



## PATIENTS Under the Influence

# How to Avoid Becoming a “Pot Doc”

Due to the passage of Proposition 203 on November 2, 2010, the Arizona Medical Marijuana Act (“Act”) permits certain individuals to obtain limited amounts of

Drug under the Controlled Substances Act (“CSA”). The DEA, which administers the CSA, continues to support its classification because it considers it to be a dangerous addictive drug with significant health risks that has no accepted medical use and lacks accepted safety. Marijuana is also not currently approved by the FDA, which has concluded that while having a high potential for abuse, it “has no currently accepted medical use,” and it has a lack of “accepted safety for use under medical supervision.” The American Medical Association (AMA), however, has recently softened its position against medical marijuana by stating that it now supports evidence based studies of marijuana to determine medical use and safety. If found to be useful and safe, it will determine if its status as a Schedule I Drug should be reevaluated.

Following several rounds of draft regulations, Final Rules were issued effective April 14, 2011. If the Act

(and its regulations) is strictly complied with, it provides protection from state criminal prosecution for patients and physicians. This article will discuss physician obligations in providing a certificate to a patient and acting as a medical director of a dispensary.

Under the Act, a patient must have a qualifying debilitating medical condition (“DMC”) to obtain an allowable amount of marijuana. The qualifying conditions are cancer, glaucoma, HIV, AIDS, ALS, hepatitis C, Crohn’s disease, agitation of Alzheimer’s disease, and a chronic or debilitating disease or condition or treatment for a chronic or debilitating disease or medical condition that produces certain qualifying symptoms: cachexia or wasting syndrome; severe and chronic pain; severe nausea; seizures; and severe and persistent muscle spasms.

### Physicians are the Gatekeepers for Medical Marijuana Use

One purpose of the Final Rules is to require that Arizona physicians be the gatekeepers who oversee the Act and are held accountable for a patient’s access to marijuana. The Director of ADHS has stated that the key to the success of the Act will depend upon “how seriously physicians take their duty as they write certificates.” Similarly, a recent Arizona Republic editorial stated that:

There will be a demand for the dubious services of pot docs by those who cannot discuss marijuana with their regular doctor, and by those who just want to get high.

State licensing boards and ADHS will be on the lookout for physicians involved with medical marijuana who stand out. For example, physicians will stand out by providing hundreds of certificates per month or by



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marijuana under certain circumstances. Arizona is the 15th state to enact a form of medical marijuana law. The Arizona Department of Health Services (“ADHS”) has the responsibility for implementing regulations for dispensing medical marijuana.

At the same time that marijuana is legalized in limited circumstances under Arizona law, it remains illegal under all circumstances as a controlled substance under federal law. Marijuana is classified as a Schedule I

providing a disproportionate share of certificates to male patients in their 20s for chronic pain.

In response to physician concerns about the Act, on April 4, 2011, ADHS published an “Open letter to Arizona Physicians on Medical Marijuana,” authored by Chief Medical Officer, Laura Nelson, M.D. and Director, Will Humble. The letter provides links to articles and sources of information about the medical use of marijuana, in particular a report published in 2000 by the Institute of Medicine. The letter also provides a warning to physicians about ADHS’ expectations for clinical assessment. The letter is included in this edition of AzMedicine.

### **Safe Harbors**

Since medical marijuana is not an approved drug, a physician does not in the traditional sense “prescribe” medical marijuana. Instead, a physician provides an opinion that marijuana is likely to provide a patient who has a qualifying DMC with therapeutic or palliative benefit. A physician who provides an opinion, after satisfying the requirements of the law, is entitled to an “immunity” from arrest, prosecution, penalty and licensing board disciplinary action.

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It is unclear whether failure to strictly comply with the Act will result in state and/or federal prosecutions of physicians. The United States Department of Justice, in acknowledging that some states have enacted medical marijuana laws, has stated that it will only prosecute physicians who are not in strict compliance with the law. However, to date, I am not aware of any physicians in other states who have been criminally prosecuted for failing to strictly comply with a state’s medical marijuana act.

In addition to potential criminal liability, the Act specifically provides that a licensing board is not precluded from disciplining a physician for failing to “properly evaluate a patient’s medical condition or otherwise

violating the standard of care for evaluating medical conditions.”

As contemplated by ADHS, licensing boards will be expected to determine whether physicians are properly assessing and evaluating their patient’s medical conditions. In view of the publicity surrounding the Final Rules, state licensing boards are likely to proactively and closely review whether practitioners are strictly complying with the Final Rules. The Arizona Medical Board has appointed a Medical Marijuana Subcommittee to discuss issues related to the Act. So far the Subcommittee has not addressed any enforcement issues, but it has questioned whether physicians should be concerned about their DEA registrations if they

provide certifications for medical marijuana.

### **Responsibilities in Providing a Certification**

Under the Final Rules, a physician may provide “written certification” which includes the use of a specific ADHS developed physician certification form (attached) stating that, in the physician’s professional opinion, the patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient’s DMC or symptoms associated with the DMC. The physician must:

- Answer all the questions on the ADHS form;
- Make or confirm a diagnosis of a DMC;
- Conduct an in-person physical examination within the previous 90 calendar days appropriate to the patient’s presenting symptoms and qualifying DMC;
- Establish and maintain a legally adequate medical record for the patient;
- Review the qualifying patient’s medical records, including medical records from other treating physicians from the previous 12 months, the qualifying patient’s responses

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to conventional medications and medical therapies, and the qualifying patient's profile on the Arizona Board of Pharmacy Controlled Substances Prescription Monitoring Program database;

- Explain to the patient the potential risks and benefits of medical use of marijuana;
- Attest that, in the physician's professional opinion, the qualifying patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the qualifying patient's DMC; and,
- Disclose to the qualifying patient any personal or professional relationship the physician has with the dispensary.

