Medical Marijuana and Opioid Analgesics in Workers’ Compensation
A Workers’ Compensation Continuing Education Course
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**SAMPLE**

Compounds make up a small number of scripts but have impacted drug spend in workers' comp in that these are **high cost meds**

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Learning Objectives

• Describe the facts about the increase of opioid analgesic use in America
• List the resulting risks of overdose and other medical conditions related to opioid analgesic use and misuse.
• Describe some of the proposed uses of medical marijuana
• Identify the ways marijuana effects the body and other medicines
• Review the latest legislative actions surrounding medical marijuana use
• Understand the impact of medical marijuana use on Medical Set Aside allocations
The Facts About Opioid Analgesics
Drug Overdose Deaths Involving Opioids

Source: National Vital Statistics System, Mortality File
Chart courtesy of the CDC; http://www.cdc.gov/mmwr, Dec 2015
Epidemiology of overuse

The number of prescriptions for opioids have escalated from around

**76 million in 1991** to nearly **207 million in 2013**

- **80%** of all opioid analgesics dispensed in the world are dispensed in the U.S.
- **99%** of all hydrocodone dispensed in the world is dispensed in the U.S.

In 2010, enough prescription painkillers were prescribed to medicate every American adult **every 4 hours for 1 month**

- **6.1 million** people have used prescription pain relievers non-medically in the past month
- **52 million** people in the U.S., over the age of 12, have used prescription drugs non-medically in their lifetime

Sources: Centers for Disease Control and Prevention (CDC)
Epidemiology of overuse

Since 2000, the rate of deaths from drug overdoses has increased 137%.

During 2014, a total of 47,055 drug overdose deaths occurred in the U.S., representing a 1-year increase of 6.5%.

46 Americans die each day from prescription opioid overdoses — 2 deaths an hour.

17,000 annually.

91% of patients who survive opioid overdose are prescribed more opioids.

Sources: Centers for Disease Control and Prevention (CDC)
The Impact of Opioid Analgesics on the Body Systems
Poll Question #1
The Facts about Medical Marijuana
The Facts About Marijuana

- Approximately 100 million American adults have used marijuana and the current use rate is reported to be 17.4 million (SAMHSA)
- Over 1.1 million legal medical marijuana patients are registered in the United States (as of Oct 2014)
- Marijuana refers to dried flowers and leaves of the cannabis plant (there are various species but Indica and Sativa most common for medical marijuana)
- Dried flowers, leaves and stems are smoked, vaporized or cooked for ingestion of the extracts
- Alternative methods of administration avoid combustion and are considered less harmful to the lungs
- Schedule I Federal Controlled Substance - Similar to ecstasy, heroin, cocaine, LSD: no legitimate medical use, lack of accepted safety under medical supervision, and a high potential for abuse
Is Marijuana Medicine?

• The use of the term medical marijuana is in reference to treating a disease or symptom with the whole unprocessed marijuana plant or its basic extracts. Some of the 483 compounds/chemicals identified are unique to Cannabis.

• There are two FDA approved medications in pill forms (THC); however, they are synthetic and not from the plant.

• “The FDA has not recognized or approved the marijuana plant as medicine”

• There are two main chemicals in the marijuana plant that are of interest medically, delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). The body also produces its own cannabinoids.
### Is Marijuana Medicine?

<table>
<thead>
<tr>
<th>Cannabinoid Chemicals</th>
<th>• The natural cannabinoid receptor system in the human body was only recently discovered in the past two decades</th>
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</table>
| **Anandamide**       | • A natural messenger chemical present in the brain at low levels  
|                      | • Endocannabinoid; role in pain, depression, appetite, memory and fertility                      |
| ![Anandamide](image) |                                                                                                  |
| **Delta-9-tetrahydrocannabinol (THC)** | • Most psychoactive cannabinoid  
|                      | • Interacts with CB₁ and CB₂ receptors giving the effects of feeling high                        |
| ![THC](image)       |                                                                                                  |
| **Cannabidiol (CBD)** | • Non-psychoactive; interacts differently with CB₁ and CB₂ receptors along with a serotonin receptor giving the effects of feeling relaxed and heavy (stoned) |
| ![CBD](image)       |                                                                                                  |
Pharmaceutical Cannabinoids

**Synthetic Cannabinoids**
Made in laboratories; examples include FDA approved Marinol® (dronabinol) and Cesamet (nabilone)

**Marinol®: Synthetic Oral THC**
- Schedule III
- Relieve nausea/vomiting from chemotherapy and loss of appetite in patients with HIV

**Cesamet®: Synthetic Oral THC analogue**
- Schedule II
- Believed to be more potent than THC
- Nausea/vomiting associated with chemotherapy

**Phytocannabinoids – Cannabis**
Found in the plants, contains hundreds of cannabinoids, most notably THC and CBD

**Sativex® (Canada/UK): herbal Cannabis extract (THC/CBD, 1:1)**
- Sublingual spray adjunct treatment central neuropathic pain in MS and cancer pain
- Rapid acting, easy to use
- Late stage study in the US
Research on Smoked Medical Marijuana

American Medical Association (AMA)

- “Despite the public controversy, less than 20 small randomized controlled trials of short duration involving ~300 patients have been conducted over the last 35 years on smoked cannabis.”

