High Time for Change?
Impact and Considerations for Medical Marijuana
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Author
Dr. Mitch Freeman, Pharm.D.
Vice President, Chief Clinical Officer
Pharmacy Solutions

Co-Authors
Michele Hibbert-Iacobacci, CCSP, OHCC
Vice President, Information Management & Support
Casualty Solutions

Kathryn Moser
Research Assistant
Pharmacy Solutions

A Mitchell Whitepaper
Introduction

As the workers’ compensation industry battles the spread of opioid abuse in the United States, new methods for the treatment of pain have entered the conversation. Since the 1990’s, prescription opioid use and abuse have nearly quadrupled. Today, one in four people receiving long-term opioid prescriptions becomes addicted and around 91 Americans die from opioid-related drug overdoses daily. In 2016, the Center for Disease Control (CDC) released guidelines for prescribing opioids and in 2017, the federal government declared a state of emergency in hopes of curtailing the widespread abuse. At the same time, the medical community is searching for alternative treatments for chronic pain, and many have turned their attention toward marijuana.

Because of its purported medical benefits and allegedly low risk of addiction, marijuana has been proposed as a possible alternative to opioids. Anecdotes suggest that marijuana may be effective in treating pain, among other ailments, and has few detrimental side effects. Several states have taken the lead in legalizing marijuana for medicinal purposes, but the drug remains illegal federally, which poses many challenges for researchers, employers and insurers. With these gaps in legislation come countless questions. Is this drug efficacious and does it provide the benefits that many claim? How do employers and insurers navigate the complicated and conflicting legislation that exists at both the state and federal levels? What does the legalization (or lack thereof) of marijuana mean for the future of the workers’ compensation industry?

With nearly 50 million adults suffering from chronic and severe pain in the United States, workers’ compensation insurers are looking for the most effective ways to get injured employees back to work. Is marijuana the answer? This paper will explore the possibility of substituting medical marijuana for opioids, current regulations on marijuana, and future implications for the workers’ compensation industry.
Marijuana’s History

Although marijuana has gained somewhat of a notorious reputation in modern day, the plant has a long history of use across cultures. The cannabis plant originated in Central Asia and many ancient cultures used the plant as an herbal medicine and to create items like textiles and rope. Marijuana was introduced to the Americas during colonial times. Throughout the 1800’s doctors in the United States and Europe used cannabis extracts to treat stomach problems and scientists discovered that the chemical THC within marijuana could reduce nausea and improve appetite.

The recreational history of marijuana is somewhat less detailed. There is evidence that ancient Greek, early Middle Eastern and early Asian civilizations used marijuana to get high. The United States did not see widespread recreational use of marijuana until the early 1900’s. By the 1930’s, 29 states had outlawed the drug.

Marijuana saw its first federal restriction in the United States in 1937, with the introduction of the Marijuana Tax Act. The use and possession of cannabis remained legal, but those selling the drug could face heavy penalties if sales taxes were not paid. In 1970, the Nixon administration signed into law the Controlled Substances Act, which effectively made marijuana illegal. This Act established five classifications, or schedules, for drugs, placing marijuana in the Schedule I classification alongside LSD and heroin. Nixon declared drugs “public enemy number one” in 1971, launching the U.S. “War on Drugs” and establishing the Drug Enforcement Agency in 1973. Only a few years after this, many states and eventually the Senate voted to decriminalize small amounts of marijuana, though the drug remained illegal and the “War on Drugs” continued in the following decades.

Until 1996, marijuana was illegal across the United States. It remains a Schedule I drug today. Modern laws and regulations will be discussed in the upcoming sections, but first we will consider why marijuana has become such a hot topic in modern day as a medicinal alternative.
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1937</td>
<td>Marijuana Tax Act</td>
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<tr>
<td>1970</td>
<td>Controlled Substances Act</td>
</tr>
<tr>
<td>1971</td>
<td>“War on Drugs” officially begins</td>
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<tr>
<td>1973</td>
<td>DEA established</td>
</tr>
<tr>
<td>1996</td>
<td>California legalizes medical marijuana</td>
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Marijuana As a Medicine?

