



**STATE OF RHODE ISLAND
DEPARTMENT OF BUSINESS REGULATION
OFFICE OF CANNABIS REGULATION
560 JEFFERSON BOULEVARD, SUITE 204
WARWICK, RHODE ISLAND 02886**

IN THE MATTER OF:

**SUMMIT MEDICAL COMPASSION
CENTER, INC.**

DBR No. 22OCR002

RESPONDENT.

CONSENT AGREEMENT

Reference is made to the Edward O. Hawkins and Thomas C. Slater Medical Marijuana Act, Rhode Island General Laws § 21-28.6-1 et seq. (the “Act”) and Rules and Regulations Related to the Medical Marijuana Program Administered by the Office of Cannabis Regulation at the Department of Business Regulation, 230-RICR-80-5-1 et seq. (the “Regulations”). The Department of Business Regulation through its Office of Cannabis Regulation (the “Department” or “OCR” respectively) and Summit Medical Compassion Center, Inc., a Rhode Island Non-Profit Corporation (“Respondent”), hereby consent and agree that:

1. Respondent currently holds a Medical Marijuana Compassion Center License and is one of four Compassion Centers that is presently licensed, operational, and lawfully permitted to dispense Medical Marijuana Products to registered patients for alleviating symptoms caused by debilitating medical conditions.¹
2. In February 2022 the Department received from Cannalytics RI, LLC, an Analytical Laboratory licensed by the R.I. Department of Health to sample and test Medical Marijuana, three Certificates of Analysis (“COA”) for three products manufactured and sold by Respondent.

¹ “‘Compassion center’ means a not-for-profit corporation, subject to the provisions of chapter 6 of title 7, and is licensed under § 21-28.6-12, that acquires, possesses, cultivates, manufactures, delivers, transfers, transports, supplies, or dispenses medical marijuana, and/or related supplies and educational materials, to patient cardholders and/or their registered caregiver cardholder or authorized purchaser.” R.I. Gen. Laws § 21-28.6-3(6)(i).

3. The COAs aforementioned in ¶ 2 reported the presence of substantial levels of Delta 8 Tetrahydrocannabinol (“THC”)^{2,3} in all three products; more specifically the COAs reported the following molecular analyses:
 - a. Batch Number 4616562037395290, associated with a 10 milligram (“mg”) strawberry-flavored Medical Marijuana “gummy,” was comprised of:
 - i. 0.052 mgs Delta 9 THC; and
 - ii. 9.72 mgs Delta 8 THC.
 - b. Batch Number 7895625412629207, associated with a 10 mg guava-flavored Medical Marijuana “hard candy,” was comprised of:
 - i. <LOQ mgs Delta 9 THC;⁴ and
 - ii. 6.68 mgs Delta 8 THC.
 - c. Batch Number 5581205789379156, associated with a 5 mg strawberry-flavored Medical Marijuana “gummy,” was comprised of:
 - i. 0.25 mgs Delta 9 THC; and
 - ii. 4.61 mgs Delta 8 THC.
4. On March 8, 2022, OCR’s Chief of Strategic Planning, Monitoring, and Evaluations, Principal Policy & Economic Analyst, and Chief Public Protection Inspector (collectively “OCR’s agents”) conducted an inspection of Respondent’s retail facility wherein OCR collected from Respondent documents and information regarding the products identified in ¶ 3.
5. During the March 8, 2022 inspection, Respondent’s General Manager stated to OCR’s agents that he was not aware there was a legal/regulatory difference between Delta 8 THC and Delta 9 THC and that many of Respondent’s products made with extracted and/or processed cannabinoids would likely contain similar concentration levels of Delta 8 THC.

² “The term THC typically refers to the delta-9 THC isomer, which is the most prominently occurring THC isomer in cannabis. However, THC has several other isomers that occur in the cannabis plant, including delta-8 THC. Delta-8 THC exists naturally in the cannabis plant in only small quantities and is estimated to be about 50-75% as psychoactive as delta-9 THC. CBD can be synthetically converted into delta-8 THC, as well as delta-9 THC and other THC isomers with a solvent, acid, and heat to produce higher concentrations of delta-8 than those found naturally in the cannabis plant. This conversion process, used to produce some marketed products, may create harmful by-products that presently are not well-characterized.” Centers for Disease Control & Prevention, Health Alert Network (“HAN”), CDC HAN00451, September 14, 2021 (*internal citations omitted*) <https://emergency.cdc.gov/han/2021/han00451.asp>.

