance:

The variance requested is to expand the authority of MinnMed to transport medical cannabis to and from additional locations as follows:

from a distribution facility to another distribution facility (dispensary); and  
from a distribution facility (dispensary) to its manufacturing facility.



We understand that these changes are already being considered in connection with the proposed Draft Rules Regulating Medical Cannabis Laboratory Requirements (Revisor's number 4427) so would propose that the duration of the variance be effective immediately, given the important program benefits it provides, and should remain in effect until the rulemaking is complete and the new rules become effective.

4. the reasons that the petitioner believes justify a variance, including a signed statement attesting to the accuracy of the facts asserted in the petition:

MinnMed believes that the reasons that justify the variance are as follows:

Intra-Dispensary Transfers:

Allowing transfers between dispensaries would enable MinnMed to ensure that it has adequate supply on hand of products to meet patient demand as it is required to do pursuant to Minn.Stat. §152.29, Subd. 3A. In the event a certain distribution facility is running low on products due to higher-than-anticipated patient demand for certain products (and there is a surplus at another distribution facility) we can more efficiently provide access to medications to patients if these intra-dispensary transfers were permitted. In addition, when low demand for one or more products results, a direct transfer from the low volume dispensary to one with higher demand and product turnover materially reduces the risk that products at the low demand dispensary expire on the shelf, wasted and unused. One of the most important benefits realized by implementing this variance is that patients will receive more timely access to their medications.

Dispensary to Manufacturing Facility Transfers:

Allowing transfers from dispensaries back to the manufacturing facility allows MinnMed to transport product returns from patients back to the manufacturing facility so such products can be analyzed, tested and corrected if necessary. As it stands currently, MinnMed is not permitted to transfer medications returned by patients and so must stockpile these returns in the dispensaries. This has a dual impact to the program. First, MinnMed is not able to conduct the necessary research and analysis to understand and rectify any product issues. Second, as it is not currently permitted to transfer product back to its manufacturing facility, for onward transfer to a waste-to-energy facility, these products simply must sit in storage at the dispensary. This does not provide any benefit to the program.

Allowing this variance will enable MinnMed to research, test and correct any product that patients have returned, enable a more efficient investigation in the unlikely event



of any products that need to be recalled and provide for efficient disposition of product waste.

5. a history of the agency's action relative to the petitioner, as relates to the variance request:

MinnMed initially submitted a written request seeking clarification on this transportation topic on June 6, 2017 in a letter from MinnMed CEO Kyle Kingsley to OMC Director Dr. Michelle Larson, a copy of which is attached hereto as Exhibit A. Prior to considering MinnMed's request OMC, through its compliance and enforcement inspector, first wanted to ensure that MinnMed was meeting its obligations under 4770.1100, subp. 2 as it relates to transportation manifests so that it could have confidence that expanding transport options (if permitted) would continue to be faithfully documented under program rules. The parties agreed on a review period of sixty (60) days, commencing as of July 26, 2017, during which time MinnMed would submit transportation manifests to OMC for review so that OMC could evaluate MinnMed's compliance with this subpart. By email dated October 2, 2017 from George T. McLaughlin, Medical Cannabis Compliance & Enforcement Inspector, OMC confirmed that the sixty (60) day review period of MinnMed's manifests can conclude immediately. A copy of this email is attached as Exhibit B.

6. information regarding the agency's treatment of similar cases, if known:

MinnMed is not aware of any similar cases.

7. the name, address, and telephone number of any person the petitioner knows would be adversely affected by the grant of the petition:

MinnMed is not aware of any person who would be adversely affected by granting of this petition.

If you have any questions about the above, please contact me directly.