### Responsibilities of a Medical Director of a Dispensary

A medical director for a dispensary is prohibited from also providing written certifications for medical marijuana. Arizona Administrative Code, R9-17-313 provides a long list of the duties of a medical director. The medical director must be on site at a dispensary or available by phone or pager.

The duties of a medical director of a dispensary

include providing guidance to both staff and patients of the dispensary and providing training to the dispensary's agents at least once every 12 months. The training must be on the following subjects:

- Guidelines for providing information to qualifying patients related to

- Guidelines for recognizing signs and symptoms for substance abuse; and,
- Guidelines for refusing to provide medical marijuana to an individual who appears to be impaired or abusing medical marijuana.

A medical director must also provide **oversight** for

impairment with use and operation of a motor vehicle or heavy machinery, when caring for children, or job performance;

- Guidelines for notifying the physician who provided the written certification for medical marijuana if side effects or contraindications occur;
- A description of the potential for differing strengths of medical marijuana strains and products;
- Information about potential drug-drug interactions, including interactions with alcohol, prescription drugs, non-prescription drugs, and supplements;
- Techniques for the use of medical marijuana and marijuana paraphernalia;
- Information about different methods, forms, and routes of medical marijuana administration;
- Signs and symptoms of substance abuse, including tolerance, dependency, and withdrawal; and,
- A listing of substance abuse programs and referral information.

A Medical Director must also **develop a system** for a qualifying patient or

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risks, benefits, and side effects associated with medical marijuana;

- Guidelines for assisting qualifying patients to perform and document a self-assessment of their symptoms, including a rating scale for pain, cachexia or wasting syndrome, nausea, seizures, muscle spasms, and agitation;

the development and dissemination of educational materials for qualifying patients and designated caregivers that includes:

- Alternative medical options for the qualifying patient's DMC;
- Information about possible side effects of and contraindications for medical marijuana including possible

the qualifying patient's designated caregiver to document the qualifying patient's pain, cachexia or wasting syndrome, nausea, seizures, muscle spasms, or agitation that includes:

- A log book, maintained by the qualifying patient and or the qualifying patient's designated caregiver, in which the qualifying patient or the qualifying patient's designated caregiver may track the use and effects of specific medical marijuana strains and products;
- A rating scale for pain, cachexia or wasting syndrome, nausea, seizures, muscles spasms, and agitation;
- Guidelines for the qualifying patient's self-assessment or, if applicable, assessment of the qualifying patient by the qualifying patient's designated caregiver; and,
- Guidelines for reporting usage and symptoms to the physician providing the written certification for medical marijuana and any other treating physicians.

The medical director must also assist in the development and implementation of review and improvement processes for patient education and support provided by the dispensary.

## **Physicians must be knowledgeable about medical marijuana and their responsibilities under state law.**

Additionally, a dispensary is required to establish and maintain a patient record for each qualifying patient, with documentation of patient education and support materials, and the reasons for refusing to provide medical marijuana to a patient. A Medical Director should be involved in developing policies and procedures for medical record keeping and for refusing to provide medical marijuana to an individual who appears to be impaired or abusing medical marijuana.

### **Conclusion**

Physicians have no legal duty to either provide patient certifications or to serve as a medical director of a dispensary. A physician who elects to extend their practice to participate in the medical marijuana program should do so only if they expend the time and effort to ensure that they and their patients fit squarely within the confines of the apparent safe harbors for state and federal criminal

prosecution relating to the administration of medical marijuana.

First and foremost, physicians must be knowledgeable about medical marijuana and their responsibilities under state law. The Arizona Medical Board has published guidelines for physicians who are seeking to change their scope of practice. These guidelines provide an excellent source of information on the Board's expectations that physicians obtain the appropriate training to obtain competency. As discussed above, physicians are required under the Act to be competent in assessing for the qualifying DMCs, conducting appropriate examinations, reviewing medical records and assessing a patient's responses to conventional therapies, counseling, providing a thorough risk benefit analysis, and monitoring. These activities require that a competent and knowledgeable physician take the appropriate

time with the patient to accomplish all of these legally mandated tasks.<sup>1</sup>

Unlike many areas of medicine where standards of practice may vary and are subject to various opinions, the Final Rules set forth specific standards and requirements for physicians to follow. These requirements should be meticulously adhered to with detailed chart documentation to demonstrate compliance. Although Arizona has joined a minority of states that have legalized marijuana, it has done so with extensive and rigid requirements for physicians to follow. Physicians who do not strictly comply with the Act are at risk for criminal prosecution, licensing board discipline, as well as civil actions from patients and third parties who are injured by negligent physician practices in administering medical marijuana. **AM**

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1 The Arizona Medical Board's guidelines for the treatment of chronic pain contain many similar requirements for the evaluation and monitoring of chronic pain patients.