

August 3, 2020

Licensed Marijuana Establishments
Licensed Medical Marijuana Treatment Centers

Case No. 2019AM-0065-00

**SECOND AMENDED QUARANTINE ORDER
APPLYING TO VAPORIZER PRODUCTS
M.G.L. c. 94I, M.G.L., c. 94G, §§ 4(a)(xix), (a½)(xxx), and § 15(a)(2)
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)(xxx), and 15(a)(2), and its associated regulatory authority, the Commonwealth of Massachusetts Cannabis Control Commission (the “Commission”), acting through its Executive Director, issued a Quarantine Order requiring all licensed Marijuana Establishments and Medical Marijuana Treatment Centers (each, the “Respondent” and collectively, the “Respondents”) to quarantine vaporizer products after determining 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.

On December 12, 2019, the Commission issued a First Amended Quarantine Order permitting specific vaporizer products manufactured after December 12, 2019, to be removed from quarantine subject to further conditions and 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 Commission now issues this Second Amended Quarantine Order (“Second Amended Order”). The Second Amended Order shall be effective upon all Respondents issued a final license by the Commission and shall take effect on August 4, 2020 at 12:00 A.M. (the “Effective Date”).

A. Factual Findings

In making its determination, the Commission finds as follows:

1. On September 24, 2019, Governor Charles D. Baker declared a public health emergency and the Commissioner of Public Health issued a temporary ban on the sale of all vaporizer products, including devices that rely on vaporization or aerosolization.



Cartridges, vaporizer accessories and devices, and refills for cartridges were removed from shelves and prohibited from sale.

2. On November 12, 2019, the Commission, acting through the Executive Director, issued its Quarantine Order Applying to Vaporizer Products (the “Initial Order”). The Initial Order required licensees to quarantine all vaporizer products.
3. On December 12, 2019, the Commission issued its First Amended Quarantine Order (“First Amended Order”) authorizing licensees to sell newly manufactured vaporizer products subject to additional testing requirements, label disclosures, and recordkeeping requirements, but required that vaporizer products manufactured before December 12, 2019 remain subject to quarantine.
4. Commission staff engaged stakeholders and licensees affected by the First Amended Order in order to better understand industry perspectives about vaporizer product manufacturing and concerns regarding device quality, specifically the interaction of the vaporizer product’s heating coil/atomizer and other device components with marijuana concentrate. Discussions encompassed concerns about product stability, particularly the shelf life and viability of vaporizer products over time, possible contamination caused by leaching of metals from device components, and the necessity of heavy metal re-testing of finished vaporizer products.
5. Commission staff requested and obtained information from licensees regarding vaporizer product manufacturing equipment, manufacturing and design specifications (including Safety Data Sheets) for vaporizer products and their component parts as well as information relating to licensee-initiated quality control and safety tests. In its own investigation, the Commission had vaporizer products tested by Commission-licensed Independent Testing Laboratories (ITLs) for Vitamin E Acetate (VEA) and heavy metals. Phase I and Phase II testing were conducted prior to the issuance of the First Amended Order and pursuant to the Initial Order.
 - a. Phase I testing consisted of ITL screening for VEA only with no reported detections among the ninety-one (91) vaporizer samples collected from nineteen (19) licensees.
 - b. Phase II testing consisted of screening for both VEA and heavy metal levels from a geographically diverse collection of one hundred and twenty-six (126) vaporizer product samples from twenty-two (22) licensees across the Commonwealth. Phase II testing was conducted between two ITLs. None of the Phase II samples returned detectable levels of VEA, however, approximately thirteen (13) vaporizer products were found to have heavy metal concentrations exceeding the acceptable levels for inhalation established by the *Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries* (the “Testing Protocol”).

- c. Phase III testing found varying results within previously tested production batches and did not conclusively establish the root cause of elevated heavy metal contamination. Phase III testing consisted of performing confirmatory tests on vaporizer products associated with twelve (12) Phase II vaporizer products that had previously failed for heavy metal concentrations above the acceptable limits for inhalation (500 ppb), including six (6) samples exceeding 1,000 ppb. In Phase III, two (2) of the twelve (12) vaporizer products sampled returned heavy metal (lead) concentrations exceeding the acceptable levels for inhalation established by the Testing Protocol. Four (4) samples tested positive for heavy metal (lead) concentrations above initial testing results but below acceptable levels for inhalation. Testing limitations identified during the investigation included limited sampling scope, product batch homogeneity, inconsistent extraction procedures for testing finished cartridge samples, and lack of known sources of metal contamination.
 - d. Phase III efforts included testing empty vaporizer cartridges to identify the source metal contamination, however, the testing methods applied precluded reliable results. Twenty (20) empty vaporizer cartridges were collected from seven (7) licensees. The empty cartridges tested positive for lead, cadmium and arsenic. However, the testing method applied raises concerns about the validity of the results. In particular, the extraction process of the metal components in the cartridges yielded exponentially higher results. Due to limited isolation of the parts within the vaporizer device, controlled and reliable data was not produced.
 - e. As of the date of this Second Amended Order, VEA has not been detected in any Commission-initiated testing.
6. The result of Commission-initiated testing suggests that heavy metal (lead) levels in vaporizer products may increase over time. As a result, vaporizer products that have been quarantined since November 12, 2019 may present elevated heavy metal concentrations exceeding the applicable testing limits set forth in the Testing Protocol, which poses a risk to the public health, safety and welfare.
7. Based on the results of the Commission investigation, further investigation and cooperation among the government, industry, and scientific community is necessary to identify the root cause(s) of heavy metal (lead) contamination, ascertain the health effects of elevated lead levels, and more fully understand whether heavy metal content within vaporizer products can become more prominent without use over time or post-use.
8. On July 2, 2020, the Commission requested public comment regarding what conditions, if any, would allow for the retesting and safe sale of vaporizer products previously subject to quarantine. Public comments were submitted between July 2 and July 14, 2020 and were taken under advisement.
9. Based on the above findings and information, the Commission issues this Second Amended Order.

