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MEDICAL CANNABIS SPECIAL REPORT

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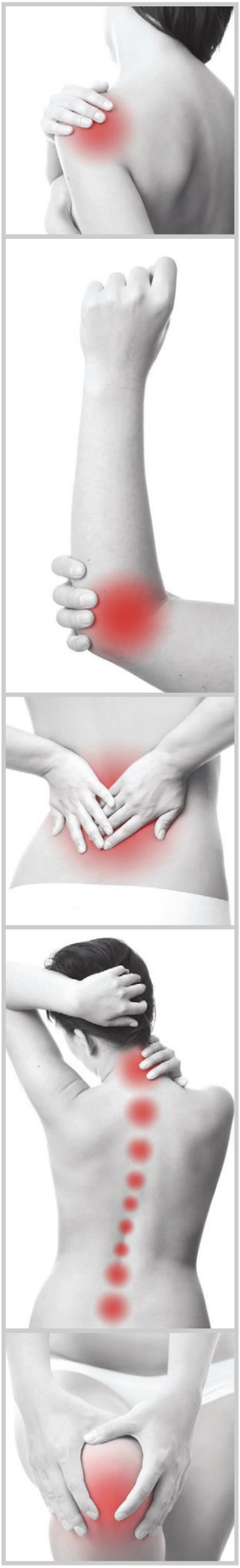

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Charles R. Meyer, MD, Editor in Chief

A year in review

After more than 50 years of widespread recreational use, we might have expected a rush of patients eager to try cannabis for therapeutic purposes.

One year ago, grass crept into the field of medicine in Minnesota. After a sometimes tempestuous battle at the Legislature, medical marijuana was approved for limited use in the state starting in July of last year. Since then, our state's physicians have been scratching their heads about which patients might benefit, how the drug is dispensed and whether they should go through the hoops to become a certified certifier for patients who may benefit from medical cannabis. In December, the addition of intractable pain as a certifiable indication led to further scratching to the point of bleeding.

Medical cannabis is a therapy chock full of curiosities. It is a drug that has entered the market by legislative fiat without the approving stamp of the FDA (it actually continues to be an illegal substance according to federal law). Physicians do not prescribe it but merely confirm that their patients have one of the diagnoses approved by the Legislature so that patients can go to a distribution site to get the appropriate dose. Few practicing physicians have much experience with the drug. Its use might normally be called "off-label," except that the Legislature and the Minnesota Commissioner of Health have declared what is "on-label." It is a strange beast in the pharmaceutical world.

Despite the peculiarities of the drug in medical practice, after more than 50 years of widespread recreational use, we might have expected a rush of patients eager to try cannabis for therapeutic purposes. But the first year's response has been underwhelming with relatively few "dispensing transactions" taking place. The high price likely is a deterrent, as it has been for those seeking marijuana for recreational use in Colorado. The fact that few physicians, nurse practitioners and physician assistants have stepped forward to become certifying practitioners may be another. And the availability of cheaper, "street" pot may have shrunk the number of patients seeking the medical version.

This supplement is a review of the first year of medical cannabis in Minnesota with statistics and stories about usage as well as the decision to add intractable pain to the indications. The conclusions from physicians and patients who have participated in this experiment are inconclusive. Certainly, no drug is 100 percent effective and medical cannabis is in its infancy.

So the jury is still out. Whether the therapeutic use of cannabis will flourish and it will become a valuable pharmaceutical remains to be seen. The grass needs watering, tending and, most of all, testing.

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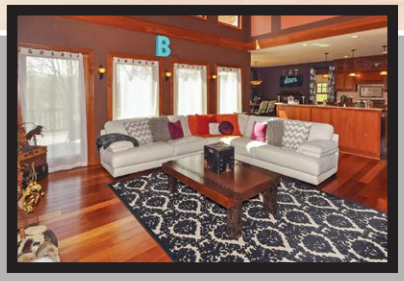

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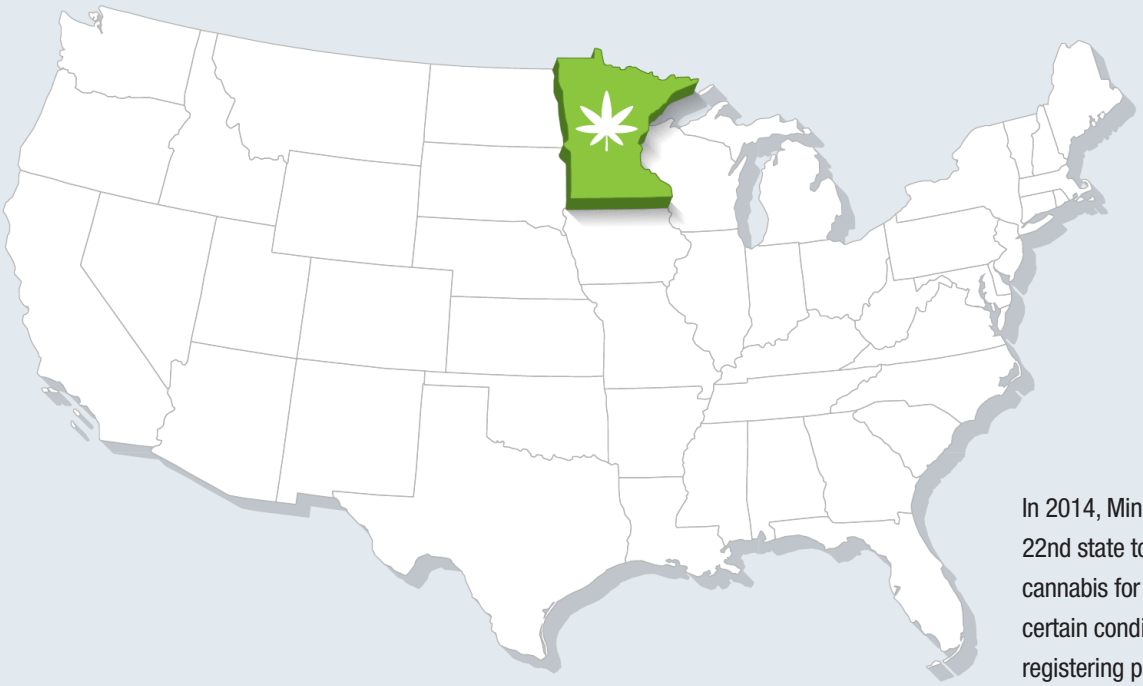

MINNESOTA *and* MEDICAL CANNABIS

In 2014, Minnesota became the 22nd state to legalize medical cannabis for use by patients with certain conditions. The state began registering patients for its program on June 1, 2015. The two state-approved manufacturers, LeafLine Labs and Minnesota Medical Solutions, began distributing medical cannabis to those patients on July 1 of that year. Here's a look at the program and who is participating in it as of May 9, 2016.