Sincerely,

Jeff Lendino

General Counsel

Minnesota Medical Solutions

**Minnesota**  
Medical Solutions LLC



EXHIBIT A

# Minnesota

## Medical Solutions LLC



June 6, 2017

Dear Dr. Larson,

We wanted to follow up on our brief discussion regarding medical cannabis transportation that occurred last Thursday. It's our understanding the Minnesota Administrative Rules ("Rules"), including 4770.1100, permit a medical cannabis manufacturer ("Manufacturer") to transport/receive medical cannabis in multiple ways, including the following:

- From a manufacturing facility to a dispensary;
- From a manufacturing facility to a state testing facility;
- From a state testing facility to a manufacturing facility; and
- From a manufacturing facility/dispensary to a waste disposal site.

We have not yet been able to determine whether existing rules or applicable statutes would permit any of the following transports of medical cannabis:

- From one dispensary to another dispensary; and
- From a dispensary to a manufacturing facility

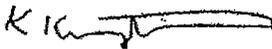
A Manufacturer's ability to move medical cannabis between dispensaries and from a dispensary back to a manufacturing facility is necessary. Without such ability, a Manufacturer will be challenged in its opportunity to maximally satisfy various obligations identified in the Rules and applicable statutes, including its obligation to provide a reliable and ongoing supply of Medical cannabis to our patients as required under Section 152.29, Subdivision 3(a).

With respect to dispensary-to-dispensary transfers, many operational and program benefits result from this being determined/interpreted as acceptable. For example, to the extent that higher than anticipated volumes of product are purchased at one dispensary and that dispensary may be unable to satisfy all additional patient needs, a transfer of Medical cannabis to such dispensary directly from a dispensary that has substantial inventory is an efficient method to ensure that Patients needs are satisfied. This redundant supply also allows for more reasonable assumptions in stocking dispensaries with the appropriate formulations. Further, when low demand for one or more products results, a direct transfer from the low volume dispensary to one with higher demand and product turnover materially reduces the risk that products at the low demand dispensary expire on the shelf, wasted and unused. A dispensary-to-dispensary transfer in this and other situations would prevent this loss and add to our efficiency as a medical cannabis provider. Moreover, it would help ensure that products are provided to patients at reasonable cost as is minimizes waste or excess inventory.

With respect to dispensary-to-manufacturing facility transfers, many operational and program benefits also result from this being determined/interpreted as acceptable. For example, from time to time we have experienced product return situations where a product returned to a dispensary needs to be returned from the dispensaries to the manufacturing facility in order to be analyzed and manufacturing, or mechanical issues, if identified, corrected. This could not occur if a dispensary to manufacturing facility transfer was not permitted. Another example of this would be a defective product that is returned to the dispensary and slated for destruction. It is currently our understanding that we are not allowed to transport this back to the manufacturing facility to later be transported with other items to the third-party destruction facility. As you can imagine, this is highly inefficient and will result in large unnecessary expenses that are passed on to our patients.

It is our understanding that similar transfers are permitted under New York's comparable medical cannabis program. For the efficiency, operational and patient-oriented reasons, including those identified above, we request that you confirm that Minnesota Medical Solutions, LLC is permitted to move Medical cannabis between its dispensaries and also is permitted to move Medical cannabis from its dispensaries back to its manufacturing facilities. To the extent that MDH determines that these transfers are not currently permitted under existing Minnesota law, we respectfully request that MDH issue MinnMed a variance permitting these transfers to occur. As required by law, these transfers would also be identified and tracked using the manifest system. Thank you in advance for your diligence and consideration and we look forward to your response.

Respectfully,



Kyle Kingsley  
CEO Minnesota Medical Solutions.

**EXHIBIT B**

**From:** McLaughlin, George (MDH)  
**To:** Jennifer Duey  
**Cc:** Thompson, Megan (MDH); Teske, Darin (MDH); Jeff Lendino  
**Subject:** RE: Manifests from week of 09/18  
**Date:** Monday, October 2, 2017 4:09:10 PM

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Good afternoon, Jennifer.

