MDs and marijuana
What you need to know about Minnesota’s medical cannabis law

BY KEVIN C. RIACH, J.D.

The Minnesota Legislature passed a law in 2014 legalizing the manufacture, sale and use of medical marijuana. Physicians, physician assistants and advance practice nurses are at the heart of the law, for without their participation, Minnesota’s medical marijuana program cannot succeed. This article discusses the basics of the new law and explains the responsibilities of physicians as well as the risks arising from participation in Minnesota’s medical cannabis program.

Minnesota’s Medical Marijuana Program

Under the law, “health care practitioners,” defined as physicians, physician assistants and advance practice nurses, will not prescribe medical marijuana or recommend the amount or dosage of medical marijuana for a patient. Instead, they will simply diagnose a patient with a qualifying condition (see box) and complete a certification form indicating the patient has such a condition. To obtain medical marijuana, the patient must apply to and register with the Minnesota Department of Health. The law requires the Department of Health to evaluate whether the patient has such a condition. To obtain medical marijuana, the patient must apply to and register with the Minnesota Department of Health [Source: Minn. Stat. §152.22, subd. 14].

The law authorizes consumption of medical cannabis in pill form or through a vaporizer, essentially an e-cigarette-type device that converts cannabis oil to vapor so a patient can inhale it. It specifically prohibits consumption of medical marijuana in raw plant form and the smoking of medical marijuana. The Department of Health is currently evaluating whether the law would permit delivery of medical cannabis via nasal spray or through a topical cream.

Registered caregivers are allowed under the law to assist registered patients incapable of obtaining or self-administering medical marijuana (eg, a child or severely disabled individual). These caregivers, unless they are a parent or legal guardian of a qualifying patient, must apply to and register with the Department of Health separately from the patient under their care. A registered caregiver may provide support to only one patient under the law, thus foreclosing any problems with “caregivers for hire.” Some have pointed out that this limit may pose issues for group homes, assisted living facilities or other facilities in which multiple patients may depend on the same caregiver(s) to obtain and administer their medical marijuana.

The State of Minnesota will license two manufacturers to produce the medical marijuana used in the state. Transport of marijuana across state lines will remain illegal and a focus of government prosecution. Thus, manufacturers must produce their medical cannabis within the state. The manufacturers must contract with independent laboratories to perform safety and quality testing on the medical marijuana they produce.

The manufacturers will operate eight distribution sites around the state. Patients (or their registered caregivers) will only be able to obtain medical marijuana from one of those eight locations. A pharmacist must staff each distribution site; however, the Minnesota Department of Health recently stated in response to questions from potential manufacturers that it may be open to distribution via telemedicine or automatic dispensing.

Pharmacists will consult with patients to determine the appropriate dosage and strain of medical marijuana for that patient, based on information about the efficacy of various strains of medical marijuana provided by the Department of Health’s newly created Office of Medical Cannabis. The law requires the health department to publish a report “on the existing medical and scientific literature regarding the range of recommended dosages for each qualifying condition and the range of chemical compositions” by December 1, 2014. The department will update this report annually. The law includes several protections for registered patients. First, it creates a presumption that a registered patient is lawfully using any medical marijuana he or she possesses. That presumption can
be rebutted by evidence that the patient used the marijuana recreationally. Second, the law prohibits housing or employment discrimination based on registered patients’ use of medical marijuana. Finally, a person’s status as a registered patient will have no effect on their custody or visitation rights.7

The law establishes a task force to consider the social and health effects of the use of medical marijuana. Task force members include representatives from law enforcement, legislators, patients, health care providers, substance abuse treatment providers and commissioners of several state agencies. The task force has been holding regular listening sessions to hear from stakeholders and the public and will report to the Legislature on what they learn. Among the specific areas on which the task force must report is “the impact [of the law] on the health care provider community.”8

Physician Responsibilities under the Law
The law does not require physicians or other health care practitioners to certify patients or otherwise participate in the program. However, for those who do choose to participate, the law imposes several duties.

