

Board of Health

Edward Cosgrove, PhD Stephen Epstein, MD, MPP Tejal K. Gandhi, MD, MPH

Robert Partridge, MD, MPH Aarti Sawant-Basak, PhD

ARTICLE 22 REGULATION FOR PROHIBITING THE MANUFACTURING, SALE, AND DISTRIBUTION OF SYNTHETICALLY DERIVED CANNABINOIDS AND OTHER DRUGS

SECTION 22.1 <u>AUTHORITY</u>

Therefore, in furtherance of its mission to protect, promote, and preserve the health and well-being of its residents, and pursuant to the authority granted to the Needham Board of Health pursuant to G. L. c. 111, § 31, the Board of Health enacts this Regulation Prohibiting the Manufacturing, Sale, and Distribution of Synthetically Derived Cannabinoids and Other Drugs.

SECTION 22.2 PURPOSE

Whereas, hemp is defined as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a Delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

Whereas, tetrahydrocannabinol (THC) is the chemical responsible for most of marijuana's psychological effects.²

Whereas, synthetically derived tetrahydrocannabinols remain schedule I controlled substances.³

Whereas, Delta-8, Delta-10, and other forms of THC are isomers of Delta-9 and, except for in trace amounts, are not found naturally in the plant cannabis, but are instead synthetically produced in laboratories.⁴

¹ Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,640 (Aug. 21, 2020).

² Alina Bradford, What is THC?, LIVESCIENCE (May 18, 2017), available at https://www.livescience.com/24553-what-is-thc.html.

³ Implementation of the Agriculture Improvement Act of 2018, supra note 1 at 51,641.

⁴ <u>See</u> Kristina Etter, *I Stand Corrected: The Truth About Delta-8 THC*, MEDIUM (March 17, 2021), <u>available at https://medium.com/seed-stem/i-stand-corrected-the-truth-about-delta-8-thc-e8085725ed9e</u> (discussing Delta-8 as synthetically produced isomer); Sarah Glinski, *Delta-10 vs. Delta-8: What's The Difference?*, FORBES (Jan. 2, 2024), <u>available at https://www.forbes.com/health/cbd/delta-10-vs-delta-8/ (discussing Delta-10 as synthetically produced isomer).</u>

Whereas, in Massachusetts, adult-use marijuana is legal, but products containing Delta-8, Delta-10, and other synthetically derived cannabinoids are not.⁵

Whereas, Delta-8 and similar synthetically derived products are psychoactive.⁶

Whereas, the production of synthetic, hemp-derived products like Delta-8 is not regulated by the federal government or in Massachusetts because the manufacture, sale, or distribution of such products in not permitted under state or federal law.⁷

Whereas the United States' Food and Drug Administration (FDA) has not approved psychoactive substances, including both naturally occurring and synthetically manufactured substances, as additives to food products and, despite this, that mushroom-laced candies and chocolates bars have been found for sale in thousands of locations nationwide.

Whereas, the Massachusetts Supreme Judicial Court has held that "[t]he right to engage in business must yield to the paramount right of government to protect public health by any rational means."

SECTION 22.3 DEFINITIONS

For the purposes of this regulation, the following words shall have the following meanings:

<u>Board of Health or Board</u>: The Needham Board of Health and its designated board of health agents.

<u>Board of Health Agent</u>: The Director of Health & Human Services, and any town employee designated by the board of health, which may include board of health and health department staff, law enforcement officers, and code enforcement officers.

<u>Business Agent</u>: An individual who has been designated by the owner or operator of any adult-use marijuana establishment to be the manager or otherwise in charge of said establishment.

<u>Egregious Violation</u>: When a permit holder refuses reasonable access to a designated Board of Health Agent or other Town of Needham official, or when a permit holder continues to operate despite a permit suspension (or operates without a permit after having failed to renew the permit).

<u>Permit Holder</u>: Any person or business who applies for and receives a permit issued by the Board of Health or their agent.