PLACES OF OPERATION

Medical cannabis manufacturing facilities

Cottage Grove (LeafLine Labs), Otsego (Minnesota Medical Solutions)

Location of distribution sites

Eagan, Minneapolis, Rochester

Location of distribution sites scheduled to open by July 1

St. Cloud, Bloomington, St. Paul, Hibbing, Moorhead

WHO'S PARTICIPATING

Health care practitioners

Approved for the program

546

Physicians	Advanced practice registered nurses	Physician assistants
454 (83.2%)	67 (12.3%)	25 (4.6%)

WHO'S PARTICIPATING

Patients

Approved for the program

1,337

By qualifying condition*

Severe and persistent muscle spasms, *including those characteristic of* **multiple sclerosis** 584 (43.7%)	**Cancer** 334 (25.0%)	**Seizures,** *including those characteristic of* **epilepsy** 292 (21.8%)
Crohn's disease 95 (7.1%)	**Terminal illness** 64 (4.8%)	**HIV or AIDS** 47 (3.5%)
Tourette syndrome 27 (2.0%)	**Glaucoma** 18 (1.3%)	**Amyotrophic lateral sclerosis (ALS)** 18 (1.3%)

*10% of all patients qualified for more than one condition

By age

Average age 43	**Younger than 18 years of age** 155	**Age 65 years and older** 148

By location

Live within the seven-county metro area 863 (64.5%)	**Live outside the seven-county metro area** 474 (35.5%)

WHO'S PARTICIPATING

Caregivers

Approved to pick up medical cannabis for a patient

159

Cost of enrollment

Cost to enroll in Minnesota's medical cannabis program
$200

Percentage of patients who pay a reduced enrollment fee
58%

April 2016 snapshot

Number of medical cannabis dispensing transactions
714

Number of medical cannabis products purchased
1,062

THE DECISION TO CERTIFY

Two physicians explain why they chose to certify patients for **MINNESOTA'S MEDICAL CANNABIS PROGRAM.**

In 2014, when Minnesota legalized medical cannabis for people with nine specific conditions, medical groups had to decide how they would handle the change in law. Would they leave it up to individual physicians and other providers to decide whether they wanted to certify patients? Would they decide as an entity whether or not to offer certification? Olmsted Medical Center is one organization that grappled with those questions and decided to accommodate patients who wanted to be certified.

Angala Borders-Robinson, DO

Kathryn Lombardo, MD

Of the approximately 200 physicians and other providers in the Rochester-based practice, a psychiatrist, a primary care clinician and a neurologist agreed to become certifiers. *Minnesota Medicine*'s Kim Kiser spoke with two of them—Olmsted Medical Center president and psychiatrist Kathryn Lombardo, MD, and neurologist Angala Borders-Robinson, DO—about their decision to certify patients and what they have learned from participating in the state's medical cannabis program.

What were your thoughts when the discussions about legalizing medical cannabis in Minnesota were taking place?

ABR: I came from Michigan, where cannabis has been legal for medical purposes for some time. When they started looking at legalization in Minnesota and the reasons for using it from a medicinal standpoint, I started doing research on marijuana so I could understand how it could be beneficial for patients, how it would work for them. Having a better understanding of cannabinoids and how they work, how we have our own cannabinoid system in our bodies, and how it would work for patients with different diagnoses made me more comfortable with the idea of certifying patients.

Had patients been asking you about medical cannabis?

KL: I did have patients approach me before it became available and I had a number who wanted to be certified. They included patients with muscle spasm.

ABR: I see a lot of MS patients, and one of the approved diagnoses is for spasticity associated with MS. Even now with intractable pain being approved, I've been getting a lot of patients coming in and wanting to know what I think. Is it something they want to consider?

Why did you think Olmsted Medical Center should participate in the program?

KL: I anticipated there might not be many physicians or other health care providers who would certify patients. In fact, initially patients had to search throughout the state to find someone to even have a conversation with about the use of medical cannabis. That's what led me to believe our organization should have at least one physician who could certify patients or at least be knowledgeable about the process.

How did you go about developing a plan to work with patients?

KL: Our clinical practice committee developed policy regarding medical cannabis. We wanted to make sure it was done appropriately within state law and that we were informing the patient of our limitations in terms of what a certifier does, which is confirming that a patient has one of the approved diagnoses for medical cannabis use.

We also wanted to take a more collaborative approach to certification. I wanted to make sure that if I wasn't the treating physician for a patient I certified for the program, that the clinician who was providing care would be informed.

How many patients have you certified for the program?

KL: Overall, the number is fairly low. The anticipation was that it would be higher. Of my patients, I had more who inquired about it than who went through the certification process. I would estimate only 10 percent of those I had conversations with went on to be certified.

ABR: I've certified 18 patients. Almost all have had spasticity. I had one patient that I certified for seizure disorder.

Have you had to turn any patients away? If so, why?

KL: Recently, a colleague referred a patient who had cancer. That patient wasn't a resident of Minnesota and didn't realize the program was limited to Minnesota residents.

ABR: I have turned a couple of people away, mainly because they were on another narcotic medication.

Why have so few patients chosen to get certified?

KL: Price became the issue. Once they discovered the expense, they realized it wasn't an option. It is $200 just to go through the registration process. The distributors have changed some of their prices over the last year, but it can still cost several hundred dollars a month. And it's not covered by insurance. Patients weren't always aware that it's an out-of-pocket expense.

ABR: Price has been a big issue. Some of my patients have been using it illegally. They purchase it on the street. When it first was legalized, it seemed like the cost was comparable to what they were purchasing illegally. I had patients saying they spent about $120 to $130 a month. That was OK with them. Then when the cost went up, it became too much for them. These patients said they actually prefer to get the medicinal form.

A lot of these patients have tried and failed other things. This is not a first-line therapy. It's nice when you find something that works; but if they can't afford it, it's frustrating.

Of those patients who did get certified, have they obtained and used medical cannabis?

ABR: Yes, I believe most of my patients have used it. The one patient with seizure disorder did not continue to use it because of the cost, so I put him back on anticonvulsive medication.

Of those who have used it, what sort of response have they had?

ABR: It's been effective for most of my patients. We have medications for spasticity, but a lot of times they come with side effects like sedation that can be pretty intolerable. I found that my patients who've been using cannabis don't get the sedation and they have relief of their spasticity. Overall, it seems to work well for them.