First, before providing a patient with the required certification, they must offer the patient “explanatory information” about the potential risks, benefits and side effects of using medical marijuana, including a disclosure that treatment with medical marijuana is experimental. The Department of Health will create the required information to be disclosed and make it available before the program begins operating on July 1, 2015. Health care practitioners are also required to notify certified patients and their caregivers about nonprofit patient-support groups and organizations.9 The law does not specify whether these support groups relate to the patient’s qualifying condition or marijuana use nor does it indicate whether the Department of Health will create a list of such organizations for providers to use.

In addition to this “explanatory information,” the law requires that the physician or other health care practitioner provide patients with what is known as a Tennesen warning. A Tennesen warning informs individuals of the purpose and intended use of the requested data, as well as any known consequence of supplying the data, which in this context includes publication in aggregate form in connection with research to be performed by the Department of Health regarding the efficacy of medical marijuana.10 The law does not clarify whether the health department will provide health care practitioners with a standardized Tennesen warning.

Second, the law requires that before certifying that a patient has a qualifying condition, a physician must “agree to continue treating the patient’s qualifying medical condition and report medical findings to [the health department].”11 Similarly, the law requires that patients “continue to receive regularly scheduled treatment” for their condition.12 Finally, the law requires that health care practitioners “determine, on a yearly basis, if the patient continues to suffer from a qualifying medical condition and, if so, issue the patient a new certification of that diagnosis.”13

Finally, once a patient is participating in the program, physicians and health care practitioners must provide the patient’s health records to the Department of Health, which will establish a patient registry to “evaluate data on patient demographics, effective treatment options, clinical outcomes, and quality-of-life outcomes for the purpose of reporting on the benefits, risks and outcomes regarding patients with a qualifying medical condition engaged in the therapeutic use of medical cannabis.”14 Physician submission of patient health records will provide the Department of Health with the information it needs to accomplish these goals. It will conduct research on data from health records submitted to the registry program and submit reports on its research results to the Legislature and scientific journals. The Department of Health will work with physicians and other health care practitioners to prevent the unauthorized release of patient data.

The law’s imposition of these responsibilities inspires many as-yet unanswered questions. For example, what should a physician do if his or her diagnosis of a qualifying condition changes before the annual required recertification? Can a physician ever refuse to treat a patient once that patient has begun participation in the medical marijuana program? What if the patient or his or her insurance company refuses to reimburse the physician? What if a patient refuses to commit to a treatment option recommended by the physician? Must the physician report this refusal to the health department?

The Department of Health clearly recognizes it will need the help of physicians to resolve these (and other) issues. It has issued draft rules for patients and providers, and it is soliciting comments on those proposed rules from the health care community. A working draft of the rules is available on the Office of Medical Cannabis’ website for review and comment by interested parties.15 These rules will undoubtedly change before they are finalized and published, however they suggest the ways in which the Office of Medical Cannabis intends to clarify some of the uncertain aspects of the law.

The draft rules list the steps a provider must take before certifying a patient as having a qualifying condition:

1. Conduct an in-person physical examination of the patient
2. Take a medical history of the patient, including a review of medical records from other treating physicians from the previous 12 months
3. Conduct relevant consultations about the qualifying condition
4. Diagnose the patient’s current medical condition
5. Develop a treatment plan for the patient.