⁵ <u>See</u> MASS. DEPT. OF AGRIC. RES., HEMP IN MASSACHUSETTS: FAQS, <u>available</u> <u>at</u> https://www.mass.gov/guides/hemp-in-massachusetts-faqs#-is-it-legal-to-manufacture-delta-8-thc-from-hemp?-(last visited April 4, 2024) (discussing illegality of synthetically derived Delta-8).

⁶ <u>See</u> U.S. FOOD & DRUG ADMIN., 5 THINGS TO KNOW ABOUT DELTA-8 TETRAHYDROCANNABINOL – DELTA-8 THC, <u>available</u> <u>at</u> https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc (last visited April 4, 2024).

TU.S. FOOD & DRUG ADMINISTRATION, FDA ISSUES WARNING LETTERS TO COMPANIES ILLEGALLY SELLING CBD AND DELTA-8 THC PRODUCTS (May 4, 2022), available at https://fda.gov/news-events/press-announcements/fda-issues-warning-letters-companies-illegally-selling-cbd-and-delta-8-thc-products; see Letter from Terrance L. Boos, Ph.D., Chief, Drug Enforcement Administration to Donna C. Yeatman, R.Ph., Executive Secretary, Alabama Board of Pharmacy (September 15, 2021), available at https://albop.com/oodoardu/2021/10/ALBOP-synthetic-delta8-THC-21-7520-signed.pdf (confirming synthetically derived Delta-8 is a controlled substance under schedule I).

⁸ Druzik v. Bd. of Health of Haverhill, 324 Mass. 129, 139 (1949) (citing Lawrence v. Bd. of Registration in Med., 239 Mass. 424, 428 (1921)).

<u>Person</u>: Any individual, firm, partnership, association, corporation, company, or organization of any kind, including, but not limited to an owner, operator, manager, proprietor, or person in charge of any establishment, business, cultivation property, or retail store.

<u>Psychoactive Substances</u>: Any naturally derived or synthetically manufactured substance used illegally as an additive to food products or dietary supplements including, but not limited to, 4-acetoxy-*N*, *N*-dimethyltryptamine, 4-acetoxy-DMT, also known as O-acetylpsilocin or psilacetin, desmethoxyyangonin, dihydrokavain, kavain, Psilocin, Psilocybin, and Pregabalin.

<u>Synthetically Derived Cannabinoid:</u> Any cannabinoid that is altered by a chemical reaction that changes the molecular structure of any natural cannabinoid derived from the plant Cannabis to another cannabinoid found naturally in the plant Cannabis. Synthetically Derived Cannabinoids include but are not limited to Delta-8 and Delta-10.

<u>Synthetic Kratom:</u> Any synthetically manufactured or derived product designed to mimic the effects of naturally occurring Kratom leaves, including synthetic mitragynine, synthetic 7-hydroxymitragynone, and any other synthetically derived compounds of the kratom plant.

SECTION 22.4 PROHIBITIONS

No person shall manufacture, distribute, or sell Synthetically Derived Cannabinoids including, but not limited to Delta-8 and Delta-10 products in the Town of Needham. Likewise, no person shall manufacture, distribute, or sell Psychoactive Substances or food products or dietary supplements which contain psychoactive substances including, but not limited to, 4-acetoxy-*N*, *N*-dimethyltryptamine, 4-acetoxy-DMT, also known as O-acetylpsilocin or psilacetin, desmethoxyyangonin, dihydrokavain, kavain, Psilocin, Psilocybin, and Pregabalin.

No person shall sell Synthetic Kratom, or any synthetically derived variant of naturally occurring Kratom, nor shall any person sell any product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the overall alkaloid composition of the product.

SECTION 22.5 <u>ENFORCEMENT AND PENALTIES</u>

- 1. Any person or entity charged with violating this regulation shall receive a notice of violation from the Needham Board of Health or its designated agent.
- 2. It shall be the responsibility of the establishment owner and/or their manager or business agent to ensure compliance with this regulation. In the case of a violation, the violator shall receive:
 - i. In the case of a first violation, a fine of one thousand dollars (\$1,000.00), and a suspension of any permit issued by the Board, including but not limited to a permit to sell tobacco products, for seven (7) consecutive business days;
 - ii. In the case of a second violation within 36 months of a previous violation, a fine of one thousand dollars (\$1,000.00), and a suspension of any permit issued by the

