

Minnesota Medical Cannabis Program Petition to Add an Approved Delivery Method

Making Your Petition

Any person may petition the Minnesota Department of Health (“the Department” or “MDH”) to add an approved delivery method to those listed in subdivision 14 of Minnesota Statutes section 152.22.

Petitions will be accepted only between June 1, 2021, and July 31, 2021. Petitions received outside of these dates will not be reviewed.

Petitions must be sent by certified U.S. mail to:

Minnesota Department of Health
Office of Medical Cannabis
P.O. Box 64882
St. Paul, MN 55164-0882

Or by email to:

Health.Cannabis.AddDeliveryMethod@state.mn.us

Instructions

- Complete each section of this petition and attach all supporting documents. Clearly indicate which section of the petition an attachment is for.
- This is a fillable PDF. Save the PDF to your computer before typing in the form fields. Otherwise, print the form and complete it by hand.
- **MDH does not have authority to add plant material or smoking as delivery methods. Petitions for adding plant material or smoking will be dismissed without being considered.**
- If you are petitioning for the addition of a delivery method that was considered but not approved in a prior year’s petition process, you **must include** new scientific evidence or research to support your petition or describe substantially different therapeutic benefits. Please refer to our website to see which delivery methods were reviewed in prior years. See [Petitions Process for Adding Qualifying Medical Conditions, Delivery Methods \(www.health.state.mn.us/people/cannabis/petitions/index.html\)](http://www.health.state.mn.us/people/cannabis/petitions/index.html).
- Each petition is limited to ONE proposed delivery method. If you want to request more than one delivery method be added, you must submit multiple petitions.
- If a petition does not meet the standards for submission, it will be dismissed without being considered.

MINNESOTA MEDICAL CANNABIS PROGRAM PETITION TO ADD
AN APPROVED DELIVERY MECHANISM

Petition review process

- If the petition is accepted for consideration, MDH will post notice of review of the petition on its medical cannabis website and allow public comment and input on the petition for at least 30 days. Please note: the citizen's review panel will not review delivery method petitions.
- The Commissioner will approve or deny the petition by Dec. 1, 2021.
- You may withdraw your petition any time before it is posted on the website for public comment by submitting a written statement to the Department stating that you wish to withdraw it.

Petition starts on next page.

Minnesota Department of Health
Office of Medical Cannabis
PO Box 64882
St. Paul, MN 55164-0882
health.cannabis@state.mn.us
www.health.state.mn.us

05/04/2021

To obtain this information in a different format, call: 651-201-5598.

MINNESOTA MEDICAL CANNABIS PROGRAM PETITION TO ADD
AN APPROVED DELIVERY MECHANISM

Section A: Petitioner's Information

Name (First, Middle, Last)

Maren Joyce Schroeder

Home Address (including Apartment or Street Number)

[REDACTED]

City

[REDACTED]

State

MN

ZIP Code

[REDACTED]

Telephone Number

[REDACTED]

Email Address

[REDACTED]

Section B: Delivery Method You Are Requesting Be Added

Please specify and provide a brief description of the proposed delivery method. Be as precise as possible in describing the delivery method you are requesting be added. ***Attach additional pages as needed.***

Gastrointestinal uptake infused edibles ("GI edibles"). Most specifically, edibles that are not dissolved orally. Orally dissolved medical cannabis was approved in 2019. GI edibles are food products infused with cannabis extracts.

Section C: Anticipated Benefits from the Proposed Delivery Method

Describe the anticipated benefits from the proposed delivery method and why it is better than currently approved delivery methods. Identify patient populations that do not benefit from current delivery methods. **Attach additional pages if needed.**

GI edibles are generally absorbed within the GI system and processed through the liver. This allows cannabinoids to spread more evenly through the body, and extends the efficacy of the medical cannabis. This is beneficial for patients who require constant, or near constant treatment, as the product's efficacy is longer than other products. Further, patients who may have an aversion to oils, liquids, or pills, may find an edible is more palatable. This includes youth patients who may have sensory processing disorders or otherwise require alternative ingestion methods. Finally, patients who use medical cannabis for sleep will find the longer efficacy more beneficial, as the effects of the medical cannabis will align closer with a full night's sleep.

Another crucial consideration is that with the availability of raw cannabis flower, patients could make their own edibles leading to inconsistent dosing and waste of medical cannabis. Allowing GI uptake edibles as a delivery method will help to mitigate this potential issue.

Section D: How Current Delivery Methods Are Inadequate

Provide information regarding the extent to which the currently approved delivery methods are unable to meet the needs of patients enrolled in the medical cannabis program. **Attach additional pages if needed.**

Minnesota allows GI uptake via capsules and pills. Unfortunately, for many patients, these are insufficient. Specifically, patients have indicated adverse reactions to additives and insufficient efficacy. One patient indicated a severe allergic reaction to something within tablets produced by one of the two Minnesota medical cannabis manufacturers.

