

MEDICAL MARIJUANA: THE LAW & HOW IT IMPACTS YOUR BUSINESS AND EMPLOYEES

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Topics to be covered

- ❖ Michigan Medical Marijuana Act
 - ❖ Physician's Role
 - ❖ Medical Qualifications
- ❖ Therapeutic and Adverse Effects
 - ❖ Current scientific literature
- ❖ Drug Testing
- ❖ Fitness for Duty & Impairment

MDCH Applications (as of 9/10)

- 55,513 received
- 29,336 approved patients
- 7,039 denied
- \$100 fee (\$25 if Medicaid/SSD/SSI)
- If not denied 20 days post submission, applicant can use application as registry ID

MDCH Applications (as of 2/10/11)

- ◎ 96,088 applications received
 - original and renewal (about 41K in 4 months)
- ◎ 56,467 patient registrations issued - (about 7k/mth)
- ◎ 10,918 applications denied
 - incomplete application or missing documentation
 - medical condition is not covered such as depression
- ◎ Presently processing applications from mid-October 2010

Physician (MD/DO) Role

- ⦿ Must have a “bona-fide” doctor-patient relationship & complete a full assessment
- ⦿ NOT a prescription (illegal under DEA)
 - Class I: no legitimate medical use
- ⦿ Certifies the qualifying condition(s)
- ⦿ Professional opinion:
 - therapeutic or palliative benefit

Physicians Protection Under MMMA

⦿ Can doctors get in trouble for discussing medical marijuana?

- Not under Michigan state law
- A physician may not be arrested, prosecuted or penalized in any manner, or
- be denied any right or privilege, including but not limited to civil penalty or disciplinary action by the Board of Medicine or Board of Osteopathic Medicine.

Physician Sanctions and Legal Risk

- Complying with the Act – No Problem
- Failing to evaluate patient or otherwise violating Std of Care – Can be sanctioned

Where to Find a Doc to Certify One for Medical Marijuana?

- Listen to the radio
- Google or Bing search results in many
- Newspaper ads

Caregiver under MMMA

- MMMA defines a "Primary Caregiver"
 - A person who is at least 21 years old
 - Who has agreed to assist with a patient's medical use of marijuana
 - Who has never been convicted of a felony involving illegal drugs
 - The qualifying patient (applicant or registrant) and caregiver must complete a "Caregiver Attestation" to be submitted by the patient
 - Up to 5 patients

Cannabinoid – Forms

- ◎ Herbal Marijuana

- Smoked, Orally Ingested, Vaporized

- ◎ Pills [Marinol (dronabinol), Cesamet (nabilone)]

- ◎ Mouth Spray [Sativex]



DEA

Cannabis in the U.S.A.

- ⦿ Tetrahydrocannabinol (THC): most active psychoactive ingredient in marijuana
- ⦿ THC content has increased in most countries
- ⦿ THC content of cannabis:
 - 2% in 1980 to 4.5% in 1997 to 8.5% in 2006
- ⦿ 10-15% content in most recent data



DEA

Patterns of Cannabis Use in U.S.A.

- 10% of those who ever use become daily users
- 20-30% of those who ever use => weekly users
- Typically begins mid to late teens, peaks in early to middle 20's
- Use declines after young people enter FT employment, marriage, and have children

Qualifying Diseases under MMMA

- ⦿ Patients must suffer from a debilitating medical condition, defined as:
 - Cancer
 - HIV/AIDS
 - Glaucoma
 - Hepatitis C
 - Amyotrophic Lateral Sclerosis (ALS)
 - Crohn's Disease
 - Alzheimer's with agitation
 - Nail Patella Syndrome

Qualifying Symptoms under MMMA

- ⦿ Chronic or debilitating disease or medical condition or its treatment that produces one or more of the following:
 - Cachexia or wasting syndrome
 - Severe nausea
 - Severe and chronic pain