³ The Department acknowledges that, while Delta 8 THC is naturally present in marijuana its presence, generally and relative to other cannabinoids (*e.g.*, Delta 9 THC), it naturally occurs only in very small/trace quantities and never in concentrations like those reported in the COAs for Respondent’s products.

⁴ “LOQ” stands for “Limits of Quantification,” meaning the lowest level that an analyte can be quantitated with any degree of certainty.

6. The Regulations do not provide for designation of products containing substantial levels of Delta 8 THC as Medical Marijuana.
7. The Department will not designate any products containing substantial levels of Delta 8 THC as Medical Marijuana unless and until:
 - a. the science surrounding long-term use of substantial levels of Delta 8 THC by Medical Marijuana Patients sufficiently demonstrates that it is both safe and effective; and
 - b. sufficient statutory and/or regulatory authority exists for the Department to do so.
8. In August 2021, the American Chemical Society ("ACS") Chemical & Engineering News ("C&EN"), Volume 99, Issue 31 reported that: "Chemists are alarmed about impurities formed during the synthesis of the cannabinoid Δ^8 -tetrahydrocannabinol (delta-8-THC), sold in gummies, vape products, and other items. Delta-8-THC is a mildly euphoric isomer of psychoactive delta-9-THC. Delta-8-THC is typically synthesized from cannabidiol (CBD) extracted from hemp. The reaction often yields a high percentage of delta-8-THC, as well as small amounts of other cannabinoids and reaction by-products. Little is known about the health effects of these impurities, and chemists have not identified all of them." <https://cen.acs.org/biological-chemistry/natural-products/Delta-8-THC-craze-concerns/99/i31>.
9. In September 2021, the FDA issued a consumer advisory expressing its concern about the proliferation of products containing Delta 8 THC that are marketed for therapeutic or medical uses. U.S. Food & Drug Administration Consumer Updates "5 Things to Know about Delta-8 Tetrahydrocannabinol - Delta-8 THC," <https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc>. The FDA explained "delta 8 THC[] is a psychoactive substance found in the Cannabis sativa plant, of which marijuana and hemp are two varieties. . . but [Delta 8 THC] is not found in significant amounts in the cannabis plant." *Id.* Because the natural amount of delta-8 THC in hemp is very low, additional chemicals are needed to convert cannabinoids like CBD into Delta 8 THC (*i.e.*, synthetic conversion) which may result in harmful byproducts and contaminants and present additional consumer concerns in terms of formulation and product labeling. *Id.*
10. In September 2021, the CDC also issued HAN-00451 entitled "Increases in Availability of Cannabis Products Containing Delta-8 THC and Reported Cases of Adverse Events." <https://emergency.cdc.gov/han/2021/han00451.asp>. The CDC Advisory confirms that "Delta-8 THC exists naturally in the cannabis plant in only small quantities" and that "CBD can be synthetically converted into delta-8 THC, as well as delta-9 THC and other THC isomers, with a solvent, acid, and heat to produce higher concentrations of delta-8 THC than those found naturally in the cannabis plant. This conversion process, used to produce some marketed products, may create harmful by-products that presently are not well-characterized." *Id.* Moreover, "[t]he health effects of delta-8 THC have not yet been researched extensively and are not well-understood." *Id.* "Products that contain delta-8 THC but are labeled with only delta-9 THC content rather than with total THC content likely underestimate the psychoactive potential of these products for consumers." *Id.* "In addition, because testing methods for products like synthetically derived delta-8 THC are still being developed, delta-8 THC products may not be tested systematically for

contaminants such as heavy metals, solvents, or pesticides that may have adverse health effects." *Id.*