B. Order

Exercising his discretion and relying on the authority delegated to him by the Commission, the Executive Director determines that based on the scientific evidence available, vaporizer products continue to pose a risk to the public health, safety and welfare. There continues to be a risk that vaporizer product hardware may contaminate marijuana concentrate over time with heavy metals and other substances that may be harmful to human health. The Executive Director finds that a measured, transparent approach to testing existing vaporizer products mitigates, but does not eliminate, the public health risk posed by vaporizer products previously subject to quarantine.

The Commission, acting through its Executive Director, hereby **ORDERS** the following:

- (1) Vaporizer products manufactured prior to December 12, 2019 may be voluntarily disposed of or released from quarantine and made available for sale if first retested in accordance with this Second Amended Order, or repurposed into other Marijuana Products after reclaiming marijuana oil from quarantined vaporizer products. Retested vaporizer products or reclaimed marijuana products with passing test results that are otherwise in compliance with this order may be sold.
- (2) Voluntary Disposal. At any time, Respondents may voluntarily dispose of vaporizer products previously subject to quarantine pursuant to 935 CMR 500.105(12) or 935 CMR 501.105(12).
- (3) Retest. In accordance with the Second Amended Order and subject to the following requirements, Respondents shall be authorized to sell specific vaporizer products that have been tested and deemed compliant with the Commission's regulations and policies, subject to the conditions below:
 - a. A sample from each quarantined production batch or new sample from a reclaimed production batch intended for sale must pass testing for heavy metal levels and VEA. Sampling shall follow existing production batch sampling requirements as set forth pursuant to 935 CMR 500.160, 935 CMR 501.160, and the Testing Protocol.
 - b. Respondents shall test production batches using representative samples of previously quarantined vaporizer products. Representative samples shall mean the greater of a single one-gram sample or 0.50% of the total production batch.
 - c. Authorization to sell specific vaporizer products may not be granted to vaporizer products that were modified or otherwise not properly entered and maintained in the "VQR-11-12" quarantine room in accordance with Condition No. 3 of the First Amended Order.

- d. The vaporizer product label must include a list of ingredients in accordance with 935 CMR 500.105(5)(c)6. and 935 CMR 501.105(5)(c)6. and the information required under Section 6 of this Second Amended Order.
- (4) Reclaiming. As a method of remediation and in accordance with the Testing Protocol, Respondents shall be authorized to reclaim marijuana concentrate from quarantined vaporizer products. Remediated vaporizer products may be used to repurpose the marijuana concentrate into other marijuana products, including new vaporizer products, if the reclaimed product passes testing for heavy metals and all other testing required under the Testing Protocol. If, after two attempts at remediation, the reclaimed product does not pass testing for heavy metals, it shall be deemed unable to be remediated and must be disposed.
 - (5) Mandatory Disposal. Consistent with 935 CMR 500.160(3) and 935 CMR 501.160(3), production batches that previously failed both Commission-initiated tests for heavy metals under Phases II and III shall be deemed unable to be remediated if, after two attempts at remediation, the product does not pass testing for heavy metals. Contaminated products that cannot be remediated pose a threat to public health, safety, and welfare. Respondents may dispose of such products voluntarily or on receiving an order of destruction from the Commission.
 - (6) Label Requirements.
 - a. For all vaporizer products, identification of specific additives shall include, but not be limited to, any additives identified on the FDA’s Inactive Ingredient Database for “Respiratory (inhalation)” or “Oral” routes of administration and based on dosage form as an aerosol product or inhalant. The FDA Inactive Ingredient Database is available at <https://www.fda.gov/media/72482/download>.
 - b. For vaporizer devices produced using only cannabis-derived terpenes, include the following statement: “This product was produced using only cannabis-derived terpenes.”
 - c. For vaporizer devices produced using terpenes other than cannabis-derived terpenes, include the following statement: “This product was produced using terpenes derived from sources other than cannabis.”
 - d. For vaporizer products retested in accordance with this Second Amended Order, the following shall appear on the product packaging: “This product was previously quarantined. Passed retesting for heavy metals and Vitamin E Acetate. Store at room temperature.”
 - e. For vaporizer products reclaimed and retested in accordance with this Second Amended Order, the following shall appear on the product

packaging: “This product was produced using previously quarantined concentrate. Passed retesting for heavy metals and Vitamin E Acetate. Store at room temperature.”

