

Minnesota Medical Cannabis Program Petition to Add a Qualifying Medical Condition

Making Your Petition

Any person may petition the Minnesota Department of Health (“the department” or “MDH”) to add a qualifying medical condition 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.AddMedicalCondition@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.
- Each petition is limited to one proposed qualifying medical condition. If your petition includes more than one medical condition, it will be dismissed.
- If you are petitioning for the addition of a medical condition 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 symptoms. The MDH website has the petitions and review material for each petitioned medical condition reviewed in prior years. See [Petitions Process for Adding Qualifying Medical Conditions, Delivery Methods \(www.health.state.mn.us/people/cannabis/petitions/index\)](http://www.health.state.mn.us/people/cannabis/petitions/index). Petitions that do not include new scientific evidence or research to support your petition or describe substantially different symptoms will not be considered.
- If the petition is accepted for consideration, MDH will send the petition documents to the Medical Cannabis Review Panel (“Review Panel”). MDH staff will also provide information to the Review Panel about the proposed qualifying condition, its prevalence, and the effectiveness of current treatments.

MINNESOTA MEDICAL CANNABIS PROGRAM PETITION TO ADD
A QUALIFYING MEDICAL CONDITION

- You may withdraw your petition any time before the Review Panel’s first public meeting of the year by submitting a written statement to MDH stating that you want to withdraw it.

Petition Review Process

- An appointed citizens Review Panel will meet to review all eligible petitions and supporting documentation.
- MDH will post notice of the public meetings of the Review Panel on its medical cannabis website.
- After the public meeting and by Nov. 2, 2021, the Review Panel will provide the Commissioner of Health a written report of findings.
- The Commissioner will approve or deny the petition by Dec. 1, 2021.

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
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Section A: Petitioner's Information

| | | |
|--|--------------|----------------------|
| Name (First, Middle, Last) | | |
| Home Address (including Apartment or Street Number) | | |
| City | State | ZIP Code |
| Telephone Number | | Email Address |

Section B: Medical Condition You Are Requesting Be Added

Please specify the name and provide a brief description of the proposed qualifying medical condition. Be as precise as possible in identifying the condition. Optional: Include diagnostic code(s), citing the associated ICD-9 or ICD- 10 code(s), if you know them. ***Attach additional pages as needed.***

Section C: Symptoms of the Proposed Medical Condition and/or Its Treatment

Describe the extent to which the proposed qualifying medical condition or the treatments cause suffering and impair a person's daily life. **Attach additional pages if needed.**

Section D: Availability of Conventional Medical Therapies

Describe conventional medical therapies available and the degree to which they ease the suffering caused by the proposed qualifying medical condition or its treatment. **Attach additional pages if needed.**

Section E: Anticipated Benefits from Medical Cannabis

Describe the anticipated benefits from the medical use of cannabis specific to the proposed qualifying medical condition. **Attach additional pages if needed.**

Section F (optional): Scientific Evidence of Support for Medical Cannabis Treatment

Strengthen your petition by including evidence generally accepted by the medical community and other experts supporting the use of medical cannabis to alleviate suffering caused by the proposed medical disease or its treatment. 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 G (optional): Letters in Support of Adding the Medical Condition

Attach letters of support for the use of medical cannabis from persons knowledgeable about the proposed qualifying medical condition, such as a licensed health care professional.

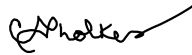
I have attached letters of support. *(check box if you have attached letters of support)*

MINNESOTA MEDICAL CANNABIS PROGRAM PETITION TO ADD
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Section H: 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.

A handwritten signature in black ink, appearing to read "S. Holker" with a stylized flourish at the end.

| | |
|------------------|--------------------------|
| SIGNATURE | DATE (mm/dd/yyyy) |
|------------------|--------------------------|



OMC Anxiety Comprehensive Review: Experience of Other States

March 17, 2021

DRAFT

PROTECTING, MAINTAINING AND IMPROVING THE HEALTH OF ALL MINNESOTANS

Eight representatives from six states were interviewed.