11. Summit informed the Department that its internal investigation and testing revealed that the elevated presence of delta-8 THC reported in the COAs for the products described in ¶ 3 occurred because the carbon powder Summit used in the extraction process for the oil used to create those products imparted high acidity levels, which unintentionally converted delta-9 to delta-8-THC through the distillation process.
12. Summit addressed the results of the internal investigation described in ¶ 11 by removing carbon powder from the extraction process, which eliminated the substantial levels of delta-8 THC in extracted and distilled oil.
13. "It is in the state's interests of public safety, public welfare, and the integrity of the medical marijuana program to ensure that the possession and cultivation of **marijuana for the sole purpose of medical use for alleviating symptoms caused by debilitating medical conditions is adequately regulated.**" R.I. Gen. Laws § 21-28.6-2(7) (*Emphasis added*).
14. "The goal of the medical marijuana program is to create a system that is **transparent, safe, and responsive to the needs of patients.** Consequently, the medical marijuana program requires regulation and a comprehensive regulatory structure that allows for oversight of all suppliers of medical marijuana while **ensuring both safety and patient access.**" R.I. Gen. Laws § 21-28.6-2(8) (*Emphases added*).
15. Pursuant to the Act, compassion centers are only authorized to acquire, possess, cultivate, manufacture, deliver, transfer, transport, supply, or dispense "medical marijuana " R.I. Gen. Laws § 21-28.6-12(a).
16. "Marijuana may only be used by patient cardholders and may only be sold to or possessed by patient cardholders, or their registered caregivers, or authorized purchasers **if it has been designated as 'medical marijuana'** pursuant to § 1.7 of this Part, the Act and any regulations promulgated thereunder." 230-RICR-80-05 § 1.7(A) (*Emphasis added*).
17. "To be designated as medical marijuana, a product must: (1) Comply with a pre-approved designation list of products published by DBR; or (2) Be designated as medical marijuana by DBR prior to sale or distribution of the product." 230-RICR-80-05 § 1.7(C).
18. "At the time of application for medical marijuana designation, the marijuana establishment licensee shall submit any known health impacts, both positive and negative, associated with the product to DBR." 230-RICR-80-05 § 1.7(D).
19. For the purposes of the Regulations, the Act and the Department's enforcement authority derived therefrom, "'Medical marijuana' means marijuana and marijuana products which satisfy the requirements of R.I. Gen. Laws Chapter 21-28.6 and have been given the designation of "medical marijuana" by DBR due to dose, potency, form or other characteristics. Medical marijuana products are only available for use by patient cardholders and may only be sold to or possessed by patient cardholders, or their registered caregiver, or authorized purchaser in accordance with the Act. Medical marijuana may not be sold to, possessed by, manufactured by, or used except as

permitted under R.I. Gen. Laws Chapter 21-28.6 and any regulations promulgated thereunder.” 230-RICR-80-05 § 1.1.1 (A)(27).

20. “Medical marijuana product designation(s) may be withdrawn, denied or revoked by DBR if the product fails to satisfy any provision of the Act or the DBR Regulations or if the product deviates or is altered from its previously approved form.” 230-RICR-80-05 § 1.7(G).
21. For the purposes of the Act and Regulations “‘**THC**’ means **delta-9-tetrahydrocannabinol**, which is a psychoactive cannabinoid found in the cannabis plant.” 230-RICR-80-05 § 1.1.1(A)(45) (*emphasis added*).
22. “All finished medical marijuana plant components, extracts and concentrates must be quantitatively analyzed following methods described in § 6.21(B) of this Part, to determine the total THC and its cannabinoid profile in the product. Although many cannabinoids and related compounds are present in the cannabis plant, characterization of the cannabinoid profile of the total THC in the medical marijuana product must include, at a minimum, the percentage of Δ 9-tetrahydrocannabinol (Δ 9-THC), cannabidiol (CBD), tetrahydrocannabinolic acid (THCa) and cannabidiolic acid (CBDa). Percentage amounts of other cannabinoids may be reported but are not required.” Licensing Analytical Laboratories for Sampling and Testing Medical Marijuana, 216-RICR-60-05-6 § 6.21(C).⁵
23. “‘Cannabinoid profile’ means the percentages of Δ 9-tetrahydrocannabinol (Δ 9-THC), cannabidiol (CBD), tetrahydrocannabinolic acid (THCa) and cannabidiolic acid (CBDa) in the total amount of THC in the **medical marijuana product as sold**. Percentage of other cannabinoids may be reported[] but are not required.” 216-RICR-60-05-6 § 6.4(I).
24. “Each package containing retail-ready medical marijuana products must be labeled with all required information pursuant to § 1.5 of this Part before being sold to a registered patient, registered primary caregiver or authorized purchaser.” 230-RICR-80-05-1 § 1.5.3(A).
25. All packages containing retail-ready medical marijuana products must be clearly labeled with the following information: “Total THC and Total CBD as provided by a licensed cannabis testing laboratory;” 230-RICR-80-05-1 § 1.5.3(E)(4).
26. 230-RICR-80-05-1 § 1.5.3(F), entitled “Additional Labeling Requirements for Retail-Ready Medical Marijuana Infused Products,” requires in part:
 1. Total contents of THC and CBD must be stated per serving unit in milligrams (mgs), and in font larger than size 6, bolded, underlined and in red, so as to stand from surrounding text to the consumer;

