

December 12, 2019

Licensed Marijuana Establishments
Licensed Medical Marijuana Treatment Centers

Case No. 2019AM-0065-00

**FIRST AMENDED QUARANTINE ORDER
APPLYING TO VAPORIZER PRODUCTS
WITH CONDITIONS**

**M.G.L. c. 94I, M.G.L., c. 94G, § 4(a)(xix) and (a½)(xxxii),
935 CMR 500.340: Quarantine Order, and
935 CMR 501.340: Quarantine Order**

On November 12, 2019, relying on M.G.L. c. 94I, M.G.L. c. 94G § 4(a)(xix) and (a½)(xxxii) and associated regulatory authority, the Commonwealth of Massachusetts Cannabis Control Commission (the “Commission”), acting through its Executive Director, ordered all licensed Marijuana Establishments and Medical Marijuana Treatment Centers (each, the “Respondent” and collectively, the “Respondents”) to quarantine vaporizer products based on the Director’s determination that these products posed an immediate or serious threat to the public health, safety, or welfare and that quarantine was necessary to protect the public health, safety, or welfare (the “Initial Order”).

On December 12, 2019, in accordance with the Initial Order, the Commission now issues this First Amended Order with conditions for removing specific vaporizer products from quarantine after demonstrating compliance with the Commission’s regulations and policies, including additional testing requirements set forth below pursuant to 935 CMR 500.160(2) and 501.160(2).

The First Amended Order shall be effective upon all Respondents issued a final license as of the date of this Order. The First Amended Order shall further be effective upon all Respondents issued a final license after the date of this Order upon issuance of this notice from the Commission.

This First Amended Order shall be effective upon all Respondents as of December 12, 2019, at 2:00 P.M. (the “Effective Date”).

A. Factual Findings

In making its determination, the Commission finds as follows:

- (1) On August 30, 2019, the Centers for Disease Control (“CDC”) issued a health advisory announcing an investigation in conjunction with the federal Food and Drug



Administration (“FDA”), state and local health departments, and public health partners into a multistate outbreak of e-cigarette or vaping product use associated lung injury (“EVALI”). The investigation included products containing THC;

- (2) Between August and October 2019, the FDA and state public health authorities collected and analyzed THC-containing product samples. During the same time period, the CDC and 10 state public health authorities collected and analyzed Bronchoalveolar Lavage (“BAL”) fluid specimens from clinical teams treating patients hospitalized with EVALI;¹
- (3) As of the date of this Order, the FDA’s laboratories have conducted testing on approximately 545 samples directly linked to 74 patients identified by the CDC. Of the 70 patients associated with analyzed samples, approximately 80% of patients were connected to products containing THC. Of those patients, 77% cases included products containing Vitamin E Acetate (“VEA”) as a diluent, 32% included products with aliphatic esters as a diluent (e.g., triglycerides) and 7% included products with polyethylene glycol (PEG) as a diluent;²
- (4) On September 5, 2019, the New York State Department of Health issued a news release disclosing laboratory test results showing high levels of VEA in sampled cannabis products;
- (5) Based on these investigations and reports identifying VEA as potentially contributing to EVALI, on September 10 and September 11, 2019, Commission investigators conducted site visits at Independent Testing Laboratories licensed by the Commission and began an inquiry about the laboratories’ capacity to detect VEA and other additives in marijuana products;
- (6) On September 24, 2019, the Governor of the Commonwealth of Massachusetts declared that a multi-state outbreak of severe lung disease associated with the use of vaping products and e-cigarettes constituted an emergency detrimental to the public health and, on that same date, the Commissioner of Public Health issued an order temporarily prohibiting the sale or display of vaping products and e-cigarettes to consumers in the Commonwealth (collectively, the “Vape Ban”);
- (7) Since the initial reports of the multi-state outbreak of EVALI, the Commission has been engaged in conversations with Independent Testing Laboratories licensed by the Commission. The Commission, through its Executive Director and staff discussed additives used in the manufacturing of vaporizer products, including but not limited

¹ Blount BC, Karwowski MP, Morel-Espinesa 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 2019;68:1040-1041. DOI: <http://dx.doi.org/10.15585/mmwr.mm6845e2>.