The use of GI edibles is popular amongst medical cannabis patients in other medical cannabis states. In Colorado, in 2014, 1.96 million units of edible medical cannabis-infused products were sold. This does not include "home made" GI edibles made from purchased oil or cannabis flower. "Homemade" edibles are risky, as the dosing is inconsistent, and contamination of the end product could happen throughout the process. Regulating GI edibles is beneficial to patient safety and consistent treatment.

Section E (optional): Scientific Evidence of Support for the Delivery Method

Strengthen your petition by including evidence generally accepted by the medical community and other experts that addresses the effectiveness of the proposed medical cannabis delivery method and discusses its potential risks and benefits. This includes but is not limited to full text, peer-reviewed published journals, or other completed medical studies. Please attach complete copies of any article or reference, not abstracts.

I have attached relevant articles. *(check box if you have attached scientific articles or studies)*

Section F (optional): Letters of Support

Attach letters of support from persons knowledgeable about the use of the delivery method with medical cannabis.

I have attached letters of support. *(check box if you have attached letters of support)*

Section G: Acknowledgement and Signature

Please note: Any individually identifiable health information relating to any past, present, or future health condition or health care contained in this petition is classified as a health record under Minnesota Statutes §144.291, and is not subject to public disclosure.

I certify that the information provided in this petition is true and accurate to the best of my knowledge.



07/31/2021

SIGNATURE

DATE (mm/dd/yyyy)



Sensible policies, safer communities.

Commissioner Jan Malcolm
Minnesota Department of Health
Office of Medical Cannabis

Dear Commissioner:

We provide this letter in support of our petition for the addition of GI edibles as an allowable medical cannabis delivery method.

Over the past three years, our team has worked tirelessly for the legislative addition of raw cannabis flower to the medical cannabis program; this was a huge victory for patients in 2021.

Now, Minnesota really only has one delivery method that is not currently permitted – GI edibles. We strongly believe that it is time to end this restriction in the interest of patient access, product diversity, and consumer safety. Minnesota is one of only four states that does not allow edibles in its medical cannabis program – the addition brings us more in-line with more successful programs.

With access to raw cannabis flower, patients could, if they so choose, make their own GI edibles at home. This will result in inconsistent dosing, wasted product, and possible criminal liability. Minnesota's medical cannabis manufacturers have a track record of producing safe, consistently dosed, cannabis products, and we believe in the interest of patient safety, this addition will allow them to add one more product type that may suit the needs of patients who are not currently being served.

As you will see in our petition, the existing GI uptake products are not working for all patients. Patients with terminal illness and chronic pain tend to report the best results from the use of cannabis edibles.

We hope to see 2021 be the year that Minnesota ends its restrictions on medical cannabis delivery methods all together through the addition of GI edibles.

Respectfully,

A black and white image of a handwritten signature in cursive script, appearing to read "Maren Schroeder".

Maren Schroeder
Policy Director, Sensible Change Minnesota



Sensible policies, safer communities.

July 30, 2021

Commissioner Jan Malcolm
Minnesota Department of Health
Office of Medical Cannabis

Dear Commissioner Malcolm:

Sensible Minnesota is a 501(c)3 charitable non-profit that has worked with the medical cannabis program since its implementation in 2015. Through our patient advocacy program, we have assisted over 1,000 patients with access to medical cannabis, navigating them through program registration and renewal, finding health care providers supportive of medical cannabis, and answering questions as they arise.

One of the common themes we have seen is the desire for patients of all ages to have access to safe and consistent GI edibles. Chronic pain patients, especially, benefit from the long-acting nature of GI edibles, which are slower to absorb and last longer in the blood stream. Some patients have reported to us adverse effects from existing GI uptake medical cannabis products, such as tablets or pills, due to additives in the products. Others report the efficacy of homemade or illicit market purchased edibles is significantly better than the legally available products. We should not force patients to break the law to have medicine that works for them.

A patient with severe, intractable, chronic pain was using upwards of 3-5 medical cannabis pills a day to manage their pain, along with the medical cannabis vapes. The pills alone cost upwards of \$300 per month, for the pills alone. After obtaining cannabis to make homemade edibles, the patient was able to decrease their intake of oral cannabinoids significantly, because of the change in length of efficacy they found change to a GI edible. In addition to reduced cost, because their pain was better controlled with edibles, they were able to decrease the opioids they were taking to control their pain.

