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## CERTIFICATE OF WAIVER OR SUSPENSION OF REGULATION

**Authority:** N.J.S.A. 24:6I-7(a)(6) and N.J.A.C. 17:30A-7.11

**Date Issued:** [DATE]

**Regulation(s) Affected:** N.J.A.C. 17:30A-10.7 Processing and packaging of marijuana

**Effective Date:** *[DATE]* 

**Expiration Date:** Upon modification or revocation by the Board of Commissioners

The New Jersey Cannabis Regulatory Commission (Commission) grants relief in the form of this temporary regulatory waiver to allow for the temporary expansion of permissible medicinal cannabis products, subject to the criteria and conditions set forth herein. N.J.A.C. 17:30A-7.11 provides that the Commission may waive a regulatory requirement regarding the operations of an alternative treatment center (ATC) if such waiver is necessary to achieve the purpose of the Jake Honig Compassionate Use Medical Cannabis Act, N.J.S.A. 24:6I-1, et seq. (P.L.2019, c.153); is necessary to 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 public health, safety, or welfare.

N.J.A.C. 17:30A-10.7 authorizes an ATC to manufacture medicinal cannabis products as dried forms, oral lozenges, topical formulations, and oil formulations. The Commission has determined to issue this regulatory waiver to immediately allow ATCs that hold a manufacturing endorsement or a vertically integrated endorsement to produce medicinal food and beverage products that do not need to be temperature controlled in order to limit pathogenic microorganism growth or toxin formation (i.e., is a "non-TCS" or "shelf stable" food or beverage).

The specific rule(s) being waived is(are) as follows:

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

. . .

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

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

This waiver applies only to the production of medicinal cannabis products. It does not apply to personal, adult-use cannabis products. Additionally, this waiver is subject to the following terms and conditions:

- 1. This waiver applies only to holders of an ATC vertically integrated permit and holders of an ATC permit with a manufacturing endorsement. Nothing herein shall be construed to authorize any person or entity that does not hold an ATC vertically integrated permit or an ATC permit with a manufacturing endorsement to engage in any manufacturing or production activities authorized by this waiver.
- 2. An Alternative Treatment Center with a manufacturing endorsement or vertically integrated endorsement may manufacture and dispense medicinal cannabis in the following forms:
  - a. Dried form;
  - b. Topical formulations;
  - c. Oil formulations;
  - d. Syrups or single-serve beverages;
  - e. Pills, capsules, or tablets;
  - f. Oral suspensions; and
  - g. Non-TCS food items, such as chocolates, gummies, baked goods, butters, jams, and jellies, such that the product does not require time or temperature control to limit pathogenic microorganism growth or toxin formation.
- 3. Medicinal cannabis products shall not:
  - a. Be an alcoholic beverage, as defined in N.J.S.A. 33:1-1;
  - b. Contain tobacco or nicotine;
  - c. Require cooking or baking by the consumer;
  - d. Require storage in sterile conditions by the consumer; or
  - e. Contain any controlled dangerous substance, as defined in N.J.S.A. 24:2I-2.
- 4. An ATC manufacturing medicinal cannabis products shall adhere to all other applicable regulations and guidance, including limitations on the amount of THC permitted in medicinal cannabis items provided in N.J.A.C. 17:30A-10.7(c).
- 5. For the purposes of this waiver, use of ingredients that are Generally Recognized as Safe (GRAS) under sections 201(s) and 409 of the Federal Food, Drug and Cosmetic shall be permissible for non-TCS food items.
- 6. Beverages must be packaged and labeled in single-serve containers. Beverage containers shall not include more than one serving per container. Single-serve beverages shall contain no more than 5 milligrams of total tetrahydrocannabinols.
- 7. To protect the health and welfare of registered patients, in addition to any labeling requirements at N.J.A.C. 17:30A, non-TCS food and beverage items shall be labeled with a list of ingredients in descending order of predominance by weight or volume as applicable, a nutritional label, and indication if the item requires refrigeration after product opening or consumption within a specified number of days after opening. For products

- manufactured such that the product's effects are intended to be felt in less than 20 minutes, the item shall contain the following consumer warning in no less than ten-point font: "The intoxicating effects of this product usually occur in less than 20 minutes but may be delayed by two or more hours."
- 8. To protect public health, employees involved in the manufacturing of medicinal cannabis products newly authorized by this waiver shall, prior to engaging in the manufacturing process, undergo food safety training that includes: the causes and prevention of foodborne illnesses; prevention of common foodborne illnesses according to the Centers for Disease Control and Prevention; and safe food handling practices, including handling of major food allergens as defined in N.J.A.C. 8:24-1.5.
- 9. For purposes of this waiver, an ATC shall abide by the Commission's Personal Use rules under N.J.A.C. 17:30-11.8 for expiration dates. Pursuant to N.J.A.C. 17:30-11.8(c)(2), the maximum expiration date for non-TCS food and single-serve beverage items is six months, beginning from the manufacture date.
- 10. Failure to adhere to the terms and conditions herein shall be considered a regulatory violation and is subject to adverse action by the Commission, which may include the imposition of fines or suspension or revocation of the ATC permit.

This relief granted by the Commission is based upon assessments of New Jersey's medicinal cannabis industry and the history of conduct by regulated entities, including any entity's history of regulatory violations committed. The relief granted is subject to review, modification, or revocation as the Commission deems appropriate.

BY: Dianna Houenou, Chair

New Jersey Cannabis Regulatory Commission