

Update on Medical Marijuana in Maryland

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MAOP Maryland Association of
Osteopathic Physicians

Objectives

1. Understand the current status of Medical Marijuana in MD
2. Understand the current Federal status of MM
3. Understand the perspective of the BPQA
4. Understand Clinical & Legal Pit falls
5. Appreciate types of conditions that may benefit from MM

Medical Marijuana Commission

- Governor Appoints 11 members to Commission on 9/12/13
 - Dario Broccolino, J.D.
 - William C. Charles: Pharm D
 - Kevin W.Chen, PhD, MPH
 - Paul W. Davies, MD - Chairman
 - Michael A. Horberg, MD, MAS
 - Robert A. Lavin, MD
 - Shawn McNamara, Ed.D, MSN, RN
 - Deborah R. Miran, Consultant, Prior Direct at Alpharma
 - Colonel Harry Robshaw, III
 - Nancy Rosen-Cohen, PhD
 - Eric E. Sterling, Esq

Medical Marijuana: Legalized in MD?

- House Bill 1101
- Create Commission that will be independent and sustained to license Academic Medical Centers, Growers
- Commission to regulate and oversee – can collect fees to monitor
- Indemnity: Safe haven created for those compliance with Commissions regulatory guidelines (TBA)
- No access to patients expected before 2016

Round Two

Senate Bill 923 and House Bill 881, signed into law by Governor O'Malley on April 14, 2014, will significantly change the medical marijuana program being implemented by the Natalie M. LaPrada Medical Marijuana Commission.

Fee Schedule (Taxes)

Grower Only Fees

- (a) Application Fee \$6,000 (\$2,000 Stage 1, \$4,000 Stage 2)
- (b) Biennial Licensing Fee \$250,000 (payable in \$125,000 annual installments).

Grower / Dispenser Biennial Fees: Application fee to dispense \$ 5,000. Add Dispensary Fee 80,000

Grower Agent Fees: Registration fee 200.

Replacement registration card \$100 (same for dispensary agent fees)

Patient / Caregiver Fees

Qualifying Patient and Caregiver Fees.

- (a) Identification Card.....\$100 There will be a sliding scale based on need
- (b) Replacement Identification Card.....\$50
There will be a sliding scale based on need

Academic Medical Center

Academic Medical Centers:

- (a) Initial Application Fee.....\$100;
- (b) Licensing Fee.....\$1,000;
- (c) Renewal Fee.....\$1,000;

Federal Perspective

- Marijuana is a Schedule I CDS at the federal level, making distribution a federal offense. In October 2009, the Obama Admin sent a memorandum advising federal prosecutors that it is not an efficient use of resources to prosecute individuals who use marijuana for medical purposes in accordance with state laws. In June 2011, however, the Obama Admin sent another memo advising that, while this view of the efficient use of resources had not changed, persons who are in the business of cultivating, selling, or distributing marijuana (and those who knowingly facilitate such activities) are in violation of federal law and are subject to federal enforcement action.

Medical Marijuana – Maryland Plan

- Medical Marijuana - Academic Medical Centers - Natalie M. LaPrade Medical Marijuana Commission
- This bill allows for the investigational use of marijuana for medical purposes. The bill establishes, as an independent commission within the Department of Health and Mental Hygiene (DHMH), the Natalie M. LaPrade Medical Marijuana Commission to (1) develop requests for applications for academic medical centers to operate programs in the State; (2) approve or deny initial and renewal program applications; and (3) monitor and oversee programs approved for operation. The bill also establishes the Natalie M. LaPrade Medical Marijuana Commission Fund as a special, nonlapsing fund.

Academic Medical Center Model - Failed

- An academic medical center that is approved to operate a program under the bill must provide to the commission, on a daily basis, updated data on patients and caregivers; the commission must then make the data available in real time to law enforcement. If a center utilizes caregivers as part of a program, the center is required to limit the number to 5 and that work with a particular patient to two.
- Because the bill establishes a tiered approach to implementation and requires the commission to take a number of actions before the program can be fully implemented, the earliest patients could benefit through academic medical centers is FY 2016.

Academic Medical Institution: Defined

- An AMI is a hospital that operates a medical residency program for physicians and conducts research that is overseen by the US Dept of Health & Human Resources involving human subjects.
- Must provide to the commission, on a daily basis, updated data on patients and caregivers; the commission must then make the data available in real time to law enforcement

UMMS and JHU have declined to participate !

Standard of Care: Acad Medical Ctr

- Specify the **medical conditions to be treated**, the **criteria** by which patients will be **included in or excluded** from participation, how patients will be **assessed for addiction** before and during treatment, and the **length of treatment** and **dosage** permitted;
- Describe the source and type of the marijuana to be used, how health care providers will be eligible to participate and what training they will receive, and the plan for defining and monitoring the success or failure of treatment;
- Describe any required training for providers and patients on diversion-related issues, steps the center will take to prevent and monitor diversion, how the program will dispose of any unused marijuana, and how the center and the program will meet any other established criteria.