⁵ While the Department acknowledges that the testing regulations are under the purview of the Rhode Island Department of Health, the Department references said regulations because all medical marijuana products are required to undergo adequate testing in accordance with these regulations in order to be sold/distributed in compliance with Rhode Island law.

2. Total contents of THC and CBD must be stated per package, in milligrams (mgs), in font larger than size 6, bolded, underlined and in red, so as to stand out from surrounding text to the consumer

27. 230-RICR-80-05 § 1.11(G), entitled “Recalls,” provides in part:

1. DBR or DOH may require a licensee to recall any marijuana or marijuana product that the licensee has sold or transferred upon a finding that circumstances exist that pose a risk to public health, safety and welfare.
 - a. The recall must be initiated by the licensee immediately as determined by their approved recall plan; and
 - b. The licensee must comply with any additional instructions made by DBR.
2. A recall may be based on, without limitation, evidence that the marijuana, marijuana product, or medical marijuana product: . . .
 - a. is not properly packaged or labeled;
 - b. Was not cultivated, processed or manufactured by a licensee or otherwise is not in accordance with the Act, DBR regulations or DOH regulations; or
 - c. Otherwise poses a threat to public health or safety as determined by DBR or DOH.

28. If the Department finds that a recall is required, it may require the licensee to place all marijuana products in quarantine or with a third-party custodian at licensee’s expense, to notify all individuals to whom such products were sold, and/or to destroy the recalled product. 230-RICR-80-05-1 § 1.11(G)(4).

29. “Pursuant to R.I. Gen. Laws §§ 21-28.6-9(e)(1)(ii), 21-28.6-12(f)(1) and 21-28.6-15(b)(3), DBR adopts the following schedule of administrative penalties with respect to violations of the Act, the DBR Regulations or any other applicable laws pertaining to a license, registration and/or operations in connection therewith: . . .

Violation:	Violations by a compassion center or other marijuana establishment licensee, where DBR determines that a violation poses an immediate threat to public health or public safety
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Administrative Penalty:	A penalty of not less than \$2,000, but not more than \$100,000 per violation per day.”
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230-RICR-80-05-1 § 1.13(D)(1).

30. Based upon the foregoing, it is the Department’s position that Respondent violated the Regulations by dispensing to Medical Marijuana Patients products that contained substantial levels of Delta 8

THC and little-to-no Delta 9 THC and did not comply with the state's product labeling requirements.