They were asked questions addressing:

- The process used to evaluate anxiety disorder as a qualified condition
- The impact adding anxiety disorder created for the program or the reasons anxiety was denied when petitioned
- Patient experience
- Public reaction

Facts and Figures

14% - 58%

where approved, anxiety disorder comprises a significant portion of qualified conditions

Research Gap

when denied, the lack of research is the top cited concern

3 out of 4

States added anxiety disorder as a qualified condition through a petition

Limited Data

most states do not have a regular or robust outcomes data collection practice

4 of 36*

States with medical cannabis have anxiety disorder(s) as a qualifying conditions

Minors & Cannabis

many states express caution regarding dispensing medical cannabis to minors

Core Data Summary

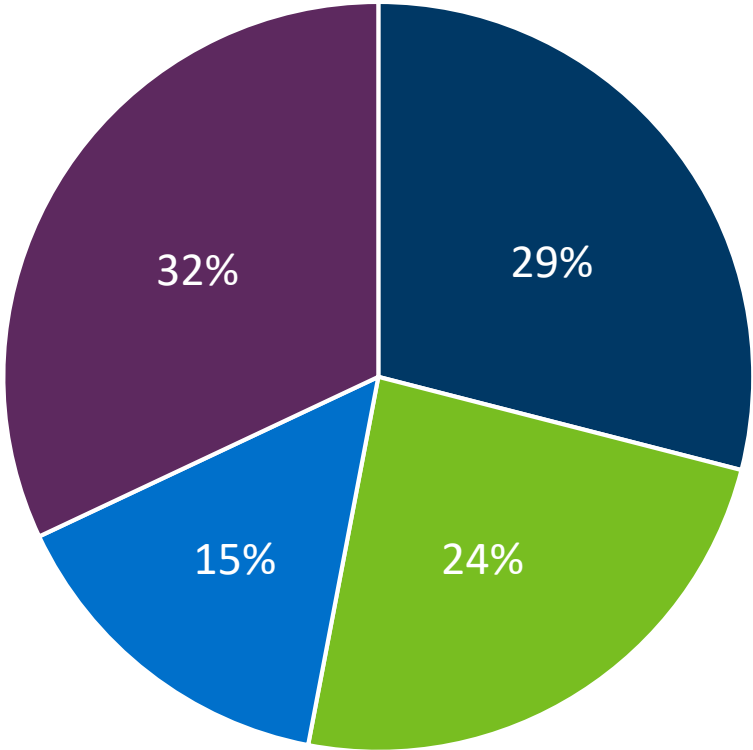
| State | First Attempt Year Added | Method To Add | Decision Maker | % of Qualified Conditions | Collect Patient Impact Data? |
|--------------|--------------------------|---------------|--|------------------------------|------------------------------|
| New Jersey | 2018 | Petition | Board recommendation, Health Commissioner decision | 24% (year 1) 58% (year 2) | No |
| Nevada | 2019 | Hybrid | Legislature | 14% | No |
| North Dakota | 2019 | Legislative | Legislature | 25% | No |
| Pennsylvania | 2019 | Petition | Board recommendation, Secretary of Health decision | 15% | No |

Note: Hawaii and Ohio have received petitions to add anxiety disorder to their list of qualified conditions, but have denied the requests.

Executive Summary

- The approach states have taken to approve a new condition varies, from petition to legislative to a hybrid model. Some states engage panels or boards to review petitions whereas some proceed with a review performed only by their Secretary or Commissioner.
- States where anxiety disorder is approved have typically used the DSM-5 definition and have not distinguished between sub-conditions.
- After anxiety disorder was approved, some states saw an increase in their registry enrollment and all noted anxiety disorder became one of the most common conditions.
- After anxiety disorder was approved, states experienced little public concern.

2019 Percent of Conditions



■ Pain ■ Anxiety Disorder ■ Intractable skeletal spasticity ■ Other

As reported in July 2019, pain comprises 29% of the conditions. Anxiety disorder is second with 24% and intraskeletal spasticity is third with 15%.

