Cannabis Control Commission
COMMONWEALTH OF MASSACHUSETTS

November 12, 2019

Licensed Marijuana Establishments
Licensed Medical Marijuana Treatment Centers

Case No. 2019AM-0065-00

QUARANTINE ORDER
APPLYING TO VAPORIZER PRODUCTS
M.G.L. c. 94I, M.G.L. c. 94G, § (a)(xix) and (a½)(xxxi),
935 CMR 500.340: Quarantine Order, and
935 CMR 501.340: Quarantine Order

Relying on M.G.L. c. 94I, M.G.L. c. 94G, § (a)(xix) and (a½)(xxxi) and associated regulatory authority, the Commonwealth of Massachusetts Cannabis Control Commission (Commission), acting through its Executive Director, orders all licensed Marijuana Establishments and Medical Marijuana Treatment Centers (each, the "Respondent" and collectively, the "Respondents") to quarantine vaporizer products based on his determination that these products pose an immediate or serious threat to the public health, safety, or welfare and the quarantine is necessary to protect the public health, safety or welfare. Marijuana Establishments remain subject to compliance with the existing order issued by the Commissioner of the Department of Public Health (DPH) and emergency regulations issued by DPH banning adult-use vaporization products.

This order shall be effective upon all Respondents issued a final license on or before November 12, 2019, at 12:01 P.M. ("effective date"). Exhibit A. Respondents issued a final license after the effective date shall be subject to the order on receipt of notice of the order.

Findings

In making its determination, the Commission finds as follows:

(1) In the course of an ongoing investigation into the nation-wide outbreak of e-cigarette, or vaping, product use-associated lung injury (EVALI), the Centers for Disease Control (CDC), Food and Drug Administration (FDA), state and local health departments, and public health partners collected data from EVALI patients during from August 2019 to October 2019. In response to this outbreak, the DPH Commissioner banned vaporization products and DPH subsequently issued emergency regulations.

(2) The Commission remains in contact with CDC, FDA, and DPH to receive updates on reported cases of illness associated with vaporizer products and devices.

(3) During its investigative process, the CDC received Bronchoscopy and bronchoalveolar lavage (BAL) fluid specimens from 29 EVALI patients in 10 states.[1]

(4) The CDC's investigative update of November 2019 found "direct evidence of vitamin E acetate at the primary site of injury within the lungs."[2]

(a) On November 8, 2019, the CDC issued an investigative update finding that vitamin E acetate was detected in all 29 BAL samples, and that THC or its metabolites were detected in 23 of 28 EVALI patient BAL samples. The CDC's investigative update further found that as of October 15, 2019, 86% of 867 EVALI patients reported using THC-containing products in the three months preceding symptom onset.[3]

(b) In its investigation, the CDC tested for a wide range of substances found in e-cigarette, or vaping, products, including plant oils, petroleum distillates like mineral oil, medium-chain triglyceride oil (MCT oil), and terpenes, which are compounds botanically found in or artificially added to THC products. Among the tested substances, only Vitamin E acetate was detected in the CDC's testing analysis.[4]

(c) The BAL fluid specimens represent the first identification of a "potential toxicant of concern" within EVALI patients. The findings yielded by the EVALI-patient biologic specimens now provide direct evidence of vitamin E acetate at the primary site of patient injury; however, further study is needed before a causal link can be established between vitamin E acetate exposure and EVALI.[5]

(d) The CDC findings do not rule out the possibility that more than one compound or ingredient may cause lung injury, or that other toxicants may also contribute to EVALI.[6]

(e) The CDC findings do not identify whether the THC products implicated in the EVALI patient study were sourced from legal or illicit markets. However, a recent coordinated epidemiologic investigation by the Illinois Department of Public Health and Wisconsin Department of Public Health involved detailed interviews with 86 patients reporting lung injury symptoms and finding that "the

[1] Blount BC, Karwowski MP, Morel-Espinosa M, et al., Evaluation of Bronchoalveolar Lavage Fluid from Patients in an Outbreak of E-cigarette, or Vaping, Product Use–Associated Lung Injury — 10 States, August–October 2019. MMWR Morb Mortal Wkly Rep. ePub: 8 November 2019, available at http://dx.doi.org/10.15585/mmwr.mm6845e2.
[2] Id.
[3] Id.
[4] Id.
[5] Id.
[6] Id.

vast majority reported using illicit THC-containing products sold as prefilled cartridges and obtained from informal sources."[7]

(5) The Commission's regulations require all marijuana products sold or marketed for sale undergo contaminant testing, including testing for heavy metals, by Independent Testing Laboratories accredited to the International Organization for Standardization 17025 (ISO/IEC 17025: 2017) and performed in accordance with the Commission's Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products. 935 CMR 500.160; 935 CMR 501.160.

(6) The Commission's existing testing regulations and protocols do not require testing for vitamin E acetate.

(7) Current manufacturing processes and information available to the Commission do not definitively preclude the possibility that licensed vaporizer products contain vitamin E acetate or other potential ingredients of concern.

(8) Current manufacturing processes and information available to the Commission do not definitively preclude the possibility that licensed vaporizer products contain devices or component parts that pose adverse health effects when used to vaporize cannabis oil.

(9) The Commission has broad authority to investigate the risk to public safety, health, and welfare posed by vaporizer products and their component parts through product testing and any other means pursuant to its statutory and regulatory authority and to quarantine products that pose an immediate or serious threat to the public health, safety or welfare. M.G.L. c. 94I, M.G.L. c. 94G, § 4(a)(xix) and (a½)(xxxi), 935 CMR 500.340, 935 CMR 501.340.

