DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

MARIJUANA REGULATORY AGENCY

MANUFACTURING 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] The presence of vitamin E acetate does not preclude other inactive ingredients playing a role in this outbreak.[6]

Analysis of sales data[7] 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.

The maximum concentration of inactive ingredients allowed for intended use by the FDA (as listed in the FDA Inactive Ingredient database) provides a widely recognized guideline

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[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] Center for Disease Control. https://www.cdc.gov/mmwr/volumes/68/wr/mm6845e2.htm?s_cid=mm6845e2_w
[7] Data from the statewide monitoring system, Marijuana Enforcement Tracking Reporting & Compliance (METRC).

for minimizing the risks of inhaling inactive ingredients. Yet the agency's current rules do not regulate the addition of or require testing for inactive ingredients in marihuana products intended for inhalation.

Because the number of EVALI cases continues to rise, these emergency rules are required to regulate the addition of inactive ingredients to marihuana products intended for inhalation and require testing for those inactive ingredients. 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 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 regulation of the addition of inactive ingredients to newly produced marihuana products, 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 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) "Final package" means the form a marihuana product is in when it is available for sale by a marihuana sales location.

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

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

(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 sales location" refers to a provisioning center under the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27101 to 333.27801, and/or a marihuana retailer or marihuana microbusiness under the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27951 to 333.27967.

(i) "Processor" means a facility licensed to operate under section 502 of the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27502.

(j) "Product label" is the label attached to a marihuana product intended for inhalation before it is sold or transferred to or by a provisioning center under R 333.273 or marihuana retailer under Rule 49 of the Adult-Use Marihuana Establishments Emergency Rules.

(k) "Records of formulation" is the documentation that includes at a minimum: the ingredients, recipe, processing in order to be shelf stable, Certificates of Analysis for any ingredients used, and description of the process in which all ingredients are combined to produce a final package.

Rule 2. Terms; meanings.

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

Rule 3. Ingredients.

(1) All inactive ingredients shall be clearly listed on the product label for any marihuana product intended for inhalation produced after the effective date of these rules.

(2) A licensee is prohibited from adding an inactive ingredient to a marihuana product intended for inhalation unless it has been approved by the FDA for inhalation. The concentration of any inactive ingredient in a marihuana product intended for inhalation shall not exceed the maximum concentration listed in the FDA Inactive Ingredient database.

(3) Processors and marihuana processors shall keep records of formulation for a minimum of two years after the use of the formulation is discontinued for all marihuana products intended for inhalation.

(4) All records of formulation and changes to formulations must be submitted to the agency for all marihuana products intended for inhalation.

Rule 4. Inspections.

(1) The agency shall regularly inspect a licensee that produces 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 5. Failure to comply.

A licensee who 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.

22 NOV 2019

Garlin Gilchrist II
Lieutenant Governor and Acting Governor

Date