Qualifying Symptoms under MMMA

- Chronic or debilitating disease or medical condition or its treatment that produces one of more of the following:
 - Severe or persistent muscle spasms, including but not limited to, those which are characteristic of multiple sclerosis
 - Seizures, including but not limited to those caused by epilepsy

Qualifying Symptoms under MMMA

- ⦿ Any other medical condition or treatment for a medical condition adopted by the department by rule
- ⦿ To date, the department has not added to the list by administrative rule

Debilitating Medical Condition

- ⦿ The mere presence of such debilitating medical condition does not entitle a patient to certification
- ⦿ To certify the patient, the physician must specifically give an opinion that the patient will “likely” receive a “palliative or therapeutic benefit”

MMMA: Truth of the Matter

- Experience with Medical Review work
- Much more common to see “The Card”
- Anyone with a medical condition will more than likely be certified by physician
- Safe haven for those who prefer to use MJ to remain safe from prosecution
- “Over-prescribed” and not used appropriately for debilitating conditions

Pharmacokinetics:

Onset & Duration of MJ

⦿ Onset: Initial Response

- Oral (ingestion): 30-120 minutes
 - “High” usually begins 30-60 min, peaks 1-3 hrs
- Smoking (inhalation): 6-12 minutes
 - Maximal effects occurs 30-120 min later

⦿ Duration: Single Dose

- Oral: 4-6 hrs duration for “high”
- Smoking: 2-4 hrs, another study 170-240 min

Making your own tinctures can be incredibly effective and fun way to medicate. Tinctures are typically made by adding kief, hash, or extremely dry, ground buds to alcohol. It can be placed in small, discreet spray bottles for patients to use “on the go.” While it may be made with any of the above mentioned medications, kief usually provides optimum results.

Ingredients:

- Everclear or other high-proof alcohol (minimum of 90 proof)
- Kief (1.25 grams for every fluid ounce)
- Glass jar
- 2 cheesecloth sheets
- 2 coffee filters
- Gloves



Keep both your alcohol and kief as cold as possible (preferably in your freezer or in a sealed bag in a dry ice bath). Place both the cold kief and Everclear in a glass jar and shake it up vigorously for 5 to 7 minutes. After you have done this, return the jar to the freezer. Every 2 hours or so repeat this process for 72 hours (it's okay if you don't do it exactly every two hours). After the 3 days is up you can take the mixture out of the freezer and strain it through two layers of clean cheesecloth. Squeeze out the cheesecloth and save the remaining ball for effective topical use. The liquid that was collected by straining through the cheesecloth should then be filtered 2 times through a single paper coffee filter. While your are conducting this part of the process, be sure to wear gloves. If a clear liquor is used, the mixture should appear as a golden-green color. For those patients who are particularly sensitive to alcohol tastes, extremely sparse amounts of flavoring may be added, such as lemon, cherry, vanilla or banana. Lastly, add this mixture to a small, sterile spray bottle, food-coloring dropper, et cetera.

Herbal Marijuana

- ⦿ Some cannabinoids are psychoactive; some are not (e.g. cannabidiol)
- ⦿ DEA Schedule I (like heroin, LSD – no acceptable medical use; cannot prescribe per FDA)
 - AMA recommends changing to Schedule II
- ⦿ Schedule I drug Michigan Public Health Code: “finds that the substance has high potential for abuse and has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.”

Herbal Marijuana

- ⦿ Can self-titrate dose
- ⦿ Contains >400 substances and >60 cannabinoids
- ⦿ Primary psychoactive component
 - delta-9-tetrahydrocannabinol (THC)

Effects of Cannabis

- ⦿ Dependent on dose received, mode of administration, user's previous experience, and the set and setting
- ⦿ Main effect: so-called “high”
 - Euphoria, relaxation, perceptual alterations
 - Intensification of ordinary experiences (such as eating, watching films, music listening, sex)

Adverse Health Effects of Non-Medical Cannabis Use

- Hall, et al., Lancet 2009. Review article summarizing results in the past 10 years on adverse health effects of cannabis
- **Acute Adverse Effects**
 - Anxiety and panic, especially naïve users
 - Psychotic symptoms (at high dose)
 - Road crashes if a person drives while intoxicated

Adverse Health Effects of Non-Medical Cannabis Use (cont.)

