Volume 21, Number 3 · November 2018 Newsletter of Physicians Reimbursement Fund, Inc.

PRF NEWS

Covering Practice and Risk Management Issues for Health Professionals www.prfrrg.com · (415) 332-3041

A Primer on the Use of Cannabis for Medical Indications

BY PERRY SOLOMON, MD

The last several years have witnessed an acceleration in the transition of cannabis from a widely available but illicit street drug to medical and/or legal acceptance in 30 states including California. While there still may be a residual "stoner" image and stigma attached to cannabis use, the reality is that individuals between the ages of 55 and 65 are the fastest-growing demographic who are looking to use cannabis for medical indications. These are often people who are looking for some alternative to traditional medications to treat pain, anxiety, insomnia, depression, and a litany of other ailments. Although it seems that cannabis is sometimes promoted as a cure-all for almost everything under the sun, it seems safe to say that most assuredly it is not. Yet it behooves all physicians to become more familiar with cannabis, since there is now a greater chance of patients using or requesting it than ever before.

ACTIVE INGREDIENTS

Cannabis contains approximately 120 cannabinoids. However, the only one that's been found to have a psychoactive effect is tetrahydrocannabidiol (THC).

In addition, cannabidiol (CBD) has received attention lately because it's one of the non-psychoactive components of cannabis and has been found to have anxiolytic and anti-inflammatory properties. CBD is also found in the hemp variety of cannabis.

LEGAL HISTORY

In 1970, the U.S. government enacted the Federal Controlled Substances Act declaring cannabis a Schedule 1 drug. This was done despite the strong objections of the American Medical Association—objections that were made in light of cannabis's widespread medical use up to that point, its established safety profile, and the fact that there was no supporting evidence that the plant belonged in this class of drugs. Unfortunately, the demonization of cannabis and its placement as a Schedule 1 drug put it alongside heroin and LSD. By definition, this means that it has a high potential for abuse, that there's a lack of accepted safety, and that there's no medically accepted use in the United States.

In 2002, the California Ninth Circuit Court ruled that physicians have a right under the First Amendment to *recommend* or *discuss* medical cannabis with their patients, as long as they're not aiding and abetting their patients in the violation of any federal drug laws.

In April 2018 the Medical Board of California issued updated guidelines for the recommendation of cannabis for medical purposes. The guidelines can be viewed at **https://www.mbc.ca.gov/Publications/guidelines_cannabis_recommendation.pdf**. These guidelines are not mandatory for the discussion of cannabis with the patient; however, the guidelines do reference the Business and Professional Code and therefore need to be followed:

Section 2266 requires a physician to maintain adequate and accurate medical records. They should be complete, legible, dated and signed.

Section 2525 makes it unlawful for a physician who recommends cannabis for a medical purpose to accept, solicit, or offer any form of remuneration from or to a facility if the physician or his or her immediate family have a financial interest in that facility.

Section 2525.4 indicates that it is unprofessional conduct for any physician recommending cannabis for medical purposes to be employed by, or enter into any other agreement with, any person or entity dispensing cannabis for medical purposes. This means that a physician should not have an office at a dispensary

(continued on page 2)

Inside PRF News

Cannabis *(continued from page 1)*
or cultivation center, be part of it in any way, or be directly or indirectly employed by one.

With one exception there are still no legal prescriptions for cannabis as it still remains a DEA Schedule 1 drug. That exception is Epidiolex, a CBD-only pharmaceutical approved by the FDA specifically for seizure disorders. The DEA recently announced that in the future FDA-approved drugs with a THC content below 0.1% would now be considered Schedule 5 drugs.

Other than these codified legal constraints, I know of no legal action in the past 10 years by the DEA against any physician in California for discussing cannabis or making proper medical recommendations. That's not to say that the DEA couldn't take action in California, or any of the other 29 states where cannabis has been legalized. In fact, on January 4, 2018, the Department of Justice announced a change in federal marijuana enforcement policy, directing federal prosecutors to "enforce the laws enacted by Congress and to follow well-established principles when pursuing prosecution related to marijuana activities." At this time it is unclear whether discussing and recommending marijuana, even in medically appropriate cases, will be prosecuted as an "aiding and abetting" violation of federal drug laws despite the First Amendment protection offered by the earlier legal decision.