It is time for Minnesota to get with most medical cannabis states, add the only delivery method not allowed in Minnesota, and approve the petition for GI uptake edibles.

Regards,

A black and white image of a handwritten signature in cursive script, which reads "Gunnar Aas". The signature is written on a dark, textured background.

Gunnar Aas
President, Sensible Minnesota

Main Office 266 Hardman Ave N
South St. Paul MN 55075
Phone: 651-451-6240
Fax: 651-451-8227



Northern Office 2002 London Rd
Duluth MN 55812
Phone: 218-728-5174
Fax: 218-728-5178

July 29, 2021

Red Wing 319 ½ West 3rd Street
Red Wing, MN 55066
Phone: 651-388-6904

Minnesota Department of Health
Office of Medical Cannabis

This letter is in support of GI edibles as a delivery system for medical cannabis.

GI edibles allow cannabinoids to spread more evenly through the body and extends the efficacy of the medical cannabis. This is beneficial for patients who require constant, or near constant treatment, as the product's efficacy is longer than other products and patients who find benefit from medical cannabis may find an edible is more palatable.

The absence of edibles will not prevent patients from perhaps making their own versions at home, a process that will likely have inconsistent and wasteful results. Allowing for the regulated production and sale of GI edibles is beneficial to patient safety and consistent treatment.

Thank you,

A handwritten signature in red ink, appearing to read 'Jennifer Christensen', is written over a horizontal line. The signature is fluid and cursive.

Jennifer Christensen, President

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July 30, 2021

Commissioner Jan Malcolm
Minnesota Department of Health
Office of Medical Cannabis
P.O. Box 64882
St. Paul, MN 55164-0882

Re: Letter in support of adding swallowed edibles as a treatment option to Minnesota's medical cannabis program

Dear Commissioner Malcolm:

My name is Karen O'Keefe, and I am the director of state policies at the Marijuana Policy Project, the largest marijuana policy reform organization in the United States. MPP has been working to enact compassionate and sensible marijuana policies for more than 25 years. It was our honor and pleasure to work with patients and their loved ones as a leading partner in Minnesotans for Compassionate Care, which led the medical marijuana advocacy campaign in Minnesota until the enactment of the law in 2014.

However, the law's passage was bittersweet because the initial program was exceptionally restrictive and left most patients behind. Since then, we are grateful to the Department of Health for granting a number of petitions to approve additional serious medical conditions, and to the legislature for expanding the law, including to allow raw cannabis/ flower this year.

While we are heartened by many improvements to the program over the years, we are concerned that the program continues to exclude treatment preparations that are available in most other medical cannabis states, meaning that many patients cannot use the form of medicine that works best for them. We are writing to urge you to approve the petition to allow edibles as a delivery option.

A significant portion of medical cannabis patients use edibles. In Michigan's medical market, for example, 11% of sales in June 2021 were infused edibles.¹ A survey of preferred treatment modes for pain patients found edibles to be more popular with medical consumers than recreational users and more common for use by females.²

¹ Michigan Marijuana Regulatory Agency, Monthly Report, June 1, 2021-June 30, 2021, p. 4, available at https://www.michigan.gov/documents/mra/June_2021_Monthly_Report_729777_7.pdf.

² See: Kevin Boehnke, et al., "Cannabis Use Preferences and Decision-making Among a Cross-sectional Cohort of Medical Cannabis Patients with Chronic Pain," *Journal of Pain*, May 24, 2019.

A 2021 survey of patients at the MS Clinic in Calgary, Alberta, Canada found that many of the responding patients found relief from cannabis and that oral-edible administration was the most common³:

There were 775 respondents out of 2899 PwMS contacted by email. Among respondents, 734 reported cannabis use in the past 3 months. There were 275 (37.5%) respondents who reported cannabis use in the prior 3 months, and 73.8% of these reported at least weekly use of cannabis. Among all users, 78.1% reported a primary medical or therapeutic indication for consumption. **The most common modes of cannabis consumption were oral-edible (69.0%) and smoked (57.1%), while 59.3% used more than one mode of consumption and 2.6% used five different modes.** The most common reasons for cannabis use were for sleep (58.3%), pain (51.5%), relaxation (44.4%), muscle spasms (40.2%), anxiety (33.8%) and depression (22.9%).

One family who shared their experience with medical cannabis edibles was the █████ family. Before he died of Alzheimer's disease, the family and caregivers of A █████ █████ a Holocaust survivor found that while other medications worsened his delirium and agitation, medical cannabis edibles brought him relief.⁴

█████ Mark uses cannabis for chronic pain, including back injuries and sciatica. Edibles are an important part of his treatment, which enable him to avoid the significant amounts of over-the-counter pain medication he previously used to deal with the pain which carry significant risks when used long-term.⁵ He uses cannabinoid-infused pills to reduce the pain enough to get a decent night of sleep, along with various strains of inhaled cannabis occasionally during the day and night for pain relief as well.