With more than 30,000 deaths resulting from opioid-related overdoses in the United States in 2015, some physicians and patients are looking to marijuana as a viable alternative. Its proposed ability to cure various ailments with few side effects styles marijuana as somewhat of a “miracle” drug. To understand the draw toward marijuana treatments, we must start with the basics: what exactly is considered medical marijuana and what does it do?

The National Institute on Drug Abuse, part of the National Institute of Health, defines medical marijuana as “using the whole, unprocessed marijuana plant or its basic extracts to treat symptoms of illness and other conditions.” More specifically, the marijuana plant contains various chemicals called cannabinoids, two of which are used in the creation of medical marijuana. The human body contains cannabinoid receptors and the cannabinoids in marijuana are understood to interact with these receptors to affect processes such as pleasure, memory, appetite, and pain.

The two main cannabinoids used in medical marijuana are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is the main mind-altering ingredient that causes the “high” attributed to marijuana use. CBD, on the other hand, does not cause a “high.”

The distinction between THC and CBD is important to note, since many debates on the use of marijuana as a medicine focus on the drug’s psychoactive properties. Because only THC causes this high, most medical strains of marijuana contain very small percentages of THC. Yet difficulty lies in standardization, which means THC levels can be much higher than anticipated.

Medical marijuana can come in many forms, including topical, edible and smoked.
Medical marijuana typically contains low levels of THC.

**Delta-9-tetrahydrocannabinol (THC)**
- Mind-altering: causes a “high”
- May be capable of treating pain, inflammation, seizures, mental illnesses, etc.
- Typically produced in small doses in medical marijuana (less than 5%), though this is often not regulated

**Cannabidiol (CBD)**
- Does not cause a “high”
- May be capable of treating pain, inflammation, seizures, mental illnesses, etc.
- Medical marijuana contains higher quantities of CBD than THC
From a medical standpoint, THC and CBD may be capable of treating pain, inflammation, epileptic seizures, and mental illnesses, among other ailments. The relief of pain, specifically, is relevant to workers’ compensation. Since marijuana purportedly is less addictive and may have fewer long-term side effects than opioids, marijuana seems like an ideal alternative to get workers back to their jobs faster and more effectively. Where, then, does the debate arise?

Simply put, marijuana leaves much to question in terms of efficacy and long-term side effects. Because no large-scale, double-blind clinical studies exist to prove or disprove marijuana’s medicinal efficacy, we must rely upon anecdotes and small-scale studies or surveys. Some studies have shown that THC causes euphoria and that lung damage is possible due to inhalation of smoke. Beyond this, however, the medical community does not know enough about marijuana’s effects to determine if it is a fully viable medicine.

Despite this lack of clinical evidence, many states have taken steps to legalize marijuana. These decisions, along with the federal government’s stance on the issue, are discussed next.
Why Marijuana?

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
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</thead>
<tbody>
<tr>
<td>• Potential treatment of pain</td>
<td>• THC levels are not standardized</td>
</tr>
<tr>
<td>• Less addictive than opioids</td>
<td>• No clinically-based guidelines exist</td>
</tr>
<tr>
<td>• CBD does not cause “high” that might</td>
<td>• Possible lung damage from smoke</td>
</tr>
<tr>
<td>impair workers</td>
<td></td>
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</tbody>
</table>
Medical Marijuana Becomes Legal—Sort Of

California was the first state to (re)legalize marijuana for medicinal purposes. Since that decision in 1996, 29 states plus the District of Columbia have passed medical marijuana legislation in some form. Additionally, eight states and the District of Columbia have legalized marijuana for recreational purposes, beginning with Colorado and Washington in 2012.

The map below illustrates the breakdown of different state laws regarding marijuana.

Marijuana Legalization by State

Marijuana legal for medicinal purposes
Marijuana legal for medicinal and recreational purposes
Marijuana not legal for any purpose
Although several states have legalized medical marijuana, there is little consistency across these states in what type of marijuana is acceptable to dispense. Many states require a low ratio of THC to CBD, yet even these quantities differ from state to state.

These examples illustrate the difficulties for patients, doctors and insurers in developing a general knowledge about marijuana treatments. Because no standardization exists across states, all stakeholders should follow state requirements closely.

