

State of New Jerzey Cannabis Regulatory Commission P.O. BOX 216 Trenton, N.J. 08625-0216

PHILLIP D. MURPHY Governor

SHEILA Y. OLIVER Lt. Governor DIANNA HOUENOU, Chair SAMUEL DELGADO, Vice Chair KRISTA NASH, Commissioner MARIA DEL CID-KOSSO, Commissioner CHARLES BARKER, Commissioner JEFF BROWN, Executive Director

RESOLUTION 2022-WAIVER OF N.J.A.C. 17:30A-10.7(e) TO ALLOW THE MANUFACTURING, PACKAGING, OR DISPENSING OF MEDICINAL CANNABIS CONCENTRATES

WHEREAS, pursuant to N.J.A.C. 17:30A-7.11, the Commission, or the Commission's designee, in accordance with the general purpose and intent of N.J.S.A. 24:6I–1 et seq., may waive certain requirements regarding the operations of Alternative Treatment Centers, if in the Commission's, or the Commission's designee's, determination, such a waiver is necessary to achieve the purpose of the Act and provide access to patients who would otherwise qualify for the use of medicinal cannabis to alleviate suffering from debilitating medical conditions, and does not create a danger to the public health, safety or welfare; and

WHEREAS, pursuant to N.J.A.C. 17:30A-10.7(e), an Alternative Treatment Center shall only package, manufacture, or dispense medicinal marijuana in dried form, oral lozenges, topical formulations, or oil formulations; and

WHEREAS, the Commission has received, reviewed, and considered multiple requests to allow for the packaging, manufacturing, or dispensing of medicinal cannabis in the form of concentrates; and

WHEREAS, Commission staff have provided the Commission with their recommendation that issuing a waiver allowing for the packaging, manufacturing, or dispensing of medicinal cannabis concentrates will benefit the patient population by providing a greater variety of forms in which to receive their medicine and does not create a danger to the public health safety or welfare; and

NOW, THEREFORE, BE IT RESOLVED, by the New Jersey Cannabis Regulatory Commission, that:

1. N.J.A.C. 17:30A-10.7(e), limiting Alternative Treatment Centers to the packaging, manufacturing, or dispensing of medicinal cannabis only in dried form, oral lozenges, topical formulations, or oil formulations is hereby waived to allow for the packaging, manufacturing, or dispensing of medicinal cannabis also in the form of concentrates, subject to the terms and conditions included in the attached Certificate of Waiver.

2. This waiver shall take effect immediately and shall remain in place until further formal action by the New Jersey Cannabis Regulatory Commission is taken to rescind or amend this waiver.

Submitted by:

Dianna Houenou, Chair

CERTIFICATION

I hereby certify that the foregoing is a true copy of the Resolution adopted by the Cannabis Regulatory Commission at its meeting held on the 24 day of Royuan 2022.

Erin Hogan, Executive Assistant

Vote on the Approval of This Resolution	Motion	Second	Yes	No	Abstain	Absent
Commissioner Barker			[X]			
Commissioner Del Cid-Kosso			X			
Commissioner Delgado		Х	X			
Chairwoman Houenou			X			
Commissioner Nash	X		X			

Certificate of Waiver for Medicinal Cannabis Pursuant to the Provisions of the New Jersey Administrative Code Specifically, N.J.A.C. 17:30A, a waiver is issued to:

ALL Alternative Treatment Centers ("ATC")

Granting relief from the following provision(s) of Chapter 17:30A of the New Jersey Administrative Code pursuant to N.J.S.A. 24:6I-7(a)(6) and N.J.A.C. 17:30A-7.11:

N.J.A.C. 17:30A-10.7 Processing and packaging of cannabis

(e) An ATC shall package, manufacture, or dispense medicinal cannabis only in:

- 1. Dried form; 2. Oral lozenges;
- 3. Topical formulations; or
- 4. Oil formulations.