Chronic (Long-term) Adverse Effects

- Cumulative and dose-dependent (amount, freq, & duration)
- Cannabis dependence syndrome (1 in 10 users)
- Chronic bronchitis and impaired respiratory function in regular smokers (3x tar)
- Psychotic symptoms and disorders in heavy users
- Impaired educational attainment in adolescents
- Subtle cognitive impairment in those who are daily users for 10 years or more

Adverse Health Effects of Non-Medical Cannabis Use (cont.)

● Possible Adverse Effects

(confounding factors so causal relation unknown)

- Respiratory cancers (50% more carcinogens)
- Behavioral disorders in children whose mothers used cannabis while pregnant
- Depressive disorders, mania, and suicide
- Use of other illicit drugs by adolescents

Smoked Marijuana as a Cause of Lung Injury

- Tashkin; Smoked Marijuana as a Cause of Lung Injury. Monaldi Arch Chest Dis. 2005;63:93-100
 - May create bronchial irritation or injury
 - Chronic lung conditions (cough and wheeze) prominent in regular cannabis smokers
- Other study shows “vaporizers” do not eliminate toxins entirely.

Neuropsychological functioning in adolescent marijuana users: Subtle deficits detectable after a month of abstinence (J Int Neuropsych Soc. 2007)

- ⊙ Controlled for lifetime alcohol use and depressive symptoms & after month abstinence
- ⊙ Results: users (vs non-users) demonstrated:
 - Slower psychomotor speed
 - Poorer complex attention
 - Deficits in planning and sequencing ability
 - Deficit in story memory
- ⊙ Increased frequency of MJ use was associated with decreased performance in these areas.

Cognitive Dysfunction (Chronic Cannabis Syndrome)

- Solowij, et al., JAMA 2002; 287(9): 1123-1131
- Shows the following in chronic users:
 - Deficits in memory, attention, and retrieval function
 - Loss of executive function and psychomotor speed
 - Decrement in manual dexterity
- These effects can last for hours to days after marijuana use.
- Twin study, 20 years abstained, no difference.

Efficacy of Marijuana

● BEST established for:

- Cachexia (Wasting Syndrome)
 - Normally seen in HIV patients
 - Appetite stimulation
- Severe Nausea & Vomiting (e.g. chemo)

Smoked Cannabis & Analgesic Efficacy

- Adams, et al; Cannabis in HIV-associated Sensory Neuropathy: a Randomized, Placebo-Controlled Trial. Neurology. 2007;68:515-521
 - 50 patients, smoked cannabis or placebo cigarette 3x per day for 5-day course of treatment
 - Smoked cannabis reduced daily pain by 34%, vs 17% in placebo group
 - No serious adverse events but reported side effects were clearly greater in treatment vs placebo group.

RCT Smoked Cannabis & Analgesic Efficacy (Adams et al)

- ⊙ Treatment vs placebo group, self-reported:
 - Anxiety (25% vs 10%)
 - Sedation (54% vs 8%)
 - Disorientation (16% vs 1%)
 - Paranoia (13% vs 4%)
 - Confusion (17% vs 1%)
 - Dizziness (15% vs 2%)
 - Nausea (11% vs 3%)
- ⊙ Rates of euphoria was not collected

Efficacy of Marijuana

- ◎ Recent Studies support use for:
 - Neuropathic pain & spasticity
 - MS, Spinal cord injuries, Nerve tract trauma, diabetic neuropathy, HIV neuropathy
 - Can be helpful as an adjunct to decrease use of opiates
 - May be effective for some who don't respond to standard treatments

Glaucoma

- ⦿ Decrease in intraocular pressure
- ⦿ Effect of MJ is short-term
 - May need to smoke every 3hrs.
- ⦿ Requires high doses
- ⦿ No established long term value

