Medical Marijuana:
Coverage Considerations for the Buckeye State

ISCEBS & CSHRM Education Session
April 20, 2018

CUBIC
the benefit of clarity

DISCLAIMER

- **Speaker has no conflicts of interest to disclose**

- Cubic is an **independent** analytics firm that evaluates, designs & manages health benefit plans for employers ranging in size from 1,000 – 600,000 employee lives – we are not a stakeholder in the medical or recreational cannabis industries in Canada or U.S.

- Speaker **neither encourages nor discourages coverage** of medical cannabis under benefits plans – **must be a decision made by every individual plan**

- **Intent of presentation: to provide objective information to support decisions surrounding medical cannabis coverage**

KEY MESSAGES

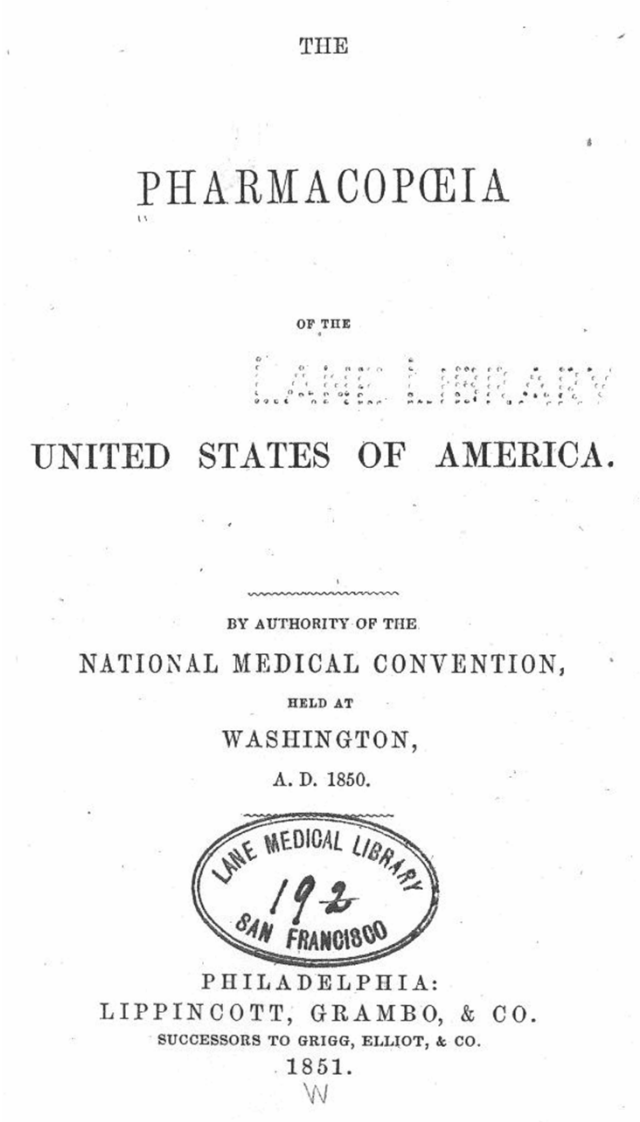
- Important to understand what considerations need to form part of a responsible medical marijuana program
- **Any program considered needs to be regionally developed**
- For plans that do not support coverage for any reason (safety, philosophy, financial, geographic scope, etc.) it is still important to understand the area because there are **over 500 clinical trials underway** – cannabinoids will form part of more clinical practice guidelines moving forward
- With political and legislative uncertainties, **wait-and-see approach is fully justified and coverage will be restricted to ASO plans**

KEY MESSAGES

Case studies of 3 plans with 3 different sets of exposure

- Case Study A: 0.8
- Case Study B: 2.24 (1st wave), 6.22 (2nd wave)
- Case Study C: 20

AN ESTABLISHED HISTORY



THE

PHARMACOPŒIA

OF THE

UNITED STATES OF AMERICA.

BY AUTHORITY OF THE

NATIONAL MEDICAL CONVENTION,

HELD AT

WASHINGTON,

A. D. 1850.

PHILADELPHIA:

LIPPINCOTT, GRAMBO, & CO.

