



MINNESOTA
MEDICAL
ASSOCIATION



SPECIAL REPORT
FROM THE MMA:

Medical cannabis

A SUPPLEMENT TO
**MINNESOTA
MEDICINE**

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Medical Cannabis Special Report

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Burning questions

Medical cannabis is almost here. If they haven't already, your patients may soon be asking you a lot of questions about the drug. Will it help my condition? How do you get it? What do you think, doc?

Are you prepared to answer?

We've created this special report to help you as you field their questions. We haven't covered everything there is to know about medical cannabis, but the information provided should make you feel a little more comfortable when you talk with your patients about the state's medical cannabis program that begins July 1.

The state seems to be moving at breakneck speed to launch this program, after the Legislature approved its creation last year. When bills were first introduced, medical cannabis didn't seem to have a chance. Gov. Dayton opposed the idea. Law enforcement opposed it. The MMA opposed it.

Then, through the persistence of lawmakers and after a few concessions, the medical cannabis program was established. Now, physicians across the state are put in the delicate position of having to work with their patients to obtain this non-FDA-approved drug.

Minnesota is certainly not the first state to pass medical cannabis legislation. We are, however, approaching the issue differently than others. We are trying to make the most of the law—to figure out as scientifically as possible how the drug in pill, liquid and capsule form can help patients with nine specific conditions.

The law passed with the intent that we'd create a patient registry from which we will gather clinical data to help physicians make more informed decisions in the future.

Now that medical cannabis has become a reality in Minnesota, we're supporting physicians as they figure out how to care for their patients who qualify for its use. We hope this report helps you navigate this ambitious experiment.

Medical Cannabis Special Report

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MAKING MEDICINE OUT OF MARIJUANA

Physicians are in charge of manufacturing Minnesota's medical cannabis

In December 2014, Minnesota's Office of Medical Cannabis (OMC) selected Cottage Grove-based LeafLine Labs and Oostego-based Minnesota Medical Solutions to grow, formulate, package and sell medical cannabis products.

Both are led by Minnesota physicians. Both are backed by investors and have enough capital to sustain them if initial patient numbers are low. And both planted their first crops in December and January and will have medicines ready for patients on July 1.

By law, each must complete all stages of the manufacturing process at one location and build and operate four distribution centers where patients can purchase the medications. LeafLine's Eagan distribution center will open July 1. Its centers in Hibbing, St. Cloud and St. Paul are scheduled to open later in 2015 or early 2016. Minnesota Medical Solutions' distribution centers in Minneapolis, Moorhead and Rochester will open in July. An Eden Prairie location will open in August or September.

LeafLine's co-founders Gary Starr, MD, and Andrew Bachman, MD, started the company along with 10 other members of the Bachman family, longtime figures in Minnesota's garden and floral business. Minnesota Medical Solutions was founded by Kyle Kingsley, MD, an emergency physician who worked at St. Francis Medical Center in Shakopee until recently. Both manufacturers have hired professional growers, extractors and formulators with advanced degrees in horticulture and chemistry, and years of medical cannabis experience in other states.

All buttoned up

Security is tight at the manufacturing facilities and distribution centers. Biometric thumbprint recognition is required to enter processing areas. Minnesota Medical Solutions' chief of security is a former Secret Service agent and narcotics agent. "We've gone to great lengths to develop extensive security systems in our distribution centers, with input from local law enforcement," Kingsley says. "It's probably overkill, but it's crucial that we do this right."

Kingsley, who was inspired by the pain and cancer patients he saw in the ED who benefited from smokable cannabis acquired ille-

gally, says his work with the medical cannabis program has become his passion. "We felt a moral imperative to throw our hat in the ring and help advance the science while helping many patients," he says. "We're the first to admit there are risks and side effects like there are for any medicine, but medical cannabis can alleviate suffering for a lot of people who aren't getting relief from other drugs." He discusses some of these in the book *Medical Cannabis Primer for Healthcare Providers*, which he co-authored with Laura Bultman, MD.

"Minnesota has adopted an entirely different, much more scientific approach to medical cannabis."