Under the draft rules, providers must confirm in their certification of a qualifying condition that they have completed these steps, have established a “practitioner-patient relationship,” and have explained the potential risks and benefits of
medical marijuana use to the patient or his or her caregiver.26

The draft rules explain that the law’s requirement that providers continue treating registered patients whom they certify means:

... follow[ing] the patient clinically at appropriate intervals at the discretion of the provider to provide follow-up care and treatment to the patient for his or her qualifying medical condition, including, but not limited to, physical examinations, to determine the health effects of cannabis for treating the patient’s qualifying medical condition or the symptom of the qualifying medical condition for which the written certification was issued.37

They also clarify that providers must notify the Commissioner of Health within 14 calendar days of becoming aware of the death of a qualifying patient, or if a change in the status of a patient’s qualifying condition affects the patient’s eligibility for medical marijuana.39 Finally, the draft rules explain what must be contained in the health records provided to the health department in connection with patient participation in the medical marijuana program.39

Physician Risks under the Law

Because marijuana remains classified as a Schedule I controlled substance, its manufacture, distribution and use are illegal under federal law. Minnesota’s medical marijuana law provides that health care practitioners will not be subject to state criminal prosecution or discipline by the Board of Medical Practice for participating in the program.29 However, the remote possibility still exists that a physician or provider could be subject to federal prosecution for his or her involvement.

Minnesota physicians can take some comfort from the way in which courts and the federal government have approached conflicts between state and federal laws on marijuana. In the past, the federal government was more aggressive in threatening to prosecute health care providers who promoted the use of medical marijuana. That posture began to change, however, after the California case Conant v. Walters made its way through the courts from 2000 to 2003.

Prior to Conant, the government had been threatening to investigate and prosecute California doctors who recommended medical marijuana to their patients as a treatment option. A group of physicians and patients filed a class-action lawsuit in federal court seeking to enjoin the government from undertaking such prosecutions.21 The court sided with the doctors and enjoined the federal government from “(i) revoking a class-member physician’s DEA registration merely because the doctor recommends medical marijuana to a patient based on a sincere medical judgment and (ii) from initiating any investigation solely on that ground.”22 The court explained that “this injunction applies whether or not the physician anticipates that the recommendation will, in turn, be used by the patient to obtain marijuana in violation of federal law”23

The case was appealed to the Ninth Circuit Court of Appeals, which upheld the injunction, explaining that investigating and intimidating health care practitioners who lawfully recommended medical marijuana treatment “strike[s] at core First Amendment issues of doctors and patients.”22

In the years after Conant, the Department of Justice issued several rounds of guidance to U.S. Attorneys, setting forth the circumstances in which it would be appropriate to prosecute an individual for marijuana possession or distribution in a state where medical marijuana is legal. Generally, the guidelines indicate that the federal government has no interest in prosecuting patients or caregivers acting in compliance with state medical marijuana laws. However, there are several federal prosecution priorities that may draw the scrutiny of the government and trigger federal prosecution even in a state where medical marijuana is legal. Those priorities include:

- Distribution to minors
- Influx of criminal enterprises, gangs and cartels
- Diversion of marijuana to other states
- Trafficking of other illegal drugs or other illegal activity
- Violence and the use of firearms
- Drugged driving and other adverse public health consequences
- Preventing the growing of marijuana on public lands
- Preventing marijuana possession or use on federal property.27

Health care practitioners and patients are unlikely to run afoul of those priorities, and thus the risk of criminal sanction is very low for doctors participating in the program. Not surprisingly, the few federal prosecutions arising from medical marijuana distribution have focused on dispensaries and growers that have through their business practices been implicated in one of the above.

The law does create several new criminal penalties for patients and providers. It provides that a person who “knowingly submits false records” or a false “certification of qualifying condition” to the Department of Health is guilty of a felony. Further, a health care practitioner who “knowingly refers” a patient to a caregiver, advertises as a manufacturer, or issues certifications of qualifying condition while holding a financial interest in a manufacturer is guilty of a misdemeanor.24 Additionally, the Department of Health’s draft rules state that a provider may not “offer a discount or any other thing of value to a qualifying patient who uses or agrees to use a particular designated caregiver, distribution facility, or cannabis product.”25

Finally, the draft rules state that providers may not “[d]irectly or indirectly benefit from a patient obtaining a written certification,” however this prohibition would not bar a provider from “charging an appropriate fee for the patient visit.”26

The bottom line is that, while participation in Minnesota’s medical marijuana program is not without risk, the risk is comparatively low. Nonetheless, health care provider organizations would be wise to incorporate specific policies regarding medical marijuana into their compliance programs to minimize those risks.