(10) The Commission will coordinate with DPH to monitor and evaluate the causes and findings related to EVALI cases. M.G.L. c. 94I, M.G.L. c. 94G, § 4(k). To this end, at its November 7, 2019 public meeting, the Commission formally requested that DPH provide the Commission with all information collected regarding cases of pulmonary illness reported from September 24, 2019 to November 7, 2019.

(11) On October 24, 2019, Suffolk Superior Court Judge Douglas H. Wilkins, issued a decision in the matter of Vapor Technology Association & others v. Charlie Baker and another, Suffolk Superior Court Civil No. 2019-3102-D, and found

[7] Ghinai I, Pray IW, Navon L, et al. E-cigarette Product Use, or Vaping, Among Persons with Associated Lung Injury — Illinois and Wisconsin, April–September 2019. MMWR Morb Mortal Wkly Rep 2019;68:865–869, available at http://dx.doi.org/10.15585/mmwr.mm6839e2 ("Among 112 THC-containing products for which the source was reported, 100 (89%) were acquired from informal sources (e.g., friends, family, school, dealers, or off the street). The remaining 12 were bought at an out-of-state cannabis dispensary (six), online (five), or from a vape or tobacco shop (one).").

that "[t]he parties have not presented any evidence specifically linking the vaping of crushed cannabis flower to the outbreak" of vaping-related illnesses. Based on this finding, he ordered that the display and sale of medical-use products for the vaping of crushed marijuana flower sold lawfully in the Commonwealth be permitted.

Order

Based on his authority and these findings, the Executive Director has determined that additional testing of certain products for vitamin E acetate and other substances of concern and the development of additional regulatory and policy safeguards is necessary to protect the public health, safety and welfare.

The Commission, acting through its Executive Director, hereby **ORDERS** as follows:

(1) Respondent shall quarantine and cease the sale and distribution of the following marijuana products and devices:

   (a) All vaporizer products defined as any product intended for human consumption by THC inhalation whether for one-time use or reusable, that relies on vaporization or aerosolization, including but not limited to vape pens, vape cartridges, aerosol products, and inhalers ("vaporizer products" or "quarantine products"); and

(2) Nothing herein shall prevent the display, sale or distribution of devices designed to exclusively vaporize marijuana flower for medical-use patients.

(3) Respondent shall place quarantined products on administrative hold in the Commission's seed-to-sale tracking system of record. Respondent shall similarly designate quarantined products in any secondary seed-to-sale tracking system utilized by the Respondent;

(4) Respondent may transfer, transport or otherwise distribute vaporizer products to other Marijuana Establishments, Medical Marijuana Treatment Centers and Independent Testing Laboratories subject to compliance with the Commission's laws, regulations, and policies, but may not sell the vaporizer products subject to this order to patients, caregivers or consumers, unless otherwise authorized by the Commission;

(5) In accordance with the Commission vote at the public meeting on November 7, 2019, and as otherwise allowed by law, the Commission may promulgate regulations and policies pertaining to new and existing vaporizer products to ensure public safety, including additional testing for vaporizer products and devices.

(6) Respondent may request an amendment or modification of this order to authorize the sale of specific vaporizer products that have been tested and deemed compliant with the Commission's regulations and policies;

(7) Nothing herein prohibits or otherwise prevents a certifying health care provider and qualifying patient from discussing the respective risks and benefits of marijuana products, including vaporizer products, within the context of a bona fide healthcare provider-patient relationship;

(8) Respondent shall post notice of this order in a conspicuous location at the Marijuana Establishment or Medical Marijuana Treatment Center;

(9) Respondent shall immediately comply with the requirements of this order upon its receipt.

(10) Respondent shall comply with all provisions of 935 CMR 500.340 and 935 CMR 501.340; and

(11) Respondent shall comply with all provisions of 935 CMR 500.000, *et seq.* 935 CMR 501.000, *et seq.*, and 935 CMR 502.000, *et seq.*.

Notice is provided pursuant to 801 CMR 1.02(6)(a)(1)(b) that his order shall take effect on Tuesday, November 12, 2019, at 12:01 P.M. The Commission may amend the effective date of this order based on developing public health findings, legal proceedings, or other matters not known to the Commission at the time the order was issued. Failure to comply with the above conditions may result in action against Respondent up to and including suspension and/or revocation of licensure.

Nothing herein should be construed as precluding or limiting the Commission's authority to take additional administrative action to protect the public health, safety, and welfare. The Commission may investigate whether certain marijuana products and/or marijuana accessories or their component parts pose a substantial risk to public health and take appropriate action.

The order shall remain in effect until the Commission rescinds or amends the order or until such other time specified in 935 CMR 500.500 and 935 CMR 501.500. The Commission may amend or modify this order as applicable to one particular licensee, a group of licensees or as applicable to all Commission licensees. The Commission may adjust the scope of quarantined products in accordance with this order and 935 CMR 500.321: *Administrative Hold* and 935 CMR 501.321: *Administrative Hold.*

Respondent may request a hearing within twenty-one (21) calendar days after the effective date stated below by making such request in writing to the Commission at 101 Federal Street, 13th Floor, Boston, MA 02210. The Commission may consolidate multiple hearing requests into a single group hearing based on common issues of fact and law.

Questions about the order may be directed in writing to the above address, by phone (617-701-8400) on Monday – Friday from 9:00 A.M. – 5:00 P.M. or email at CannabisCommission@ma.state.us.

Effective this 12th day of November 2019:

Commonwealth of Massachusetts Cannabis Control Commission

Shawn Collins, Executive Director