Personal communication from a state staff member stated anxiety disorder comprised ~58% of the conditions in 2020.

Source: [Department of Health | News | NJ's Medicinal Marijuana Program Triples Patient Count Since Start of Murphy Administration](#)

New Jersey

Program Start: 2009

Process Used: Petition

Status: Approved in 2018, effective in 2019

- First petition process
- Engaged a panel of physicians and mental health experts, primarily those with academic backgrounds. Held public hearings and reviewed available research
- Provided recommendations to the Commissioner of Health
- The Commissioner evaluated the petition against regulatory criteria and five factors: the acceptance of anxiety disorder as a valid medical condition within the medical community, if the available treatments cause suffering for the patients and if the suffering is accepted by the medical community, if the condition itself and/or the treatments cause severe suffering, the availability of conventional medical therapies (other than those which cause suffering), and whether there is generally accepted benefit evidence within the medical community.
- The Commissioner found anxiety disorder to be “debilitating” and medical marijuana may be beneficial to alleviate this effect

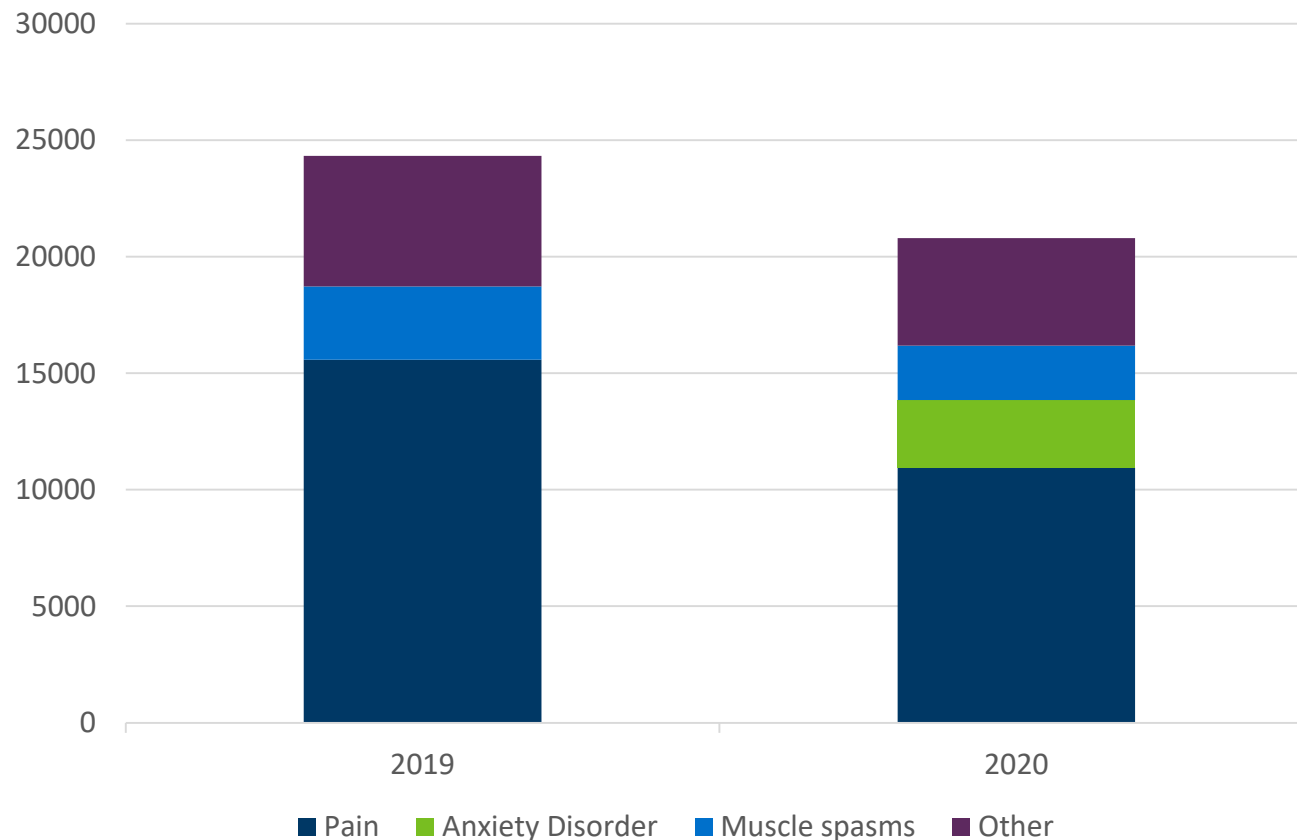
| | | | | | |
|---------------------------------------|---------|---|---------|---|---|
| Number of patients in program: | 104,253 | Number (%) of patients with anxiety disorder as a primary diagnosis: | unknown | Anxiety disorder as a percent of the total conditions: | Increased from 24% in year 1 to ~ 58% in year 2 |
|---------------------------------------|---------|---|---------|---|---|