² Lung Illnesses Associated with Use of Vaping Products. Food and Drug Administration, available at <https://www.fda.gov/news-events/public-health-focus/lung-illnesses-associated-use-vaping-products> (last updated Dec. 5, 2019).

to substances identified on the Food and Drug Administration Inactive Ingredient Database, which is available at <https://www.fda.gov/media/72482/download>, toxicants of concern identified by the CDC. The Commission, through its Executive Director and staff also engaged the Independent Testing Laboratories in discussions about the hardware and components used in the manufacturing of vaporizer products, storage and testing methods for vaporizer products. Through these discussions, the Independent Testing Laboratories notified the Commission that they have developed fully validated methods for detecting VEA in vaporizer products and are capable of performing those tests on a broad scale;

- (8) Since the initial reports of the multi-state outbreak of EVALI, the Commission has received correspondence from the public, observed public testimony from non-commission venues and comments related to the Commonwealth's declared public health emergency, and reviewed survey results from research organizations suggesting that the unavailability of laboratory-tested vaporizer products from regulated entities after implementation of the Vape Ban may have encouraged an increased number of Massachusetts cannabis patients and consumers to seek vaporizer products from illicit sources;
- (9) On November 8, 2019, the CDC published findings providing direct evidence of VEA at the primary site of EVALI patient injury. The CDC noted that further study is needed before a causal link can be established between VEA exposure and EVALI. The CDC findings did not then, and have not yet, ruled out the possibility that more than one compound or ingredient may cause lung injury, or that other toxicants may also contribute to EVALI;
- (10) On November 12, 2019, the Commission issued its Quarantine Order Applying to Vaporizer Products;
- (11) Between November 13 and November 19, 2019, the Commission collected approximately 91 vaporizer product testing sample sets from 19 licensees. The testing samples consisted of vaporizer cartridges or devices containing usable marijuana concentrate in their finished product form. The testing samples were submitted to licensed Independent Testing Laboratories for screening for detectable levels of VEA. All 91 samples passed screening for VEA with no detectable levels;
- (12) On December 6, 2019, the Department of Public Health (DPH) notified the Commission of interview data compiled from confirmed and probable EVALI cases. Patients identified as confirmed and probable EVALI cases were asked whether the THC product was "reported as having been purchased at a Massachusetts dispensary" and identified reported product names;
- (13) Among the reported patient interviews conducted by DPH, no patient with a confirmed case responded "Yes.";

- (14) According to DPH, six patients with probable cases responded “Yes.” However, the reported data cannot rule out, without further investigation, the possibility that responding patients did not want to report acquiring illicit market products or consuming illicit market products in addition to regulated products, or that responding patients erroneously characterized an unlicensed dispensary operation as a “Massachusetts dispensary”;
- (15) The Commission conducted a package trace for any inventory entered into the seed-to-sale electronic tracking system designated by the Commission as the system of record which contained item naming conventions similar to the product names identified by interviewed patients;
- (16) The Commission continues to investigate information from DPH as it is received;
- (17) Between December 4 and December 10, 2019, the Commission obtained approximately 126 vaporizer product test sample sets from 22 licensees across the Commonwealth. Based on the Commission’s ongoing investigative findings, testing samples were submitted to Commission-licensed Independent Testing Laboratories for both VEA screening and retesting of metals;
- (18) As of the date of this Order, the Commission is awaiting completed test results from the Independent Testing Laboratories for the majority of testing samples collected between December 4 and December 10, 2019;
- (19) The Commission has not identified any vaporizer product containing detectable levels of VEA from the 91 samples collected by the Commission between November 13 and November 19, 2019, or from preliminary test results from samples collected by the Commission between December 4 and December 10, 2019;
- (20) Among the samples collected between December 4 and December 10, 2019 and retested for heavy metals, the Commission has determined that continued investigation is necessary based on initial testing results. The Commission continues to investigate whether any vaporizer product samples exceed threshold levels for heavy metals, as established by the Commission’s Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products;
- (21) Among the hospitalized EVALI patients reporting using vaporizer products containing THC, the most commonly reported product brands referred to commonly used brands for illicit market products including: “Dank Vapes” (56% of responding patients), “TKO” (15%), “Smart Cart” (13%) and “Rove” (12%). The CDC further noted that reports of “Dank Vapes” usage was particularly high in the Northeast and Southern U.S. regions;³

³ See MMWR, Lozier, Matthew J., PhD, Wallace, Bailey, MPH, et al. Update: Demographic, Product, and Substance-Use Characteristics of Hospitalized Patients in a Nationwide Outbreak of E-cigarette, or Vaping, Product



- (22) On December 11, 2019, the Commonwealth terminated its public health emergency declared on September 24, 2019; and
- (23) This Order incorporates the findings of the U.S. Centers for Disease Control and Prevention, U.S. Food and Drug Administration and the information made available from the Massachusetts Department of Public Health as of the date of this Order.