Drug Testing in the Workplace

⦿ Percent and testing by employers

- 84% Pre-employment and/or Pre-offer
- 73% Reasonable Suspicion
- 58% Post-accident
- 39% Random
 - True deterrent for a drug-free workplace

Herbal Marijuana Concerns as Drug

- ⦿ Undesirable CNS effects
- ⦿ Dose optimization may not be realized before onset of excessive side effects
- ⦿ Not delivered/distributed in manner to ensure consistent composition, potency, quality, or safety
- ⦿ Concern with present supplies/distribution
 - Quality control & Dosage standardization
- ⦿ Possible adulteration and/or contamination



200% MONEY BACK GUARANTEE!

FOR UNSUPERVISED URINE DRUG TESTS

This product cannot be shipped to residents of...
AR, IL, KY, OK, NJ, NC, PA or SC.

Synthetic Urine Kit (2-ounce Size)

The Ultra Pure synthetic urine is premixed laboratory urine designed to protect your privacy during a urinary drug test. The Ultra Pure synthetic urine is unisex so a male or female can use it to pass drug tests. To ensure passing a urinalysis, the synthetic urine contains all the ingredients normally found in urine and is balanced for pH, specific gravity, creatinine, and several other urine characteristics. The bottle comes with an attached temperature strip and heating pad to ensure the sample is at body temperature. The product contains two ounces of synthetic urine as required by the DOT guidelines. If a lab demands more than two ounces, that demand is operating outside of the DOT guidelines. Request the lab record the volume of the sample before disposal and be sure to document the error.

Instructions:

Heat Ultra Klean Ultra Pure synthetic urine in advance and simply pour contents into sample cup. **The synthetic urine temperature must be 94°-100°F.** The container can be microwaved up to 10 seconds for initial heat. If the temperature remains out of range after first heating, repeat procedure (read the blue dot on temperature strip). If the bottle is out of temperature range after two heatings, cool down (over heated) and retry. Using the enclosed heater pad alone will require approximately an hour to heat to 90°-100°F (see enclosed heater pad for heating instructions). Attach heater pad with tape or rubber band to the bottle, opposite the temperature strip. The heater pad will last up to six hours. Coloration may vary from batch to batch. **Shake bottle before and after heating.** If unused, sample can be reheated for random usage.

Specimens for Drug Testing

- ◎Urine
- ◎Hair
- ◎Saliva
- ◎Blood
- ◎Sweat

Metabolism

- ⦿ THC is the psychoactive ingredient
- ⦿ THC is oxidized to 11-hydroxy-THC (11-OH-THC)
- ⦿ 11-OH-THC is rapidly oxidized to THCA
 - 11-nor-delta-9-tetrahydrocannabinol (THCA)
 - Is not psychoactive
 - Is metabolite appears in urine
 - The target for screening and confirmation tests

Reduce your Detection Period (as found on the Net)

10 Free Things You Can Do To Reduce Drug Detection Periods

Avoid using any toxins, products that might set off your test and/or any toxic environment for at least 48 hours before your deadline. The longer the better. Better yet, do not do drugs at all!

Maintain a healthy diet prior to your test. Avoid high fat foods such as butters, cream sauces and/or fried foods as they slow the detoxification process substantially.

Consume only light meals the day of your personal deadline.

Avoid alcoholic beverages, over the counter and/or unnecessary medications.

For at least (4) days prior to your personal deadline (if time allows) consume (3) 16 ounce glasses of water. Spread these out and do not consume them at one time

Try not to test first thing in the morning. This is a time where the concentrations of metabolites are the highest.

Disclose all the medications you have been taking. You never know which over-the-counter or prescription medication will set off a test.

BE CAREFUL, EVERYTHING ONE READS IS NOT TRUE!

