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To: Medical Cannabis Policy Advisory Board
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Subject: Medical cannabis dosage forms

Introduction

The <u>Utah Patients Coalition</u> (UPC) would like the board to consider amending the statute to add suppositories and eye/ear drops as a legal dosage form for medical cannabis products. The following are options the board may consider for a recommendation.

- **1.** Add suppositories to the list of legal dosage forms.
- **2.** Add ear and eye drops to the list of legal dosage forms.
- **3.** Consider recommending the addition of other dosage forms beyond suppositories and eye/ear drops.
- **4.** Consider recommending new product types be allowed under certain dosage forms, such as chocolate as an infused edible.

Background

Utah's legal dosage forms, referred to in statute as "medicinal dosage forms," are codified Utah Code <u>26B-4-201(42)</u> and require statutory approval for any changes. Most recently, lawmakers added aerosol as a legal dosage form in 2022.

Table 1 lists current legal dosage forms, examples of dosage forms in their finishedproduct state, and corresponding legal routes of administration.



BOARD AGENDA: 12/19/23 ITEM: 6

Legal Dosage Form	Legal Dosage Form Examples	Typical Routes of Administration
Tablet	Tablet	Oral
Capsule	Capsule	Oral
Gelatinous cube	Gummy, chews, gelatin cube, lozenge	Oral
Liquid suspension	Liquid suspension	Oral
Unprocessed flower	Flower, Bud	Vaporization
Wax	Wax	Vaporization
Resin	Resin	Vaporization
Concentrated oil or viscous oil	Vape cartridge	Vaporization
Transdermal preparation	Skin patch	Transdermal
Sublingual preparation	Extract, Tincture	Sublingual
Topical preparation	Salve, balm, lotion, cream	Topical
Aerosol	Inhaler	Inhalation

Table 1. Legal dosage forms, examples, and routes of administration

Suppositories, which are administered rectally or vaginally, and eye and ear drops, are not currently legal dosage forms. Processors cannot manufacture products that do not conform to the list above. UPC is advocating for additions to this list as a way to address unique patient conditions, therapeutic goals, and individual preferences.

Analysis

Suppositories as a legal dosage form

Cannabis suppositories are legal in some states, but their esoteric nature and niche consumer base makes information sparse. Suppositories are legal in the Canada medical cannabis market and 5 of 16 medical-only states: Louisiana, Alabama, Mississippi, Florida, and Pennsylvania. They are typically allowed or are unregulated



in adult-use states. Common rationales for the allowance of suppositories as a medical cannabis product form include the following:

- Inability to use cannabis orally or via inhalation due to esophageal or gastrointestinal issues.
- Localized relief for vaginal or colon-related conditions such as menstrual pain, endometriosis, hemorrhoids, and interstitial cystitis/bladder pain syndrome.
- Dyspareunia (genital pain due to sex).

Safety and efficacy of cannabis suppositories

The safety and efficacy of cannabis suppositories from the scientific and medical communities is inconclusive and requires further study. There are very few studies that mention, let alone examine, cannabis suppositories. Below are 2 studies with limited thoughts on the subject.

- In a 2022 Canadian metastudy of available literature regarding routes of administration for medical cannabis in oncology, suppositories were highlighted as a rare but used and understudied dosage form by cancer patients. The researchers suggested that cancer patients may be drawn to suppositories for their rapid onset time of around 15 minutes.
- A 2018 study by cannabis researchers at the University of Mississippi rectally administered THC-hemisuccinate (THC-HS), a synthetic THC analog, via suppository to examine the safety and pharmacokinetics of rectally-administered THC-HS when compared to orally administered delta-9 THC. The researchers reported no observed safety issues and that suppositories may have benefits over oral administration, such as less THC being lost to stomach acid and use for individuals who have difficulty swallowing.



Cannabis Research Review Board (CRRB) position on suppositories

After a June 8, 2021 presentation on cannabis suppository administration for medical conditions, <u>the CRRB concluded</u> that there isn't sufficient evidence to support the effectiveness of cannabis administration rectally or vaginally. The board may want to ask the CRRB if it can assess any new scientific literature that may have been published since June 2021.

Eye and ear drops as a legal dosage form

A review of adult-use and medical cannabis states found no programs that explicitly allow eye or ear ear drops that predominantly contain THC. California expressly prohibits products administered through the eye in both their adult-use and medical markets, as does Nevada, which prohibits cannabis processors from manufacturing eye drops. A high level review of academic research reveals numerous concerns with eye drops. Below are brief considerations from 2 studies.

- THC isn't water-soluble and can't be administered in a water-based drop, <u>according to the University of Utah</u>.
- The ability of THC to reduce intraocular pressure (IOP), a primary symptom of glaucoma, has long been controversial among researchers and cannabis users. From <u>the early 1980s</u> to <u>recent years</u>, there is limited evidence that cannabis has a demonstrated ability to reduce IOP, and <u>higher doses of CBD</u> <u>may possibly increase IOP</u>.

Ear drops appear to have less academic research than eye drops. It doesn't appear that any state has explicitly approved the manufacturing of cannabis ear drops. For adult-use states that don't regulate dosage forms and product types, cannabis ear drops can be found in the market.



Safety and efficacy of cannabis eye and ear drops

The safety of cannabis eye and ear drops is uncertain, as they are understudied methods of administering cannabis. What is clear is that they're receiving more attention and market shelf space without evidence of their safety. Should the board remain interested in the potential of these dosage forms, it may want to ask if the CRRB or the University of Utah Center for Medical Cannabis Research could more thoroughly study the effectiveness and safety of these unique dosage forms.

Other dosage forms and product types

The list of medicinal dosage forms in Utah is generally comparable to other medical cannabis-only states. Board chair J. D. Lauritzen requested that the board evaluate product types within dosage form categories that are currently not legal in Utah, such as chocolate as an infused edible. Should the board want to explore more product types as possibilities for the medical cannabis program, more research is needed to present these to the board.

Options

The board may consider a recommendation of one or more of the following:

- **1.** Add suppositories to the list of legal dosage forms.
- **2.** Add ear and eye drops to the list of legal dosage forms.
- **3.** Consider recommending the addition of other dosage forms beyond suppositories and eye/ear drops.
- **4.** Consider recommending new product types be allowed under certain dosage forms, such as chocolate as an infused edible.