MDH Minnesota Department of Health

OFFICE OF MEDICAL CANNABIS

Medical Cannabis Manufacturer Enforcement

IMPROVE ENFORCEMENT OF MEDICAL CANNABIS LAWS

Proposal Overview

This proposal updates and improves the Minnesota Department Health's (MDH) regulation and oversight of medical cannabis manufacturers. It would:

- Provide MDH with a greater array of enforcement options over the manufacturers and variable fine amounts proportionate to violations.
- Clarify criteria for re-registration of manufacturers and establish processes for temporary suspension, revocation or non-renewal of a manufacturer.
- Allow destruction of medical cannabis if deemed necessary to protect patient health and safety.
- Require manufacturers to use tracking software for products.
- Require notification to MDH for any manufacturer ownership change of 5% or more and a background check for new owners. Clarify the legal status of manufacturer application data.
- Authorize approved third-party laboratories to collect and transport samples for safety testing.

Figure 1. Medical cannabis products

Enforcement Authority

MDH's current enforcement penalties are limited to non-renewal of a manufacturer registration or a $1,000 fine. The flexible enforcement tools would allow MDH to better protect patients and program integrity, and ensure compliance and establish clearer enforcement procedures. MDH proposes regulating the medical cannabis program with existing enumerated powers under the Health Care Enforcement Consolidation Act of 1993 ("HECA") (M.S. 144.99). HECA is a well-tested, graduated penalty authority used by MDH for other health care industries and includes:

- Less rulemaking
- Correction orders for violations
- Administrative penalty orders
- Collecting assessed penalties
- Cease/desist orders if immediate risk to public health
- Suspension or revocation of permits, licenses, registrations or certificates

This proposal would also authorize MDH to order the destruction of medical cannabis to protect patient health and safety.

Suspension, Revocation and Non-Renewal

MDH's proposal makes a manufacturer registration non-transferable without MDH

pre-approval, adds the manufacturer's history of past violations as a reregistration criterion.

For a revocation or non-renewal of registration, the proposal requires notice to the manufacturer, an opportunity for a contested case hearing under Chapter 14 and notice to registry patients.

Figure 2. Medical cannabis products from LeafLine Labs

The proposal allows registration suspension for:

- Violations of statute or rule
- Acts contrary to patient welfare
- Use of fraud or misrepresentation to obtain a registration

Manufacturer Requirements

The proposal would require a manufacturer to provide timely notice to MDH of any transfer of ownership of 5% or greater and require the new owner to undergo a criminal history check through the Bureau of Criminal Apprehension.

The proposal requires manufacturers to use a seed-to-sale tracking system, something they both already do.

Manufacturer Applications

A state district court recently ruled that the information submitted by an applicant to become a medical cannabis manufacturer is private data under current law.[1] As a result, MDH removed information from its website. This proposal conforms state law with the district court's opinion that an application from a non-selected applicant is private or nonpublic data.

Independent Laboratories

This proposal authorizes employees of an approved third-party testing laboratory, when necessary to investigate an imminent threat to patient health or public safety, to transport cannabis plant material and medical cannabis from a manufacturer to the third-party laboratory for quality control testing in order to protect against any chain-of-custody concerns.

Minnesota Department of Health
Office of Medical Cannabis
P.O. Box 64882
St. Paul, MN 55164-0882
651-539-3000
Health.Cannabis@state.mn.us
www.health.state.mn.us

MDH Minnesota Department of Health

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[1] Cross Nurseries, LLC v. MDH, no. 62-CV-15-7603 (Sept 30, 2016).