B. Amended Order

Based on the Executive Director's authority as specified in the Commission's regulations and as delegated to the Executive Director by the Commission and, through the Director, to the Commission's staff, and these findings, the Executive Director finds the following:

- (1) That the adverse health effects of vaporizer products⁴ containing VEA pose an immediate and serious risk to public health, safety and welfare;
- (2) That VEA has been identified as having a scientifically significant correlation with EVALI, but may not ultimately be the only substance identified as such;
- (3) That testing of vaporizer products prior to introduction to the market and satisfaction of certain conditions specified herein may help to mitigate some of the risk associated with the use of vaporizer products by facilitating the availability of regulated, tested vaporizer products; and
- (4) That protection of the public health and safety being paramount to the mission of the Commission, the Executive Director shall continue to assist the Commissioners as the policymaking body of the Commission in the development of regulations informed by science and the continued study of the health effects posed by vaporizer-product inhalation.

The Commission, acting through its Executive Director, hereby **ORDERS** the following amendments to the terms of the Initial Order:

- (1) Condition No. 2 shall be deleted and replaced with the following:
 - (a) Respondent may display, sell or distribute devices designed to vaporize marijuana flower;
 - (b) Respondent may display, sell or distribute devices designed to vaporize marijuana concentrate but not containing usable marijuana subject to including a written insert at the point of sale which identifies the manufacturer of the device and its known components, including battery, and discloses the materials used in the device's atomizer coil (e.g., titanium, titanium alloy, quartz, copper,

Use-Associated Lung Injuries — United States, December 6, 2019. MMWR Morb. Mortal Wkly. Rep. ePub 6 December 2019, available at <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6849e1-H.pdf>.

⁴ This First Amended Order incorporates the definition of "vaporizer products" set forth in Condition No. 1 of the Commission's Quarantine Order Applying to Vaporizer Products issued November 12, 2019.



nichrome, kanthal, or other specified material);

- (2) Condition No. 3 shall be deleted and replaced with the following:
 - (a) Respondent shall enter all existing vaporizer products manufactured prior to the Effective Date of this Order, into a quarantine room named "VQR-11-12" in accordance with Metrc Bulletin No. MA_IB_0016. Respondent shall similarly designate quarantine products in any secondary seed-to-sale tracking system utilized by Respondent;
 - (b) Existing vaporizer products entered into VQR-11-12 shall not be transferred, transported or otherwise distributed except to other Marijuana Establishments, Medical Marijuana Treatment Centers or Independent Testing Laboratories in accordance with the Commission's laws, regulations, policies and Condition No. 4 of the Commission's Initial Order; and
 - (c) The Commission may place existing inventory on administrative hold pursuant to 935 CMR 500.321 and 935 CMR 501.321.

The Commission, acting through its Executive Director and consistent with Condition No. 6 of the Initial Order and the authority cited herein, hereby **ORDERS** the following terms in addition to the Initial Order:

- (1) Vaporizer products manufactured prior to the Effective Date of this Order, shall remain quarantined subject to the Commission's Initial Order. The Commission's investigation into the presence of contaminants, including heavy metals, in vaporizer products remains ongoing;
- (2) Respondent may sell vaporizer products manufactured on or after the Effective Date of this Order subject to the conditions set forth in this Order and after the submission of test results to the Commission in accordance with 935 CMR 500.160(1) and 935 CMR 501.160(1) (the "Released Product");
- (3) A vaporizer product manufactured on or after the Effective Date of this Order may be released from quarantine if the finished product is first tested for both VEA and a full-contaminant screening panel in accordance with 935 CMR 500.160(2), the Commission's Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products, and validated methods for VEA screening. Finished product means the vaporizer cartridge or device after injection of usable marijuana concentrate;
- (4) Nothing herein shall prevent the Commission from ordering additional testing and screening of vaporizer products based on additional scientific findings that implicate public health, including but not limited to specific toxicants of concern that have been, or in the future may be, identified in accordance with 935 CMR 500.160(2)

(“The Commission may require additional testing.”) and 935 CMR 501.160(2). In accordance with 935 CMR 500.160(3)(a)(2) and 935 CMR 501.160(3)(a)(2), Respondent shall notify the Commission of any vaporizer product containing VEA. In accordance with 935 CMR 500.160(3)(b) and 935 CMR 501.160(3)(b), the notification must be provided with two-day notice to the Commission and must describe the method of destruction. Respondent shall not destroy or waste a vaporizer product containing VEA without first providing the Commission notice of the date and time of destruction;