SUCCESSORS TO GRIGG, ELLIOT, & CO.

1851.

THE SCIENCE OF CANNABINOIDS

The Human Endocannabinoid System

CBD, CBN and THC fit like a lock and key into existing human receptors. These receptors are part of the endocannabinoid system which impact physiological processes affecting pain modulation, memory, and appetite plus anti-inflammatory effects and other immune system responses. The endocannabinoid system comprises two types of receptors, CB1 and CB2, which serve distinct functions in human health and well-being.

THC
Tetrahydrocannabinol

CBD
Cannabidiol

CBN
Cannabinol

CB1

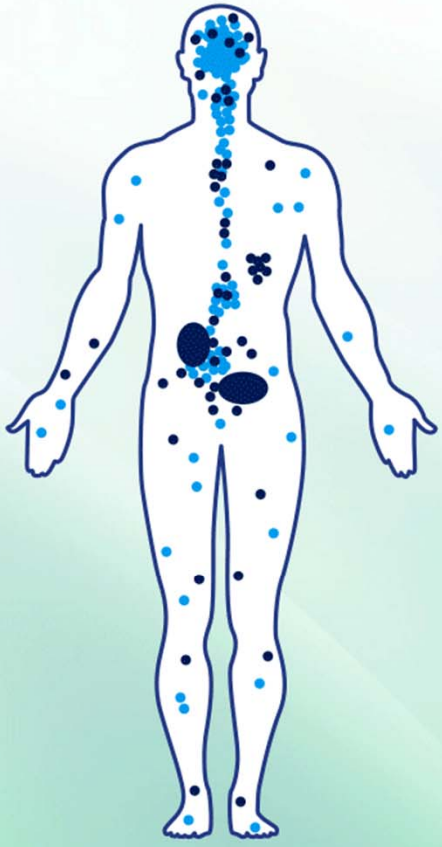
CB2

CB1 receptors are primarily found in the brain and central nervous system, and to a lesser extent in other tissues.

CBD does not directly "fit" CB1 or CB2 receptors but has powerful indirect effects still being studied.

CB2 receptors are mostly in the perepheral organs especially cells associated with the immune system.

Receptors are found on cell surfaces



source: www.the-human-solution.org

MEDICAL MARIJUANA: THE SCIENCE

- > 100 Cannabinoids in marijuana, but the major 2 are:

Tetrahydrocannabinol (THC)

- Main psychoactive component causing many of the physical and psychotropic effects
- Effective for pain, spasms & nausea; although it can lead to impairment, can't be totally dismissed as it has clinical value
- Levels of THC can vary widely among strains

Cannabidiol (CBD)