- Board, including but not limited to a permit to sell tobacco products, for fourteen (14) consecutive business days;
- iii. In the case of a third violation within a 36-month period, a fine of one thousand dollars (\$1,000.00), and a suspension of any permit issued by the Board, including but not limited to a permit to sell tobacco products, for thirty (30) consecutive business days;
- iv. In the case of a fourth violation within a 36-month period, a fine of one thousand dollars (\$1,000.00), and a suspension of any permit issued by the Board, including but not limited to a permit to sell tobacco products, for ninety (90) consecutive business days; and
- v. In the case of a fifth violation or repeated, egregious violations of this regulation within a 36-month period, a fine of one thousand dollars (\$1,000.00), and the Board of Health shall hold a public hearing and permanently revoke any permit issued by the Board.
- 3. Every day that a violation exists shall be deemed to be a separate offense. Separate but simultaneous violations shall be treated as separate violations. Multiple permit suspensions may not be served concurrently.
- 4. Any person who receives notice of a violation of this regulation may request a hearing before the Board. The request must be made in writing and filed within seven (7) days of the date the violation was received.
- The authority to inspect establishments for compliance and to enforce this regulation shall be held by the Needham Board of Health, its agents and designees, and the Needham Police Department.
- 6. Any person may register a complaint pursuant to this regulation to initiate an investigation and enforcement with the Needham Board of Health and its designees.
- 7. Upon accrual of five (5) violations of this regulation within a thirty-six (36) month period, or upon the commission of two (2) or more egregious violations of this regulation within thirty-six (36) months as determined by the Board of Health, the Board may issue a notice of intent to revoke and shall hold a hearing in accordance with this regulation and, after such hearing, may permanently revoke any permits held by the violator, including any permits to sell tobacco products in Needham.
- 8. Before suspending or revoking any permit issued by the Board, including a permit to sell tobacco products, the Board of Health shall provide notice of the intent to suspend or revoke such permit, which notice shall contain the reasons therefor and shall establish a time and date for a hearing, to be held no earlier than seven (7) days from the date of the notice. The permit holder or their designee shall have the opportunity to be heard and shall be notified of the Board's decision and the reasons therefor in writing. If after hearing, the Board of Health finds that a violation of this regulation occurred, the Board shall impose fines and suspend or revoke the subject permit. For purposes of such suspensions or revocations, the Board shall make the determination notwithstanding any separate criminal

or non-criminal proceedings concerning the same offense. Upon suspension or revocation of a permit, all permitted products must be removed from the retail establishment. Failure to remove such products shall constitute a separate violation of this regulation.

9. Failure to comply with the terms of a permit suspension imposed pursuant to this regulation is considered an egregious violation and shall subject the permit holder to an additional suspension of all permits issued by the Board of Health for a further thirty (30) consecutive business days.

SECTION 22.6 <u>SEVERABILITY</u>

If any provision of this regulation is declared invalid or unenforceable, all other provisions shall not be affected thereby but shall be in full force and effect.

SECTION 22.7 COMMUNITY PARTNERSHIP

Any police officer, code enforcement officer, physician, nurse, or other concerned individual that has knowledge of the sale or possession of a dangerous product within the Town of Needham may inform the Needham Police Department Business Line (781-455-7570) or the Public Health Department Main line (781-455-7940) of the location of the dangerous product.

SECTION 22.8 <u>EFFECTIVE DATE</u>

This revised regulation was approved by a unanimous vote of the Board of Health on December 13, 2024 and the regulation becomes effective on February 1, 2025. Adoption of this regulation occurred following discussion at open meetings on March 8, April 12, May 10, and June 14, 2024. Public hearings about this regulation occurred on July 12, September 5, October 8, and November 22, 2024.

The initial synthetic drug regulation was approved by a unanimous vote of the Needham Board of Health on September 9, 2016, and the regulation became effective on October 15, 2016. Adoption of the initial regulation occurred following open meetings held on May 13, 2016 and on June 17, 2016, and public hearings on July 29, 2016 and September 9, 2016.