Mark also uses cannabis-infused cookies during the daytime to help reduce the need for inhaled/smoked cannabis. Cookies provide him with longer-lasting relief and more consistent quality of effect compared to pills and tinctures and work better as supplementary dosing alongside inhaled cannabis.

Thirty-six states, including Minnesota, have what MPP considers to be comprehensive medical cannabis laws. All but three of the other states — Pennsylvania, West Virginia, and North Dakota — allow commercially produced edibles.⁶

³ Shunaha Kim-Fine, et al., "Cannabinoids and bladder symptoms in multiple sclerosis," *Multiple Sclerosis and Related Disorders*, Volume 54, September 2021.

⁴ <https://abcnews.go.com/Health/marijuana-edibles-helped-dying-holocaust-survivor-battle-alzheimers/story?id=59637115>

⁵ See, i.e., "FDA strengthens warning that NSAIDs increase heart attack and stroke risk," Harvard Health Blog, June 25, 2019.

⁶ See our chart at: <https://www.mpp.org/issues/medical-marijuana/modes-administration-medical-cannabis-laws/>

If states do not allow commercially produced edibles, patients often will produce them on their own or get them on the illicit market. Without a commercial kitchen, patients risk inconsistent dosing, with one serving having far more THC and CBD than the next. Commercially produced edibles can ensure consistent, accurate dosage. And unlike home produced edibles, commercial kitchens can also have requirements for childproof packaging to prevent inadvertent ingestion and improve safety.

We hope that you will grant this petition and add edibles as a qualifying treatment to Minnesota's medical cannabis program. This will improve consistency and safety for patients and bring the state's program closer in line with other states.

Sincerely,

Karen O'Keefe
Director of State Policies
Marijuana Policy Project



July 30, 2021

Commissioner Jan Malcolm
Minnesota Department of Health
Office of Medical Cannabis

Dear Commissioner Malcolm:

Minnesotans for Responsible Marijuana Regulation (MRMR) is a statewide, multi-partisan campaign organized by leaders from state and local units of government, a broad range of non-profit organizations, Minnesota's business community, organized labor, and individuals advocating for Minnesota to join the growing number of states that have replaced failed marijuana prohibition laws with sensible regulations that ensure responsible use of cannabis products and improve the safety of our communities.

MRMR has been and continues to be supportive of responsible expansions to Minnesota's medical cannabis program. One of the common themes we hear when engaging with Minnesotans is that the existing program is expensive, difficult to access, and inadequate in its scope of qualifying conditions and approved delivery methods. We are pleased and appreciative of the addition of chronic pain as a qualifying condition and raw cannabis flower as a delivery method. While these are important improvements to the program, Minnesota can do more for those that suffer with conditions such as PTSD, chronic pain, or terminal illness.

The addition of gastrointestinal uptake infused edibles ("GI edibles") will give patients an additional option for those who do not find relief with existing products to responsibly consume medical cannabis. Without the addition of GI edibles, many patients will continue to resort to consuming edibles that are either homemade or purchased through the illicit market, thereby risking their health and safety with unregulated and inconsistent products.

We believe adding GI edibles is the responsible decision for protecting the safety and security of Minnesotans who find benefit in the use of medical cannabis.

Minnesota is ready for safe and legal access to cannabis products, and the addition of GI edibles to the medical cannabis program is a step in that direction.

Thank you for your consideration,

Lili Fatehi
Campaign Manager
Minnesotans for Responsible Marijuana Regulation



www.mnnorml.org

July 30, 2021

Commissioner Jan Malcolm
Minnesota Department of Health
Office of Medical Cannabis
P.O. Box 64882
St. Paul, MN 55164-0882

Commissioner Malcolm:

Today I write in support of the petition to add GI edibles as a delivery method for medical cannabis.

Hundreds of thousands of Minnesotans use cannabis, and a significant number use cannabis for medical reasons. Minnesota's medical cannabis program has been a failure over its life cycle, but most recently, with the addition of raw cannabis flower, amongst other administratively added delivery methods, we have seen the program slowly improve.

Our membership supports this addition, for safety reasons. Many patients already make their own edibles or purchase them in free states and bring them back to Minnesota, risking safety, consistent dosing, and freedom in simply obtaining medicine that works for them.

Every opportunity we have as a state to work toward the end of cannabis prohibition is a win for Minnesotans. I urge your office to approve the petition and make one more improvement to what has been the worst medical cannabis program in the country.

Sincerely,

Michael Ford
Executive Director