

Federal Law: Controlled Substance Act (CSA

Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970

- Regulates the manufacture, importation, possession, use, and distribution of certain substances
- Initially created five Schedules with defined qualifications
- DEA and FDA maintain scheduling
- Scheduling can change through legislative amendments and petitioning or administratively by the US Attorney General
- States can maintain a separate classification list that can conflict with federal classifications (Oregon, Wisconsin, Iowa, etc.)



Marijuana is a Schedule I drug under the Federal Controlled **Substances Act**

- Makes possession, usage, purchase, sale, and/or cultivation of marijuana illegal at the federal level
- May not be prescribed, administered, or dispensed
- Other Schedule I drugs include:
 - Lysergic acid diethylamide (LSD)
 - Diacetylmorphine (Heroin)
 - Gamma Hydroxybutyric Acid (GHB)
 - MDMA (AKA "ecstasy")
 - Mescaline

- As of April 2016:
 - Medical marijuana is now legalized in some form in 41 states, the District of Columbia, and Guam
 Recreational use is now legal in 4 states and the District of Columbia

 - Nevada may become the 5th state to legalize recreational use later this year
 An additional 20 states have decriminalized the possession of certain quantities of marijuana



2016 Pending Medical Marijuana Legislation:

- Florida
- Kentucky
- Missouri
- Nebraska
- South Carolina
- Tennessee



State Law

Colorado's Amendment 64 was the first successful attempt to regulate marijuana in a similar fashion to alcohol:

- The initiative was passed on November 6, 2012
- Allows for the legal use and possession of marijuana by adults age 21 and older
- The amendment was supported by:
 - The Colorado Democratic Party
 - 56% of the Denver County Republican Assembly
 - NAACP
 - Members of the Colorado's law enforcement community
 - More than 300 Colorado physicians
 - More than 100 college professors from across the nation

States v	with Active I	Registry	
State	Total # of Reaistrants	Per 1,000 of	Voluntar
Alaska	1.132	1.5	
Arizona	89,405	13.1	 California
California	758,607	19.4	
Colorado	107,798	19.8	
Connecticut	8,685	2.4	
DC	3,445	5.1	
Delaware	102	0.1	
Hawaii	13,021	9.1	
Illinois	4,037	0.3	
Maine	24,377	18.3	

Voluntary Registration

Medical Marijuana

- · Wind of Change
 - Debates have centered on the cost of enforcement and in the disparities of those incarcerated
 - Proponents of medicinal use have framed the discussion as "compassionate use" for those stricken with a severe or terminal illnesses
 - Very little focus has been on scientific evidence for the use of marijuana of which there is limited evidence to support is use

- Wind of Change continued
 - Elected officials are the ones making these decisions through legislation and they are greatly influenced by public opinion
 - Gallup first polled Americans who were in favor of legalization in 1969 and at the time ONLY 12%
 - Pew recently published a poll that shows 52% of Americans favor legalization

- A bipartisan bill, titled the Compassionate Access, Research Expansion, and Respect States (CARERS) Act, was introduced in both the Senate and House of Representatives in March and April 2015
- Intent to reclassify marijuana as a schedule II drug
- Purpose is to allow medical marijuana businesses access to banking and VA prescribers to recommend patients for medical marijuana
- No chance of passing however, the congressman claims "they're carrying out the will of the people" and it will eventually pass

Therapeutic Potential:

- 1) Relieving pain
- 2) Controlling nausea and vomiting
- 3) Stimulating appetite
- 4) Decreasing ocular pressure

Cannabinoid-based medications:

- 1) Dronabinol (Marinol®)
- 2) Nabilone (Cesamet®)
- 3) Nabiximols (Sativex®)







Completed studies: Study to Evaluate the Efficacy and Safety of Dronabinol Metered Dose Inhaler (MDI) in Acute Treatment of Migraine Headache <u>Supporting Effect of Dronabinol on Behavioral Therapy in Fibromyalgia and Chronic Back Pain</u> A Study to Evaluate the Effects of Cannabis Based Medicine in Patients With Pain of Neurological Origin A Study of Sativex® for Pain Relief in Patients With Advanced Malignancy Evaluate the Maintenance of Effect After Long-term Treatment With Sativex® in Subjects With Symptoms of Spasticity Due to Multiple Sclerosis Study to Evaluate the Efficacy of Dronabinol (Marinol) as Add-On Therapy for Patients on Opioids for Chronic Pain Unknown status: • Efficacy Trial of Oral Tetrahydrocannabinol in Patients With Fibromyalgia • Effect of Delta-9-Tetrahydrocannabinol on the Prevention of Chronic Pain in Patients With Acute **CRPS (ETIC-Study)** Appetite loss from wasting syndrome (Cachexia): Stimulates appetite in patients with AIDS Increases caloric intake and causes weight gain Cachexia also experienced in cancer, heart failure, severe trauma, Nausea and Vomiting: Modestly effective Poorly tolerated by cancer patients Unique antiemetic mechanism; may be useful as adjunctive therapy

