

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of the Proposed Exempt
Rules of the Department of Health
Relating to Dried Raw Cannabis,
Minnesota Rules Chapter 4770

**ORDER ON REVIEW
OF RULES UNDER
MINN. STAT. § 14.386
AND MINN. R. 1400.2400**

This matter came before Administrative Law Judge Jim Mortenson upon the request of the Minnesota Department of Health (Department) for a legal review of the above-entitled rule under Minn. Stat. § 14.386 (2020) and Minn. R. 1400.2400 (2021).

On January 27, 2022, the Department filed required documents with the Office of Administrative Hearings seeking review and approval of its proposed rules.

Based upon a review of the written submissions by the Department,

IT IS HEREBY DETERMINED THAT:

1. With the exception of proposed rules listed below, the Department's rules were adopted in compliance with the legislature's directive and with the procedural requirements of Minn. Stat. § 14.386, Minn. R. 1400.2400, and Minn. R. 1400.2100, items A, D-G (2021).

2. Except for the proposed rules listed below, the Department has the statutory authority to adopt the proposed rules using the exempt rulemaking process under 2021 Minn. Laws, ch. 30, part. 3, § 32.

3. The Department lacks the statutory authority to adopt the following proposed rules:

- Minn. R. 4770.0200, subp. 40a
- Minn. R. 4770.0200, subp. 41
- Minn. R. 4770.0350
- Minn. R. 4770.0351
- Minn. R. 4770.0352
- Minn. R. 4770.0353
- Minn. R. 4770.0800
- Minn. R. 4770.0850, subp. 1
- Minn. R. 4770.0850, subp. 3
- Minn. R. 4770.1750, subp. 4
- Minn. R. 4770.1860
- Minn. R. 4770.2000, subp. 2
- Minn. R. 4770.3001

IT IS HEREBY ORDERED THAT:

The adopted rules are **APPROVED**, except for:

- Minn. R. 4770.0200, subp. 40a
- Minn. R. 4770.0200, subp. 41
- Minn. R. 4770.0350
- Minn. R. 4770.0351
- Minn. R. 4770.0352
- Minn. R. 4770.0353
- Minn. R. 4770.0800
- Minn. R. 4770.0850, subp. 1
- Minn. R. 4770.0850, subp. 3
- Minn. R. 4770.1750, subp. 4
- Minn. R. 4770.1860
- Minn. R. 4770.2000, subp. 2
- Minn. R. 4770.3001

which are **DISAPPROVED**.

Dated: February 10, 2022



JIM MORTENSON
Administrative Law Judge

NOTICE

Minn. R. 1400.2400, subp. 4a, provides that when a rule is disapproved, the agency must resubmit the rule to the Administrative Law Judge for review after it has revised the proposed rules. The Administrative Law Judge then has five working days to review and approve or disapprove the rule. Minn. R. 1400.2400, subp. 5, provides that an agency may ask the Chief Administrative Law Judge to review a rule that has been disapproved by a Judge. The request must be made within five working days of receiving the Judge's decision. The Chief Administrative Law Judge must then review the agency's filing and approve or disapprove the rule within 14 days of receiving it.

MEMORANDUM

The Proposal

The Department, through its Office of Medical Cannabis (OMC), regulates medical cannabis in Minnesota. The medical cannabis program is governed by Minn. Stat. §§ 152.22 - .37 (2020), and Minnesota Rules, chapter 4770 (2021). It was designed to enable patients with certain serious medical conditions to use cannabis for therapeutic treatment while preventing its misuse or diversion from medical purposes.¹

In 2021, the Minnesota Legislature authorized the Department to adopt or amend rules using the exempt rulemaking procedure of Minn. Stat. § 14.386(a) “to implement the addition of dried cannabis as an allowable form of medical cannabis under section 152.22, subdivision 6, paragraph (a), clause (4).”² The Legislature also excluded the rules from the two-year expiration period under section 14.386(b).³

Despite being granted exempt rulemaking authority, the Department posted a Request for Comments on the Office of Administrative Hearings’ Rulemaking eComments website in October 2021. The request sought comments on the proposed rules from October 7, 2021, until November 8, 2021. The Department received 36 written comments on the proposed rules during this period.

The proposed rules and rule amendments add dried raw cannabis to the list of approved medical cannabis delivery forms and permit smoking as a delivery method.