I think once you take the majority of the THC out of it and mainly use the cannabinoids, you really do alleviate a lot of the side effects that have been known to be associated with marijuana. My patients haven't complained of those side effects.

As physicians, what are the challenges of working with the program?

KL: As a health care provider, all we do is certify. That's very different from prescribing and taking responsibility for the response. It's the pharmacists working with the distributors who are the ones who determine the dose and the form of medical cannabis to use.

ABR: Unless you follow up with the patient in clinic, you don't really know what happens. You don't know if the pharmacist makes adjustments in the cannabis. You don't really know if they're coming every month to pick up refills or if they're coming two or three times a year.

That's one of the reasons I don't want to get into chronic pain management. I don't do a lot of chronic pain management with my patients anyway. But I would hesitate to do it because there's no way to really follow them. If patients don't come back or keep their follow-up appointments, they're certified for an entire year and there's nothing we can do about it. But if they're on a narcotic, and they don't keep a follow-up appointment and allow me to know what's going on with them, I won't continue to prescribe it.

What are you anticipating for your practice with the addition of intractable pain as a qualifying condition?

KL: I believe it's going to create increased interest for patients. I think there is some anticipation that the opioid crisis will contribute to patients and possibly clinicians considering this treatment option. Is medical cannabis a better alternative? There have been discussions and articles about it. I have many patients in my practice who have intractable pain. But, again, I think the price point will be the barrier for them.

Has your thinking about medical cannabis changed in the last two years?

ABR: I'm definitely more comfortable with it than I anticipated I would be when I started to certify patients. I think it's just another form of treatment. It's another option. I like the idea that there's not the cognitive impact you get with the THC part of it, so patents are clear-headed.

KL: I remain concerned about the consequences of cannabis use especially among adolescents and the potential side effects regarding chemical dependency. I'm waiting for the evidence the state's Office of Medical Cannabis is gathering to demonstrate potential benefits. **MM**

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The Intractable Pain conundrum

Medical cannabis will soon be available for a new set of patients–those with intractable pain. A look at the controversial decision to expand eligibility for the state's program and what it could mean.

BY HOWARD BELL

Last December, Minnesota Commissioner of Health Edward Ehlinger, MD, MSPH, added intractable pain to the list of qualifying conditions for Minnesota's medical cannabis program. Starting July 1, physicians, physician assistants and advanced practice nurses can certify patients with "pain whose cause cannot be removed, and according to generally accepted medical practice, the full range of pain management modalities appropri-

ate for this patient has been used without adequate result or with intolerable side effects." Those patients will be able to purchase medical cannabis starting August 1.

Adding intractable pain is expected to increase the number of patients enrolled in Minnesota's medical cannabis program, although no one knows by how much. In other states in which medical cannabis is legal, chronic pain is often the most common reason for its use.

Unified uncertainty

The decision to add intractable pain as a qualifying condition came after lengthy study and debate. The Minnesota Department of Health's Office of Medical Cannabis (OMC) held 13 public meetings around the state last fall and solicited comments online. It heard from about 500 Minnesotans, more than 90 percent of whom supported the addition of intractable pain.

The OMC also asked for input from an eight-member advisory panel of physicians, physician assistants, pain psychologists, nurses and pharmacists. The panel, which met four times, reviewed a large number of published papers and heard expert opinion on the safety and effectiveness of cannabis for pain, risk for addiction and other adverse effects. They analyzed the research and clinical evidence with help from the University of Minnesota's Evidence-Based Practice Center. Initially, a majority of the eight panel members supported adding intractable pain. But after the panel's fourth meeting, sentiment changed, and the majority recommended not adding it. The primary reason cited: the lack of good studies.

Advisory panel member Erin Krebs, MD, MPH, an associate professor of medicine at the University of Minnesota who studies chronic pain management, says there just wasn't strong enough evidence to support it. "Most of what's out there is so weak," she says. "Studies are too small, too short and we found lots of reporting bias where results showing no benefit were left out and only results showing benefits were reported." (The panel found there was "low-strength" evidence that cannabis

Certifying pain patients

Minnesota's medical cannabis program will work the same way for intractable pain as it does for other eligible conditions. Physicians, physician assistants and advanced practice nurses can create an Office of Medical Cannabis (OMC) account at any time and certify patients for intractable pain starting July 1. Creating an account takes just a few minutes; certifying a patient for intractable pain will take another five minutes, according to Tom Arneson, MD, MPH, the OMC's research director.

Certifying patients for intractable pain, as opposed to other conditions, requires three additional steps:

1. Stating that the patient has intractable pain.
2. Identifying the primary medical condition causing the pain (chosen from a drop-down menu of 30-plus conditions).
3. Providing the date and score of the most recent pain severity assessment so that the effect of the cannabis on the patient's pain can be tracked over time. (Practitioners can select from six commonly-used pain scales or specify one that isn't listed.)

The OMC recommends using the **PEG** pain scale, which uses a score of zero to 10 to measure **P**ain on average over the past week, how much pain interfered with one's **E**njoyment of life, and how much it interfered with the patient's **G**eneral activity.

The certifying clinician gives the patient a list of their clinical problems and their current medications. The patient then takes those to the dispensing pharmacist at the medical cannabis distribution center. The pharmacist reviews the patient's health history and uses that information to suggest a dosage and formulation. The pharmacist also is responsible for educating the patient about the medication, monitoring its effects and reporting adverse reactions.

Pharmacists must give patients a hard copy summary of information about the drug product and dose. Patients are encouraged to share this with their clinician.

Certifying clinicians can see this summary any time by logging into their OMC account, where they also can see which cannabis medicine the patient purchased and when. (This feature became available last fall.) Arneson says the OMC encourages clinicians to call pharmacists at the distribution centers with any questions or concerns.

Minnesota's medical cannabis law requires that the certifying clinician continue treating the patient's intractable pain and report outcomes and side effects to the OMC as long as the patient is taking cannabis for intractable pain.

Six months after a patient's first cannabis purchase, the certifying clinician must submit to the OMC a brief survey (they must re-submit the survey every six months thereafter). The survey is the same as the one used to document benefits and harms for other eligible conditions. However, these two questions have been added for patients with intractable pain:

1. Over the past six months has this patient's use of medical cannabis assisted in reducing dosage or eliminating other medications used for pain? If yes, specify the change(s) in medication(s).
2. What is the pain rating scale, score and date of the most recent assessment?—H.B.

relieves MS-related pain and peripheral neuropathic pain.)

"We could find only 10 or 12 legitimate studies, so instead of saying approve it, we said study it," says panel member Daniel Truax, PA-C, who treats chronic pain at the Center for Pain Management in Sartell.