Multiple Sclerosis:

THC reduces tremor and spasticity Reduces urge incontinence Effective when smoked or taken orally

Glaucoma:

- Reduces intraocular pressure
- Decreases blood flow to optic nerve
- Unknown if visual function is improved



Pain:

- Animal studies suggest mild to moderate analgesic properties
- · Modestly effective for chronic pain (including neuropathic)
- Relatively high risk of adverse events (NNH= 5 to 8 for altered perception and altered cognitive function)

Conditions common to most states:

- Chronic pain (ill-defined origin) AIDS/HIV

- Cancer Multiple Sclerosis
- Persistent muscle spasms (not limited to MS)
- Epilepsy Crohn's disease

Other conditions: subject to approval by Department of Health

Delaware: "chronic pain; if the condition has not responded to previously prescribed medications"

District of Columbia: "For which there is scientific evidence that the use of medical marijuana is likely to be significantly less addictive than the ordinary medical treatment for that condition"

California: "deemed appropriate and has been recommended by a physician"

Physiological Risk:

- Acute use: diminished psychomotor performance, dry mouth
- (xerostomia), reddening of the eyes
- Chronic use:

Effects from Smoking

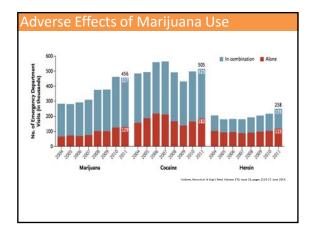
- Abnormalities of respiratory tract cell lining

 ↑ risk of cancer, lung
- damage and poor pregnancy outcomes
- Effects from THC
- Cognitive impairment
- Apathy Psychic decline
- Sexual dysfunction
- · Abnormal menstruation



Adverse Health Effects of Marijuana Use Volkow, Nora et al. N Engl J Med. Volume 370, Issue 23, pages 2219-27. June 2014. Risk of Addiction Approximately 9% of those who experiment with marijuana will become addicted (according to the criteria for dependence in DSM-IV) Relation to Mental Illness Regular marijuana use is associated with an increased risk of anxiety and depression Linked to psychoses and exacerbates the course of illness in patients with schizophrenia יס יאיטניסי-venuce Accidents Both immediate and long-term exposure to marijuana impair driving ability Recent marijuans amoking and blood THC levels of 2 to 5 ng/mL are associated with substantial driving impairment Risk of Motor-Vehicle Accidents Risk of Cancer and Other Effects on Health Evidence suggests that the risk of cancer is lower with marijuana than with tobacco Associated with inflammation of airways, increased airway resistance, and lung hyperinflation Associated with vascular conditions that increase the risks of myocardial infarctions, stroke, and transient ischemic attacks during marijuana intoxication Adverse Effects of Marijuana Use Effects of Short-Term Use Impaired short-term memory, making it difficult to learn and to retain information Impaired motor coordination, interfering with driving skills and increasing the risk of injuries Altered judgment, increasing the risk of sexual behaviors that facilitate the transmission of sexually transmitted diseases In high doses, paranoia and psychosis Effects of Long-Term Use Addiction Altered brain development Cognitive impairment Diminished life satisfaction and achievement Symptoms of chronic bronchitis Increased risk of chronic psychotic disorders • Researchers at the Karolinska Institutet in Stockholm published a study in the American Journal of Psychiatry that followed 45,000 men over 42 years - Of these men - 4,000 died during the study - Investigators found that those who were heavy marijuana users in their late teens were 40 % more likely to die by age 60 than those who The long duration of the study might provide us clues to the long term effects of marijuana use, including its role in cancer and cardiovascular disease development

Adverse Effects of Marijuana Use



Marijuana Effects on Workplace Motivation

Does smoking cannabis affect work commitment?

Christen Hyggen. Addiction. Volume 107, Issue 7, pages 1309-1315, July 2012

Setting: The panel survey was a nation-wide study set in Norway

Participants: 1997 respondents born between 1965 and 1968: separated into groups of "abstaining", "exposed", "experimenters", and "involved"

Findings

- The level of work commitment was associated with involvement with cannabis
- "Involved" group and "experimented" reported less work commitment compared to the "abstainer" group
- "Experimented" group converged towards the "abstainers "and "exposed" as they grew older
- "Involved" reported decreasing work commitment into adulthood
- Factors related socio-economic background, education, labor market experiences, mental health and family characteristics were factored in

Medical Risks of Marijuana Use

Abuse, Dependence , & Addiction:

- Less significant than that associated with alcohol, nicotine, and others controlled drugs
- Risk factors: mental illness, history of substance abuse, younger age
- Anti-social personality and conduct disorder are closely associated with abuse.
- 10% of regular marijuana users become addicted

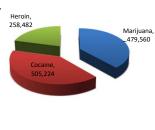
Withdrawal:

- Mild and transient
- Symptoms: restlessness, irritability, mild agitation, insomnia, sleep disturbance, nausea, and cramping.