— KYLE KINGSLEY, MD

LeafLine's Bachman and Starr are also emergency physicians motivated by the same reasons, seeing the same types of patients at the Methodist Hospital ED in St. Louis Park where they used to work. "We've studied the science of medical cannabis for many years," says Bachman, who's had a long-time interest in the medicinal properties of the drug. He says many patients with chronic pain who might benefit from cannabis use opioids instead. "Unfortunately, overdoses from prescription pain killers now kill more people than motor vehicle accidents in Minnesota."

According to research published in the August 25, 2014, *JAMA Internal Medicine*, states with medical cannabis laws had a 25 percent lower average annual opioid overdose death rate, as compared with states that haven't legalized medical cannabis. "Maybe there's a cause and effect, maybe not," Bachman says. "But when you look at all the data and when you see firsthand patients suffering from debilitating conditions with little or no treatment options left, you have to act. It's not about opening the medical cannabis floodgates. It's about providing patients with another option to alleviate their suffering, all in a tightly controlled medical environment."

During their trips to states where medical cannabis is legal to learn about their programs, Starr, Bachman and Kingsley all noticed a lack of physician leadership. "Minnesota, to its credit, has adopted an entirely different, much more scientific approach to medical cannabis," Kingsley says. "We know many physicians are apprehensive about medical cannabis, and we share their concerns. We're doing this because we want to make sure it's done right."

A variety of strains

Doing it right starts with growing several different strains of pharmaceutical-grade cannabis that differ in their ratios of THC to cannabidiol (CBD), the two cannabinoids thought to have the most therapeutic value. Strains high in CBD, for example, are used in medicines to control spasms and seizures. Medicines made from high-CBD strains (Sativex and Epidiolex) are already helping patients in other countries. Strains high in THC are used in drugs to control cancer-related pain, nausea and wasting. Marinol (dronabinol), which is synthetic THC, has been used to control these symptoms in the United States since 1985.

The manufacturers are not allowed to make products that can be smoked or injected. Instead, they can only make pills, capsules, solutions and tinctures than are taken orally, and oils that are vaporized at low heat and inhaled. Dose will be determined by distribution center pharmacists, who will rely on expertise that they have acquired through work done in other states, research-based guidelines posted on the OMC website, and the evidence on Marinol, Sativex and Epidiolex.

All medications will be protected in the same child-proof packaging used for traditional prescription medicines. Each manufacturer will test their medications for purity, consistency and quality. Outside labs approved by the OMC also will test all medications. "We will meet FDA manufacturing rules, if the FDA was in the business of approving medical cannabis facilities," Kingsley says.

Bachman adds that LeafLineLabs' Cottage Grove facility will mirror, and in some ways surpass, pharmaceutical-grade manufacturing facilities elsewhere in the country.

Both manufacturers are taking a start-low-go-slow approach to dosing. "These medicines can take two to three hours to take effect," Kingsley says, "so we encourage patients to wait a long time before they take more."



Medical cannabis plants grow at one of Minnesota Medical Solutions' greenhouses.

PHOTO COURTESY OF MINNESOTA MEDICAL SOLUTIONS

A flow of feedback

LeafLine Labs and Minnesota Medical Solutions will each have a helpline for patients to call to get answers to their questions and report adverse events. "We will report all adverse events to the state, no matter how mild or serious," Kingsley says. "That doesn't happen in other states."

Patients picking up their meds at a distribution center will need to complete a form, on which they'll be asked questions about their condition. For example, an epilepsy patient would report seizure count and duration. A Crohn's patients would report severity and frequency of belly pain. The distribution center will upload this information to the OMC database when the medication is purchased. Each month, the patient's condition and response will be re-assessed.

The manufacturers are permitted to advertise their products. They plan to focus initially on directly reaching out to patients, providers and advocacy groups.

Kingsley describes the relationship between Leaf Line Labs and Minnesota Medical Solutions as one of "collegial cooperation." "We want each other to succeed because a rising tide raises all ships," he says. "We hope to make Minnesota's a national flagship program, where true pharmaceutical-grade medicines are dosed and monitored using the best available science."