After reviewing the panel's discussions and recommendations, the public testimony and the literature, however, the commissioner chose to add intractable pain to the list of qualifying conditions. His reasoning: the strong public support for doing so, a clear need for more chronic pain treatments, and the significant anecdotal and limited scientific evidence that medical cannabis helps some people with some types of chronic pain. "Clinical trials show a thread of effectiveness," says OMC Research Director Tom Arneson, MD, MPH.


Erin Krebs, MD, MPH


Daniel Truax, PA-C


Tom Arneson, MD, MPH


Arthur Wineman, MD


Brian Erickson, MD

The commissioner also cited the Minnesota medical cannabis program's rigor and conservative approach as other reasons for approving the addition of intractable pain. Minnesota has one of the most restrictive programs in the country. Its medical cannabis products are available only in pill, liquid and vapor forms—no edibles or whole-plant medicines that can be smoked. The manufacturing facilities and distribution centers are physician-run. Standardized testing by manufacturers and outside labs goes far beyond what most states do to assure consistent purity and dose. A "black box" warning sheet is given to all patients, cautioning them against using medical cannabis if they have a family history of psychosis or are pregnant or breast-feeding, or allowing its use by children or adolescents. In addition, the OMC's data collection and analysis of effectiveness and adverse effects may be the most rigorous in the country.

Although he voted against adding intractable pain as a qualifying condition, advisory panel member Arthur Wineman, MD, says he's comfortable with the commissioner's decision. Wineman chairs HealthPartners family medicine department and is regional medical director for HealthPartners Medical Group, where he helps design protocols for managing chronic pain. "It was a decision based less on scientific evidence and more on compassion, acknowledging that medical cannabis may help some people," he says,

Less need for opioids?

One hope is that allowing medical cannabis to be used for intractable pain may help curb the problem of prescription opioid abuse in Minnesota. That possibility has led some to take a more open view.

Hennepin County Medical Center addiction medicine expert Charles Reznikoff, MD, who served on the Department of Health's medical cannabis advisory committee in 2014, says he's heard hopeful stories from colleagues. "An oncologist who wasn't a believer told me he's becoming a believer because some of his patients taking cannabis have less pain, are more engaged with life and have lowered their opioid use."

A study published in the October 2014 *JAMA Internal Medicine* found that states with medical cannabis laws had a 25 percent lower annual opioid overdose death rate, on average, compared with states that haven't legalized medical cannabis. Another study published in the February 2016 *Clinical Journal of Pain* showed that among 274 chronic pain patients, medical cannabis lowered pain severity scores by 10 percent and raised ability to function scores by 18 percent. Opioid consumption at follow-up decreased by 44 percent. "We're guardedly hopeful that medical cannabis will decrease opioid use in Minnesota," Arneson says. "We're hearing from more clinicians who tell us cannabis has helped them get patients off of opioids or reduce their use."

More eligible conditions possible

More medical conditions may be added to the list of those eligible for medical cannabis use. During June and July, groups and individuals can petition for the addition of other conditions by completing a form on the Office of Medical Cannabis website. A new advisory panel will be appointed to shape arguments for or against adding each condition. The Commissioner of Health will review those arguments and announce his decision by December 1, 2016. Tom Arneson, MD, MPH, research director for the OMC, says they have already received calls from patients wanting other conditions to be added. These include PTSD, ulcerative colitis and rheumatoid arthritis. Patients with a newly eligible condition would be certified for medical cannabis starting July 1, 2017, and could begin purchasing medicine starting August 1, 2017.

Brian Erickson, MD, has seen firsthand how it can help alleviate pain and reduce the need for opioids. The psychiatrist and medical director for HealthEast's pain clinic in St. Paul treated more than 70 pain patients with medical cannabis when he practiced at the University of Vermont's pain clinic.

Vermont has used cannabis tinctures that can be vaporized or placed under the tongue for pain since 2011. "It was very helpful for patients with peripheral neuropathy, back pain and headaches, who weren't responding to other treatments," he says. "About 75 percent of my patients were able to reduce their opioid use and about 25 percent were able to get off of them entirely. I had a patient who was on 80 mg a day of oxycodone and another who was on 100 mg a day of methadone who got off opioids entirely."

That's a "no brainer" benefit of using cannabis for intractable or chronic pain, says Kyle Kingsley, MD, founder and CEO of Otsego-based Minnesota Medical Solutions, one of Minnesota's two medical cannabis manufacturers. (Eagan-based LeafLine Labs is the other.)

In April, Minnesota Medical Solutions' parent company, Vireo Health, released a protocol for physicians wishing to help patients replace opioids with medical cannabis. "Opioids kill 16,000 people in the U.S. each year, more than motor vehicle accidents. Cannabis doesn't do that," Kingsley says.

Nor is cannabis as addictive, according to Reznikoff. "Most marijuana addiction is relatively harmless and remits on its own," he says. "Opioids are far more addictive, far more harmful, and the addiction does not remit on its own." That said, Reznikoff cautions not to think of cannabis as a fix for the opioid crisis. "It's a false choice," he says. "If you change from opioids to cannabis, you're just changing to a new, still unproven therapeutic for a complex problem." Patients could end up using both

New protocol for replacing opioids with medical cannabis

Vireo Health of Minnesota, the parent company of Minnesota Medical Solutions, one of the state's two medical cannabis manufacturers, has created a protocol to help patients replace opioids with medical cannabis. The protocol called Flexible Reduction and Expedited Discontinuation of Opioid Medications (FREDOM) includes guidance for clinicians on medical cannabis dosing and formulation, "gentle tapering" from opioids, and monitoring for side-effects and scoring patients' pain.

FREDOM uses a "slowed-down" version of the opiate discontinuation methods used by the Department of Veterans Affairs.

"The FREDOM protocol is for patients who, along with their health care team, have decided that opioid reduction would increase their quality of life," says Kyle Kingsley, MD, founder and CEO of Vireo Health and Minnesota Medical Solutions. "We're providing a framework for physicians to interact with patients to decrease opioid use while using medical cannabis to support pain management." A March 2016 study in the *Journal of Pain* showed that chronic pain patients receiving medical cannabis from state-approved dispensaries were able to reduce their total opioid use by 64 percent.

Despite this promising finding, addiction experts remain skeptical. Charles Reznikoff, MD, an addiction medicine specialist with Hennepin County Medical Center, says he's concerned a protocol for weaning patients from opioids would be mistaken for treatment of addiction. "Medical cannabis substitution for opioid addicts would likely expose those patients to serious risk. Opioid addicts should be referred to evidence-based treatment programs."