Standard of Care: AMI - continued

- Include a description of whether and how caregivers will interact with participating patients, a plan for monitoring aggregate data and outcomes and publishing results, and a description of the sources of funding;
- demonstrate approval of the program by the center's institutional review board;
- Can only obtain MM from Federal Government or Commission licensed growers.

What conditions qualify for Tx

A suffers from a medical condition — or its medical treatment — that causes one or more of the following:

- Cachexia, anorexia, or wasting syndrome;
- Severe or chronic pain;
- Severe nausea;
- Seizures; or
- Severe or persistent muscle spasms

Bona-fide physician-patient relationship

A treatment or counseling relationship between a physician and patient in which all of the following are present:

a) The physician has **reviewed** the patient's relevant **medical records** and completed a **full assessment** of the patient's medical history and current medical condition, including a relevant, **in-person**, medical evaluation of the patient; b) The physician has **created and maintained records** of the patient's condition in accord with medically accepted standards; (c) The physician has a **reasonable expectation** that the **physician will provide follow-up care** to the patient to **monitor the efficacy** of the use of **medical marijuana** as a treatment of the patient's debilitating medical condition; and (d) If the patient has given permission, the physician has notified the patient's primary care physician of the patient's debilitating medical condition and certification for the use of medical marijuana to treat that condition.

Qualifying Patient

- “Qualifying patient” definition
- (a) A **resident of Maryland** who has been provided with a **written certification** by a certifying physician in accordance with a bona fide physician-patient relationship; or
- (b) Is enrolled in a research program with a registered academic medical center; and
- (c) If under the age of 18 years, has a caregiver.

“Usable Marijuana”

- “Usable marijuana” does not include seedlings, seeds, stems, stalks or roots of the plant or the weight of any non-marijuana ingredients combined with marijuana, such as ingredients added to prepare **a topical administration, food, or drink.**

Licensed Growers

- Commission is required to license 5 growers to provide MM to and only to licensed AMI programs.
- Can only license up to 5 per program
- Required to define Security including product tracking and manufacturing

Indemnity - Protection

- The following persons may not be subject to arrest, prosecution, or any civil administrative penalty – or be denied any right or privilege – for the medical use of marijuana in accordance with the bill: (1) a **patient enrolled** in an approved program who is in possession of an amount of marijuana that is authorized under the program; (2) a **licensed grower** (or the grower's employee) who is acting in accordance with the terms of the license; or (3) an academic **medical center or employee** of the center (or any other person associated with the operation of a program in accordance with their licensure).

Law explicitly does not authorize

Any individual to engage in (and does not prevent the imposition of any civil, criminal, or other penalties for) any of the following: (1) undertaking **any task under the influence** of marijuana when doing so would constitute negligence or professional malpractice; (2) **operating, navigating, or being in actual physical control of any motor vehicle, aircraft, or boat** while under the influence of marijuana; or (3) **smoking marijuana in any public place, in a motor vehicle**, or on a private property that is subject to specified policies prohibiting the smoking of marijuana on the property. Furthermore, the bill may not be construed to provide immunity to a person who violates the bill from criminal prosecution for a violation of any law prohibiting or regulating the use, possession, dispensing, distribution, or promotion of controlled dangerous substances, dangerous drugs, detrimental drugs, or harmful drugs (or any conspiracy or attempt to commit any of those offenses).

Protect your License !

Universal Precautions:

1. Make a diagnosis with an appropriate differential. Treatable causes of chronic pain should be considered and identified so treatment to eliminate the pain manage condition can occur. Substance use disorders and other psychiatric illnesses (psychosis) must be addressed.
2. Conduct a patient assessment, including risk for addictive disorders. Urine drug testing should be discussed with all patients.
3. Obtain informed consent from the patient for treatment with opioids / Marijuana. The practitioner should discuss the proposed treatment plan with patients and questions.
4. Have a written treatment agreement to clearly set forth in writing the expectations and obligations of both the patient and the treating practitioner. This helps to clarify appropriately set boundaries on patient behavior, making possible early identification of and intervention for aberrant behaviors.
5. Perform pre- or post intervention assessments of pain (condition) and function. Documenting the pre-intervention pain scores and level of function increases the practitioners ability to assess success in any medication trial. Ongoing assessment and documentation of successfully met clinical goals supports the continuation of any mode of therapy and failure to meet such goals requires reevaluation and possible alteration of the treatment plan.