**Varying State Laws on Cannabinoid Levels**

**Florida:**
“Cannabis with low THC = below .8% THC and above 10% CBD by weight”

**Georgia:**
“Cannabis oils with low THC = below 5% THC and at least an equal amount of CBD”

**Iowa:**
“‘Cannabidiol - a non-psychoactive cannabinoid’ that contains below 3% THC, no more than 32oz, and essentially free from plant material”

**Missouri:**
“‘Hemp extracts’ equal or less than .3% THC and at least 5% CBD by weight”

**Oklahoma:**
“A preparation of cannabis with no more than .3% THC in liquid form”

**Texas:**
“‘Low-THC Cannabis’ with no more than 0.5 percent by weight of tetrahydrocannabinols; and not less than 10 percent by weight of cannabidiol”

**Virginia:**
“Cannabis oils with at least 15% CBD or THC-A and no more than 5% THC”

*Source: NCSL.org*
Federal Stance

The move toward legalized marijuana continues on a state-by-state basis, but federally any use of marijuana remains illegal. In April 2017, the U.S. Drug Enforcement Agency (DEA) denied a petition to reclassify marijuana as a Schedule II drug, meaning the drug is still “illegal to distribute, prescribe, purchase, or use outside of medical research in the United States.” The reasons for these changes are listed at the bottom of this page.

As the last point addresses, the U.S. Food and Drug Administration has not accepted marijuana as a “safe and effective drug for any indication.” Until this happens, no standardized, commercially available cannabis drugs will be available and no clinically-based guidelines will exist nationwide.

As of now, the only cannabis-like drugs approved by the FDA are Marinol, Syndros, and Cesamet. Marinol and Syndros contain Dronabinol, which is a synthetic THC, and Cesamet contains Nabilone, which contains chemical structures similar to THC. These drugs are used narrowly in medical treatment for chemotherapy-related nausea and appetite loss in AIDS patients. They are not created from the marijuana plant, but are chemically produced medications that have undergone the same FDA approval process as other prescription drugs in the United States. Although they act similarly to marijuana, these drugs do not fall under the same category as medical marijuana since they are not created from the plant itself and therefore are not included in the debate on marijuana.

Reasons for DEA Denial of Marijuana Rescheduling

“Marijuana has a high potential for abuse.”

This was determined after a review from the Department of Health and Human Services (HHS) and the DEA.

“Marijuana has no currently accepted medicinal use in treatment in the United States.”

Marijuana failed the DEA’s five-part test to establish medical use. This includes: the drug’s chemistry is unknown and not reproducible; no adequate safety studies exist; no “adequate and well-controlled studies proving efficacy” exist; there is a lack of acceptance by experts; and there is no widely available scientific evidence.

“Marijuana lacks accepted safety for use under medical supervision.”

The Food and Drug Administration (FDA) has not approved any marijuana products and there is no New Drug Application (NDA) for marijuana at this time. Any proposed benefits have not been shown to outweigh the known risks through clinical trials that evaluate safety and efficacy.
There are, however, two cannabis extract products currently undergoing the FDA clinical trial process. These are Epidiolex and Sativex, two drugs that use cannabis extracts. Epidiolex is 100 percent CBD, while Sativex is a mix of CBD and THC. These drugs, similar to the currently FDA-approved synthetic drugs, have very narrow medical use: rare types of epilepsy and multiple sclerosis, respectively. It is unclear, however, if these medicines will be relevant for pain relief.

**Synthetic**

Marinol, Syndros and Cesamet are approved by FDA

**Cannabis Extracts**

Epidiolex and Sativex are undergoing FDA clinical trials
The FDA requires an extensive approval process for any medication hoping to make it into pharmacies in the United States. First, a company must develop a drug and conduct laboratory testing on it before even applying for FDA-approved human testing. Since marijuana is a Schedule I drug, the researchers must also obtain a Schedule I license from the DEA and complete special registration requirements to begin research. If approved for FDA human testing, the drug must then pass through three phases of clinical trials:

**Phase I**

Phase I tests for the drug’s safety. This phase typically includes a sample size of 20 to 80 participants and lasts around one year.