What physicians need to know

Starting June 1, patients can register with Minnesota's Office of Medical Cannabis (OMC). Starting July 1, they will be able to purchase cannabis medications at any distribution center in the state.

"The physician's role in all of this is limited," says Michelle Larson, director of Minnesota's OMC. "Their job is to certify that the patient has an eligible condition."

These are the eligible conditions:

- **Cancer**, if the condition or treatment causes severe or chronic pain, nausea or severe vomiting, or cachexia or severe wasting
- **Glaucoma**
- **Human immunodeficiency virus** or **acquired immune deficiency syndrome**
- **Tourette's syndrome**
- **Amyotrophic lateral sclerosis**
- **Seizures**, including those caused by epilepsy
- **Severe and persistent muscle spasms**, including those caused by multiple sclerosis
- **Crohn's disease**
- **Terminal illness** with a life expectancy of less than one year, if the illness or its treatment produces severe or chronic pain, nausea or severe vomiting, or cachexia or severe wasting

The law allows the Commissioner of Health to consider adding other conditions in the future. Intractable pain is one that may be added to the list sometime in 2016.

The physician's role

Physician participation is voluntary. Larson says the hope is that physicians will take time to learn how the program works and the science behind medical cannabis' effect on the qualifying conditions before deciding whether or not to participate. Here are a few key things to know:

Whole plant marijuana will NOT be used. Instead, only pharmaceutical-grade pills, capsules, liquids and oils made of cannabinoids extracted from plants will be made and sold. The liquid and

capsule forms will be swallowed or absorbed through the mouth's mucosal membranes. Oils will be vaporized at low heat and inhaled.

Physicians will NOT be writing cannabis prescriptions. Marijuana is a Schedule 1 drug, so no one in any state can prescribe it in any form. Medical cannabis is not reportable to the Minnesota Prescription Monitoring Program.

Physicians will NOT need to recommend cannabis to their patients or make a determination as to whether it might help a patient. They do not need to become "cannabis-literate;" however, patients will have questions, so physicians may want to learn more about the science of medical cannabis.

Resources FOR physicians

Physicians and health systems wanting general information about the state's medical cannabis program can call the OMC at 651-201-5598 or go to www.health.state.mn.us/topics/cannabis. Resources of particular interest to physicians include:

- A review of medical cannabis studies relating to chemical compositions and dosages for qualifying medical conditions (www.health.state.mn.us/topics/cannabis/practitioners/index.html).
- Details about how Minnesota's two medical cannabis manufacturers will grow, process and formulate medical cannabis (www.health.state.mn.us/topics/cannabis/manufacture/index.html).

Website for the Office of Medical Cannabis:

www.health.state.mn.us/topics/cannabis

Company website for LeafLine Labs:

www.leaflinelabs.com

Company website for Minnesota Medical Solutions:

minnesotamedicalsolutions.com



Physicians do NOT determine dosing, nor are they responsible for monitoring and managing patients' use of cannabis medications.

Physicians are NOT legally liable if a patient has an adverse event, is involved in an accident while under the influence, or diverts or otherwise misuses their medication. Physicians are not subject to any civil or disciplinary penalties by the Board of Medical Practice for participating in the registry program.

Physicians are NOT required to participate in the medical cannabis program. And they are not required to certify a medical condition for a patient—even if the patient has the condition.

Participating in the program

The physician's role in the medical cannabis program boils down to simply confirming that a patient has an eligible condition. The OMC calls this "certifying a patient's condition for registry eligibility."

To do that you will need to set up an account with the OMC, www.health.state.mn.us/topics/cannabis. Physician assistants and advanced practice registered nurses also can set up accounts.

Setting up an account requires entering some basic information, including your medical license number.

Once you have an account, you can certify that a patient has an eligible condition by clicking on the certification button. You will be prompted to enter the patient's name, address and contact information, then select the patient's eligible condition from a drop-down menu. Patients will need to have their physician re-certify their eligibility annually.

There is an option to check a box if the patient is developmentally or physically disabled and is unable to self-administer medication or pick-up medical cannabis from a distribution center. Checking this box allows the patient to register a caregiver who can assist them. "We're making this as simple as possible for physicians and patients," Larson says.