Some patients who have pain caused by cancer or other eligible conditions are already using the protocol. No outcomes data are available yet. Kingsley expects a significant increase in use of the protocol when intractable pain patients can begin purchasing medical cannabis.

The FREDOM protocol is available at http://vireohealth.com/research. It is considered a working draft, and Kingsley wants feedback from participating clinicians. Clinicians interested in the protocol can contact Vireo Health at 612-999-1606 or provider@vireohealth.com.—H.B.

cannabis and opioids, which Reznikoff says "would be the worst-case scenario."

Clinician concerns, misconceptions

Many physicians admit they just aren't ready to participate in the medical cannabis program—for intractable pain or any other eligible condition. Reznikoff surveyed 262 physicians at four health systems in October 2015 and found 74 percent of those who responded said they didn't have the knowledge to discuss the risks and benefits of medical cannabis with a patient seeking certification for a qualifying condition. Fifty-three percent said they didn't think intractable pain should be a qualifying condition. Eighty-one percent said even if they believed medical cannabis was appropriate for a patient, they wouldn't have the time or know-how to go about certifying patients and managing their response to treatment. "The results show that some clinicians feel uncomfortable with the whole program," Reznikoff says. "It places an undesired burden on them and forces them to practice medicine outside of evidence-based norms and rely on unconventional production, regulation and dispensing of medication."


Charles Reznikoff, MD

Some of their reluctance stems from misunderstandings about how the cannabis program works. For example, some still think whole-plant products are used. Some think pain patients must get a second opinion from a pain specialist. "Certification for pain doesn't require a second, concurring opinion," Arneson says.

Those who have certified patients for the program expressed concern over the high cost of medical cannabis, which has prevented some eligible patients from buying it. Kingsley anticipates prices will go down with the addition of intractable pain. "It may double the number of patients certified to use medical cannabis," he predicts, explaining that economies of scale will allow manufacturers to produce it at a lower cost.

Regardless of cost, some clinicians are concerned that using cannabis for pain will create another opioid-like epidemic of addiction and abuse, despite evidence that this hasn't happened in other states. "Clinicians are still reeling from the opioid crisis and now they want us to provide access to a drug the federal government doesn't even consider legal," Truax says. That said, he acknowledges that "cannabis is safer than opioids and probably helpful to some patients."

That's because cannabinoids attach to a completely different set of receptors than opioids. There are almost no cannabinoid receptors in the respiratory center of the brain, making medical cannabis far less likely than opioids to cause respiratory suppression.

As for giving patients a drug that makes them "high," Kingsley points out that side effect is reduced or eliminated when THC is properly combined with another cannabinoid, cannabidiol (CBD). "We don't make any pure THC products," he says. Minnesota Medical Solutions uses a variety of THC/CBD ratios in its products. Kingsley says most patients start at a 50/50 ratio.


Kyle Kingsley, MD

Some clinicians fear an onslaught of patients demanding medical cannabis once those with intractable pain can become certified. They're also concerned about having to turn patients away, if they feel a patient doesn't qualify. Part of the reason for that concern is the difficulty of diagnosing pain. "It's the only eligible condition that can't be objectively diagnosed," Reznikoff says. Yet Arneson points out clinicians face that same diagnostic challenge when pain patients ask about opioids. "We rely on a clinician's professional judgement to decide whether a patient has intractable pain, what treatments to try first and for how long, before resorting to cannabis," he says.

More education needed

The OMC's website (www.health.state.mn.us/topics/cannabis) provides an abundance of information and resources, and HealthPartners and other health systems are doing their own clinician education. Yet clearly, physicians have questions about medical cannabis and Minnesota's program. "Most clinicians get their education through CME, and CME is about more mainstream elements of medicine," Reznikoff says. "None of the specialty medical societies are jumping on board to educate their members about medical cannabis. There needs to be more effort to inform doctors about this."

Kingsley says he believes that in time and as evidence mounts, many of the concerns about medical cannabis will fade. (The OMC is required by law to study whether patients in the program are experiencing benefits or harms. See p. 18 to read about their preliminary findings.) "We realize that only a small number of clinicians will ever register to certify patients, based on numbers from other states that have had programs for longer," he says. "And we realize some Minnesota clinicians will never be comfortable until medical cannabis goes through the entire FDA vetting process." But in the meantime, a number of patients are already benefitting, and the number of clinicians and patients signing up for the state's program grows every week. "In time," Kingsley predicts, "medical cannabis will be a standard option for intractable pain management." **MM**

Howard Bell is a medical writer and frequent contributor to *Minnesota Medicine*.

Early Survey Results from the Minnesota Medical Cannabis Program

BY DEEPA MCGRIFF, MPH, SUSAN ANDERSON, PHD, AND TOM ARNESON, MD, MPH

As part of its legislative mandate, the Minnesota Department of Health's Office of Medical Cannabis (OMC) is required to study and report on the state's medical cannabis program. This article describes preliminary findings from the OMC's research about who is using the program and whether patients and their certifying health care practitioners are noticing benefits and harms.

In May 2014, Minnesota became the 22nd state to create a medical cannabis program. Distribution of extracted cannabis products in liquid or oil form to qualified, enrolled patients began July 1, 2015. Minnesota's medical cannabis program is distinct from those in other states, as the Department of Health's Office of Medical Cannabis (OMC) is required by law to study and learn from the experience of participants. Its online registry, which integrates information from patients, certifying health care practitioners and manufacturers, is the mechanism used to capture data.

In Minnesota, medical cannabis treatment falls outside the traditional medical model. Physicians, physician assistants and advanced practice registered nurses certify patients as having conditions that by law qualify them for the program (Table 1). Those clinicians do not have a direct role in determining the dose or form of cannabis to be used. That is handled by pharmacists at the distribution centers (certifying clinicians can communicate their recommendation to the patient and the distribution center pharmacist, however).

In order to participate in the program, a patient is expected to have an ongoing relationship with their certifying clinician. Thus, our research seeks to integrate clinicians' and patients' observations in an attempt to understand the patient experience. This article describes what we have learned thus far about who is using the program, and what patients and their certifying health care practitioners are seeing in terms of benefits and harms. At this point, the numbers of patients and health care providers reporting are still small, and the findings must be considered preliminary.