**Phase II**

Phase II tests the drug’s effectiveness. The sample size is around 100 to 300 participants and the phase lasts around two years.

**Phase III**

Phase III tests the drug’s effectiveness and attempts to identify adverse reactions. This phase has a large sample of between 1,000 and 3,000 participants who are monitored in clinics and hospitals. This phase can last around three years.

After these clinical trial phases are complete, the company will submit another application to the FDA for approval. In all, the approval process can take around twelve years to complete.
During the FDA approval process, the FDA evaluates if the benefits of the drug outweigh the risks, especially related to the drug’s intended purpose. Drugs that are intended to treat life-threatening illnesses “may be considered to have benefits that outweigh the risks even if those risks would be considered unacceptable for a condition that is not life threatening.” Therefore, Epidiolex and Sativex, which are currently undergoing Phase III trials, may be approved for their treatment of epilepsy and multiple sclerosis, but may not be accepted for any treatments beyond these.

Given this, research is currently limited to a select few places. The only marijuana approved for study must be requested through the National Institute on Drug Abuse (NIDA) and is grown at the University of Mississippi. This limits the quantity available as well as the strains with which to study. Additionally, while clinical research is slowly gaining approval, only a few institutions have permission to conduct research. The University of Colorado, Denver, is the most recently approved institution and will commence research to compare marijuana to opioids. Unfortunately, even with this clinical research beginning, it will still be several years before the research provides any clear direction for the use of marijuana in medicine and for prescribing guidelines (that is, if the drug is ever rescheduled).

The FDA approval process can take around twelve years to complete.
Current Evidence for Medical Marijuana

Numerous small-scale studies appear to support cannabis as an effective pain-reducing medicine, and the findings of a few are summarized below.

### Chronic Pain

<table>
<thead>
<tr>
<th>Study</th>
<th>Product</th>
<th>Type</th>
<th>Participants</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Benefits of Cannabis: A Patient Survey</td>
<td>Cannabis, general</td>
<td>Survey</td>
<td>100</td>
<td>Average reported pain decrease of 64%</td>
</tr>
<tr>
<td>Low Dose Vaporized Cannabis Significantly Improves Neuropathic Pain</td>
<td>Vaporized Cannabis</td>
<td>Double-blind, placebo-controlled clinical trial</td>
<td>39</td>
<td>Low dose and medium doses effective at reducing pain</td>
</tr>
<tr>
<td>Smoked Cannabis for Chronic Neuropathic Pain: A Randomized Controlled Trial</td>
<td>Smoked Cannabis</td>
<td>Randomized</td>
<td>23</td>
<td>Reduced pain and improved sleep</td>
</tr>
<tr>
<td>A Randomized, Placebo Controlled Cross-Over Trial of Cannabis Cigarettes in Neuropathic Pain</td>
<td>Smoked Cannabis</td>
<td>Double-blind, placebo-controlled clinical trial</td>
<td>32</td>
<td>Low and high doses effective reducing pain from various causes</td>
</tr>
<tr>
<td>Cannabis Use for Chronic Non-Cancer Pain: Results of a Prospective Survey</td>
<td>Smoked Cannabis</td>
<td>Survey</td>
<td>32</td>
<td>Participants self-reported pain relief</td>
</tr>
<tr>
<td>Efficacy of Dronabinol as an Adjuvant Treatment for Chronic Pain Patients on Opioid Therapy</td>
<td>Dronabinol</td>
<td>Randomized, single-dose, double-blind, placebo-controlled, crossover trial</td>
<td>30</td>
<td>Phase 1 showed decrease in pain, no difference in doses. Phase 2 showed significant relief of pain</td>
</tr>
</tbody>
</table>

