

# MEMORANDUM

Medical Cannabis Policy Advisory Board

BOARD AGENDA: 2/20/24

ITEM: 7

**Released:** February 13, 2024

**To:** Medical Cannabis Policy Advisory Board

**From:** Trevor Eckhoff, policy analyst, Utah Department of Health and Human Services (DHHS), Center for Medical Cannabis

**Subject:** **Legal dosage limit exceptions**

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## Introduction

The board may consider the following options for recommending a statutory change allowing exceptions to the legal dosage limit:

1. Retain the existing legal dosage limit for all patients. Do not allow any exceptions to the limit (status quo).
3. Allow a patient's qualifying medical provider (QMP) to petition the DHHS Center for Medical Cannabis or the Compassionate Use Board (CUB) on behalf of the patient for an exception to the legal dosage limit.
4. Allow a pharmacy medical provider (PMP) to petition the DHHS Center for Medical Cannabis or CUB on behalf of the patient for an exception to the legal dosage limit.
5. Allow either a QMP or a PMP to petition the DHHS Center for Medical Cannabis or the CUB on behalf of the patient for an exception to the legal dosage limit.
6. Only allow patients with certain qualifying conditions who are also receiving palliative care to be eligible for the limit.

## Background

**UPDATE:** [S.B. 233 Medical Cannabis Amendments](#), released on Monday, February 12, 2024 by Senator Luz Escamilla, includes a provision allowing an exception to the legal dosage limit. The bill would allow a QMP to petition the Department of Health

# MEMORANDUM

Medical Cannabis Policy Advisory Board

BOARD AGENDA: 2/20/24

ITEM: 7

and Human Services (DHHS) to waive the 28-day period limit for a patient if the patient:

- has been diagnosed with a terminal illness;
- has a life expectancy of six months or less; and
- needs the waiver for palliative purposes.

Under the bill, DHHS would consult with the CUB on the petition and issue a response within 10 days of the petition submission date. The waiver would not be allowed to last for more than 180 days. **The board may consider discussing whether it supports this provision of S.B. 233 as is or if it recommends changes.** However, a substitute bill may be released before the board meeting. Board staff will update the board at the February 20th meeting.

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[Utah Code section 26B-4-245](#) allows a medical cannabis cardholder to purchase medical cannabis products up to the “legal dosage limit,” unless their recommending medical provider specifies dosing guidelines in the EVS which limit their patients’ ability to purchase specific kinds and/or amounts of products. “Legal dosage limit” is defined as:

- An amount that is sufficient to provide 30 days of treatment based on the dosing guidelines that the relevant recommending medical provider or pharmacy medical provider recommends, and may not exceed:
  - For unprocessed cannabis in a medicinal dosage form, 113 grams by weight; and
  - For a cannabis product in a medicinal dosage form, a quantity that contains, in total, greater than 20 grams of active tetrahydrocannabinol.

26B-4-245 allows a patient to purchase up to the legal dosage limit in any one 28-day period on a rolling basis.

# MEMORANDUM

Medical Cannabis Policy Advisory Board

BOARD AGENDA: 2/20/24

ITEM: 7

The proposal to allow exceptions to the legal dosage limit is out of concern for patients who may benefit from consuming more medical cannabis than the statutory limit allows a patient to purchase.

## Analysis

Is there a need to increase dosage limits for some patients?

Calculating how many patients would benefit from additional medical cannabis beyond the current legal dosage limit is not straightforward, because there are many factors that affect which products and cannabinoids are effective for each individual patient. While THC and CBD are the most common cannabinoids in cannabis, there are many other cannabinoids found in specific cultivars that may provide therapeutic benefits for individual patients and specific medical conditions. Processors may create products using specific cannabinoids to help specific symptoms or medical conditions that include varying amounts of each cannabinoid. All cannabinoids in a product work together synergistically when consumed.

Additionally, individual patients metabolize and absorb cannabinoids differently, which means that the products and amounts of each product that each patient needs will vary. While medical providers and pharmacists may recommend some products or cannabinoid profiles for patients to try, ultimately, the patient will need to try different products to find what works best for them. In short, whether a patient requires more than 20 grams of active THC in a 30-day period can only be determined on a case-by-case basis.

Currently, there are no universally accepted dosing guidelines for cannabis, as only a handful of randomized control trials have been conducted. A [2021 article in the Journal of Cannabis Research](#) tried to fill this knowledge gap with consensus-based recommendations from 20 medical cannabis experts with clinical or academic expertise regarding chronic pain, a very common condition for medical cannabis users. Expert opinion studies are generally considered to have a low level of evidence, but the panel recommended that any individual taking a daily dose higher

# MEMORANDUM

Medical Cannabis Policy Advisory Board

BOARD AGENDA: 2/20/24

ITEM: 7

than 40 milligrams for chronic pain consult with an experienced, specialty medical provider. While overdose potential with cannabis is low, tolerance issues and unwanted or serious side effects can occur with higher dosing. If a patient were to consume the maximum state limit of 20 grams of THC in equal amounts over 30 days, after converting the calculation to milligrams, the patient would consume 666 milligrams each day. This is much higher than the cannabis expert guideline of a 40 milligram daily dose.