- (5) Respondents selling vaporizer products shall post conspicuously at each location (e.g., counter, terminal) where a retail sale of vaporizer products occurs, in lettering reasonably large enough to read from the purchaser’s perspective, the following warning: “This product has been tested for contaminants, including Vitamin E Acetate, with no adverse findings. **WARNING: Vaporizer Products may contain ingredients harmful to health when inhaled.**”;
- (6) In accordance with 935 CMR 500.105(5) and 935 CMR 501.105(5), Released Product shall include a physical insert provided to the patient or consumer at the point of sale including the following information:
 - (a) A clearly visible disclosure stating: “This product has been tested for contaminants, including Vitamin E Acetate, with no adverse findings. **WARNING: Vaporizer Products may contain ingredients harmful to health when inhaled.**”
 - (b) In accordance with 935 CMR 500.105(5)(c)(6), a list of additives, including the amount of specific additives infused or incorporated during the manufacturing process, whether active or inactive, including but not limited to thickening agents, thinning agents, and specific terpenes, expressed in absolute terms and as a percentage of volume:
 - i) Identification shall include, but not be limited to, identification of any inactive ingredient identified on the Food and Drug Administration’s Inactive Ingredient Database for “Respiratory (inhalation)” or “Oral” routes of administration and based on dosage form as an aerosol product or inhalant (i.e. vaporizer pen or vaporizer cartridge). The FDA Inactive Ingredient Database is available at <https://www.fda.gov/media/72482/download>; and
 - ii) Identification shall include, but not be limited to, whether the marijuana product contains or was manufactured with substances that contain Polyethylene glycol (PEG) or medium chain triglycerides (MCT).

- (c) The sale of vaporizer products shall include a disclosure that the patient or consumer may request to inspect a copy of the associated testing results (i.e. Certificate of Analysis) at Respondent's retail establishment or dispensary; and
 - (d) The sale of disposable and reusable vaporizer pens and devices must be accompanied by a product insert identifying the materials used in the device's atomizer coil (e.g., titanium, titanium alloy, quartz, copper, nichrome, kanthal, or other specified material), and manufacturer identification of the device hardware, cartridge, battery and other components;
- (7) Respondent shall disclose the information contained in Paragraph No. 6 in the product description available at the point of sale. The same information shall be made available on any product list posted on Respondent's website or third-party application (e.g., "reserve ahead" and delivery platforms);
 - (8) A licensee that has wholesaled vaporizer products to other licensees shall provide the recipient licensee with a copy of the Certificate of Analysis and physical insert necessary to comply with Paragraph No. 6;
 - (9) Respondent shall retain all records of purchases from any manufacturer or supplier of any ingredient, additive, device, component part or other materials obtained by the Respondent in relation to the manufacturing of vaporizer products for the course of the Commission's investigation. Such records shall be available for inspection by the Commission, on request, in accordance with 935 CMR 500.105(9) and 935 CMR 501.105(9);
 - (10) On request of the Commission and in accordance with 935 CMR 500.101(3)(c)(2) and 935 CMR 501.101(1)(c)(14), a Respondent licensed as a Product Manufacturer or Medical Marijuana Treatment Center shall make all reasonable efforts to identify the name and business address of the manufacturer of any vaporizer device hardware, cartridge, battery, atomizer coil or other component of all vaporizer products manufactured by Respondent. Further, Respondent shall, on request, identify the materials used in the device's atomizer coil (e.g., titanium, titanium alloy, quartz, copper, nichrome, kanthal, or other specified material) or state if such information cannot be reasonably ascertained; and
 - (11) Respondent shall not make, and an Independent Testing Laboratory shall not receive, remuneration for the purpose of expediting or granting priority for processing the samples submitted by Respondent or any particular licensee for testing. Any such payment shall be deemed a financial interest and not a reasonable contract fee as defined by 935 CMR 500.029(10).

The Commission's Initial Order is incorporated by reference and shall otherwise remain in full effect subject to the above amendment

Notice is provided pursuant to 801 CMR 1.02(6)(a)(1)(b) that this order shall take effect on Thursday, December 12, 2019, at 2:00 P.M. 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.

Respondent may request a hearing within twenty-one (21) calendar days after the Effective Date of this Order by making such request in writing to the Executive Director at 2 Washington Square, Worcester, MA 01604. Respondent may seek representation of counsel at any such hearing. 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 (774-415-0200) on Monday – Friday from 9:00 A.M. – 5:00 P.M. or email at Commission@cccmaass.com.

Signed this 12th day of December 2019:

Commonwealth of Massachusetts Cannabis Control Commission



Shawn Collins, Executive Director