The proposed rules also implement a state-centralized tracking and tracing system for medical cannabis. This system tracks cannabis from seed-to-sale, pursuant to Minn. Stat. § 152.29, subd. 1(n) (2020). The proposed rule amendments also modify where medical cannabis manufacturers may transport medical cannabis. The proposed rule amendments also address labeling requirements for medical cannabis.

The proposed rules establish a limit of 450 grams of dried raw cannabis that can compose a 90-day supply, the statutory maximum supply allowed. Under the proposed rules, if a pharmacist calculates a 90-day supply that exceeds the limit, the pharmacist must file written justification with the Department. There is also a maximum size limit placed on pre-rolled cannabis cigarettes of 1 gram, which is the industry standard in medical cannabis programs. The Department has included laboratory testing requirements for dried raw cannabis in the proposed rules as well as provisions that permit the Department to conduct surveillance testing for prohibited pesticides. Finally, because dried cannabis products are available on to enrolled patients who are at least 21 years old, the proposed rules govern point-of-sale requirements, including age verification.

¹ See Minn. Stat. § 152.22, subds. 9, 14 (2020).

² 2021 Minn. Laws chap. 30, art. 3, § 32 codified at Minn. Stat. §152.26 (b).

³ *Id.*

The proposed rules, including amendments to current rules, are comprehensive. The question under such a comprehensive revision and addition to the rules is whether all the proposed rules, including amendments, are designed to meet the legislature’s directive “to implement the addition of dried cannabis as an allowable form of medical cannabis” as a form of medical cannabis? While much of the proposal does just that, several provisions exceed the limited authority the Department was provided to promulgate rules without following the rulemaking provisions of Chapter 14. The proposed rule provisions outside of the scope of authority provided to the Department are addressed below.

The Standards

The legality determination by the Office of Administrative Hearings is governed by Minn. R. 1400.2400, subp. 3. The agency must establish its exemption from rulemaking under Minn. Stat. §§ 14.386 or .388. Here, the authorizing statute, Minn. Stat. § 152.26(b), clearly provides the Department the power to promulgate rules and amendments to rules under Minn. Stat. § 14.386(a).

Minn. R. 1400.2400, subp. 3, also references the standards the judge is to use in reviewing proposed rules exempt from the more public rulemaking process. Specifically, the proposed rule must meet the standards of Minn. R. 1400.2100, items A and D to G, and those standards of review require a proposed rule to be disapproved if the rule:

- A. was not adopted in compliance with the procedural requirements of the Minn. R. 1400.2000 - .2570 (governing rulemaking);
- D. exceeds, conflicts with, does not comply with, or grants the agency discretion beyond what is allowed by, its enabling statute or other applicable law;
- E. is unconstitutional or illegal;
- F. improperly delegates the agency’s powers to another agency, person, or group; or
- G. is not a “rule” as defined in Minn. Stat. § 14.02, subd. 4, or by its own terms cannot have the force and effect of law.⁴

The Administrative Law Judge finds that much of the proposed rules meet the standards for legality under Minn. R. 1400.2100, items A and D to G. Specifically, proposed rules and rule amendments that implement the safe use of dried raw cannabis as medical treatment are within the authority of the Department granted under state law and the promulgation of those rules satisfies the procedural requirements of the Minnesota Administrative Procedures Act.

The Disapproved Rules

The following proposed provisions within the rules are not specific to implementing the safe use of dried raw cannabis, or they do not appear necessary to update the regulatory scheme for medical cannabis based on the addition of dried raw cannabis.

⁴ Minn. R. 1400.2100 (2021).

These provisions revise medical cannabis rules as a whole and create new regulatory systems which the Department has authority to develop, but not under Minn. Stat. § 14.386 or pursuant to Minn. Stat. § 152.26(b). Therefore, they must be disapproved at this time. The disapproved rule provisions are as follows:

- Minn. R. 4770.0200, subps. 40a “Supplemental label,” and 41 “Testing laboratory.”