Sources listed on last page
Other Pain

<table>
<thead>
<tr>
<th>Study</th>
<th>Product</th>
<th>Type</th>
<th>Participants</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Marijuana Utilization and Perceived Therapeutic Value in Patients with ALS</td>
<td>Cannabis, general</td>
<td>Survey</td>
<td>102</td>
<td>Majority of those who used medical marijuana reported that it is effective in improving appetite, aiding sleep, reducing anxiety, relieving depression, and relaxing muscles</td>
</tr>
<tr>
<td>Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study of the Efficacy, Safety, and Tolerability of THC:CBD Extract and THC Extract in Patients with Intractable Cancer-Related Pain</td>
<td>THC:CBD extract &amp; THC extract</td>
<td>Double-blind, randomized, placebo-controlled study</td>
<td>177</td>
<td>THC:CBD reduced pain, worsened nausea &amp; vomiting; THC had no statistical difference</td>
</tr>
<tr>
<td>A Preliminary Controlled Study to Determine Whether Whole-Plant Cannabis Extracts Can Improve Intractable Neurogenic Symptoms</td>
<td>Cannabis extracts</td>
<td>Double-blind</td>
<td>24</td>
<td>Pain relief from THC &amp; CBD was statistically greater than placebo</td>
</tr>
<tr>
<td>Nabilone for the Treatment of Pain in Fibromyalgia</td>
<td>Nabilone</td>
<td>Randomized, double-blind, placebo-controlled</td>
<td>177</td>
<td>Nabilone reduced pain better than placebo</td>
</tr>
<tr>
<td>Comparison of Analgesic Effects and Patient Tolerability of Nabilone and Dihydrocodeine for Chronic Neuropathic Pain: Randomised, Crossover, Double-Blind Study</td>
<td>Nabilone and Dihydrocodeine</td>
<td>Randomized, double-blind, crossover trial</td>
<td>96</td>
<td>Dihydrocodeine provided greater pain relief than Nabilone with fewer side effects</td>
</tr>
<tr>
<td>Low Dose Treatment with the Synthetic Cannabinoid Nabilone Significantly Reduces Spasticity-Related Pain: A Double-Blind Placebo-Controlled Cross-Over Trial</td>
<td>Nabilone</td>
<td>Randomized, double-blind, crossover trial</td>
<td>11</td>
<td>Use of Nabilone of 1mg per day decreased pain</td>
</tr>
<tr>
<td>Preliminary Assessment of the Efficacy, Tolerability and Safety of a Cannabis-Based Medicine (Sativex) in the Treatment of Pain Caused by Rheumatoid Arthritis</td>
<td>Sativex</td>
<td>Randomized, double-blind, parallel group study</td>
<td>58</td>
<td>Sativex decreased pain</td>
</tr>
</tbody>
</table>
Of the evidence that currently exists about marijuana, personal narratives provide the most exhaustive support for the drug’s benefits. For instance, after a worker was injured on the job, he was prescribed an opioid. Mitchell’s PBM, ScriptAdvisor, alerted adjusters that the opioid prescription was a relatively high dose and suggested intervention. The resulting drug test showed no trace of opioids in his system. The claimant revealed that he was in fact selling his opioid prescriptions to buy marijuana – a decision he made in fear of becoming addicted to opioids. This worker said he was able to manage his pain with marijuana effectively without the addiction risk often associated with opioid use. However, since marijuana was not legal in the worker’s state of residence, the claimant was not reimbursed for the marijuana. Many stories similar to this claimant’s exist and are currently the most extensive support for medical marijuana.
However, this small-scale and anecdotal support is not enough. For instance, each study looks at a different potency, application, and type of marijuana product. Additionally, the small sample sizes and varying methods of study make these claims impossible to generalize. In fact, in August 2017, the Annals of Internal Medicine alongside the U.S. Department of Veteran Affairs released a retrospective review of 27 chronic pain trials. The study found insufficient evidence that marijuana alleviates chronic pain and noted lung damage and mental impairments as viable concerns. Although the small studies are important to observe, we ultimately must wait for FDA-approved clinical trials to gain any clear scientific insight into marijuana.

Despite this lack of evidence, states are continuing legalizing marijuana and these choices have shown both positive and negative effects. For instance, a study by Bachhuber, Solner, Cunningham and Barry (2014) found that opioid overdose decreased by 25 percent more in states that have medical marijuana laws than those without. However, this does not tell whether the legalization of marijuana caused a drop in opioid overdose. This can also relate to the recent attempts to stem opioid addiction federally; for instance, prescriptions for opioids dropped nationwide by 13.1 percent between 2012 and 2015. Yet it is still important to note the significant difference in overdoses between states with and those without medical marijuana laws.