Data Collected: Dispensaries are responsible for data collection. To date, the quantity and quality of data are not adequate. Anecdotal information is overwhelmingly positive, in particular among those with autism or dementia where anxiety disorder is an underlying condition.

- Other Important Insights:**
- The autism community played a significant role in the inclusion of anxiety disorder due to it manifesting as an underlying condition.
 - Some members of the substance abuse community view medical cannabis as a potential option for addressing secondary anxiety disorder in order to introduce psychotherapy.
 - The legislature is adding more conditions through a reform, thereby ending the petition process.
 - Cases of psychosis development among patients with a severe mental health disorder have been reported. In these situations, the office collaborated with the patient’s prescriber to remove them from the program.

Contact: Jeff Brown, Assistant Commissioner, Medicinal Marijuana, NJ Department of Health

Number of Qualifying Conditions, 2019 vs 2020



On July 31, 2019, Nevada had 17,908 active cardholders, representing 24,330 qualifying conditions.

Anxiety disorder was added August 1, 2019 as a qualifying condition.

On July 31, 2020, Nevada had 13,210 active cardholders, representing 20,802 qualifying conditions. Anxiety disorder (N= 2,913) became the second most common condition, following pain, representing 22% of the cardholders and 14% of the conditions.

Note: Nevada added adult use of marijuana on January 1, 2017. The number of medical cardholders peaked at 28,308 in May 2017. This number has steadily declined to 13,210 as of July 31, 2020, which is attributed to the adult use option.