Two QMPs, both with hundreds of patients, confirmed with board staff that their respective clinics have had no patients needing or requesting a higher dose than the legal dosage limit. One of them stated that generally, their patients who request more than the limit do not have terminal conditions and have high tolerance to THC. Additionally, the provider said they have not had terminal patients who, in their evaluation, could tolerate a dose higher than the legal limit.

Both providers understood increasing the legal dosage limit for patients with terminal conditions (particularly cancer) or who are undergoing end-of-life care. However, one highlighted the importance of recognizing the need for patients to receive conventional care and not to rely on medical cannabis as a first-line or singular treatment. The other provider feared that with an increased dosage limit, patients may sell or give away their medical cannabis. The provider emphasized a need for sufficient guardrails against baseless requests for legal dosage limit exceptions.

## How many patients reached the legal dosage limit in 2023?

The majority of the medical cannabis program's patients did not reach the legal dosage each month. In 2023, only 6% of the 77,644 registered patients reached the legal dosage limit 1 time during the entire year. Most patients who reached the legal dosage limit in 2023 only reached it 1 time. Some reasons that a patient reaches the legal dosage limit may include the following:

# MEMORANDUM

Medical Cannabis Policy Advisory Board

BOARD AGENDA: 2/20/24

ITEM: 7

- Patients may be taking advantage of a discount or a sale that only lasts for a certain time frame.
- Patients may be trying to “stock up” if they expect a product will not be restocked or fear a supply chain disruption could impact their access.
- Patients may need to consume higher amounts of cannabis to treat their medical condition.
- Patients may have a higher cannabis tolerance and use more to treat their medical condition.

Number of times an individual patient reached the legal dosage limit in 2023	Patients reaching limit for processed products	Patients reaching limit for unprocessed flower
1	4891	131
2	1279	44
3	392	6
4	118	4
5	32	1
6	10	2
7	4	-
8	2	-
11	-	1
<b>Grand Total</b>	<b>6728</b>	<b>189</b>

## Rick Simpson Oil (RSO): a prominent example of high-THC use

There may be rare exceptions where exceptionally high doses of THC can combat specific conditions. Rick Simpson Oil (RSO) is a well known, THC-potent extract currently sold in the cannabis market. Some patients try using RSO as a potential treatment for cancer, tumor growth, and neuropathic conditions.

Standard RSO protocol is to consume 60 grams total of THC over a 90-day treatment window. This protocol isn’t generally recommended by medical providers due to its lack of clinical approval, but it is still practiced by patients. Patients start with a low dose and increase the dose up to 1 gram per day until the 60 grams are gone. Some individuals may use RSO for longer than the 90-day treatment window.

# MEMORANDUM

Medical Cannabis Policy Advisory Board

BOARD AGENDA: 2/20/24

ITEM: 7

If a Utah patient followed the RSO protocol and reached a 1 gram dose with more than 20 days left in their treatment window, they could not buy more oil because it would go beyond the current legal dosage limit.

There are thousands of anecdotal patient accounts of RSO treating, or even curing, certain conditions. However, there is no identifiable clinical evidence that confirms these case reports. While there are human and animal studies that support the safety of cannabinoid use in conjunction with conventional cancer treatment, no studies published in conventional journal databases have administered hundreds of milligrams of THC in a single setting.

RSO products are sold in the Utah medical cannabis market and sell for a higher price, due to their high THC content. A manufacturer reported that a few patients and PMPs have made requests for RSO specifically. While RSO is available, the legal dosage limit and cost factor into its limited use for those seeking to undergo the RSO protocol. As of the release of this memo, less than 1% of medical cannabis products sold in 2024 are RSO products.

## A Utah patient story with RSO

A Utah medical cannabis pharmacist and processor offered an example of a patient who underwent RSO protocol and could not complete their treatment in Utah due to the legal dosage limit. This patient, who held a medical cannabis card for chronic pain, underwent surgical removal of a spinal tumor. Some of the tumor was left on the patient's spine due to risk of paralysis. Despite post-surgery radiation treatment, the tumor continued to grow. Doctors recommended a second surgery even though the operation had a high paralysis risk. Due to this risk, the patient sought alternative treatments. After other treatments, including stem cell therapy, the patient expressed interest in the RSO protocol.