Legalization in California also means an increasing number of patients who use cannabis being seen in a medical practice. This awareness should prompt the physician to ask patients specifically if they use cannabis since not every patient may offer that information.

DISCUSSING CANNABIS WITH PATIENTS

As of January 1, 2018, any California resident over the age of 21 no longer needs a cannabis recommendation by a physician to purchase cannabis. This has led to many patients going to a cannabis dispensary and obtaining "medical advice" from the workers there. Although often well-intentioned, the scope of knowledge of these "budtenders" can be quite limited.

Legalization in California also means an increasing number of patients who use cannabis being seen in a medical practice. This awareness should prompt the physician to ask patients specifically if they use cannabis since not every patient may offer that information. At this point, the physician should be in the position of commenting upon cannabis as it relates to their patient. Since almost all medical schools and residencies have failed to include cannabis as part of medical education, the responsibility is really on the physician to become informed.

CME FOR CANNABIS EDUCATION

There are several CME-approved courses that are available online that can serve to familiarize physicians on the current knowledge about cannabis in the medical setting. One course is given in association with the Society of Cannabis Clinicians and TMCI Global. The Answer Page gives another course that's also accredited for New York and Pennsylvania physicians wishing to perform evaluations in those states. Urls for those two courses are:

- https://themedicalcannabisinstitute.org/product/clinical-cannabinoid-medicine-curriculum-2/
- https://www.theanswerpage.com/library.php?sid=9)

Upon completion of these or other reputable CME courses, a physician will be in a position to discuss cannabis with their patients. The physician may not feel comfortable issuing a recommendation for cannabis if a patient asks for one, but the physician can at least inform the patient about the use of cannabis. Knowing the patient's medical condition also gives the physician the ability to comment upon any issues that may be of concern.

SPECIFIC MEDICAL ISSUES AND CANNABIS

Here are some examples of clinical situations to illustrate how the need for a working knowledge of cannabis fits into current medical practice:

Pregnant and breast-feeding women. There is no recognized medical society that approves of the use of cannabis for women to treat the nausea and emesis that can occur with pregnancy, or for women to use for other medical conditions while breast-feeding. While some patient groups cite the rare study justifying the use of cannabis in these situations, the clinician should be aware of the mainstream medical opinion that pregnant and breast-feeding women should not use cannabis.

Patients taking anticoagulants. CBD can act as a competitive inhibitor for the cytochrome p-450 enzyme system in the liver. That means that any medication that also uses that enzyme system for metabolism, such as warfarin, may result in increased levels resulting in prolonged bleeding times. This may require a more frequent testing of bleeding times and/or a reduction in the amount of warfarin used.

Cannabis "overdose." Since the LD50 of cannabis has never been found, an "overdose" of cannabis generally does not result in an emergency room visit. Much more common, however, is for emergency physicians to see patients who have taken too much cannabis, generally edibles, in one sitting. Because the onset time for edibles is usually 60-90 minutes after ingestion, these patients don't feel the effects of cannabis as quickly as they'd like and ingest more, or too much, of the product. When seen in the ER, they may be anxious, tachycardic, and worried about being "too" high. Reassurance will usually work and, if severe, benzodiazepines may be needed.

Cannabinoid hyperemesis syndrome. This rare condition can occur with long-term heavy users of cannabis and presents with episodic vomiting. The patient seems to seek relief (even compulsively) from bathing or showering in hot water. It is thought that this can re-set the receptors in the area postrema located in the medulla that regulates vomiting.

CANNABIS AND MALPRACTICE INSURANCE

PRF will cover malpractice actions or Medical Board actions stemming from or related to the discussion and/or recommendation of cannabis as long as all of the other requirements for coverage set out in your policy contract are met. If you have questions about the scope of coverage, contact the PRF office. ■

Perry Solomon is the chief medical officer for HelloMD, a cannabis consulting company based in San Francisco.

What Doctors and Office Staff Should Know About Basic Life Support

BY EMILY HU, MD

Medical offices and waiting rooms are full of patients, many of whom are ill or waiting to see a provider. Every now and then a patient may "pass out" or be in need of urgent attention. Sometimes it is an office staff member and not a health care provider who ends up being the "first responder." We suggest that all practicing health care providers know the answers to these questions:

- Is my office staff adequately trained to handle unexpected emergency situations?
- What is involved in certification for emergency care and who is required to be certified?
- What is the medico-legal liability in such situations?