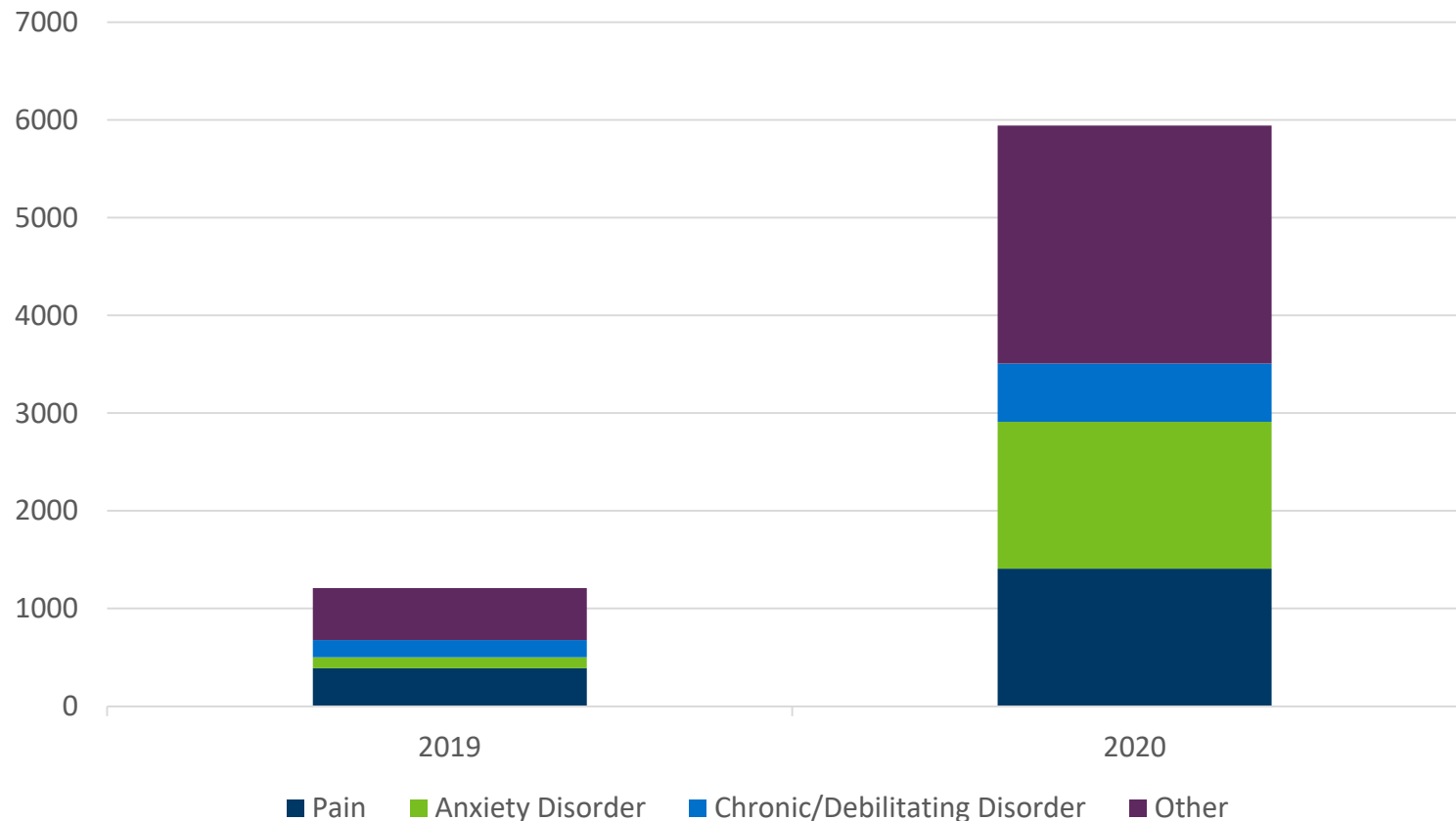
Sources: [Nevada Medical Marijuana Registry Monthly Statistics June 2019 \(nv.gov\)](#)

[Medical Marijuana Registry Monthly Statistics July 2020 \(nv.gov\)](#)

| | | | | | |
|---|--|---|-------------|---|-----|
| Program Start: 2012 | | Process Used: Hybrid | | Status: Approved in 2019 | |
| <ul style="list-style-type: none"> Anxiety disorder received as a petition in 2019. The Public and Behavioral Health Division chief medical officer received the petition and determined the petition met criteria for legislative consideration. All changes to qualified conditions must be made through legislation. The legislature added anxiety disorder to a bill, which was then passed and signed by the Governor in 2019. The Public and Behavioral Health Division manage and oversee the patient registry and patient communications. The Cannabis Compliance Board oversees the manufacturing and dispensary regulations. | | | | | |
| Number of patients in program: | 13,210 | Number (%) of patients with anxiety disorder as a primary diagnosis: | 2,913 (22%) | Anxiety disorder as a percent of the total conditions: | 14% |
| Data Collected: | Data is not collected on patients | | | | |
| Other Important Insights: | <ul style="list-style-type: none"> Established the Cannabis Compliance Board in 2019 to tighten the regulations. Following the gaming regulations model. PTSD approved first. In 2019, legislation changed to broaden condition to include anxiety as well as PTSD. When recreational use became effective in 2017, the medical program has experienced an overall reduction of approximately 54% among active card holders (28,308 in May 2017 to 13,210 in July 2020). However, some card holders returned to the program because of the product availability and cost savings. | | | | |
| Contact: | Tyler Klimas, Executive Director, Nevada Cannabis Compliance Board; Kara Cronkhite, Health Program Manager, Nevada Cannabis Compliance Board Minden Hall, Program Officer I, Medical Marijuana Registry Program, NV Department of Health and Human Services | | | | |