The definitions in these rules are not specific to implementing the addition of dried raw cannabis as an allowable form of medical cannabis. While the Commissioner has the authority under Minn. Stat. § 152.25, subd. 1(e), to approve laboratories chosen by medical cannabis manufacturers and to determine how testing results from such laboratories are reported to the Commissioner, the authority to promulgate such rules does not come from the statute under which this rule package was promulgated, Minn. Stat. § 152.26(b). This is critical here because that authority permits the Department to use the procedures for exempt rules, and only for rules implementing the addition of dried raw cannabis as a medical treatment.

- Minn. R. 4770.0350, .0351, .0352, .0353. The state track and trace system.

These proposed rules are all new and make up the comprehensive scheme for tracking and tracing cannabis in Minnesota from seed-to-sale. The legislature contemplates such a system.⁵ The regulatory proposal here, however, is comprehensive and not limited to what is necessary to implement the addition of dried raw cannabis as an allowable form of medical cannabis. Minn. Stat. §§ 152.26(b) and .29 do not authorize the use of the procedures for exempt rules to promulgate the state track and trace system. The state track and trace system, while part of the system the legislature expects the Department to put in place for the regulation of medical cannabis, is in excess of the authority granted under Minn. Stat. § 152.26(b) and must be disallowed at this time.

- Minn. R. 4770.0800 “Advertising and marketing”

The list of prohibitions proposed to be added to this rule, except for number 7⁶, are in excess of what is necessary to implement the addition of dried raw cannabis as an allowable form of medical cannabis. Therefore, they must be disallowed as part of this rule-making process.

- Minn. R. 4770.0850, subps. 1 “Medical cannabis packaging,” and 3 “Labeling”

The proposed changes to Minn. R. 4770.0850 - which concerns packaging and labeling - include changes within the authority granted for this exempt process under Minn. Stat. § 152.26(b) (see subparts 2 and 4, addressing labeling provisions specific to

⁵ Minn. Stat. § 152.29, subd. 1(n).

⁶ “A manufacturer shall not publish or disseminate any advertising or marketing that: (7) could reasonably be interpreted as representing smoking as safe or without health risks.”

the implementation of dried raw cannabis as a medical cannabis). But two of the subparts exceed this authority by addressing packaging and labeling more broadly than allowed by the enabling statute. First, subpart 1 includes nothing specific to dried raw cannabis and are changes applicable to all medical cannabis. Second, subpart 3 does include a provision (paragraph C) which is specific to dried raw cannabis. But the overall impact of the changes to the subpart are in excess of what Minn. Stat. § 152.26(b) permits under the exempt process and do not appear to be necessary to accomplish the safe addition of dried raw cannabis. Thus, the entire subpart must be disallowed as written.

- Minn. R. 4770.1750, subp. 4 “Purchasing limits”

The proposed changes to Minn. R. 4770.1750 are largely in conformity with the authority bestowed on the Department for an exempt process to implement the use of dried raw cannabis as a medical cannabis. Subpart 4, however, exceeds this authority by applying to medical cannabis generally, with the exception of paragraph C. If rewritten, paragraph C would be permissible under Minn. Stat. § 152.26(b).

- Minn. R. 4770.1860 “Quality complaints”

This proposed rule states, on its face, that it addresses “complaints about any medical cannabis finished good.”⁷ This exceeds the authority granted under Minn. Stat. § 152.26(b) and must be disapproved.

- Minn. R. 4770.2000, subp. 2 “Application requirements; commissioner’s evaluation”

The text addition to this rule pertains to testing on cannabis and cannabis-derived products generally and exceeds the authority for this exempt rule making process. The Department must rely on other statutory authority for making this change.

- Minn. R. 4770.3001 “General testing requirements”

This proposed rule is not specific to implementing the use of dried raw cannabis as a safe form of medical cannabis and must be disallowed in this exempt proceeding. If the testing requirements addressed only dried raw cannabis, the rule may be permissible. The specific authority granted by the legislature may not be used to bootstrap other regulatory provisions into the exempt process, no matter how well-intentioned.

Conclusion

These proposed rule provisions fall outside the scope of the changes set forth in the 2021 session laws quoted above. The session law language directs the Department to “to implement the addition of dried cannabis as an allowable form of medical cannabis” and no more. Thus, only those provisions limited to achieve this directive are permitted

⁷ Proposed Minn. R. 4770.1860 (A).

and the remaining proposed amendments as detailed above are in excess of the Department's limited specific authority for exempt rulemaking.

J. R. M.