



Minnesota
Department
of Health

PROTECTING, MAINTAINING AND IMPROVING THE HEALTH OF ALL MINNESOTANS

**Summary of Rulemaking Process and Advisory Committee Role
Medical Cannabis Laboratory Testing Requirements Rules Advisory Committee Meeting -
January 25, 2017
Minnesota Department of Health**

The Rulemaking Process, Documents, and Time Line. Rulemaking is governed by Minnesota Statutes, chapter 14, and Minnesota Rules, chapter 1400. This short summary describes the main parts of the process, important documents, and time line for developing and adopting rules. If you have questions about this, ask Darin Teske at 651-539-3004 or darin.teske@state.mn.us.

- **Request for Comments.** The Request for Comments begins the formal rulemaking process. For this project, the Minnesota Department of Health (MDH) published the Request in the September 19, 2016 State Register and mailed it to our rulemaking mailing list.
- **Proposed Rules.** We are now writing the Medical Cannabis Laboratory Testing Requirements Rules. The Revisor of Statutes will review the rules draft and edit, as necessary, for form and style.
- **Statement of Need and Reasonableness.** MDH must justify that each rule requirement is needed and reasonable. “Needed” means that there are problems or a legislative directive that requires us to adopt or amend rules. “Reasonable” means that a proposed requirement is a reasonable solution to a problem. We will spell out this justification in a document called the “Statement of Need and Reasonableness (SONAR).” The SONAR states our statutory authority for the rules, contains a modified cost-benefit analysis, and includes our analysis of each proposed rule.
- **Notice of Intent to Adopt Rules.** When we have finished writing the proposed rules, we will publish a Notice of Intent to Adopt Rules in the State Register. We will also publish the proposed rules. In addition, we will mail both the Notice and proposed rules to interested persons and to certain legislative committees.
- **30-Day Comment Period.** After the Notice of Intent to Adopt Rules is published, there is a 30-day comment period, during which persons can submit written comments on the proposed rules. Persons can also request a hearing on the rules during the 30-day comment period.
- **Rules Hearing.** If there are 25 hearing requests, MDH must hold a hearing on the rules in front of an Administrative Law Judge (ALJ).
- **Review by Administrative Law Judge.** Whether there is a hearing or not, an ALJ reviews the proposed rules and all the documents from the rulemaking. The ALJ will approve the rules if MDH has statutory authority for the rules, has shown the rules to be needed and reasonable, has given proper notice of the proposed rules, and has complied with all other rulemaking requirements.

- **Governor Veto.** After the rules are adopted by MDH and approved by the ALJ, the Governor has 14 days to review them. The Governor may veto the rule amendments or let them become effective.
 - **Notice of Adoption.** After the Governor’s review period, MDH will publish a Notice of Adoption in the State Register.
 - **Effective Date.** The rules become effective five working days after the Notice of Adoption is published, unless the rules provide a later effective date.
- Time Line.** This process of drafting the rules can be open-ended, although we plan to complete the rules draft in summer 2017. The formal part of the rulemaking process, from publishing the Notice of Intent to Adopt Rules until the date the rules become effective, takes about three months if there is no hearing and about five months if there is a hearing.

The Role of the Advisory Committee.

- **Advice, not voting.** The role of the Advisory Committee is to advise MDH on the development of these rules. MDH looks to the Advisory Committee for its expertise in these regulations. The Advisory Committee does not have voting authority on what will go in the rules; the Commissioner of Health makes any final decisions. The Advisory Committee does, however, have the power of persuasion and the power that comes from having the information needed to make these rules workable.
- **Represent your interest group.** Each of you likely represents an interest group in one way or another, be it registered patients, potential patients, testing laboratories, or medical cannabis manufacturers. We encourage you to maintain communication with others who share your interests.
- **Consensus.** Our goal is to achieve consensus on as many issues as possible. Even where there is disagreement on some issues, we hope to make the rules as workable as possible for those who have to comply with them.
- **Reasonable comments and suggestions.** We will carefully consider all comments and suggestions about the rules. You will have the most success persuading MDH with your comments and suggestions if you give reasons along the same lines as how MDH has to justify the need for and reasonableness of everything in the rules.

Regulatory Analysis. Minnesota Statutes, section 14.131, lists eight factors that an agency must analyze when it adopts or amends rules. We will look to you for advice and information as we analyze these factors.

From Minnesota Statutes, section 14.131. The SONAR “must include the following to the extent the agency, through reasonable effort, can ascertain this information:

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

(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;

(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;

(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; and

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

Cost to Small Businesses and Small Cities. Minnesota Statutes, section 14.127, requires the agency to determine whether, in order to comply with proposed rules during the first year after they become effective, any small business or small city would have to spend over \$25,000. A small business is defined as a business (either for profit or nonprofit) with less than 50 full-time employees. A small city is defined as a city with less than ten full-time employees. We will look to you for information about the cost of compliance for small businesses and cities.

Performance-Based Rules.

- Minnesota Statutes, sections 14.002 and 14.131, require that the SONAR describe how the agency, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals.
- MDH will look to you for advice and information on how we can make the rules work better for you, while still meeting our goals for these rules.
- Are there any special situations that we should consider in developing the rules?
- Are there any ways to reduce the burdens of the rules?
- Do you have any other insights on how to improve the rules?

Additional Notice.

- When MDH publishes the proposed rules and the Notice of Intent to Adopt Rules, we also have to "provide additional notification to persons or classes of persons who might be affected by the proposed rule or must explain why these efforts were not made."
- MDH will look to you to help us identify all interested persons and to come up with ways to let them know about the rules. This includes both likely supporters and opponents of the rules.

Local Government Impact

- MDH has to evaluate the fiscal impact and benefits of proposed rules on local governments. As part of this, MDH has to consult with the Department of Minnesota Management and Budget (MMB).
- In addition to consulting with MMB, MDH will look to you to help us identify the fiscal impact and benefits of the proposed rules on local governments.]