

STATE OF HAWAII
DEPARTMENT OF HEALTH
OFFICE OF HEALTH CARE ASSURANCE
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KAPOLEI, HAWAII 96707

Hawaii State Department of Health
Office of Health Care Assurance
Medical Marijuana Dispensary Licensing Program

Policy on Manufactured Marijuana Products
July 1, 2016

Purpose

The purpose of this policy is to clarify Section 329D HRS and Chapter 11-850 HAR on the definitions of manufactured marijuana products.

Regulatory Responsibility

The Office of Health Care Assurance (OHCA) Medical Marijuana Dispensary Licensing program (MMDL) is assigned the regulatory responsibility to ensure that medical marijuana dispensaries comply with licensing regulations of Chapter 11-850, and to coordinate with county and/or state and/or federal agencies to ensure compliance with regulations under the respective jurisdiction of county, state, or federal agencies. This responsibility is to ensure patient safety, product safety, and public safety.

Policy

Licensed medical marijuana dispensaries shall be allowed to manufacture and dispense manufactured marijuana products pursuant to Section 329D Hawaii Revised Statutes (HRS) and Chapter 11-850 Hawaii Administrative Rules (HAR). The OHCA has adopted from the U.S. Food and Drug Administration (US FDA) the definitions of forms of medicine products for products not defined in Section 329D HRS.

Manufactured marijuana product means "any capsule, lozenge, oil or oil extract, tincture, ointment or skin lotion, or pill that has been manufactured using marijuana." (Section 329D-1, HRS)

Manufactured marijuana product "has the same meaning as defined in section 329D-1, HRS, except that it excludes chemically synthesized marijuana or its psychoactive constituents. (Chapter 11-850-2 HAR)

Lozenge means "a small tablet manufactured in a manner to allow for the dissolving of its medicinal or therapeutic component slowly in the mouth." (Section 329D-10)

The US FDA defines forms of medicine products as follows:

Capsules: A solid oral dosage form consisting of a shell and a filling. The shell is composed of a single sealed enclosure, or two halves that fit together and may be sealed with a band. Capsules may be hard or soft, and are filled with solid or liquid ingredients that can be poured or squeezed.

Oil or oil extract: An unctuous, combustible substance which is liquid, or easily liquefiable, on warming, and is soluble in ether but insoluble in water. Such substances, depending on their origin, are classified as animal, mineral, or vegetable oils.

Tincture: An alcoholic or water and alcohol solution prepared from marijuana.

Ointment: A semisolid dosage for external application to the skin or mucous membranes.

Skin lotion: An emulsion, liquid dosage form for external application to the skin.

Pill: A round, solid dosage form containing a medicinal agent intended for oral administration.

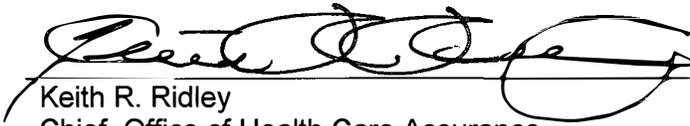
Transdermal Patch: A drug delivery system that contains an adhesive backing that is applied to the skin in order for ingredients to either passively diffuse from, or are actively transported from, some portion of the patch.

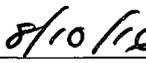
Pre-filled and sealed container used to aerosolize and deliver marijuana orally: Product that is packaged under pressure, sealed to prevent contamination, and contains therapeutically active ingredients that are released upon activation of an appropriate valve system intended for application into the mouth.

Authorities, References, and Guides

1. Section 329D HRS
2. Chapter 11-850 HAR
3. Dosage Form Version 008, U.S. Food and Drug Administration (link [here](#))

This Policy is effective beginning July 1, 2016 and is approved by:


Keith R. Ridley
Chief, Office of Health Care Assurance



Signature Date