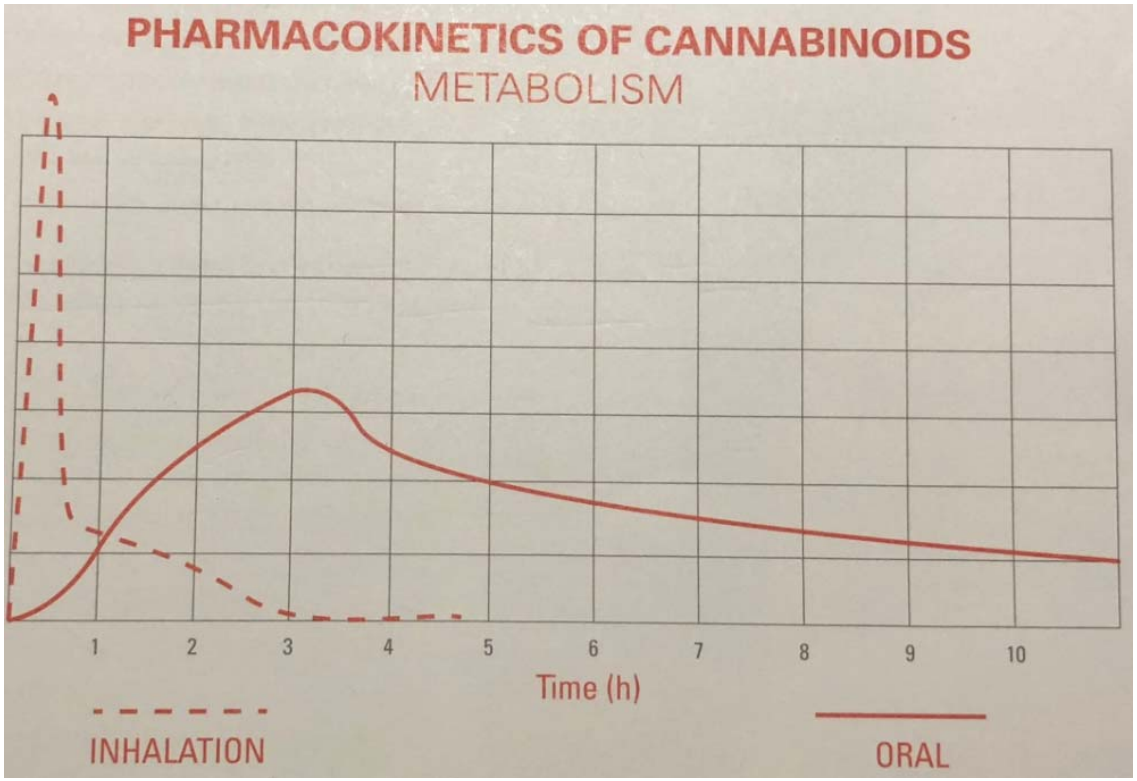
- Non-psychoactive, can be synergistic or antagonistic to THC effects depending on dose and ratio
- Anti-inflammatory, analgesic, anti-emetic, anxiolytic and anti-convulsant properties

DOSAGE FORMS

	Smoking	Vaporization	Oral	Sublingual
Amount Entering Blood Stream	10 - 50%	10 - 50%	10 - 20%	10 - 20%
Onset of Action	Within seconds	Within seconds	30 - 120 minutes	30 - 60 minutes
Duration of Action*	2 - 4 hours	2 - 4 hours	5 - 8 hours	5 - 8 hours
Advantage	Quick onset of action	Quick onset & less exposure to harmful chemicals	Better dosage form for workplace use	Better dosage form for workplace use
Disadvantage	Harmful respiratory effects	More frequent administration required	Higher risk of intoxication due to delayed onset of effect	Higher risk of intoxication due to delayed onset of effect

DOSAGE FORM CONSIDERATIONS

- The **onset of effect** and **duration of action** are vastly different between inhaled versus orally ingested medical cannabis



- Implications for **safety of driving or working** after an administered dose

EXISTING CLINICAL EVIDENCE

- Medical marijuana is currently being used in the treatment of dozens of medical conditions, largely based on anecdotal evidence.

- However, based on current studies, there is **Conclusive or Substantial Evidence to support the use of medical marijuana in only these conditions:**

  1) **Chronic Pain**
  2) **Chemotherapy Induced Nausea & Vomiting**
  3) **Spasticity Symptoms in Multiple Sclerosis**

EXISTING CLINICAL EVIDENCE

- **Moderate Evidence** (currently) to support use of medical marijuana in the following areas:

1) **Pediatric Epilepsy**
2) **Opioid Dose Reduction for Chronic Pain**
3) **Short-Term Sleep Disturbance (patients with Apnea, Fibromyalgia, Chronic Pain & Multiple Sclerosis)**
4) **Post-Traumatic Stress Disorder**

EXISTING CLINICAL EVIDENCE

- **Weak Evidence** (currently) to support use of medical marijuana as an **effective therapeutic option** in the following areas:

  1) Appetite & Weight Loss in HIV & AIDS
  2) Tourette Syndrome
  3) Anxiety in Social Anxiety Disorders

EXISTING CLINICAL EVIDENCE

- Current evidence to suggest that **medical marijuana is ineffective** in the treatment of:

  1) **Improving Symptoms of Dementia**
  2) **Improving Intraocular Pressure in Glaucoma**
  3) **Reducing Depressive Symptoms in patients with Chronic Pain or Multiple Sclerosis**

  Example of glaucoma is in direct contrast to a number of existing state-specific medical marijuana programs, including Ohio's.