North Dakota

Number of Qualifying Conditions, 2019 vs 2020



On June 30, 2019, North Dakota had active 838 cardholders, representing 1,209 qualifying conditions. Anxiety disorder (n=113) comprised 13% of the active cardholders and 9% of the conditions.

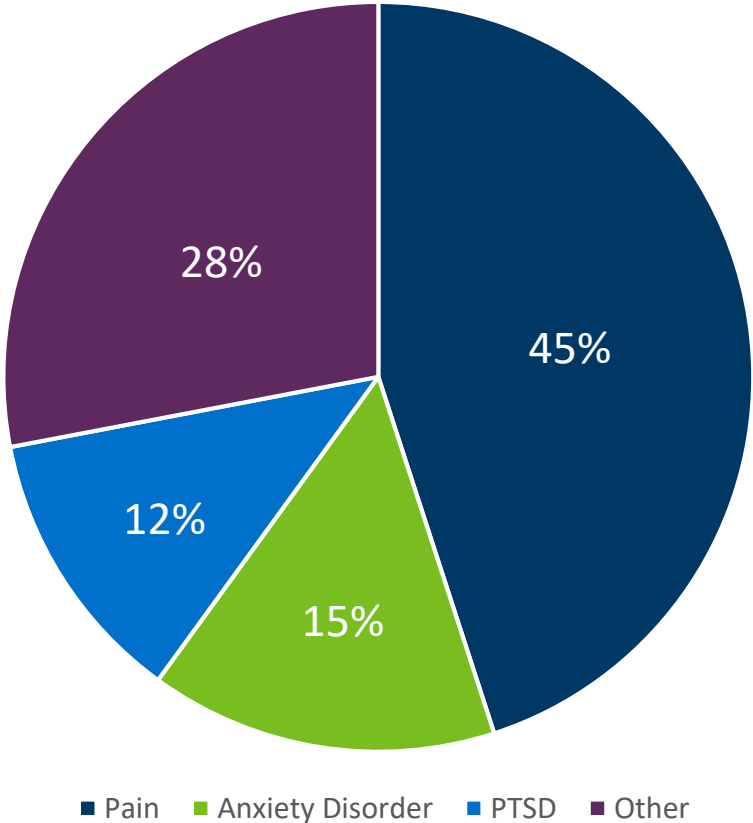
On June 30, 2020, North Dakota had 3,752 active cardholders, representing 5,942 qualifying conditions. Anxiety disorder (N=1,502) became the most common condition, representing 40% of the active cardholders and 25% of the conditions.

Sources: [Annual Report 2019.pdf \(nd.gov\)](#)
[Annual Report 2020.pdf \(nd.gov\)](#)

North Dakota

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|--|--|---|------------|---|-----|
| Program Start: 2016 | | Process Used: Legislation | | Status: Approved in 2019 | |
| <ul style="list-style-type: none"> • Conditions are set in statute by the legislature • Anxiety disorder quickly became the number one condition among enrolled patients • Medical community remains concerned over minors participating in the program | | | | | |
| Number of patients in program: | 3,752 | Number (%) of patients with anxiety disorder as a primary diagnosis: | 1502 (40%) | Anxiety disorder as a percent of the total conditions: | 25% |
| Data Collected: | Have a survey drafted but have not implemented it yet. Using Minnesota's survey as their template. | | | | |
| Other Important Insights: | <ul style="list-style-type: none"> • Set a cap at 6% THC for anyone under 18 years of age | | | | |
| Contact: | Jason Wahl, Director, Division of Medical Marijuana, ND Department of Health | | | | |

2020 Percent of Conditions



As reported in the February 2020 report to the Medical Marijuana Advisory Board, pain comprises 45% of the conditions. Anxiety disorder is second with 15% and PTSD is third with 12%.