Definition of Basic Life Support (BLS)

BLS is advanced CPR. It is the level of medical care given to acutely decompensated patients until the ambulance and emergency medical providers arrive. The object of BLS is to maintain an **A**irway, **B**reathing, and **C**irculation—the traditional "ABCs" of CPR—until the patient can be transported to a hospital for diagnosis and treatment.

Who must have BLS certification?

Workers required to have BLS Certification include first responders such as firefighters, police officers, and EMTs.

Medical personnel—for example, physicians, nurses, dentists, certified nursing assistants, and medical assistants—are also typically required to have BLS certification, as are teachers, school bus drivers, daycare providers, flight attendants, and lifeguards.

Definition of Advanced Cardiac Life Support (ACLS)

ACLS is a set of life-saving protocols and skills that extend BLS. These include tracheal intubation, rapid sequence induction, cardiac monitoring, cardiac defibrillation, transcutaneous pacing, IV cannulation, cricothyrotomy, needle compression of tension pneumothorax, and advanced medication administration.

Who must have ACLS certification?

Outside of a hospital setting, those required to have ACLS certification include EMTs, paramedics and medics.

In the hospital setting, certification is required of "code teams" and physicians and senior nurses from various specialties such as emergency medicine, anesthesia, intensive care, and cardiology. Ongoing recertification is required.

Does the Good Samaritan law apply if someone receives emergency assistance in my office waiting room?

The Good Samaritan Law offers legal protection to people who give reasonable assistance to those who are or who they believe to be injured, ill, in peril, or otherwise incapacitated. The protection is intended to reduce bystanders' hesitation to assist for fear of being sued or prosecuted. This law does NOT extend to health care providers that have a preexisting duty to, or responsibility for, the patient.

Sometimes it is an office staff member and not a health care provider who ends up being the 'first responder.'

California Health and Safety Code Section 1799.102 states: "No person who in good faith, and not for compensation, renders emergency medical or nonmedical care or assistance at the scene of an emergency shall be liable for civil damages resulting from any act or omission other than an act or omission constituting gross negligence or willful or wanton misconduct. The scene of an emergency shall **not** include emergency departments and other places where medical care is usually offered."

If an office staff member provides emergency assistance in your waiting room, he/she may be protected under the Good Samaritan law if he/she responded in a normal and appropriate manner. This is especially true if CPR is provided and the office staff member has "completed a basic cardiopulmonary resuscitation course which complies with the standards adopted by the American Heart Association or the American Red Cross for cardiopulmonary resuscitation and emergency cardiac care." *California Civil Code Section 1714.2(a)*.

OSHA-required equipment for medical offices

According to Occupational Safety and Health Administration (OSHA) standards, "adequate first aid supplies" shall be readily available at workplaces. Your medical office should have a dedicated first aid kit and you should make sure that all providers and staff know where it is. This kit should contain personal protective equipment (gloves and breathing masks to provide rescue breathing/CPR) in addition to basic first aid supplies. If there is an automated external defibrillator (AED) device in the office, make sure that it is regularly maintained.

Options for getting office staff/MDs trained

The American Red Cross and the American Heart Association both offer classes and certification in BLS. Hospitals often provide BLS training courses as well.

Our practice chose to offer BLS training and certification to all our office personnel and physicians this spring. We closed our office for one morning and hired an instructor who came to the office and spent three hours training our entire staff. The cost of the training was $925 for the instructor plus compensation to the staff for their attendance. After taking the course we all felt much more confident about what to do in an emergency and for patient care in general! We agreed that it was a worthwhile investment in our practice, and we plan to make BLS certification and renewal a regular part of our practice management. ■

Emily Hu, MD, an obstetrician-gynecologist at Bay Area Obstetrics and Gynecology, is a member of the Education and Risk Management Committee.