The agency in charge of the program

On May 29, 2014, Gov. Mark Dayton signed one of the most conservative medical cannabis laws in the country. The program it created is designed to allow patients with eligible conditions to use a limited variety of cannabis medications, while minimizing the chance these medications will be diverted or misused. The program will collect and analyze data on the use of medical cannabis in Minnesota in order to advance the science related to therapeutic cannabis.



Tom Arneson, MD, MPH

Minnesota's program is run by the newly created Office of Medical Cannabis (OMC), which is part of the Department of Health. It currently employs five full-time employees including Michelle Larson, MPA, director; Tom Arneson, MD, MPH, research manager; and Darin Teske, JD, policy analyst.

The OMC oversees the two manufacturers that will grow, process and sell legal cannabis medicines in Minnesota. It will set up and run the patient registry, which will keep track of all patients and their caregivers who have been approved to legally buy cannabis medications and all adverse events caused by those medicines. The OMC will collect data on each patient's condition, dose, response to the dose and side effects. And it will provide education to health care providers who want to learn more about the program.

Currently, the OMC's focus is on making sure the program is up and running by July 1, when the law requires that distribution centers operated by the manufacturers have cannabis medicines on their shelves, ready to sell to patients. The OMC is putting the finishing touches on its patient registry so that starting June 1, physicians can certify that a patient has an eligible condition—a necessary step before patients can apply to the registry.

Minnesota's list of eligible conditions is short compared with the lists in most of the other 24 states and the District of Columbia where medical cannabis is legal.

The list of approved cannabis medications is also short, compared with those in most other states. Whole plant marijuana is not on the list. Instead, manufacturers will make pharmaceutical-grade pills, capsules, liquids and oils from cannabinoids extracted from plants. Patients will be able to buy up to a 30-day supply at one time. Also different than in other states is the fact that in Minnesota, only two manufacturers will make all of the state's medical cannabis, and both of those companies are led by physicians.

Participation uncertain

As many as 5,000 patients could sign up for the program during the first year. In an OMC survey of 1,361 Minnesotans with eligible conditions conducted this past winter, 70 percent of respondents said they were likely to register. The most common eligible conditions among those who responded were multiple sclerosis or severe muscle spasms (51.5 percent), cancer (17.6 percent), and epilepsy or seizures (17.5 percent).

"We know that pediatric seizure patients will be there Day 1," says Kyle Kingsley, MD, founder and CEO of Otsego-based Minnesota Medical Solutions, one of the manufacturers. "We know from talking to these patients that there are a lot of them out there and they're motivated to register."

If intractable pain is added to the list in 2016, the number of

For more ABOUT the OMC

- Website: www.health.state.mn.us/topics/cannabis
- Michelle Larson, MPA, OMC director, 651-539-3002, Michelle.larson@state.mn.us
- Tom Arneson, MD, MPH, OMC research manager, 651-539-3005, Tom.arneson@state.mn.us
- Darin Teske, JD, policy analyst, 651-539-3004, Darin.teske@state.mn.us

patients could grow considerably, Larson says. Minnesota statutes define intractable pain as "a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts."

The state's Intractable Pain Advisory Panel is expected to make a recommendation to the Commissioner of Health by the end of the year.

How many physicians will participate is another unknown. Many don't have patients with eligible conditions. Specialists such as neurologists, oncologists, gastroenterologists and nephrologists will likely be well-represented. "We're finding that physicians in many special-

ties very much buy into the program quickly once they understand how it works,” Kingsley says. “The program is not pro-cannabis. It’s pro-patient. We’re giving a select group of patients access to a drug that could greatly improve their lives when other medications have not.”

Quality control

The OMC is responsible for ensuring that all medical cannabis sold in Minnesota is pharmaceutical-grade in terms of purity, consistency and quality. The manufacturers will do their own testing, plus have their products tested by an outside lab approved by the state. The OMC is also responsible for collecting and analyzing all adverse reactions to medical cannabis. Physicians and distribution center staff will report these instances on the OMC website.