Medical Risks of Marijuana Use Substance Abuse and Mental Health Services Administration 2011:

- Over 125 million Emergency Department visits
- Over 5 million drug related
- 2.5 million drug misuse or abuse
- 1,247,500 (49%) related to pharmaceuticals
- 1,252,500 (51%) illicit drugs
- 479,560 (38%) marijuana

Source: Drug Abuse Warning Network, 2011.



Medical Marijuana: Implications for WC

Questions:

Issue for employers:

What accommodations should employers make?

Issues for Payers:

- How should a recommendation ("prescription") for MM be handled?
- Where should MM be placed within a pain management treatment plan?
- How can we best prepare for the emergence of MM during the administration of a claim within the scope of IW treatment?

Issues for Employers

What accommodations should employers make?

- Private sector: employers can accommodate unless the company receives federal contracts (Drug-Free Workplace Act of 1988)
- DOT guidelines: prohibit MM for transportation workers
- OSHA: employers have general duty to provide safe work environment
- 2008 California Supreme Court case: Ross v. Ragingwire Telecommunications, Inc> drug testing is legal and not discriminatory

Issues for Employers

What accommodations should employers make?

- Washington State Human Rights Commission: "will decline to investigate any claims of discrimination involving MM
- CO, HI, MI, MT, NJ, NM, VT: only on-the-job consumption/impairment is grounds for termination
- Battle Creek, MI: Walmart terminates cancer patient for using MM
- RI, ME: "no school, employer or landlord may refuse to enroll, employ or lease to or otherwise penalize a person solely for his or her status as a card holder" § 21-28.6-4



Issues for Pavers

How should a "prescription" for MM be handled?

- No prescriptions for medical marijuana should be covered:
 - Not FDA approved
 - Not covered by any private or public health plans
 - Violation of federal law



Issues for Pavers

How should marijuana be addressed within a pain management treatment plan?

- No evidence-based place in therapy
- · Counterproductive to goals of therapy
- Indicative of aberrant behavior

Medical cannabis and chronic opioid therapy Reisfield GM. J Pain Palliat Care Pharmacother. 2010 Dec;24(4):356-61. National Survey on Drug Use and Health (NSDUH): positive association between past year cannabis use and past year nonmedical use of opioids · Association is stronger in persons 50 and older Prevalence of past year nonmedical use of opioids was 10.7%, compared to 1.1% in cannabis users vs. non-users Prevalence of cannabis use multiple times higher among patients in nearly Significant associations between cannabis use and a spectrum of aberrant behaviors - opioid abuse and diversion, use of illicit substances and non-prescribed controlled substances, doctor shopping and opioid trafficking. Marijuana correlates with use of other drugs in a pain patient population Pesce A, West C, Rosenthal M, et al. Pain Physician. 2010;13:283–287. • 21,746 urine specimens were obtained from chronic pain patients • 13.0% incidence of patients positive for THC • 4.6% positive for cocaine • 1.07% positive for methamphetamine Conclusion: that there was a correlation between marijuana use and the use of other illicit drugs • The odds ratio was > 3.7 for other illicit drug use **Proactive Approach** Establish an authorization policy for MM Baseline UDS Insist on opioid contract Determine the physician's policy on marijuana Utilize advanced technologies to evaluate appropriateness of therapy Alert, Review, Manage® – analyze claimant data for adverse trends myRisk Predictor[™] - assessment tool to identify injured workers who are at high risk for potential abuse and misuse of prescription medications. nunication between PBM and physicians Targeted intervention Detailed Drug Regimen review

Urine Drug Screening (UDS)

- What does this mean for the employer's ability to enforce a "Drug Free Workplace"?
 - Thus far the courts have ruled in favor of the business



- Reason: American with Disabilities Act is a federal law and marijuana is considered an illegal drug under federal law therefore employers do not have to accommodate patients using marijuana

- Exclude coverage under workers' compensation?
 - Montana and Vermont specifically exclude marijuana in their w/c system



- All, but six states, passed laws that have similar wording "No governmental, private, or any other health insurance provider shall be required to be liable for any claim for reimbursement for the medical use of marijuana"
- New Mexico, the exception?

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