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disparate systems can cause hybrid records to persist indefinitely.)

Sources of information including transcribed documents, faxed documents and X-ray films also can contribute to the creation of hybrid records.

Jane's case illustrates one point at which problems can arise—during an initial EHR implementation. However, problems involving hybrid records can occur any time disparate systems are maintained.

How to avoid problems
You can do number of things to minimize the risks associated with hybrid records.

Know where and when to look for information.
When EHR modules are rolled out over time, medical records can become moving targets. And no formula for “going live” fits all practices. Some groups bring their EHR online one location at a time, others do so according to physicians’ specialty or even their technical aptitude, still others use a combination of approaches. During transitions, knowing where to look for certain information is crucial to patient care and avoiding risk.

A helpful tool for tracking this during transitions is a simple and easily accessible spreadsheet on which you document shifts of information. At the very least, it should allow you to list the record type (eg, lab results, X-rays) and the system (eg, film, CD-ROM, EHR, picture archiving and communication system, lab information system). If groups of providers transition at different times, information about that should be noted as well. This becomes especially important when a physician sees a patient on behalf of a colleague. A useful example of a tracking tool can be found in the American Health Information Management Association’s guide for the legal record.¹

Think through how you notify staff about critical information.
With an EHR, incoming documents can easily be missed if they are not routed through a messaging inbox or logged in a task queue or other monitoring system. Make sure you staff understand the importance of filing and tasking test and lab results accurately, no matter where those results originate (from electronic interfaces with external organizations or manually scanned or filed documents). Help staff define the different levels of notifications for critical and noncritical results.

Look for open orders.
Make sure your staff can use your EHR to identify all modes for ordering tests, so they are able to create appropriate audit reports. Had such a process been in place, Jane Doe's adverse outcome would likely have been avoided.

Conclusion
To minimize the risk of problems associated with hybrid records, physicians must stay engaged throughout EHR implementation. They must be able to identify gaps in information related to patient care, define critical thresholds for notification and empower EHR support staff to create appropriate audit processes. MM

Trish Lugtu is research and development manager of health informatics on MMIC's Patient Safety Solutions team.

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Conclusion
Medical marijuana is here to stay in Minnesota. Although details about the state’s new law and how it will be implemented are yet to be determined, in the future we will likely see increased access and more qualifying conditions, if the experience of other states is any indication. Regardless of the direction the law takes, physicians will be critical to its implementation and will play a valuable role in setting its course. MM

Kevin Riach is a senior associate in the White Collar and Regulatory Defense and Health Care Fraud and Compliance practice groups at Fredrikson and Byron, P.A.

R E F E R E N C E S
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5. § 152.25, subd. 1.
6. §152.25, subd. 2.
7. § 152.32.
8. § 152.36.
9. § 152.28.
10. § 13.04, subd. 2.
11. § 152.28, subd. 1(a)(5).
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13. § 152.28, subd. 1(b)(3).
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15. Minnesota Office of Medical Cannabis. Medical Cannabis Program Key Dates.
16. Draft Rules for Medical Cannabis Registry, Rule 4770.XX13, subp. 2; Rule 4770.XX14(E).
17. Draft Rules for Medical Cannabis Registry, Rule 4770.XX13, subp. 3(B).
18. Draft Rules for Medical Cannabis Registry, Rule 4770.XX13, subp. 3(G).
19. Draft Rules for Medical Cannabis Registry, Rule 4770.XX17, subp. 2.
20. § 152.32, subd. 2(c).
22. Conant v. Walters, 309 F.3d 629, 636 (9th Cir. 2002).
24. § 152.33.
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26. Draft Rules for Medical Cannabis Registry, Rule 4770.XX16(H).