Ultimately, though some evidence has shown support for pain management, marijuana’s side effects are still not well studied. As with any other drug introduced in the United States, more extensive research needs to be conducted to give a robust understanding of medical marijuana’s effects. At this point, there is no way to conclude that marijuana is in fact a “miracle” drug.

greater decrease of opioid overdoses in states that have legalized medical marijuana than in those that have not
decrease in national opioid prescription rate between 2012 and 2015

25% 13%
The legalization of both medical and recreational marijuana at the state level has many implications for the workers’ compensation industry. When faced with interstate commerce, vague state laws and the challenge of keeping a workforce safe, it is easy to see why marijuana has created such confusion among employers and insurers. Beyond the challenges of navigating the conflicting and often confusing rules at the state and federal levels, employers face issues with impairment on the job and insurers must consider options around reimbursement.

Impairment at Work

The use of marijuana can impair workers cognitively and physically, creating challenges in balance, coordination, and alertness. These impairments naturally lead to an increased risk of injury while on the job, especially in jobs that require physical and mental acuity, such as transportation or construction. As states legalize marijuana both medically and recreationally, the likelihood of impairment and subsequent injuries on the job increases.
Traditionally, employers have used drug tests to monitor employee health, but the challenge with marijuana is that the drug stays in the blood system for up to a month. Even if an employee may never have been intoxicated while at work, tests will still detect THC. Therefore, the employer cannot prove when the employee was intoxicated or if the marijuana was medicinal or recreational. As more states enact medical marijuana laws, employers must reconsider how to approach workplace rules regarding marijuana. Recent legislation and court rulings provide some direction, yet conflict from state to state.
States such as Florida and Colorado have upheld employers’ right to a zero-tolerance drug policy, giving businesses the right to fire employees who use medical marijuana. Colorado additionally passed legislation that declares a 50 percent loss of wages or benefits if an employee is injured at work due to marijuana impairment.

However, the recent ruling in Massachusetts’ Barbuto v. Advantage Sales and Marketing, LLC. case questions whether employers can create a blanket zero-tolerance policy. The contrasting cases in Colorado and Massachusetts are summarized below:

**Coats v. Dish Network**

**Colorado, 2015**

Dish Network fired Coats for using medical marijuana outside of work, which is legal in Colorado. The court upheld Dish Network’s decision to fire Coats because marijuana is illegal federally.

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**Barbuto v. Advantage**

**Massachusetts, 2017**

Advantage fired Barbuto for using medical marijuana. Medical and recreational marijuana are legal in Massachusetts. The court denied Advantage’s defense that marijuana is federally illegal and said that Barbuto is protected under Americans with Disabilities Act.

These decisions make clear that businesses can no longer create blanket zero-tolerance drug policies, especially when operating across state lines.
It is unclear how to determine marijuana intoxication.

Source: National Council on Compensation Insurance
Recreational marijuana laws may also create difficulty for employers, as recent legislature in Maine shows. Because of the state’s legalization of recreational marijuana, employers cannot require drug tests for job applicants nor terminate employees for positive marijuana tests without proving impairment on the job. These various decisions create possible new precedents for other states to follow and new questions for employers to consider. Most importantly, employers must be cognizant of these changes and create new policies to keep their workplace safe.
Reimbursement

The morass of conflicting legislation and court rulings also creates confusion for insurers on whether to cover the costs of medical marijuana. Recent updates give an idea of where insurance coverage may be heading.

- In a recent ruling in New Jersey’s Watson v. 84 Lumber, the insurance company was also required to pay for an injured worker’s medical marijuana.

- Florida and North Dakota, on the other hand, passed legislation recently stating that marijuana is not reimbursable.

- New Mexico has led the way in outlining rules for medical marijuana coverage. In 2015, the state passed a law requiring insurers to reimburse employees for medical marijuana prescriptions related to a workers’ compensation claim. The state has also seen three court rulings wherein medical marijuana was deemed “reasonable and necessary” for the workers injured on the job and had to be covered by workers’ compensation.