The patient's medical cannabis pharmacist collaborated with a cannabis processor to supply RSO in glass syringes so the patient could consume RSO orally. Both the pharmacy and processor helped the patient pay for the products. Following the

# MEMORANDUM

Medical Cannabis Policy Advisory Board

BOARD AGENDA: 2/20/24

ITEM: 7

RSO protocol, the patient increased their dose to 1 gram of oil per day after ~42 days. With nearly 50 days left in their treatment window, the patient could not purchase additional RSO to complete treatment due to the legal dosage limit purchasing restriction of 20 grams of composite THC in a 28-day period. In an effort to complete the RSO protocol, the patient traveled to another state where they could purchase the more RSO. They then completed the RSO protocol out of state.

3-4 weeks after the RSO protocol was completed, the patient received a PET scan to detect active tumor growth. Reportedly, the scan did not show any growth. A follow-up MRI additionally showed no tumor growth. Because the patient was undergoing other alternative treatments at the time, attributing success to the RSO protocol is not possible. However, advocates for the RSO protocol and legal dosage limit exceptions endorse a “right to try” in cases such as these.

## Other states’ allowances for dosage limit increases

A review of 16 medical-only states identified 2 states that allow for exceptions to their respective legal purchase limits. [Florida](#) allows a qualified physician to [petition the state Office of Medical Marijuana Use](#) for an exception. The physician must specify their patients’ qualifying condition, why an exception is necessary, and the amount in excess of the legal purchase limit that they recommend for the patient each month. The Florida Office of Medical Marijuana Use must make a determination within 14 days of submission. The [Iowa Office of Medical Cannabidiol](#) follows a similar procedure for requesting an amount beyond the legal limit.

## Approval bodies for a legal limit increase

If legal dosage limit exception requests were added to the statute, the request could be granted to the Compassionate Use Board (CUB) or the DHHS Center for Medical Cannabis. The CUB meets monthly to review medical cannabis card petitions for minors and those who do not have a qualifying condition. While CUB may appear to be a more appropriate body to review limit increase requests, the DHHS Center for Medical Cannabis could alternatively review a request and make a determination. Because the CUB only meets monthly, DHHS Center for Medical

# MEMORANDUM

Medical Cannabis Policy Advisory Board

BOARD AGENDA: 2/20/24

ITEM: 7

Cannabis review may have a faster turnaround time. For patients diagnosed with a terminal illness or who have pressing pain management needs, swift approval could be essential. The DHHS Center for Medical Cannabis could be statutorily required to issue a determination within a certain number of days, like in Florida.

2 kinds of individuals could be allowed to make a legal dosage limit increase request: QMPs and PMPs. As medical providers, QMPs should understand their patients' medical history, conditions, and treatment needs. QMPs are the only individuals who may submit petitions to the CUB. A PMP expressed that they believed PMPs should be allowed to request legal dosage limit exceptions. They argued that in some cases, patients extensively consult with PMPs who can review their purchase history and provide consultations on medical cannabis use. Some stakeholders believe a PMP is in a better position to understand which types of conditions or situations may require an exception, as they are more likely to possess greater knowledge of medical cannabis products and often interact with patients more than the patient interacts with their QMP.

## Potential concerns with legal dosage limit exceptions

Potential concerns with allowing legal dosage limit exceptions include the following:

1. **Risk of diversion.** Patients could seek a legal dosage limit exception and then give away or sell their medical cannabis products to others. The medical provider or pharmacist making the exception request must practice due diligence in determining this likelihood.
2. **Unintended health consequences.** A high cannabinoid intake, particularly THC, could cause significant negative effects. In severe cases, hospitalization can occur. For some patients, consuming more cannabis than the legal dosage limit could be a high-risk situation with unknown outcomes. Patients who start with a high dose instead of increasing slowly from a lower dose could experience negative outcomes. Encouraging patients to use caution, to start with a low dose and increase their dose slowly, and to have someone they trust with them when they are using cannabis or a new product for the first time can help with these concerns. However, some patients may not



# MEMORANDUM

Medical Cannabis Policy Advisory Board

BOARD AGENDA: 2/20/24

ITEM: 7

follow best practices, which is why having legal limits can help protect patients.

## Options

Should the board want to make a recommendation on whether state statute should be amended to allow exceptions to the legal dose limit, it may consider the following options:

1. Retain the existing legal dosage limit for all patients. Do not allow any exceptions to the limit (status quo).
2. Allow a patient's QMP to petition the DHHS Center for Medical Cannabis or the CUB on behalf of the patient for an exception to the legal dosage limit.
3. Allow a patient's PMP to petition the DHHS Center for Medical Cannabis or CUB on behalf of the patient for an exception to the legal dosage limit.
4. Allow either a QMP or PMP to petition the DHHS Center for Medical Cannabis or the CUB on behalf of the patient for an exception to the legal dosage limit.
5. Only allow patients undergoing palliative care with certain qualifying conditions to be eligible for the limit.