Research is another big part of the OMC’s efforts. The OMC will collect and analyze data regarding:

- What medications were used for each condition?
- How often do patients change from one product to another? Do patients with certain conditions change more often? Are patients with certain severities of a condition more likely to change? Why do they change? Because one product is more or less effective than another?
- What were the starting dosages? Overall and by product type?
- In what percent of patients did a drug appear to be effective for each condition? How long does it take for indications of effectiveness to appear for each condition and product type?
- What is the frequency of side-effects (overall and by condition) with stratification by severity?
- At what dosages for each product do side effects tend to occur? How is that different for each condition? How is it different for various severities of each condition?
- How long do patients remain in the program? Why do they drop out?

Answers to these questions should inform best practices for using medical cannabis. Results of this research will be posted on the OMC’s website.



Medical cannabis begins in plant form but will end up as a pill, liquid or oil.

The patient registry part of the program is crucial because it facilitates further research, says Andrew Bachman, MD, co-founder and chief medical officer of LeafLine Labs, the other manufacturer. “Because cannabis is a Schedule 1 drug, almost no federal funding is available for further research and study,” he explains. “There’s a growing body of independent, evidence-based research; but we owe it to the people of Minnesota to keep learning about the medicinal application of cannabis in highly controlled and monitored settings. The registry will allow us to do that like no other state thus far.”

In addition, the OMC and both manufacturers provide speakers to clinics, hospitals and patient groups wanting to learn more about how the program works.

What patients may ask

How can I register as a medical cannabis patient?

Patients must register with the Minnesota Office of Medical Cannabis (OMC), www.health.state.mn.us/topics/cannabis. They must be 18 years of age or older to apply on their own and they must be Minnesota residents.

STEP 1:

A physician who is treating a patient with an eligible condition must certify with the OMC that the patient has that condition. If a patient needs a caregiver to pick up or administer the medical cannabis, he or she should let the physician know because the physician needs to indicate when certifying a patient that the patient is disabled and will need assistance.

STEP 2:

After a patient's physician, advanced practice registered nurse or physician assistant certifies that the patient has a qualifying medical condition, the OMC emails the patient an invitation to complete the online application for the registry. Patients must pay an annual \$200 fee with a credit or debit card. The fee is \$50 for those enrolled in Medical Assistance or MinnesotaCare.

A patient's application form must be accompanied by a copy of a government-issued ID such as a Minnesota driver's license. The ID should be scanned and uploaded to the OMC website.

Patients do not need to show that they tried other medications that didn't work or weren't tolerated.

If patients need help completing the online application, they should call the OMC helpline. If they are unable to complete the form online, they should call the OMC and ask for a print copy of the application.

Caregivers do not need to be a Minnesota resident; however, they must pay for the OMC to do a criminal background check through the Minnesota Bureau of Criminal Apprehension to make sure they have no controlled-substance felonies.

The OMC is not working with any outside businesses that help patients complete their application for a fee. If anyone claims they can do this, they have no relationship with the OMC.

STEP 3:

The OMC emails (or mails) each patient a confirmation that he or she is now on the state's medical cannabis registry. Patients should keep this in their records. The OMC will notify both medical cannabis manufacturers and all eight distribution centers that the patient has been added to the registry. The patient's information will be accessible from each of these sites. The OMC will notify patients when it's time to pay their annual fee in order to stay on the registry another year.

What if I switch doctors?

While taking cannabis medications, patients must remain under the care of the physician who certified that they have an eligible condition. If they switch to a new physician, that doctor will need to re-certify that the patient has a qualifying condition.



PHOTO COURTESY OF MINNESOTA MEDICAL SOLUTIONS

Planting began in December and January in order to have medication ready for patients on July 1.

What if I can't find a doctor who will certify that I have an eligible condition?

Doctors are not required to participate in the medical cannabis program. And they are not required to certify a medical condition for a patient—even if the patient has the condition. If a patient believes his or her doctor is not providing the best medical care, he or she may want to work with a different doctor. Keep in mind that the law requires patients to have an ongoing relationship with the doctor who is treating their eligible condition. The OMC cannot refer patients to another physician.

Where do I get medical cannabis?