Protect Your License: Continued

Initiation of an appropriate trial of opioid/MM therapy with or without adjunctive medications. Treatment plans need to begin with a “trial” of therapy when controlled substances are contemplated. This allows a stable therapeutic platform from which to base treatment changes.

Reassess the pain score / treatment success and level of function. Regular reassessment of the patient, combined with corroborating information from family or other knowledgeable third parties, will help to document the reasons to continue or modify the current therapeutic trial.

Regularly assess the “4 A’s” of pain medicine. Routine assessment of analgesia, activity, adverse effects and aberrant behaviors will help to direct therapy and support the selection of pharmacologic options.

Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders. Underlying illnesses and diagnoses evolve and as they do, the focus of treatment may need to change as well. If an addictive disorder presentation develops, the treatment should include the addictive disorder being addressed otherwise aggressively treating the pain problems is likely to fail.

Document careful and complete initial evaluations and each follow-up visit. This is clinically and legally indicated and in the best interest of all parties.

BPQA: Reprimand, Fine, Suspension, Revocation

In response to the Board's questions:

- 1) Did the Respondent sell, prescribed, give away or administer drugs for illegal or illegitimate medical purposes?
- 2) Engage in unprofessional conduct in the practice of medicine?
- 3) Do the facts in this case raise a substantial likelihood of risk of serious harm to the public health, safety or welfare of patients in Maryland?

It is a diverse peer group who will judge. "If it looks like a duck, swims like a duck and smells like a duck" cardinal rule

First things first: Do no harm !

Curr Psychiatry Rep. 2013 Dec;15(12):419. doi: 10.1007/s11920-013-0419-7. Gordon AJ, Conley JW, Gordon JM of the Center for Health Equity Research and Promotion, VA Pittsburgh Healthcare System.

- Medical consequences of marijuana use: a review of current literature.
- “Literature suggest Marijuana use can cause physical harm”
- Evidence is needed, and further research should be considered to prove causal association of MM and many physical health conditions

“Do no harm” continued

Schizophr Res. 2013 Nov 4. pii: S0920-9964(13)00564-1. doi: 10.1016/j.schres.2013.10.018. [Epub ahead of print]

- Association between cannabis use, psychosis, and schizotypal personality disorder: Findings from the National Epidemiologic Survey on Alcohol and Related
- Conditions. Davis GP, Compton MT, Wang S, Levin FR, Blanco C.
- Department of Psychiatry, Division on Substance Abuse, Columbia University Medical Center/NYSPI, 1051 Riverside Drive, Unit 66, New York, NY 10032, United States.
- Electronic address: gpd2114@columbia.edu.

Legitimate medical purposes? MM

- Pain
- Wasting / Anorexia / Nausea
- Cancer, AIDS (wasting, neuropathy), Multiple Sclerosis
- Glaucoma
- Anxiety, insomnia
- Severe childhood epilepsy, Tourettes
- Crohn's Disease, Hep C,

Marijuana Ingestion

- Classic combustion inhalation (pipe, cigarette, water pipe)
- Oral consumption (brownies, fudge)
- Transdermal (ointment / cream)
- Vaporizer (portable pipe like or table top)
- Mixed with tobacco or alone
- Daily, bid, qh, prn.

Marinol legally available in MD for years

Clin J Pain. 2013 Nov 25. [Epub ahead of print]

The Subjective Psychoactive Effects of Oral
Dronabinol Studied in a Randomized, Controlled
Crossover Clinical Trial For Pain.

Issa MA, Narang S, Jamison RN, Michna E, Edwards
RR, Penetar DM, Wasan AD.*Department of
Anesthesiology, Perioperative, and Pain Medicine,
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Marijuana: research highlights

- **Cell. 2013 Nov 21;155(5):1154-65. doi: 10.1016/j.cell.2013.10.042.**
- **Δ⁹-THC-Caused Synaptic and Memory Impairments Are Mediated through COX-2 Signaling.**
- **Chen R, Zhang J, Fan N, Teng ZQ, Wu Y, Yang H, Tang YP, Sun H, Song Y, Chen C.**
- **Neuroscience Center of Excellence, School of Medicine, Louisiana State University, Health Sciences Center, New Orleans, LA 70112, USA.**
- **These results suggest that the applicability of MM would be broadened by concurrent inhibition of COX-2.**

Protect your House

- Policy and Procedures Manual (include physician training – CME)
- Clinical guidelines for what conditions you will treat and how you will monitor progress. EBM & Appropriate Consultations.
- Informed consent (legal, potential for harm etc), and compliance contract. Length of treatment & Exit plan?
- Risk assessment: Low – Medium - High for misuse, abuse, diversion.
- Medical records: comprehensive initial H&P (PMH, Social Hx, Mental health, Vocational, Family HX, ROS, labs, imaging, Assessment with DDX, Plan, Monitoring – Universal Precautions

Questions