State staff estimates pain, anxiety disorder and PTSD comprise ~80% of the indications in 2021. Moreover, the addition of anxiety disorder increased program volume by 30%.

Source: PA Medical Marijuana Advisory Board Meeting Feb 13, 2020 (private communication)

Pennsylvania

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|--|--|---|---------|---|-----|
| Program Start: 2016 | | Process Used: Petition | | Status: Approved in 2019, effective in 2019 | |
| <ul style="list-style-type: none"> Created the independent Medical Marijuana Advisory Board to determine which conditions will be added or removed. The board is comprised of ~15 individuals with backgrounds in medicine, pharmacy, law enforcement, patients, and advocacy. The board take a vote and then submits their recommendation to the Secretary of Health. The Secretary of Health has up to one year to respond to the board’s recommendation. In this case, the Secretary reviewed additional research and made her decision in approximately six months to approve anxiety disorder. | | | | | |
| Number of patients in program: | ~150,000 | Number (%) of patients with anxiety disorder as a primary diagnosis: | unknown | Anxiety disorder as a percent of the total conditions: | 15% |
| Data Collected: | <ul style="list-style-type: none"> The program collects anecdotal information. Reports thus far indicate an improved quality of life for patients. Research level data would be collected through an agreement with a Pennsylvania state university | | | | |
| Other Important Insights: | <ul style="list-style-type: none"> .The Secretary of Health was proactive and engaged the medical community across the state. She positioned medical marijuana as a “tool in the toolbox” The Secretary provided professional recommendations through a press release. These recommendations include medical marijuana is not a first line treatment, it is for short term use, low THC/high CBD products are preferred, not recommended for children and adolescents, and pregnant women should not use medical marijuana | | | | |
| Contact: | John Collins, Director, Office of Medical Marijuana, PA Department of Health | | | | |

States which declined petitions



| | | | |
|--|--|-------------------------------|-----------------------|
| Program Start: 2000 | | Process Used: Petition | Status: Denied |
| <ul style="list-style-type: none"> • Generalized anxiety disorder petitioned in 2017, anxiety disorder petitioned in 2020 • Hold a public hearing and look at decisions made by other states • Will only review human research studies. Thus far the data is not deemed to be of high-quality evidence • The administration (Director of Health) is very cautious with considering any mental health disorder for medical cannabis • PTSD was added through legislation in 2015 | | | |
| Number of patients in program: | 31,509 | | |
| Data Collected: | Follow up data on patients is not collected | | |
| Other Important Insights: | After PTSD was added, it became one of the top 3 conditions. As of January 2021, it is the second highest condition and represents ~15% of the patients. | | |
| Contact: | Tamara Whitney, Program Coordinator, Medical Cannabis Registry Program, HI Department of Health | | |

| | | | |
|--|---|-------------------------------|-----------------------|
| Program Start: 2016 | | Process Used: Petition | Status: Denied |
| <ul style="list-style-type: none"> Anxiety disorder petitioned in 2019 and 2020, panic disorder petitioned in 2021 Medical Board expects scientific evidence to demonstrate effectiveness for approval because they are unable to remove a condition once it is approved An internal Medical Marijuana Expert Review committee is charged with reviewing the petitions. Will engage external experts as needed. They vote to approve or deny a petitioned condition | | | |
| Number of patients in program: | >168,000 | | |
| Data Collected: | Conduct surveys from certifiers, but data is not collected on patients | | |
| Other Important Insights: | Due to the way their law is written, they may not have the ability to restrict access by age or other factors | | |
| Contact: | Brandi Dorcy, Chief of Compliance, State Medical Board of Ohio | | |