TABLE 1

Qualifying conditions for Minnesota's medical cannabis program

Cancer (if disease or treatment causes severe/chronic pain, nausea or severe vomiting, cachexia or severe wasting)

Glaucoma

HIV/AIDS

Tourette syndrome

Amyotrophic lateral sclerosis (ALS)

Seizures (including those characteristic of epilepsy)

Severe and persistent muscle spasms (including those characteristic of multiple sclerosis)

Crohn's disease

Terminal illness (with a probable life expectancy of less than one year or if the illness or treatment causes severe/chronic pain, nausea or severe vomiting, cachexia or severe wasting)

Survey Tools and Process

We developed a patient experience survey to capture information about the benefits and harms of program participation. A parallel survey developed for certifying health care practitioners (HCPs) captures similar information from the clinician's perspective.

Both the patient and the HCP surveys include multiple choice and open-ended questions. They are administered through an online platform and are accessible through the patient or practitioner registry page and through emails that include links to them. The surveys are released three months after the patient's first medical cannabis purchase (starting July 1, patients will receive surveys at three months and six months after their first purchase, then approximately every six months thereafter for the duration of their participation in the program). Health care practitioners receive a survey six months after the patient's first medical cannabis purchase and approximately every six months thereafter, as long as they remain the certifying provider for that patient. Each online survey remains active for 45 days; if patients and practitioners do not complete it within two weeks, a paper version is mailed to them. To maximize response rates, the survey

can be submitted even if it is incomplete. (To see a copy of the survey, go to the "Print Materials and Forms" section of the Office of Medical Cannabis website: www.health.state.mn.us/topics/cannabis/index.html.)

Response Rates and Findings

A total of 435 patients made their first medical cannabis purchase during the first three months of the program (July 1 to September 30, 2015). Those patients were certified by 345 clinicians between June 1 and September 28, 2015. Of the 435 patients, 241 (55%) completed the survey. Of the 345 HCPs who certified the 435 patients, 94 (27.2%) completed surveys for 169 (39%) patients. Since enrollment in the program began, 29 (7%) of the 435 patients are known to have passed away; we included those patients in our report, as in some cases their caregivers or relatives and HCPs completed surveys. Patient demographics are shown in Tables 2, 3 and 4.

Patient response rate did not vary significantly by age group (Table 2), with the lowest response rate among patients 65 years of age and older. The response rate among HCPs was generally higher for younger patients. Distribution across qualifying medical conditions varied widely. Patient and HCP response rates tended to be lower for ALS and terminal illnesses (Table 3). Patients in the program are predominantly white (84.5%) and male (61.3%); we found no significant variation in response rates by race (Table 4).

Of the 435 patients, both a patient survey and HCP survey were completed for 98 (22.5%); neither survey was completed for 96 (22.1%).

Perception of Benefits from Medical Cannabis

Both the patient and HCP surveys asked respondents to rate the benefits experienced by the patient from medical cannabis on a scale of 1 (no benefit associated with treatment) to 7 (a great deal of benefit associated with treatment). For both patients and HCPs, perception of benefit was quite high (Figure); 209 patients (87.8%) and 97 HCPs (68.3%) indicated

TABLE 2

Patient and health care practitioner responses by age group

PATIENTS' AGE (YEARS)	NUMBER OF PATIENTS	PATIENT RESPONSES (RESPONSE RATE)	HCP RESPONSES (RESPONSE RATE PER PATIENTS IN AGE CATEGORY)
0-4	12	8 (67%)	7 (58%)
5-17	61	34 (56%)	29 (48%)
18-24	24	15 (63%)	13 (54%)
25-35	69	35 (51%)	22 (32%)
36-49	103	60 (58%)	39 (38%)
50-64	123	70 (57%)	41 (33%)
65+	43	19 (44%)	18 (42%)

TABLE 3

Patient and health care practitioner responses by qualifying medical condition*

QUALIFYING MEDICAL CONDITION	NUMBER OF PATIENTS	PATIENT RESPONSES (RESPONSE RATE)	HCP RESPONSES (RESPONSE RATE PER PATIENTS WITH CONDITION)
Glaucoma	6	4 (67%)	2 (33%)
HIV or AIDS	19	12 (63%)	11 (58%)
Tourette syndrome	8	6 (75%)	4 (50%)
ALS	9	3 (33%)	3 (33%)
Seizures	112	76 (68%)	45 (40%)
Muscle spasm	157	85 (54%)	61 (39%)
Crohn's disease	30	14 (47%)	13 (43%)
Cancer	103	44 (43%)	36 (35%)
Terminal illness	25	12 (48%)	6 (24%)

*Thirty-five patients are certified for multiple qualifying conditions and are represented more than once.

TABLE 4

Patient and health care practitioner responses by race*

RACE	NUMBER OF PATIENTS	PATIENT RESPONSES (RESPONSE RATE)	HCP RESPONSES (RESPONSE RATE PER PATIENTS IN EACH GROUP)
American Indian	3	1 (33%)	2 (67%)
Asian	8	3 (38%)	3 (38%)
Black	18	6 (33%)	6 (33%)
Hawaiian	0	0 (0%)	0 (0%)
White	368	216 (59%)	146 (40%)
Other	5	3 (60%)	3 (60%)
2+ Races	13	4 (31%)	4 (31%)
Unknown	24	8 (33%)	5 (21%)

*Hispanic ethnicity was captured as a separate question from race.

the patient experienced at least some benefit (score of 4 or higher) from medical cannabis.