Urine Drug Testing

⦿ **Advantages**

- Relatively inexpensive (screen, confirm, MRO)
- Detects recent use, primarily within the last week
 - 2-10d occasional, up to 45d regular
- Option to do point of service (instant), followed by lab confirmation (false positives removed)
- Temperature tested to insure sample integrity

⦿ **Limitations**

- Adulteration, dilution, substitution
- Are considered an intrusive method of testing
- Limited detection window (out to 45d)

Cannabis Metabolism

Occasional Cannabis Smoker

- Mean peak urinary metabolite 10-18 hrs after smoking single 3.55% cigarette
- Remained >15 mg/dl for 80-100 hours
- Concentrations decreased rapidly at first with more gradual decrease over several days

Urine Drug Testing for Marijuana

- ⦿ Unlike alcohol testing – does NOT correlate with impairment
 - 7-45 days can detect metabolites
- ⦿ MJ drug tests do not correlate with symptoms or degree of exposure
- ⦿ Cannot distinguish use several days ago from someone actively using
 - Change in the science?
 - Too numerous cannabinoids and psychoactive metabolites may limit correlation

Positive Urine Drug Screen

⊙ Marijuana

- Initial screening, confirmation, MRO'd
- Reported as positive with “card”
- When? How?
- Impaired or previous use?

⊙ Other drugs/prescription medication

- Illegal or illicit use

Hair Drug Testing

⦿ **Advantages**

- Detects past several months' use (90 days)
- Adulteration, substitution, dilution not a problem
- Specimen stability, not affected by brief abstinence
- Relatively unintrusive method of drug testing

⦿ **Limitations**

- Can't detect recent use (0-7 days)
- Collection when bald
- Not SAMHSA certified
- Expensive (\$75-125)

Jolly Ranchers

These mouth-watering treats are becoming widely popular in many dispensaries. They are renowned by patients for their flavor, price and potency. Marijuana-infused Jolly Ranchers are also a way to medicate discreetly or in a public area.

These delicious treats are extremely potent, with a strong danky, hashy flavor. Took between an hour and an hour-and-a-half to kick in, but once it did, it lasted for around 4 or 5 hours.

Ingredients:

- Sugar (2 cups)
- Light corn syrup (2/3 cup)
- Flavor of your choice (3/4 cup)
- Hash (amount depends of personal dosage preferences)



To make your own dosed Jolly Ranchers, first mix the sugar, hash and syrup thoroughly together until they are well blended. As each batch may vary, there is not a specific amount of time to put this mixture of corn syrup, hashish and sugar in the oven. Instead, heat this mixture until it is 295 F. Once it reaches this temperature, remove the mix from the oven and mix in your choice of flavoring. Line some trays with either wax paper or another non-stick material and place in the freezer until completely hard. This medication should be ready after 1 or 2 hours in the freezer. Just break apart to medicate. Warning: use pieces that are around the same size as a normal Jolly Rancher to start with.

Saliva Drug Testing

● Advantages

- Direct collection minimizes adulteration, substitution, dilution
- Detects very recent use, primarily within past 24 hours
- Easy to administer but require lab processing to ensure accuracy
- Less invasive
- Can detect more recent use than other testing methods
- Can do point of service, followed by lab confirmation

● Limitations

- Short detection window (24 hours)
- Not SAMHSA certified
- No nationally accepted standards or cutoff concentrations for detection
- Results greatly dependent on the specific product purchased
- Could also make results less-reliable and/or acceptable for legal cases

Blood

⦿ **Advantages:**

- **Most accurate method of testing**

⦿ **Limitations:**

- **Multiple metabolites and not long in plasma**
- **Non-linear r'ship between plasma THC and degree of intoxication**
- **Lacks correlation standards with impairment**
- **Most expensive method of testing**
- **Most intrusive method of testing**

Sweat Drug Testing

⦿ Advantages:

- Can detect use which would not trigger other tests
- Gathering sweat over an extended period of time, it is possible that any use during that time will produce a positive result

⦿ Limitations:

- Relatively intrusive method of drug testing?
- Relatively uncommon
- Controversial in terms of accuracy
 - surface contamination (such as cannabis smoke)
- Relies on patient compliance

**Differentiating New Cannabis Use From Residual Urinary Cannabinoid Excretion in Chronic, Daily Cannabis Users

- Schilke, et. al., Society for the Study of Addiction; Oct. 2010
 - Validated a model to aid in differentiation of new cannabis use from residual.
 - Requires multiple UDS's, use may be for parolees and in drug programs
 - 2 specimens collected 48-720 hours apart, depends on levels of creatinine once normalized
- Utilization for workplace programs problematic and not realistic

Can the Employee Work?