Patients can go to any of eight distribution centers around the state. The Eagan center will open July 1, the date manufacturers are required to have cannabis medicines ready for patients. Distribution centers in Rochester, Minneapolis and Moorhead will open later in July. A facility in Eden Prairie will open in August or September. Distribution centers in Hibbing, St. Cloud and St. Paul are scheduled to open later in 2015 or in early 2016 (by law, they must open no later than mid-2016). Patients should call ahead to schedule an appointment. Phone numbers and driving directions will be posted on the OMC website and the manufacturers' websites by July 1.

What happens at the distribution center when I pick up my medical cannabis?

A patient or their caregiver must present a government-issued ID. First-time appointments take longer because the pharmacist will need to review the patient's medical history, explain how to use the medication and answer any questions.

Patients will learn about the potential risks, benefits and side effects of the medicine they're about to receive. They'll learn how to take it and what to do if they have an adverse reaction. By law, they can receive no more than a 30-day supply. It may come in pills or capsules, a liquid that can be swallowed or absorbed in the mouth, or oil that can be vaporized at low heat and inhaled.

Each time patients pick up their medication, they will be asked to provide information about their condition. This will enable the pharmacist to determine if it is helping the patient. For example, an epilepsy patient will report seizure count and duration. A Crohn's patient will report severity and frequency of belly pain. Each month, patient conditions and responses to the medicine will be re-assessed.

The pharmacist will also give patients a sheet that lists the type of cannabis medicine they bought, the dose, other medications they are taking, the symptoms their eligible condition is causing, and side-effects from the cannabis medicine and their severity. Patients will be encouraged to share this summary with their doctor.

How much will cannabis medicine cost?

Minnesota's two manufacturers will determine their prices by July 1. Patients should plan to pay on average \$250 to \$500 per month, depending on the type of cannabis medication and the dosing that is recommended for them, according to Andrew Bachman, MD, of LeafLine Labs. Prices will be consistent with prices for similar medications in other states, in which medical cannabis is legal but recreational cannabis is not. Health insurance plans do not cover any of the cost. Both manufacturers have compassionate-care programs that will reduce the cost of medicine if patients meet certain income qualifications.

Will my personal information be protected?

Yes. The OMC does not share a patient's personal medical information with anyone except the patient's physicians and the distribution

centers. Protecting patient privacy is a key part of Minnesota's medical cannabis program.

Can I take cannabis medication wherever I want to?

No.

- Patients cannot take it in public.
- They cannot possess or take it on school grounds. A child who needs the medicine during school hours will not be able to receive it in the school nurse's office or anywhere else at school.
- Nursing homes, assisted living facilities and hospitals may have policies restricting medical cannabis use.
- Patients cannot possess or take their medicine at work, which is considered a public place. Their employer has the right to prohibit their use of medical cannabis during work hours.

What happens if I am in a motor vehicle accident or an accident at work?

Patients could be found liable if they are at fault and found to be impaired by cannabis medications. It is illegal to drive a motor vehicle or use heavy machinery while under the influence of cannabis medication.

Will I be exempt from state and federal marijuana laws if I'm on the cannabis registry?

Yes and no. Patients on the medical cannabis registry are exempt from prosecution under state law as long as they comply with the rules and requirements of the medical cannabis program. They are not exempt from prosecution under federal law; however, in other states the federal government so far has chosen not to prosecute medical cannabis users.

Do I have any protection against discrimination?

Yes.

- A landlord cannot refuse to rent to patients or take action against them solely because they are a registered medical cannabis user.
- A student cannot be denied enrollment in or expelled from a public or private school because they legally take cannabis medication.
- Patients cannot be denied employment because they are a registered medical cannabis user.
- Patients cannot be terminated from a job because they take a cannabis medication, unless they used, possessed or were impaired by medical cannabis while at the workplace during hours of employment.
- Patients who are in the state's medical cannabis program cannot be denied employment, terminated or penalized at a job because their drug test was positive for cannabis components or metabolites. If they are required to undergo periodic drug tests, they should present the form they received to their employer that proves they are registered with Minnesota's medical cannabis program.

