DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

MARIJUANA REGULATORY AGENCY

TESTING OF MARIHUANA PRODUCTS INTENDED FOR INHALATION

EMERGENCY RULES

Filed with the Secretary of State on November 22, 2019

These rules take effect upon filing with the Secretary of State and shall remain in effect for 6 months.

(By authority conferred on the executive director of the marijuana regulatory agency by sections 7 and 8 of the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27957 and 333.27958, by sections 206 and 302 of the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27206 and 333.27302, and by Executive Reorganization Order No. 2019-2, MCL 333.27001)

FINDING OF EMERGENCY

These emergency rules for marihuana products intended for inhalation are promulgated by the marijuana regulatory agency (agency) to address the public health crisis of e-cigarette, or vaping, product use-associated lung injury (EVALI).

The Michigan Department of Health and Human Services (MDHHS) began tracking the EVALI outbreak in other states in the beginning of August 2019, issuing a Health Alert to public health and health care providers to identify cases. In late August 2019, MDHHS issued a public statement, warning e-cigarette users to seek immediate medical attention if they developed symptoms. At that time, MDHHS was investigating 6 reports from physicians, but no cases were yet listed as probable or confirmed.

By October 1, 2019, MDHHS had identified and investigated 30 confirmed or probable cases of EVALI in the state of Michigan, including one confirmed death associated with the illness.

As of November 20, 2019, MDHHS has now identified 55 EVALI cases, with one patient requiring a double lung transplant. Approximately 88 percent of EVALI patients reported using a product containing tetrahydrocannabinol (THC). As part of the investigation, MDHHS sent samples from 5 Michigan EVALI patients to the Food and Drug Administration (FDA) for testing. The materials were tested and the FDA found that one patient's products contained THC and vitamin E acetate; and one product, a THC cartridge "Dank Vape Birthday Cake," contained 23 percent vitamin E acetate. Most of the patients have been hospitalized for severe respiratory illness. Many of these persons

are likely to suffer permanent effects from these illnesses. The age range of the patients is 15 to 67 years old.

Multiple states have found vitamin E acetate and other additives in their testing. The New York State Department of Health found high levels of vitamin E acetate in nearly all THC-containing samples analyzed.[1] Utah Public Health Laboratory showed evidence of vitamin E acetate in 89 percent of THC-containing cartridges[2] provided by 6 EVALI patients. Additionally, the state of Massachusetts declared a state of emergency related to EVALI indicating that they found flavorings, propylene glycol, and vegetable glycerin in products.[3]

As of November 13, 2019, the Centers for Disease Control and Prevention (CDC) has confirmed 42 deaths and over 2,100 cases of EVALI across 49 states, the District of Columbia, and two U.S. territories. All cases have a history of vaping products containing THC, nicotine, or a combination of THC and nicotine.[4]

On November 8, 2019, the CDC announced the results of recent testing performed on bronchoalveolar lavage (BAL) fluid samples from 29 EVALI patients in 10 states, including Michigan. Vitamin E acetate was identified in 100 percent of the BAL samples tested. THC was identified in 82 percent of the samples. This is the first time that a potential toxin has been detected in biologic samples from patients with EVALI. While vitamin E acetate does not usually cause harm when ingested as a dietary supplement or applied to the skin, ongoing research suggests that inhalation of vitamin E acetate may interfere with normal lung function.[5]

Analysis of sales data[6] of marihuana products intended for inhalation from late August 2019 through November 7, 2019, show a decrease of over 52 percent in sales. This trend coincides with the increase in documented EVALI cases and awareness of the potential impact of using marihuana products intended for inhalation. The Marijuana Regulatory Agency therefore concludes that emergency rules are required to increase consumer confidence in the regulated marihuana supply of marihuana products intended for inhalation.

Because the number of EVALI cases continues to rise, these emergency rules are required to regulate the presence of inactive ingredients in existing marihuana products intended for inhalation through testing. Preservation of the public health, safety, and welfare requires consumers to use the regulated marihuana market rather than the illicit market because product from the regulated market is tested for the presence of harmful contaminants and

---

[1] New York State Department of Health. https://www.health.ny.gov/prevention/tobacco_control/campaign/e-cigarettes/
[2] Center for Disease Control. https://www.cdc.gov/mmwr/volumes/68/wr/mm6842e1.htm?s_cid=mm6842e1_w
[3] Commonwealth of Massachusetts. https://www.mass.gov/doc/governors-declaration-of-emergency/download
[4] Center for Disease Control. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information
[5] New York State Department of Health. https://health.ny.gov/press/releases/2019/2019-09-05_vaping.htm
[6] Data from the statewide monitoring system, Marijuana Enforcement Tracking Reporting & Compliance (METRC).

generates tax revenue for the people of Michigan. Preservation of the public health, safety, and welfare requires promulgation of these emergency rules, because without immediate testing for vitamin E acetate or other contributors to EVALI of existing marihuana, the public health risk of EVALI will continue unmitigated. Moreover, preservation of the public health, safety, and welfare requires promulgation of these emergency rules because ensuring that existing regulated marihuana products intended for inhalation are reasonably free from contaminants will promote consumer confidence in the regulated market.