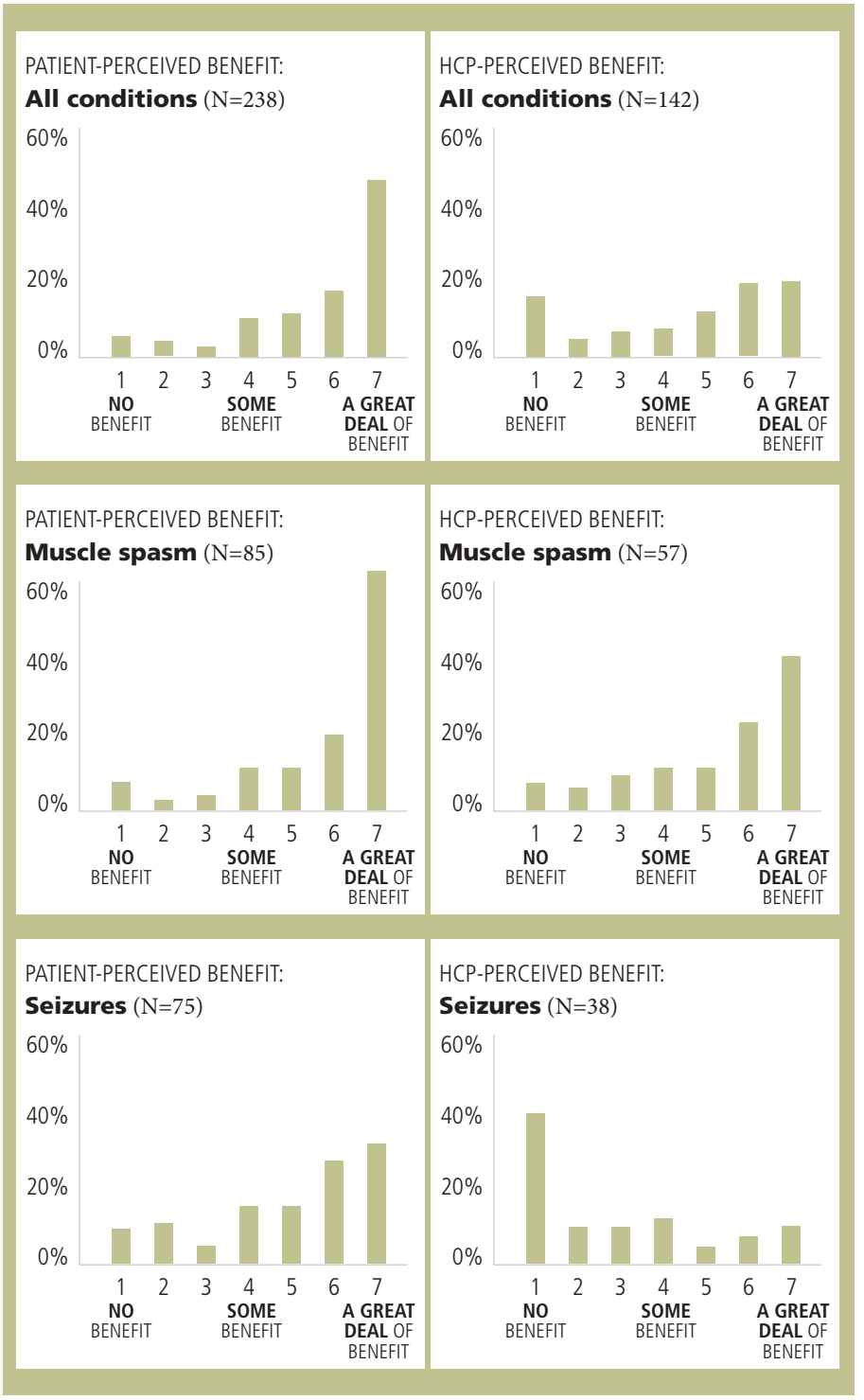
Notably, both patient and HCP scores varied by condition. HCPs reported that patients certified for muscle spasm seemed to have experienced a greater degree of benefit than the overall patient population. Patients certified for seizures reported experiencing less benefit than the overall patient population. Of the 38 HCPs who certified patients with seizures, only 36.8% reported at least some benefit for those patients.

HCP reports of benefit were generally more conservative than patient reports. We also looked at benefit scores for patients for which both the patient and HCP surveys were completed. Of the 78 patient-HCP pairs that provided benefit scale data, 3 (4%) agreed that there was no or little benefit to medical cannabis treatment (score of 1 or 2); 11 (14%) agreed that there was mild or moderate benefit (score of 3 to 5) and 35 (45%) agreed that there was significant benefit (score of 6 or 7).

Both patients and HCPs were asked to describe the most significant benefit to the patient. One hundred forty-four (59.8%) of the 241 patient surveys had listed improvement in symptoms related to qualifying medical conditions as the most significant benefit (Table 5). An additional 38 (15.8%) described indirect benefits such as improved sleep or reduced anxiety as the most significant benefit. Five patients (3%) reported access to legal and/or safe cannabis as the primary benefit. Of the 169 surveys HCPs completed, 80 (47.3%) listed improvement in symptoms as the most significant benefit for patients and 12 (7.1%) described indirect benefits as being the most significant benefit.

FIGURE

Distribution of reported benefit scores from patients and health care practitioners



Perception of Harms from Medical Cannabis

Patients and HCPs who responded to the survey also had the opportunity to rate harm from medical cannabis treatment on a scale of 1 (no harm) to 7 (a great deal of harm) and to describe the most significant harm as a result of medical cannabis treatment. To address the issue of medication cost separately, we asked patients to rate the cost of medical cannabis on a scale of 1 to 7 with 1 being "very affordable" and 7 being "very prohibitive." Many patients (177; 73%) reported that medical cannabis was unaffordable (score of 5 to 7). Despite our intention to have respondents exclude cost from their reporting on harm, 18 (7.5%) patients and 17 (10%) HCPs reported cost as the most significant harm. Another common response was distance to or inconvenience of visiting a cannabis distribution center (six patients; 2.5%).

TABLE 5

Summary of most significant benefits experienced by patients, as reported by patients and health care practitioners

	PATIENT REPORTS (% OF 241 COMPLETED SURVEYS)	HCP REPORTS (% OF 169 COMPLETED SURVEYS)
Direct benefits	144 (59.8%)	80 (47.3%)
Reduced muscle spasms	47 (19.5%)	16 (9.5%)
Reduced pain	32 (13.3%)	25 (14.8%)
Fewer/less severe seizures	28 (11.6%)	15 (8.9%)
Reduced symptoms relating to nausea, vomiting and cachexia	27 (11.2%)	23 (13.6%)
Reduced symptoms relating to Tourette syndrome	4 (1.7%)	1 (0.6%)
Reduced symptoms relating to Crohn's disease	4 (1.7%)	0 (0%)
Reduced symptoms relating to glaucoma	2 (0.8%)	0 (0%)
Indirect benefits	38 (15.8%)	12 (7.1%)
Improved quality of life	8 (3.3%)	4 (2.4%)
Improved sleep	11 (4.6%)	2 (1.2%)
Improved alertness/cognitive functioning	10 (4.1%)	0 (0%)
Improved mobility/general functioning	4 (1.7%)	1 (0.6%)
Improved comfort	3 (1.2%)	1 (0.6%)
Reduced anxiety	2 (0.8%)	4 (2.4%)

TABLE 6

Summary of most significant harms experienced by patients, as reported by patients and health care practitioners

HARMS	PATIENT REPORTS (% OF 241 COMPLETED SURVEYS)	HCP REPORTS (% OF 169 COMPLETED SURVEYS)
Physical side effects	39 (16%)	13 (8%)
Mental side effects	8 (3%)	14 (8%)
Access issues (cost/access to distribution center)	24 (10%)	17 (10%)

Forty-seven of the 241 patients who responded (20%) reported physical or mental harms associated with medical cannabis use (Table 6). Four reported an increase in seizures. Others described harms that mirrored the side effects reported in clinical trials of medical cannabis.[1,2] For those who experienced the highest levels of harm, the physical or mental effects they reported were as follows: hives (score: 7; n=1); stomach pains, increase in seizures, burning in mouth, dizziness, sedation and high (score: 6; n=5); lightheadedness, paranoia, sleepiness (score: 5; n=3). Another 24 (10%) reported a variety of other issues, including desire for different types of products (n=3); stigma or negative reactions from family or health care providers (n=6); wishing the cannabis were more effective (n=5); and experiencing other nonclinical effects (n=10).