- Reduce the schedule and conduct more research

Institute of Medicine (IOM)

- Strong evidence for use in chronic and neuropathic pain with multiple sclerosis, spinal cord injury, cancer, tremors, spasms, spasticity, nausea/vomiting produced by cancer chemotherapy, loss of appetite in AIDS/cancer

- Development of non-smoked, reliable delivery systems for cannabis-derived products
How Medical Marijuana Works

The body contains molecular structures known as receptors that are activated by chemical substances contained in Marijuana

- Chemical substances in marijuana are called cannabinoids; 483 compounds/chemicals identified
- The body contains two major receptors that interact with cannabinoids:
  - $\text{CB}_1$ receptors in the nervous system and brain
  - $\text{CB}_2$ receptors in the immune system
- Similar to a lock and key where the receptor is the lock and the key is the cannabinoid
  - Once the cannabinoid enters the receptor, various effects occur in the body
**System CBD Effects**

### Side Effects of CBD
- Possible Immunosuppressive effects
- Sedation – what are comorbidities
- High concentrations of CBD and potential effects on blood sugar
- Feeling heavy
- Overdoses (up to 300 mg/kg IV) in Monkeys – Tremors, convulsions, vomiting, sedation to prostration in 30 minutes, cardiac failure

### Drug Interactions - CBD
- **BIGGEST CAUTION**
- Drugs metabolized by CYP450 3A4, 2C19, and 2B subfamilies can be affected when given at the same time as CBD; may induce or inhibit metabolism, which can lead to increased or reduced amounts of other drugs. Interacts with THC as THC is metabolized by 3A4 and 2C19.
- The potential for drug interactions may be large and includes interactions with HIV medications, antibiotics, and others
- CBD could interact with anticancer drugs (P-glycoprotein)
- CBD unclear if there is an interaction with NSAIDs
How the Body Interacts with Cannabinoids

- Rate and amount of drug entering the body varies greatly on administration method and formulation
  - Smoking, swallowing, topical, rectal
  - Smoking provides quicker effects than swallowing
- THC and CBD go into the brain and body tissues from the bloodstream giving rapid effects
- The body interacts with THC and CBD making new modified chemicals, some are active with the receptor(s) and others are not
- 80% - 90% excreted within five days
- In heavy cannabis users, THC can accumulate in fatty tissues giving prolonged detection of cannabis use (up to 30 days and longer)
# The Body’s Response to Marijuana

## Delta-9-Tetrahydrocannabinol (THC)
- Mood changes such as anxiety or depression
- Cognition effects
  - Decreased concentration
  - Short-term memory loss
  - Decreased attention span
  - Paranoia
  - Time distortion
- Decreased spasticity
- Increased appetite
- Analgesia
- Abuse and dependence potential
- Psychologically and physically

## Cannabidiol (CBD)
- Synergistic effect with THC
- Anxiolytic
- Antipsychotic
- Anticonvulsant
- Neuroprotective properties
- Analgesic
- Anti-inflammatory
- Antispasmodic
Systemic Marijuana Side Effects

Wadsworth et al, 2006

- Short-term memory problems
- Impaired thinking and ability to perform tasks requiring mental alertness
- Loss of balance and motor function (e.g., coordination)
- Decreased ability to concentrate
- Changes in sensory perception
- Decreased reaction time

Ammerman et al, 2015

- Increased heart rate
- Increased blood pressure
- Dry mouth
- Increased appetite, thirst
- Drowsiness
- Anxiety, insomnia, panic attacks
- Hallucinations
Safety – Marijuana

Study from 1993-2013 by Dr. Wayne Hall, University of Queensland

Major findings based on recreational use of marijuana:

• No respiratory depression (person stops breathing) with Marijuana when used alone

• There are no reports of fatal overdoses in the epidemiological literature

• It doubles the chance of a driving accident: DUI for marijuana increased the risk of car crashes by 2-3 times, as compared to a risk with comparable intoxicating alcohol levels being 6-15 times
Safety – Marijuana

• Dependence can occur
  – Estimates show 1 in 6 adolescents and half of daily cannabis users
  – Tolerance develops to THC and withdrawal symptoms can occur if suddenly stopped
  – Strongly associated with use of other illicit drugs
• Negatively impacts IQ (Only where initiated in adolescence and continued into adulthood)
• Effect on respiratory health is inconclusive
• Smoking marijuana has been associated with an increased risk of cardiovascular side effects – caution in middle age and older
Marijuana and Prescription Drug Misuse

