

Act 230 LOWG - Product Subcommittee

RECOMMENDATIONS:

- A. **HRS 329D-10 (Act 230 Section 17) “(7) Transdermal [patches] devices;”**
- o Limitation to patch vs device was unintentional.
 - o The technical flaw impedes viable products and innovation.¹
- B. Allow for stationary “at home” (non-portable/ non-handheld) medical-grade volatilization devices that are regulated to prevent the combustion of cannabis (i.e. heat convection or conduction)²
- o Align with Hawaii’s “smoke free” campaign and expand patient choice to administration with fewer undesirable side-effects³
 - o Examples of stationary volatilization devices that do not utilize combustion:
- i. [Example 1](#)
 - ii. [Example 2](#)
 - iii. [Example 3](#)
- o Recommended Rules from August 2017 meeting (attached)
- C. **HRS 329D-10 “(9) Cannabinoid suppository;”**
- o Like transdermal devices, suppository delivery is an advantageous form of drug administration because it avoids the first-pass metabolic effects of oral ingestion and can ensure stable blood levels of the administered drug over long periods of time, which can reduce side effects.⁴
 - o Suppository administration is a favorable option for patients who have difficulty with oral administration
 - o See Oregon section 333-007-0200 for Definition: *“Cannabinoid suppository” means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina, containing a cannabinoid product, concentrate or extract.*
- D. Create a legislative pathway for Edibles
- o Florida passed a bill for edible products, subject to DOH rulemaking. This approach could create a pathway for the future expansion, while establishing certain priorities: not geared for children, THC/CBD limits, food safety standards.
 - o Working – provide context and research surrounding Edibles as a guide for future policy.

INTENT:

1. In highest interests of patient and community safety, there is a need to promote smoke-free products
2. Alternative, safe manufactured products, up to speed with current medical technology, need to be provided in order to better meet patients’ needs and to promote business and industry development.

CONCERNS:

The current market for volatilization devices features a variety of handheld, portable products that mimic eCigarette products. Such devices induce risks of (1) Enforcement of public cannabis vs. eCigarette usage (2) Diversion of legal medical cannabis product (3) Increased gateway to cigarette or tobacco use by medical cannabis program patients; (4) Potentially dangerous technology present in eCigarette technology

BACKGROUND:

HRS § 329D-10 Stipulated that:

“the types of medical marijuana products that may be manufactured and distributed pursuant to this chapter shall be limited to: (1) Capsules (2) Lozenges (3) Pills (4) Oils and oil extracts; (5) Tinctures (6) Ointments and skin lotions; and (7) Other products as specified by the department.”

Act 230 Section 17 expanded the parameters set forth in HRS § 329D regarding medical marijuana products to include:

“(7) transdermal patches and (8) Pre-filled and sealed containers used to aerosolize and deliver marijuana orally, such as with an inhaler or nebulizer.”

HAR 11-850-33 (d)

Retail dispensing locations shall **not**:

1. Provide free samples of marijuana or manufactured marijuana products;
2. Dispense marijuana or manufactured marijuana products as premade or manufactured cigarettes or in any form prepared specifically for smoking or inhaling
3. Make available for sale or as gifts or premiums any supplies or paraphernalia that provide for the use of medical marijuana in smokable or inhalable form

REFERENCES:

1. For recent developments in transdermal delivery mechanisms including chemical penetration enhancers, physical permeabilization (sonophoresis, iontophoresis and microneedles) and novel nanocarriers. See: 1) Zhang H. et. al. Breaking the skin barrier: achievements and future directions. *Curr Pharm Des.* 2015;21(20):2713-24. <https://www.ncbi.nlm.nih.gov/pubmed/25925124> 2) Prausnitz MR, Langer R. Transdermal drug delivery. *Nature biotechnology.* 2008;26(11):1261-1268. doi:10.1038/nbt.1504. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2700785/>
2. Volatilization through heat convection or conduction reduce the risk of product combustion, through allowing the device to heat at a lower temperature.
3. A survey of 6,883 cannabis users found that volatilization, compared with smoking, causes fewer respiratory symptoms (coughing, wheezing, shortness of breath, mucus production) ([Earlywine and Barnwell 2007](#)). Because of the tars and gases produced during the combustion process, cannabis smoke is toxic to airway tissue, and probably carcinogenic ([Fung et. al.](#) 1999), whereas volatilization may significantly reduces Toxins (Pyrenes and Polynuclear Aromatic Hydrocarbons) in cannabis smoke ([Gieringer, St. Laurent, and Goodrich 2004](#))
4. Suppositories bypass the first-pass effect and led to sustained elevation of drug plasma levels. Higher, more sustained plasma drug levels should enhance antiemetic efficacy ([Mattes RD et. al](#)1993). ([Larry A. Walker et. al.](#) 1999) Administration of the THC-HS via suppositories resulted in excellent bioavailability, sustained plasma levels of THC, and improved efficacy as compared to the oral formulations
5. *Tampa Bay Times* (10/02/2017) [A Florida medical marijuana company prods state to finish rules for edible products](#)

Topic	Comments
Vaping enabled: (a) vaporizer cartridge, (b) device	Florida has a vertically integrated program and whole flower is being sold in canisters designed for vaporizers. Recommended Rules from August-2017 LOWG meeting.

<u>Edible pathway?</u>	<u>Florida passed a bill for edible products</u> , subject to DOH rulemaking. <u>This approach could create a pathway for the future expansion, while establishing certain priorities: not geared for children, THC/CBD limits, food safety standards.</u>
<u>Transdermal [patch]device</u>	<u>Limitation to patch vs device was unintentional. The technical flaw impedes viable products and innovation.</u>
<u>Suppositories</u>	<u>Like transdermal devices, suppository delivery is an advantageous form of drug administration because it avoids the first-pass metabolic effects of oral ingestion and can ensure stable blood levels of the administered drug over long periods of time, which can reduce side effects.</u> <u>Suppository administration is a favorable option for patients who have difficulty with oral administration</u> <u>See Oregon section 333-007-0200</u>

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<u>Recommendations</u>	<p style="text-align: center;"><u>HAR §11-850-72</u></p> <ol style="list-style-type: none"> <u>1. "Transdermal [patches] devices;"</u> <u>2. "Pre-filled and sealed containers used to aerosolize or vaporize and deliver marijuana orally, such as with an inhaler, [or nebulizer]; nebulizer or (DOH approved) vaporizers; and"</u>
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