Yet the fact remains that marijuana is illegal federally. Despite the legislation moving forward at the state level, the federal government has the ultimate authority on the use of marijuana. This is especially important for insurers and employers that operate across state lines. The decisions above may provide other states precedent in regards to coverage, but the current landscape of legislation means that all stakeholders must pay close attention to each state’s laws.
Challenges for Medical Marijuana’s Future in Pharmacy Management

Where does all of this leave us in the complicated and confusing world of medical marijuana? What are the implications for the workers’ compensation industry? The current challenge for payers as legalization moves forward is how to manage medical marijuana.

Pharmacy management today relies heavily on PBM systems to manage and monitor claims. These systems are highly automated and driven by multiple areas of standardization, from NDC drug codes to the transaction format. The coding is extremely specific, controls are put on claims in an automated fashion, and decisions follow formularies that are developed from state and federal guidelines.

With that said, the management of a drug that has no standardization is nearly impossible within a standardized system. Marijuana’s status as a Schedule I drug means there are no rules on standardization in the creation of medical marijuana drugs and no clinically based guidelines on prescribing. Because of this, the potency and dosage can vary drastically. For instance, recent years have seen a sizeable increase in THC levels, from around four percent in the 1990’s to around 12 percent in 2014, with some strands ranging up to 37 percent THC. Additionally, medicinal marijuana can come in various forms, intended to be applied topically, smoked, or ingested. However, no guidelines exist on what form is most appropriate for what ailment.

The variation in strengths and dosage forms combined with an absence of guidelines, make the evaluation of medical marijuana for appropriateness extremely challenging. Until a standardized medication is created and approved by the FDA, it will be difficult for traditional PBM’s to effectively evaluate medical marijuana therapy.

Payers should be aware of differing state laws and develop flexible claims plans.
With these points in mind, there are steps that payers can take now to stay at the forefront of medical marijuana management. Knowing that reimbursement is becoming more and more common, some insurance companies have taken steps to anticipate this change and develop flexible plans that allow for action on a state-by-state basis. Payers need to consider the regulatory and legal landscape in each state, as well as the patients on an individual basis. PBM systems will be useful in providing payers with medical history to determine if medical marijuana is appropriate, and understanding individual jurisdictional laws will be vital in determining if the claimant should be reimbursed. Although this is more complicated than creating a holistic policy, it will be necessary until such time that we see federal guidelines emerge.

The future of marijuana is sure to be complicated. Employers, physicians, pharmacists and insurers alike must continue to monitor the shifting landscape. As legalization and research moves forward, we will hopefully develop a clearer picture of the best uses and full range of side effects of this controversial treatment.
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For more information, please visit mitchell.com/scriptadvisor or contact us at 877.750.0244.
About the Authors

**Dr. Mitch Freeman, Pharm.D.**
Vice President, Chief Clinical Officer
Mitchell Pharmacy Solutions

Mitch Freeman is the Chief Clinical Officer for Mitchell International, Pharmacy Solutions. Prior to joining Mitchell, Freeman was the CEO of First Coast Health. He has a wealth of industry expertise and leadership in the workers’ compensation industry including the chief sales and marketing officer of PMSI, vice president of sales at Ameritox, vice president and general manager for ExpressScripts, and president of pharmacy services for MSC.

Freeman is a frequent guest speaker and author. Freeman is a graduate of Florida A&M University where he received his doctorate of pharmacy.

**Michele Hibbert-Iacobacci, CCSP, OHCC**
Vice President, Information Management & Support
Mitchell Casualty Solutions

Michele Hibbert-Iacobacci’s responsibilities include managing the Health Information Management Group, Regulatory Compliance, Litigation Support, Professional Services and Consulting within Mitchell’s Casualty Solutions Group. For the past 30 years, Hibbert-Iacobacci’s focus has been working with major casualty insurers in implementing rules committees, quality assurance, risk management, compliance programs and review processes necessary in delivering objective bill review systems. Hibbert-Iacobacci is a Certified Clinical Coding Specialist (CCS-P), an Officer of Healthcare Compliance (OHCC) and a member of the American Health Information Management Association (AHIMA) and American Institute of Healthcare Compliance.

Hibbert-Iacobacci has authored many articles on insurance fraud, analytics, training, claims processing and ICD-10 implementations.


Studies listed on pages 14 and 15 (in order listed in chart):