31. In an effort to effect a timely and amicable resolution of the issues raised in this Consent Agreement without an administrative hearing, the Department and the Respondent enter into this Consent Agreement solely for the purpose of avoiding the burdens and expenses of litigation. Based upon Respondent's representations and agreements set forth herein, the Department agrees to abstain from pursuing further enforcement action(s) surrounding the product batches identified in ¶ 3 and subject to satisfaction of the following terms and conditions as set forth in this ¶ 31:
- a. Respondent neither admits nor denies the Department's factual allegations set forth in this Consent Agreement. It is Respondent's position that the presence of elevated levels of delta-8 THC reported in the COAs for the products identified in ¶ 3 resulted from the unintentional and inadvertent conversion of delta-9 THC to delta-8 THC caused by the use of carbon powder during the extraction process.
 - b. Respondent acknowledges and agrees that if the Department presented its factual allegations as set forth in this Consent Agreement at a hearing on the matter without proof to the contrary, the Department would have demonstrated sufficient evidence to overcome its burden of proof to demonstrate a violation of Law and/or Regulation governing the Medical Marijuana Program;
 - c. Respondent represents to the Department that Respondent conducted a recall of all the affected products. Respondent agrees to quarantine and destroy any returned recalled product in accordance with the Regulations;
 - d. Respondent represents to the Department that in response to the Department's allegations it conducted an internal investigation and developed and implemented a corrective action plan;
 - e. Respondent represents to the Department and agrees that Respondent will not dispense or otherwise distribute any products which it has reason to believe may also contain substantial levels of delta-8 THC which, for the purposes of this Consent Agreement means marijuana products whose THC profiles consist of 10% or more Delta-8 THC;
 - f. Respondent agrees that any medical marijuana products Respondent dispenses moving forward will comply with § 1.5 of the Regulation, specifically § 1.5.3(E)(4) which requires each package containing retail-ready medical marijuana products to be labeled with all required information including the total THC (delta-9-tetrahydrocannabinol) and total CBD as provided by a licensed cannabis testing laboratory. Respondent shall satisfy all the following conditions by the dates listed below, including, but not limited to, the delivery to the Department of the following items as part of a corrective action plan to prevent the distribution of inadequately labeled products containing substantial amounts of delta-8 THC from occurring:

- i. Concurrently with the execution of this Consent Agreement, Respondent shall appoint Emily Almeida as its new Compliance Officer;
 - ii. No later than September 1, 2022, Respondent shall submit to the Department updated Standard Operating Procedures for extraction processes;
 - iii. No later than September 1, 2022, Respondent shall submit to the Department documentation reflecting personnel changes including satisfactory evidence that national criminal background checks have been completed, and registry identification cards issued, for all officers and directors (or managers/members of the LLC), employees, and agents; and
 - iv. Upon execution of this Consent Agreement and continuing on the 15th day of each month thereafter for the next six (6) months, until February 15, 2023, Respondent shall submit Certificates of Analysis (COAs) or a document that summarizes the data displayed on each COA for the previous month's testing for every batch of product cultivated, produced, processed, and/or manufactured by Summit Medical Compassion Center as reported by a licensed testing lab to the Department via e-mail to OCR Chief Matthew Santacroce at Matthew.Santacroce@dbr.ri.gov, OCR Chief Public Protection Inspector Peter Squatrito at Peter.Squatrito@dbr.ri.gov, and OCR Senior Economic & Policy Analyst Erica Ferrelli at Erica.Ferrelli@dbr.ri.gov.
- g. Pursuant to 230-RICR-80-05-1 § 1.13(D)(1), Respondent shall remit an administrative penalty of \$100,000 made payable to the "General Treasurer, State of Rhode Island."
32. Upon execution of this Consent Agreement, Summit Medical Compassion Center shall be deemed to be in good standing with the Department pursuant to R.I. Gen. Laws § 21-28.11-10(a)(1), provided that Respondent satisfies all continuing compliance obligations under applicable law, rules and regulations.
33. *Final Determination.* The parties agree that this Consent Agreement and its terms represent the final determination of this matter.
34. *Waiver of Hearing and Appeal.* By agreeing to resolve this matter through the execution of this Consent Agreement, Respondent knowingly and voluntarily waives any right to an administrative hearing and waives any right to pursue an appeal to the Superior Court under the Rhode Island Administrative Procedures Act, R.I. Gen. Laws § 42-35-1, *et seq.*
35. *Enforcement.* If the Respondent fails to comply with any term or condition of this Consent Agreement within any applicable time period set forth herein, the Respondent will be in violation hereunder and

the Department shall be entitled to immediately take enforcement or other action in accordance with applicable law.

36. *Compliance; Laws.* Compliance with the terms of this Consent Agreement does not relieve the Respondent of any obligation to comply with other applicable laws or regulations administered by or through the Department or any other governmental agency.

Signature Page

For the Department:



August 15, 2022

Signature

Date

Name:
Matthew Santacroce

Title:

Interim Deputy Director, RI Dept. of Business Regulation

For Respondent:



August 5, 2022


Signature

Date

Name: Joseph Centracchio

Title: Interim General Manager, CPG
for Summit Medical Compassion
Center, Inc.

Respondent's Counsel:



August 5, 2022

Signature

Date

Name: Adam M. Ramos, Esq.

Title: Attorney for Summit Medical
Compassion Center, Inc.