Lab data (22K + UDTs) correlation between marijuana and prescription drug use in national population

Marijuana most frequently detected drug in >26% of patients who do not use medications as prescribed

Marijuana most frequently detected non-prescribed drug in >26% of patients who do not use medications as prescribed

Approximately 45% of patients who use recreational marijuana also used other non-prescribed drugs (i.e., sedatives and narcotics)

37% of medical marijuana users misused other drugs

Marijuana most frequently detected drug in the nation’s workforce, March 2013 drug test index report

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The laws in many states define the medical conditions, circumstances and methods of consumption in which an individual can secure and use medical marijuana.

California allows treatment with marijuana when determined by a doctor to be appropriate for the following "serious medical conditions."

- AIDS
- Anorexia
- Arthritis
- Cachexia/wasting away
- Cancer
- Chronic/severe pain
- Migraine
Proposed Medical Uses

- Persistent muscle spasms, including, but not limited to spasms associated with multiple sclerosis
  - Seizures, including, but not limited to seizures associated with epilepsy
  - Epilepsy/seizure disorders - (Charlotte’s Web) Hemp Oil – used for children
  - Severe Nausea
- Any other chronic or persistent medical symptom that either:
  a. Substantially limits the ability of the person to conduct one or more major life activities as defined in the Americans and Disabilities Act of 1990 (Public Law 101-336).
  b. If not alleviated, may cause serious harm to the patient’s safety or physical or mental health.
Poll Question #2
Legislative Update
Medical Marijuana

Medical use of marijuana currently prohibited with legalized usage of cannabidiol (CBD) for limited purposes

Legalized medical marijuana

Legalized recreational and medical marijuana

Medical use of marijuana currently prohibited

Policy Maker Concerns

• Gaining ground as acceptable treatment for pain
• Chronic pain as a qualifying condition frequent in workers’ compensation
• Touted as an opioid replacement for pain therapy
• Lack of comprehensive clinical studies/data
Recent Legislative Activity

• Court Case/Reimbursement issues in New Mexico – Adopted into Fee Schedule
• Legal cases in California and Colorado and regulatory action in Minnesota
• California enacted laws to create more structure around regulation and enforcement
• Federal agencies reevaluated the Schedule I status. The Drug Enforcement Agency (DEA) announced in August 2016 that medical marijuana will remain a Schedule I drug but they relaxed the standards to make it more accessible for researchers.
• Pennsylvania passes Senate Bill 3
• Ballot initiative failed to pass in Ohio in 2015; legislature responded in 2016 by passing legislation to legalize medical marijuana; Kasich signed the bill making Ohio the 25th state to legalize medical marijuana
Employer Challenges

• Heightened level of concern when claimant returns to a safety-sensitive occupation, such as driving or construction, while subject to potential adverse cognitive and psychological effects of marijuana

• Quantification of the amount of marijuana consumed by claimant is not available through urine medication testing, thereby limiting ability to determine if he or she has consumed prescribed dose, or is in fact acutely intoxicated

• Understanding the potential impact to medication Free Workplace policies as well as other safety and risk management protocols and programs
Marijuana Vote 2016

- Recreational
  - California Proposition 64
  - Arizona Proposition 205
  - Nevada Question #2
  - Maine Question #1
  - Massachusetts Question #4

- Medical
  - Montana Initiative 182
  - North Dakota Measure 5
  - Arkansas Medical Cannabis Act
  - Florida Amendment #2
  - Possible votes in Michigan, Missouri, Oklahoma pending litigation

- 2017 Legislative proposals still to be determined
Cockrell v Farmer’s Insurance

- Treating physician and medical evaluator agreed marijuana was reasonable and necessary.

- In 2012 the workers’ compensation administrative law judge (WCJ) ruled that Cockrell was entitled to be reimbursed for marijuana at the same rate as other FDA approved THC derivatives, such as Marinol.

- Upon appeal, the Workers’ Compensation Appeals Board (WCAB) held that the WCJ had not considered the question of whether a workers’ compensation insurer is considered a “health insurance provider” or “health care service plan” and therefore not obligated to reimburse under the terms of the law. The WCAB returned the case to the WCJ for consideration of that question.

- After the WCJ ordered reimbursement, the WCAB again heard the case on appeal in March, 2015, and again returned the case to the WCJ for further review, holding that the WCJ had considered whether a comp insurer is a “health care service plan” but had not considered whether it is a “health insurance provider.” The case remains unresolved.
California Medical Marijuana Regulation and Safety Act (MMRSA)

Three bills signed by Governor Brown in 2015 make up the new law.