Thanks for sending the manifests for review of the past weeks. The OMC acknowledges Minnesota Medical Solutions' efforts regarding this deficiency. Minnesota Medical Solutions' staff has been maintaining completed and legible medical cannabis transportation manifests. Therefore, the sixty day review period for the manifests can conclude effective immediately. As always, the OMC will review manifests as part of the inspection process at Otsego.

Thanks again and have a great evening.

George

**George T. McLaughlin**  
Medical Cannabis Compliance & Enforcement Inspector  
Minnesota Department of Health  
Office of Medical Cannabis  
Post Office Box 64882  
St. Paul, MN 55164-0882  
Office: 651-539-3006

**mn** DEPARTMENT  
OF HEALTH



**From:** Jennifer Duey [mailto:JenniferDuey@vireohealth.com]  
**Sent:** Monday, October 2, 2017 1:49 PM  
**To:** McLaughlin, George (MDH) <george.mclaughlin@state.mn.us>  
**Cc:** Thompson, Megan (MDH) <megan.thompson@state.mn.us>; Teske, Darin (MDH) <darin.teske@state.mn.us>; Jeff Lendino <jefflendino@vireohealth.com>  
**Subject:** Manifests from week of 09/18

George,

Good afternoon. Here are the manifests from the week of 09/18. After this review, do we need to continue to send these over, as we have surpassed the 60 day review time period?

Thank you,

Jennifer

**Jennifer Duey**  
Chief Compliance Officer and Security Director

th

207 South 9 Street | Minneapolis, MN 55402  
Cell 954-292-4903 | JenniferDuev@vireohealth.com



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*Protecting, Maintaining and Improving the Health of All Minnesotans*

November 28, 2017

Mr. Jeff Lendino, General Counsel  
Minnesota Medical Solutions  
207 South 9<sup>th</sup> Street  
Minneapolis, MN 55402

Mr. Lendino,

The Minnesota Department of Health has considered the variance from Minnesota Rules, part 4770.1100, subpart 1 requested by Minnesota Medical Solutions on October 16, 2017.

The rule authorizes the manufacturer to only transport medical cannabis from its cannabis patient centers (CPCs) to a waste-to-energy facility. The manufacturer may also transport medical cannabis from its production facility to CPCs, approved testing labs, and to a waste-to-energy facility. Minnesota Medical Solutions seeks a variance that would allow it to transport medical cannabis from its CPCs to its production facility or to any of its other CPCs.

The request for a variance is **approved**.

The relevant facts and reasons for this approval are:

- (1) Minnesota Medical Solutions has shown hardships under the current rule by having to stockpile returned and expired medical cannabis at its CPCs rather than having a centralized collection site to store products being taken for destruction at a waste-to-energy facility.
- (2) the variance is consistent with the purpose of the rule (i.e., the security interest in being able to track medical cannabis shipments) as long as Minnesota Medical Solutions complies with the transportation manifest requirements of Minnesota Rules, part 4770.1100, subpart 2. The variance also reduces the security risks associated with stockpiling medical cannabis at the CPCs.
- (3) no other entity's legal or economic rights are prejudiced by the variance.
- (4) Minnesota Medical Solutions has demonstrated compliance with the transportation manifest requirements in Minnesota Rules, part 4770.1100, subpart 2. Minnesota Medical Solutions' transport manifests have been reviewed by MDH for the period beginning in early June 2017 and ending in October 2017.

(5) The variance does not contravene the intent of the rule: to ensure the ability to track medical cannabis transports.

(6) MDH has already determined the rule should be modified consistent with the variance petition in an ongoing rulemaking (Revisor's ID 4427).

For these reasons, MDH approves the requested variance to allow the transport of medical cannabis among Minnesota Medical Solutions' CPCs. This variance will remain in effect from the date of this approval until the effective date or withdrawal date of the rules to be proposed in the current laboratory testing rulemaking, Revisor's ID 4427.

Sincerely,



Gilbert Acevedo, Assistant Commissioner  
Minnesota Department of Health