The waiver is subject to the following terms and conditions:

- 1. The following words and terms, as used in this waiver, shall have the following meanings, unless the context clearly indicates otherwise:
 - a. "Electronic smoking device" means a pre-filled, tamper-resistant, non-refillable, disposable "all-in-one" e-cigarette or pre-filled, tamper-resistant, non-refillable cartridge and separate battery used to heat and aerosolize or vaporize a cannabis product for inhalation.
 - b. "Lozenge" means a solid oral dosage form that is designed to dissolve or disintegrate slowly in the mouth.
 - c. "Medicinal cannabis concentrate" means a product manufactured by a medicinal cannabis manufacturer, either in solid form or in liquid form as oil, that contains only the resin, cannabinoids, terpenes, and other substances extracted from any part of the cannabis plant.
 - d. "Medicinal cannabis product" means a medicinal cannabis concentrate or a medicinal cannabis-infused product, that a medicinal cannabis manufacturer manufactures, produces, or creates from usable medicinal cannabis or medicinal cannabis concentrate.
 - e. "Medicinal cannabis-infused product" means a product manufactured by a medicinal cannabis manufacturer in an authorized form that contains usable medicinal cannabis or medicinal cannabis concentrate, in solid or liquid form, and one or more ingredients intended for human consumption or use, including an ingestible product, inhalable product, or dermal product.
 - f. "Oil" means a viscous liquid substance containing cannabinoids, such as THC and cannabidiol, which are extracted from the cannabis plant.

- g. "Topical formulation" means a transcutaneous therapeutic cannabis extract formulation comprising of water, short carbon chains, alcohol, dimethylsulfoxide, polyethylene glycol, polypropylene glycol, glycerin, mineral oil, and mixtures thereof.
- h. "Vaporized formulation" means oil, or oil and one or more inactive ingredients, in an electronic smoking device that is meant to be heated, aerosolized, and inhaled.
- 2. To help patients safely acquire forms of medicinal cannabis and medicinal cannabis products necessary to meet their medical needs, the Commission authorizes an ATC to package, manufacture, or dispense medicinal cannabis in the following forms:
 - a. Dried form
 - b. A medicinal cannabis concentrate, either in solid form, including "wax" and "shatter," or in liquid form as oil
 - c. A medicinal cannabis-infused product, either in solid form or liquid form, containing either dried form or medicinal cannabis concentrate along with an additional ingredient that includes, but is not limited to:
 - i. Vaporized formulation;
 - ii. Drops, tinctures, and other sublabial and sublingual forms;
 - iii. Oral lozenges and other buccal forms;
 - iv. Ingestible forms, which shall only include syrups, pills, tablets, capsules, and chewable forms; and
 - v. Topical formulations and transdermal forms;
- 3. The ATC, in manufacturing medicinal cannabis products, shall comply with the March 10, 2015, Standard for Manufacturing Lozenge, Topical Formulations and Edible Form Products by an Alternative Treatment Center, established by the Commission, and the relevant good manufacturing practices at N.J.A.C. 8:21. This manufacturing standard is available at

https://www.nj.gov/cannabis/documents/Resources/Manufacturing%20Standard%20Final%203-10-15.pdf.

4. Any medicinal cannabis product manufactured, produced, or created pursuant to this Waiver must utilize testing from a third-party testing lab that has been approved by the CRC, is in compliance with the interim testing standards adopted by the CRC through Resolution 2021-9 and is equipped to test cannabis concentrates.

N.J.S.A. 24:6I-7(a)(6), authorizes the manufacture and dispensing of medicinal cannabis in the following forms: "dried form, oral lozenges, topical formulations, transdermal form, sublingual form, tincture form, or edible form, or any other form as authorized by the commission. Edible form shall include pills, tablets, capsules, drops or syrups, oils, chewable forms, and any other form as authorized by the commission, except that edible forms made available to minor patients shall be limited to forms that are medically appropriate for children, including pills, tablets, capsules, chewable forms, and drops, oils, syrups and other liquids." Pursuant to the authority established at N.J.S.A. 24:6I-7(a)(6) allowing the Commission to authorize "any other form," the Commission approves the forms listed in this waiver.

Pursuant to N.J.A.C. 17:30A-7.11, the Commission finds this waiver to be necessary to achieve the purpose of the Act and provide access to patients who would otherwise qualify for the use of medicinal cannabis, to alleviate suffering from debilitating medical conditions, and does not create a danger to the public health, safety, or welfare.

BY: Dianna Houenou, Chair New Jersey Cannabis Regulatory Commission

DATE ISSUED: February 24, 2022 EXPIRATION DATE: Upon further action by the Commission.