EXISTING CLINICAL EVIDENCE

- **Insufficient clinical evidence available today** to assess effectiveness of medical marijuana in:
  - **Treatment of General Depression**
  - **Irritable Bowel Syndrome**
  - **Crohn's Disease & Ulcerative Colitis**
  - **Anorexia**
  - **Symptoms of Huntington's & Parkinson's Disease or ALS**
  - **Dystonia**
  - **Dozens of additional medical conditions**

EXISTING CLINICAL EVIDENCE

Why does this matter to Plan Sponsors?

- Current evidence base **will only continue to grow**
- Will become a consideration for many plan sponsors in terms of coverage parameters and **what is feasible**
- Providing coverage for all purported medical marijuana indications could negatively impact long-term plan sustainability
- Factors driving increased research include:
  - More jurisdictions legalizing medical & rec marijuana
  - Partnerships between producers & research institutions
  - Increased medical exposure focusing on benefits

SAFETY

- Medical marijuana **is not first-line therapy** for any medical condition

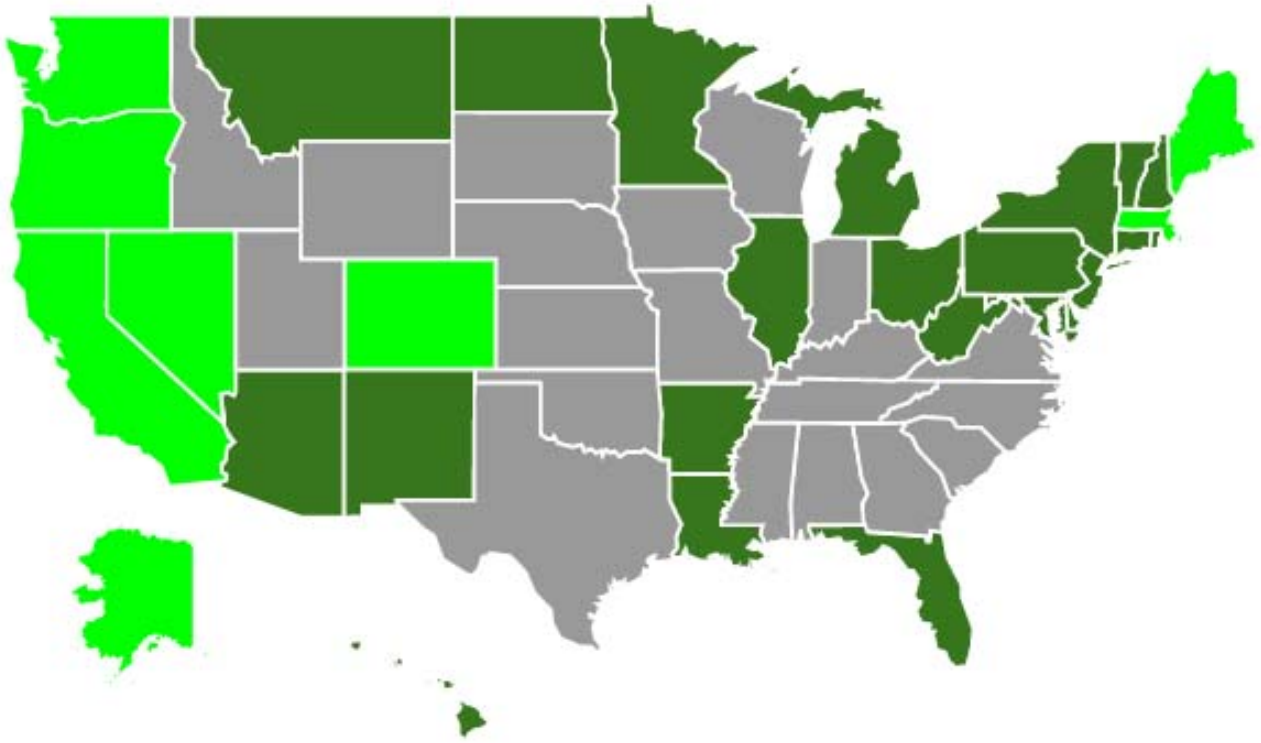
- **Medical marijuana is considered generally inappropriate for patients who:**
  - Are under the age of 25
  - Have personal or strong family history of psychosis
  - Have current or past marijuana use disorder
  - Have an active substance abuse disorder
  - Have severe cardiovascular or respiratory disease
  - Are (or plan to become) pregnant or breastfeeding