The Role of Digital Breast Tomosynthesis (3D mammography)

BY M. ALLEN FRY, MD

Breast cancer is the most common cancer diagnosed in women and the second most common cause of cancer death in women in developed countries. Screening with mammography can assist in detecting breast cancer at earlier stages, which has contributed to a decrease in breast cancer mortality. However, there are well known limitations to mammography including false positives (50 percent over 10 years) and false negatives (screening mammograms miss one in five breast cancers). Both limitations are more common in younger women and/or women with dense breast tissue.

These limitations of mammography are at least partly related to the fact that with conventional imaging the three-dimensional volume of the breast is imaged and presented in a two-dimensional format. Because normal breast tissue and breast cancer attenuate X-rays to a similar degree, clinically relevant malignancies may be obscured by normal overlapping tissue, especially if the patient has dense breast tissue. In addition, complex areas of normal tissue may be interpreted as suspicious.

In an effort to address these limitations, the U.S. Food and Drug Administration approved 3D mammography, or digital breast tomosynthesis (DBT), as a new breast imaging procedure in 2011. Subsequent studies of screening DBT have shown decreased false positive callback rates and increased rates of cancer detection (particularly for invasive cancers), resulting in increased sensitivity and specificity. DBT has been utilized at the California Pacific Medical Center Breast Health Center (CPMC-BHC) since 2015.

With DBT, multiple low-dose X-ray images are acquired in an arc and reconstructed to create a type of three-dimensional image, thus minimizing the impact of overlapping breast tissue and improving lesion conspicuity. Reconstructed DBT images, spaced in one millimeter increments, can be displayed either in video mode or manually scrolled frame by frame. Patient positioning and overall patient experience of DBT is similar to that of conventional 2D mammography.

DBT is commonly utilized during diagnostic breast imaging to further evaluate suspected mammographic abnormalities such as asymmetries, masses, and architectural distortions. Architectural distortions (when breast parenchyma is focally altered) are associated with a greater chance of underlying invasive cancer. Our experience at the CPMC-BHC has shown that DBT is especially good at detecting architectural distortion in patients with dense breast tissue (both heterogeneously and extremely dense).

As an additional benefit, the three-dimensional nature of DBT can be used to triangulate a suspicious breast lesion and more effectively target a sonographic evaluation or a percutaneous core biopsy. DBT is also helpful for localization of lesions and calcifications in the skin. This is an important distinction because skin findings in the breast are often benign.

The drawbacks to DBT are primarily an increase in radiation exposure to the patient and an increase in cost. At many breast imaging centers (including the CPMC-BHC), DBT screening mammography is usually performed in combination with conventional 2D mammography. While this doubled radiation dose still remains within the accepted standards of the Mammography Quality Standard Act set by the FDA, it is higher than 2D alone. Women who are particularly concerned about radiation dose may consider this important. Due to the increased radiation dose, women who require additional images to complete an exam, such as women with large breasts or breast implants, may not opt for DBT as an increase in radiation may not be desired.

The second concern is the added expense of DBT. As the equipment is more expensive and the exams require more time to interpret than 2D, there is an increased cost to providing DBT. While Medicare is currently paying the additional DBT fee, many private payers are not. Insurance coverage for DBT is widely variable across the country. Even if insurance companies are supposed to be covering DBT, they may apply the charge to a patient's deductible. It is prudent to encourage patients to verify their costs with the breast imaging facility and with their insurance provider before undergoing DBT.

Although there is no set standard as to which patient population should be imaged with DBT, many groups, including the National Comprehensive Cancer Network and the American College of Radiology, have concluded that DBT should be considered for all patients having screening mammography. However, patients should be advised of the increased cost and radiation exposure associated with DBT. ■

M. Allen Fry, MD, is a radiologist at CPMC who specializes in breast imaging. He is co-director of CPMC's Breast Health Center.

PRF NEWS Volume 21, Number 3 · November 2018
Covering Practice and Risk Management Issues for Health Professionals

Katherine L. Gregory, MD, MPH, *Executive Editor*
Robert D. Nachtigall, MD, *Editor*

Physicians Reimbursement Fund, Inc.
3 Harbor Drive, Suite 116
Sausalito, CA 94965
(415) 332-3041 - voice
(415) 332-3243 - fax
Andrea@PRFrrg.com • www.PRFrrg.com
Andrea McArtor, *Executive Director*
Soad Kader, *Director of Membership*
Shannon Gates, Esq., *Associate General Counsel & Claims Adminstrator*