Twenty-seven (16%) of the 169 HCPs who responded reported physical or mental harms resulting from medical cannabis treatment in patients; as with the patient reports, the harms generally mirrored side effects described in clinical trials. Two exceptions were a report of worsening symptoms of Parkinson's disease (with reported harm score of 4) and a report of some seizure types worsening (with a reported harm score of 5). The physical or mental effects associated with the highest levels of harm were abdominal discomfort (score: 7; n=1); sedation (score: 6; n=1); constipation and lethargy with worsened seizures and "too strong for patient" (score: 5; n=2). Another five HCP surveys indicated other issues, including lack of benefit (n=3).

Drug Interactions and Other Clinical Observations

The HCP survey includes space for practitioners to share insights about a patient's medical cannabis treatment. They used this space to report observations on clinical issues ranging from lack of efficacy (n=4) to difficulties in the patient obtaining other pain medications because of their medical cannabis use (n=2). Twelve stated that the patient reduced their pain medication dosage as a result of their medical cannabis use; six specifically mentioned decreased opioid use; another three indicated reduction of nonpain medications.

Other Feedback from Health Care Practitioners

The HCP survey also solicited feedback on the state's medical cannabis program. Some HCPs expressed a desire to see the program expanded to include new conditions and/or accommodate the addition of intractable pain (n=13) and to see published research and/or statistics on the program's patient population (n=2). Additionally, 18 respondents indicated concerns over the medication's cost.

Many HCPs also noted that they are seeking an in-depth understanding of their patient's medical cannabis treatment. Thirteen HCPs requested formulation and dosing information for their patients,

with some requesting detailed notes from the manufacturers' pharmacists. (Note: Certifying HCPs can see medical cannabis purchases made by their patients, along with their symptom score and side effect information; this feature became available after the program's launch.)

Learning from Early Experience

One of our goals was to keep the surveys short. As we reviewed responses, we realized that the surveys can be improved. We found some questions provided less granular information than desired and that the open-ended format of many questions required adjudication of each response. As a result, when the registry is updated to prepare for the addition of intractable pain as a qualifying condition, some survey questions will be eliminated and others will be consolidated. This should reduce the burden on HCPs.

The early results show that for many patients and HCPs, their experience with medical cannabis treatment and with the program itself are not easily separated. Complaints about the high cost of medical cannabis frequently appeared in both patient and HCP responses. Inability to find a certifying practitioner and having to travel long distances to a cannabis distribution center also were mentioned. Having learned from early results, we plan to revise the survey to more effectively separate responses related to the program from those related to the health consequences.

Future Directions

We plan to release a comprehensive report on the state's first-year experience in late 2016. This will include patient and HCP survey results along with information about patient characteristics, patient symptoms and side effects, medical cannabis product use, results from the SF-12 quality-of-life assessment at baseline and at three and 12 months after program initiation, medical history and other medication use. After reviewing the findings, we may conduct further studies of populations with specific diseases and their experiences with medical cannabis; those studies may include medical record data. A limitation of our current effort is that it relies on patient reports and clinician observations; however, those insights are invaluable for potential patients and for clinicians who are already caring for patients in the program and working with those who are interested in trying this treatment. **MM**

Deepa McGriff, Susan Anderson and Tom Arneson are with the Minnesota Department of Health's Office of Medical Cannabis.

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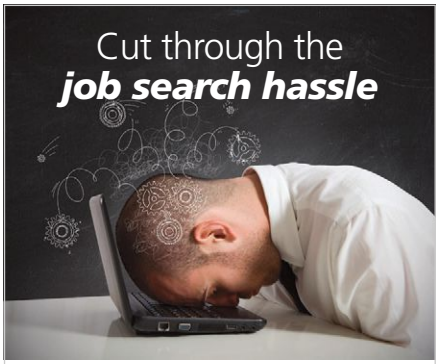

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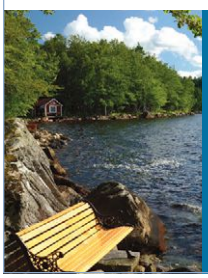

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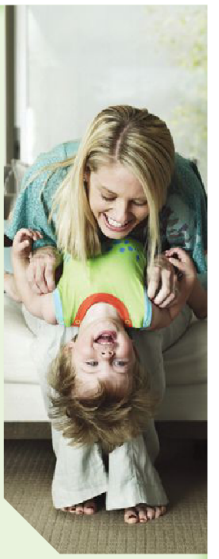

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(also known as Zubin Damania, MD) LAS VEGAS-BASED PHYSICIAN WHO MIXES MEDICINE, MUSIC AND HILARIOUS VIDEOS TO EDUCATE AND ENTERTAIN. LIVE PERFORMANCE FRIDAY NIGHT!

DAMON TWEEDY, MD

NY TIMES BESTSELLING AUTHOR OF *"BLACK MAN IN A WHITE COAT"* AND PROVOCATIVE PRESENTER ON HEALTH CARE DISPARITIES.

BREAKOUT SESSIONS ON:

- Medical Innovation
- Resiliency
- Health Care Disparities

ADDITIONAL HIGHLIGHTS:

- CME credits available
- Student/resident poster symposium
- Dozens of health care exhibitors

SAVE THE DATE

SEPT 23+24 2016

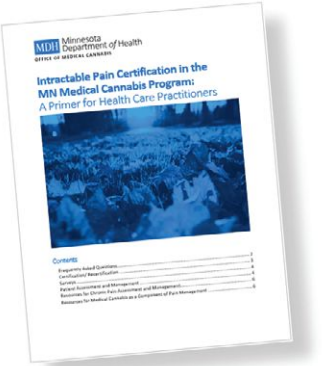
Doubletree by Hilton Park Place
St. Louis Park, MN

WWW.MNMED.ORG/AC2016

This activity has been approved for *AMA PRA Category 1 Credit™*

The Minnesota Medical Association is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Are you ready for questions about medical cannabis and intractable pain?



Get the MDH intractable pain primer for doctors at mn.gov/medicalcannabis

Doctors can start certifying intractable pain patients starting July 1. Certified patients can start receiving medical cannabis for intractable pain August 1.

MDH Minnesota Department *of* Health