- Creates a marijuana regulatory structure
- To license, test, and track from “seed to sale”
- Cultivator, Processor, Transporter, Distributor, Dispensary
- Permits total local control over zoning. Local government can ban dispensaries.
- Establishes the Bureau of Medical Marijuana Regulation (BMMR), which will make, implement, and enforce the rules, with other agencies.
Poll Question #3
The Potential Impact on Medicare Set-Aside Allocations
The use of marijuana for medicinal purposes at the federal level has been illegal since 1970, when Congress passed and President Nixon signed into law the Controlled Substances Act (CSA).

CSA classified marijuana as a Schedule I substance. Schedule I substances are considered to have high abuse potential, no accepted medical use and a lack of accepted safety data.

Since 1970, there have been numerous petitions to reclassify marijuana as a Schedule II substance in an attempt to decriminalize the use of marijuana for medical purposes at the federal level. None of these efforts have been successful.
Medical Marijuana is Illegal at the Federal Level

• The Schedule I status of marijuana continues to prohibit assignment of a National Drug Code (NDC), thus pharmacy benefit managers (PBMs) are unable to process claims for this treatment option.

• Today, while marijuana is legal for medicinal purposes in 25 states and Washington, DC, it’s still illegal at the federal level.
Pending Federal Legislation and Regulations

• At the federal level, the CARERS Act was introduced in the U.S. Senate last February and is currently pending in congressional committee.

• The bill is designed to relax federal restrictions on allowing individuals to cross state lines to access medical marijuana and would also ease controls for researchers looking to engage in studies on the medical uses of the drug.

• While the bill, at this point, has little chance of passage, it may have had some impact on the recent changes announced by the Drug Enforcement Agency (DEA).

• In late December, the DEA relaxed regulations related to research on cannabidiol, an extract of the marijuana plant. The new rules allow for easier access to greater quantities of cannabidiol for research purposes.

• To this end, Congressman Jason Chaffetz R-Utah, has introduced legislation in the U.S. House of Representatives to decriminalize the possession of cannabidiol.
State Case Law Awarding Medical Marijuana

Vialpando v Ben’s Automotive Services (New Mexico Court of Appeals, May 2014)

The appellate court upheld a workers’ compensation judge’s decision mandating the employer/carrier pay for the injured workers’ medical marijuana. Appellate judge James Wechsler indicated that the employer/carrier had not indicated a specific federal law that would have been violated by the payment for medical marijuana.
Medical Marijuana and Medicare Set Asides

• As the Medicare Secondary Payer Act (MSP) requires, and the Centers for Medicare and Medicaid Services (CMS) has provided, parties settling workers compensation claims in which the injured worker is a current or potential Medicare beneficiary must take Medicare’s future interests into account.

• One of the acceptable methods of taking such interests into account is by producing a Medicare set aside, allocating a specific amount for future medical needs associated with the work related injury that Medicare would otherwise allow and pay for.

• Since marijuana remains a Schedule I substance, CMS will not provide payment for expenses related to the use of medical marijuana. Consequently, even if an authorized medical provider has appropriately and legally prescribed medical marijuana pursuant to that state’s law, because Medicare will not allow for and pay for such care, CMS will not allow for marijuana in a Medicare set aside.

• Instead, Medicare may require either previously prescribed or other similar medication, which could be significantly more costly to fund.
Recent CMS and CDC Guidance on Opioid Analgesics

• Effective January 1, 2013, CMS adopted an opioid analgesic overutilization policy to assist Part D sponsors in identifying high risk beneficiaries.
  – Beneficiaries who are dispensed opioid analgesics that exceed 120 mg of cumulative morphine equivalent dose (MED) for at least 90 consecutive days, and whose opioid prescriptions are associated with more than three prescribers and more than three pharmacies are identified as high-risk beneficiaries, or potential overutilizers.

• On March 15, 2016, the Center for Disease Control (CDC) published guidelines that provide recommendations for primary care clinicians who are prescribing opioid analgesics for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.
  – Clinicians should use caution when prescribing opioid analgesics at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.
Opioid Analgesics and Medicare Set Asides

• Despite these published guidelines and recommendations, CMS routinely approves and requires, based on physician orders, that Workers’ Compensation Medicare Set-Aside Arrangements (WCMSA) include lifetime opioid analgesics that are inconsistent with such guidelines.

• On March 23, 2016, the National Alliance of Medicare Set Aside Professionals (NAMSAP) proposed evidence-based limits on opioid analgesics in WCMSAs.

• Based on the 2013 CMS and 2016 CDC guidelines, NAMSAP has recommended a hard cap of 90 MED for no more than one month when the WCMSA includes a surgical projection; and/or, a hard cap of 40 MED for no more than one month, followed by a 10% per week mandatory tapering and weaning plan until fully weaned from opioid analgesics.

• To date, no response, policy memo, announcement, or alert has been published by CMS.
Thank you

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