- Marijuana use is prohibited for those subject to Federal drug testing rules and regulations
- Others subject to state law, employer's policies, and collective bargaining agreements
- Recent opinion on *Casias v. Wal-Mart*
 - MMMA use does not = employment
- Your choice as an employer

MDCH FAQs: Can I use medical marijuana at work?

- This is up to the employer
- Even if you are a registered patient, your employer may still prohibit medical marijuana use in the workplace

Studies Show...

- ◎ Sedative effects of MJ use is well established:
 - users report mental slowness, tiredness, anxiety, paranoia, relaxation, and euphoria (Parrott et al., 2004)
- ◎ Long-term cannabis use
 - subtle and selective impairment of specific higher cognitive functions (Solowij, 1998)
- ◎ These findings also are seen in workers under a separate study; impact of cannabis use on cognitive performance (Wadsworth et al., 2005)

Cannabis Use and Impact on Safety

- ⦿ Cannabis impairs driving skills (Parrott, 1987),
 - similar to a level of 0.07 and 0.10% BAC (Hall et al., 1994)
- ⦿ Cannabis intoxicated drivers have an increased risk of motor vehicle crashes (Grotenhermen et al., 2007)
- ⦿ Impairment on driving simulation for up to 3 hours
 - Decreased car handling performance
 - Slower reaction time
 - Impairs time and distance estimations

Fitness for Duty Considerations

⦿ Safety-Sensitive Work

- Driving
- Construction/Maintenance
- Power equipment use
- Public Safety positions
- Medical Decision making

⦿ Non-safety Sensitive Work

- Monitor productivity & quality of work

Fitness for Duty

⦿ Impairment

- Duration of “high”
- Dependent on smoked, ingested
- Objective testing: limitations of drug screens

⦿ Presenteeism

- Recall scientific evidence

⦿ Self-dosing, lack of standardization of potency leads to variable effects day to day

Science points to...

- Prohibit use in the workplace
 - Very least the safety-sensitive positions
- Unable to distinguish when last use and/or impairment objectively
- Subtle, longer lasting effects that will not be realized by users
- Rely on subjective / observations for “under the influence”

Future Scientific Evidence

- ⊙ Cannabinoids showing potential therapeutic use in treatment of:
 - Psychomotor disorders Multiple sclerosis
 - Epilepsy ADHD
- ⊙ Development of methods for verifying impairment, as with ETOH
- ⊙ Herbal marijuana in smoked form will not be a recommendation from physicians

References

- ◎ American College of Occ. and Environmental Medicine
 - www.acoem.org
- ◎ Michigan Department of Community Health
 - www.michigan.gov/mdch
 - Health systems..., Medical Marijuana Program
- ◎ Substance Abuse and Mental Health Services Administration, Workplace Resource Center
 - <http://workplace.samhsa.gov/>

References

- ⦿ Drug-Free Workplace Helpline
 - 800-967-5752
- ⦿ MROCC (Medical Review Officer Certification Council)
 - www.mrocc.com
- ⦿ DOT, Office of Drug & Alcohol Policy & Compliance
 - www.dot.gov/ost/dapc
- ⦿ Searches via Google or Bing

QUESTIONS



MDCH FAQs: What should I tell my employer if I am subjected to a drug test?

- ④ The MMMA states that employers are not required to accommodate employees who use medical marijuana
- ④ You may wish to consult an attorney about whether or not to tell your employer that you are a patient in the MMMP