Minnesota Medical Cannabis Program launches July 1, 2015

Minnesota's program **excludes smoking**
and **whole plant cannabis**

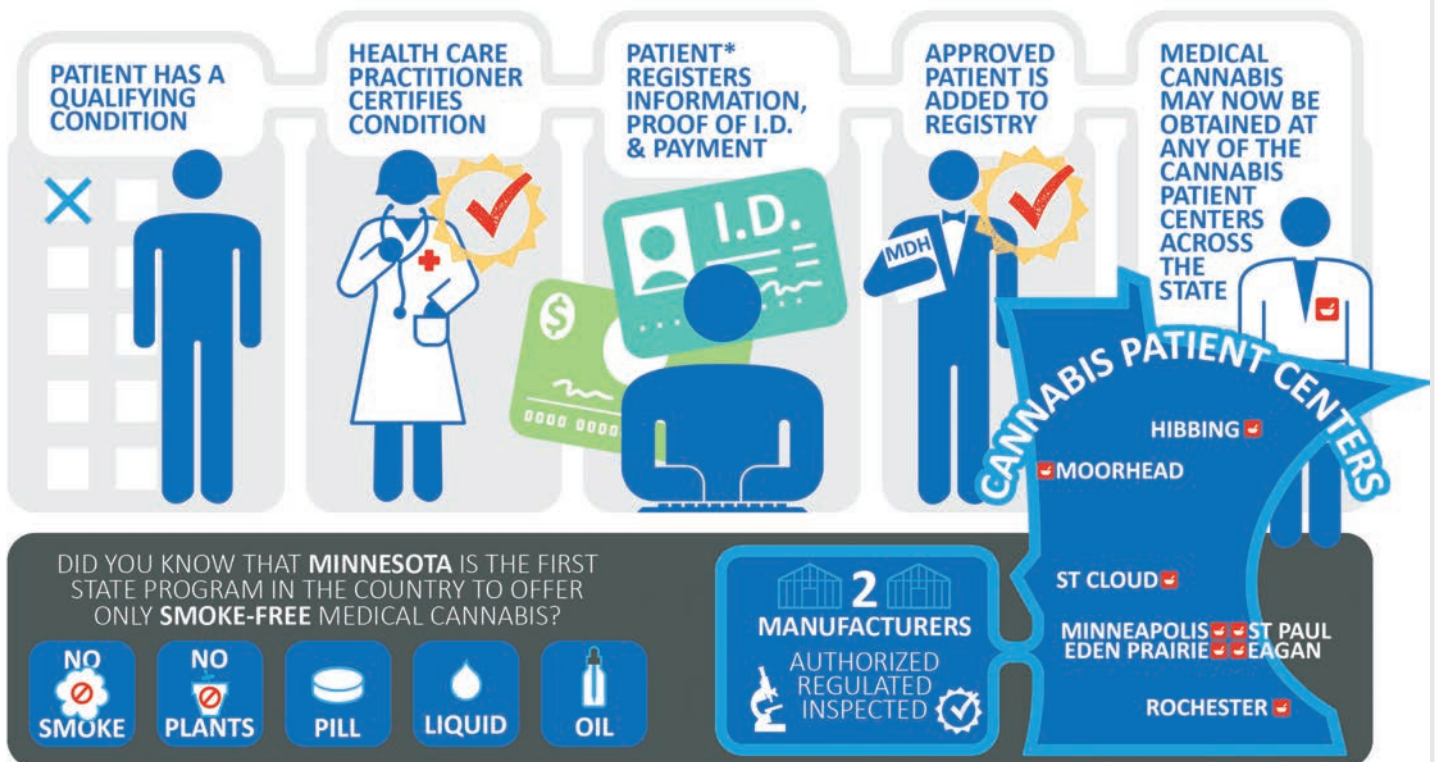
Physician participation in the program is **voluntary**

Patient certification begins **June 1, 2015**

Depth and quality of clinical trial evidence varies by condition; use by patients is admittedly experimental. The program offers a legal option to qualifying patients who could possibly benefit.

For more information on the program, go to
mn.gov/medicalcannabis

OVERVIEW OF MN MEDICAL CANNABIS PROGRAM



*Care-giver may represent a patient by applying and meeting conditions including a background check.