For the reasons described above, if the complete process specified in the administrative procedures act of 1969 (APA), 1969 PA 306, MCL 24.201 to 24.328, for the promulgation of rules were followed, the process would not be completed in time to address the current EVALI crisis.

The agency, therefore, finds that the preservation of the public health, safety, and welfare requires the promulgation of emergency rules as provided in section 48 of the APA, MCL 24.248, without following the notice and participation procedures required by sections 41 and 42 of the APA, MCL 24.241 and 24.242.

PART 1. GENERAL PROVISIONS

Rule 1. Definitions.

As used in these rules:

(a) "Active ingredient" means marihuana as defined in section 7106 of the public health code, 1978 PA 368, MCL 333.7106.

(b) "Acts" refers to the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27101 to 333.27801, and the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27951 to 333.27967.

(c) "Agency" means the marijuana regulatory agency.

(d) "Failed sample" means a marihuana product intended for inhalation that contains the presence of a target analyte.

(e) "Inactive ingredients" means binding materials, dyes, preservatives, flavoring agents, and any other ingredient that combines with the active ingredient.

(f) "Limit of quantitation" or "LOQ" means the minimum concentration or mass of a target analyte in a given matrix that can be reported as a quantitative result.

(g) "Marihuana product intended for inhalation" means any marihuana concentrate that is intended to be inhaled using an e-cigarette or vaping device.

(h) "Marihuana safety compliance facility" means that term as defined in section 3 of the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27953.

(i) "Presence of a target analyte" means any concentration of a target analyte detected in the sample.

(j) "Safety compliance facility" means a facility licensed to operate under section 505 of the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27505.

(k) "Target analyte" means a non-marihuana inactive ingredient designated for analysis.

Rule 2. Terms; meanings.

Terms defined in the acts have the same meaning when used in these rules.

Rule 3. Sale or transfer of marihuana products intended for inhalation.

(1) A licensee shall not sell or transfer a marihuana product intended for inhalation unless one of the following conditions is met:

(a) The marihuana product intended for inhalation has received a passing test result for target analytes under these rules.

(b) The marihuana product intended for inhalation was produced by a licensed processor or marihuana processor after the effective date of these rules and in compliance with the Emergency Rules for Manufacturing of Marihuana Products Intended for Inhalation and all other rules promulgated by the agency.

(2) All marihuana product intended for inhalation that is possessed by a licensee at the time the licensee obtains a license must be tested pursuant to these rules and R 333.247 and Adult-Use Marihuana Establishments Emergency Rule 43.

Rule 4. Testing.

(1) A safety compliance facility and marihuana safety compliance facility shall conduct the safety tests for target analytes on a marihuana product that is intended for inhalation, as required by the agency.

(2) The agency shall publish a list of target analytes and the limit of quantitation (LOQ) for the safety compliance facility and marihuana safety compliance facility to achieve for each target analyte.

(3) A licensee shall destroy a failed sample, unless the agency approves the product for remediation pursuant to the rules promulgated by the agency.

Rule 5. Inspections.

(1) The agency shall regularly inspect a licensee that sells marihuana product intended for inhalation.

(2) A licensee shall comply with random quality assurance compliance checks upon request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product intended for inhalation from a licensee or designate a safety compliance facility or marihuana safety compliance facility to collect a random sample of a marihuana product intended for inhalation in a secure manner to test that sample for compliance pursuant to these rules.

Rule 6. Failure to comply.

A licensee who fails to destroy a marihuana product intended for inhalation that contains the presence of a target analyte, or who otherwise fails to comply with these rules shall be subject to disciplinary proceedings.

MARIJUANA REGULATORY AGENCY

Andrew Brisbo, Executive Director
Marijuana Regulatory Agency

Pursuant to Section 48(1) of 1969 PA 306, as amended, MCL 24.248(1), I hereby concur in the finding of the Marijuana Regulatory Agency that the circumstances creating an emergency have occurred and the promulgation of the above rules is required for the preservation of the public health, safety, and welfare.

Garlin Gilchrist II
Lieutenant Governor and Acting Governor

22 NOV 2019
Date