- f. 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.
- g. The sale of disposable and reusable vaporizer pens 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 device hardware, cartridge, battery and other components.
- h. Marijuana Retailers and MTCs shall make available the information contained in this Section 6 in the product description at the point of sale and as part of any product list posted on the Marijuana Retailer’s website or third-party technology platforms or applications employed for pre-ordering or delivery.
- i. Original packaging date of the quarantined vaporizer product.

(7) General Requirements. All Marijuana Product Manufacturers, including Medical Marijuana Treatment Centers (MTCs), shall maintain the following information for vaporizer products sold pursuant to this Second Amended Order:

- a. A Marijuana Product Manufacturer shall retain all records of purchases from any manufacturer or supplier of any ingredient, additive, device, component part, or other materials obtained by the Marijuana Product Manufacturer in relation to the manufacturing of marijuana vaporizer devices and such records shall be made available to the Commission on request.
- b. A Marijuana Product Manufacturer shall maintain records of the name and business address of the manufacturer of any cartridge, battery, atomizer coil, hardware, or other component of marijuana vaporizer products acquired by the Licensee from device manufacturer. Further, the Product Manufacturer shall, on request by the Commission, identify the materials used in the device’s atomizer coil (e.g., titanium, titanium alloy, quartz, copper, nichrome, kanthal, or other specified material).
- c. A Marijuana Product Manufacturer shall retain a copy of the Certificate of Analysis for each thickening agent, thinning agent, and terpene infused or incorporated into a marijuana vaporizer device during production. The

Marijuana Product Manufacturer shall provide the Certificate of Analysis as a part of any wholesale transaction with a marijuana retailer or MTC.

- d. A Marijuana Product Manufacturer that wholesales marijuana vaporizer devices to a Marijuana Retailer or MTC shall provide the recipient with the information insert required by 935 CMR 500.105(5)(c)6. and 935 CMR 501.105(5)(c)6 and Section No. 6 of this Second Amended Order. Alternatively, a Marijuana Product Manufacturer may provide the recipient with the necessary information to produce the insert, in addition to the appropriate labeling information required under Commission regulations.
- (8) Vaporizer products with original, full-panel testing dates in excess of one year shall be deemed expired and may not be dispensed, sold, transferred or otherwise conveyed until another screen for all contaminants, excluding pesticides, is conducted.
- (9) A Marijuana Product Manufacturer may repurpose concentrate for topical products or marijuana products administered by ingestion or topical use if the retest passes testing for acceptable levels of heavy metals for ingestion and topicals (1,000 ppb) and all other ingredients are at acceptable levels.
- (10) In accordance with 935 CMR 500.160(3)(b) and 935 CMR 501.160(3)(b), the Respondent shall notify the Commission of any vaporizer product test result exceeding acceptable levels for heavy metals and describe method for remediation or disposal.

The First Amended Order is incorporated by reference and shall otherwise remain in effect to the extent applicable to vaporizer products manufactured after December 12, 2019. This Second Amended Order shall control to the extent any term of this Second Amended Order conflicts with the First Amended Order. The Commission's existing regulations, or any regulations subsequently promulgated, shall control to the extent that any conflict arises between the terms of this Second Amended Order or any term of the First Amended Order.

Notice is provided pursuant to 801 CMR 1.02(6)(a)(1)(b) that this Second Amended Order shall take effect on August 4, 2020, at 12:00 A.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 Commission authority to take additional administrative action to protect the public health, safety, and welfare.

The Commission reserves the right to rescind or amend the order or take additional action under 935 CMR 500.500 and 935 CMR 501.500. 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 thirty (30) calendar days after the Effective Date of this Second Amended Order by making such request by email to Commission@CCCMass.com, for it to be considered timely under 935 CMR 500.500(4) and 935 CMR 501.500(4). Respondent may appear pro se or be represented by counsel in the administrative hearing process. The Commission may conduct pre-hearing conferences, require stipulations of law and fact, consolidate multiple hearing requests into a single hearing, or take other actions it deems necessary to hear and decide common issues of fact and law.

Questions about the Second Amended 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@cccmass.com.

Signed this 3rd day of August 2020:

Commonwealth of Massachusetts Cannabis Control Commission

A handwritten signature in black ink, appearing to read "Shawn Collins", with a long horizontal flourish extending to the right.

Shawn Collins
Executive Director