SAFETY

- Edible marijuana has not been included in any formal clinical studies to date – its use is strictly based on extension of available studies
- Dosing is **highly individualized**, requires gradual escalation
- THC is broken down in the liver to **11-OH-THC** (a potent psychoactive metabolite) – found in higher concentrations when cannabis is **ingested** vs. inhaled
- There can be **clinically meaningful drug interactions** between cannabis and other prescription drugs (bigger issue when cannabis is consumed orally)

LEGISLATIVE CONSIDERATIONS

- 30 States + DC allow Medical Cannabis use
- 16 Additional States allow Low-THC/High-CBD



LEGISLATIVE CONSIDERATIONS

State-level legalizations exist despite the fact that Federal law consider marijuana a **Schedule 1 Drug** under the Controlled Substances Act. Therefore:

- **Physicians cannot legally "prescribe" medical marijuana**, but rather recommend it under the First Amendment
- Not eligible as tax-exempt benefit
- FSAs cannot reimburse expenses given IRS does not consider marijuana as medical care
- **No National Drug Code**

LEGISLATIVE CONSIDERATIONS

- The conflict between Federal and State Law has been largely minimized since August 2013:
  - "**Cole Memorandum**" – Fostered a passive policy of federal non-interference with marijuana state laws (both recreational and medical)
  - Federal prosecutors focused efforts outside of states with legalized cannabis. Within legalized states, federal law was to **focus only on more severe crimes** (e.g. distribution to children or trafficking to other states)
  - Overall, this memorandum served to protect the legal medical and recreational markets and **allowed for rapid expansion of marijuana programs**

LEGISLATIVE CONSIDERATIONS

- Further protection for **legalized medical cannabis** came with Congress' 2014 Rohrabacher-Farr Amendment, now known as the **Rohrabacher-Blumenauer (RB) Amendment:**

  - Prohibits Department of Justice (DOJ) from using federal funds to prevent states from implementing laws that authorize the use, distribution, possession or cultivation of **medical marijuana**

  - The RB Amendment has been recently extended, however the extension currently expires Sept 30/18

LEGISLATIVE CONSIDERATIONS

- **January 4, 2018 – Attorney General Jeff Sessions' Memo:**
  - **Rescinds the Cole Memo** and the protection it afforded to states with established legal marijuana programs
  - This allows federal prosecutors to decide how to prioritize prosecution of state-legal marijuana activities
  - Sessions directed prosecutors to follow established principles when deciding what cases to prosecute, in order to target infractions considering the seriousness of the crime and its impact on the community.

POTENTIAL IMPACT OF SESSIONS' MEMO

- Some uncertainty with medical marijuana in legalized states
  - Will depend on if the RB Amendment is extended long-term
  - Short-term impact will likely be very state-specific, depending on how U.S. attorneys decide to interpret the application of the Memo

- This highlights the importance of medical cannabis coverage being **considered regionally.**
  - Colorado example

- Rec Cannabis market is likely to be impacted first, but any **reduction in rec markets could lead to more individuals seeking medical cannabis.**

REGIONAL CONSIDERATIONS

From a regional perspective, feasibility of medical marijuana coverage by a plan sponsor needs to consider safeguards of the state-level medical marijuana program:

- Extent of eligible conditions
- Availability of dosage forms & dosage restrictions
- Equivalency Factor (levels of THC)
- Distribution model
- Product consistency
- Cost considerations

OHIO MEDICAL MARIJUANA CONTROL PROGRAM: Qualifying Medical Conditions

Conditions with the Strongest Evidence:

1) Chronic Pain
2) Spasticity in MS
3) Chemotherapy Induced Nausea and Vomiting

Ohio Qualifying Medical Conditions:

1) AIDS
2) ALS
3) Alzheimer's Disease
4) Cancer
5) CTE
6) Crohn's Disease
7) Epilepsy
8) Fibromyalgia
9) Glaucoma
10) Hepatitis C
11) Inflammatory Bowel Disease
12) Multiple Sclerosis
13) Chronic Severe Pain
14) Parkinson's Disease
15) HIV
16) Post-Traumatic Stress Disorder
17) Sickle Cell Anemia
18) Spinal Cord Disease
19) Tourette's Syndrome
20) Traumatic Brain Injury
21) Ulcerative Colitis

OHIO MEDICAL MARIJUANA PROGRAM - TIMELINE

Sept 2016: OH's Medical Marijuana Control Program established (House Bill 523)

May – Sept 2017: Rules Adopted for Cultivators, Processors (who will make marijuana oils/edibles etc.), Testing Laboratories, Dispensaries, Physician, Patient Registration

Nov–Dec 2017: State chose 11 cultivators to begin producing medical marijuana (up to 24 cultivators will receive licenses)

Sept, 8 2018: OH Medical Marijuana Program Operational

Program developed through collaboration with the **Ohio Department of Commerce, State Medical Board of Ohio, and State of Ohio Board of Pharmacy.** Cities will be allowed to ban marijuana businesses.

OHIO MEDICAL MARIJUANA PROGRAM - FRAMEWORK

Registration: Medical marijuana patients required to register with the State Board of Pharmacy (one year expiration)

Distribution: Medical marijuana will be available from retail dispensaries licensed by the Board of Pharmacy (up to 60 licenses will be awarded)

Dosage Forms: Permitted products include oils, tinctures, plant material, edibles, and patches. The law prohibits the use of medical marijuana by smoking, but allows for vaporization. No home growing is permitted.

Authorizing Physicians: Must obtain a certificate to recommend medical marijuana from the State Medical Board of Ohio (involves 2 hours of education)

Possession Limit: 90-Day Supply

OHIO MEDICAL MARIJUANA PROGRAM – UNKNOWNS

Multiple key factors are **yet to be finalized**, including:

- **Pricing and taxation** of medical marijuana products
- Product availability and diversity of strains (i.e. **range of CBD products, limits on THC content, THC:CBD ratios, Equivalency Factors**)
- How many municipalities will ultimately prohibit medical marijuana businesses (which will impact access)
- **Level of education** medical marijuana patients will receive from their physician & the dispensary

OH employers can look to other jurisdictions to see the dramatic impact these factors can have & why they need to be considered in a medical cannabis program

OHIO OVI CONSIDERATIONS

Under OH OVI law, impairment is judged at:

- 2 nanograms per mL in driver's blood
- 10 nanograms per mL in driver's urine

First OVI conviction:

- Fine of $375 - $1,075, 3 days – 6 months in jail or both
- 1 to 3 year driving suspension

Second OVI conviction within 10 years:

- Fine of $525 - $1,625, 10 days – 6 months jail or both
- 1 to 7 years of driving suspension

Third OVI conviction within 10 years:

- Fine of $850 - $2,750, 30 – 365 days in jail, or both
- 1 to 12 years of license suspension

REGIONAL COST CONSIDERATIONS

- **Regional prices can vary drastically:**

Colorado	Oregon
• Medical: $4.20 Per Gram • Rec: $6.92 Per Gram • Medical priced at almost 40% discount compared to Rec	• Medical: $8.33 Per Gram • Rec: $8.94 Per Gram • Medical priced at only 7% discount compared to Rec

- Even within a jurisdiction prices can vary significantly:
  - NY: If patient receiving 10mg THC and 20mg CBD used 2 suppliers, **price could range from $100 to $650/month**
- **Financial coverage limits need to be customized for each region & treated like specialty drug**

QUANTIFYING EXPOSURE

- It is possible to determine your organization's risk of exposure to medical cannabis claims using claims experience
- For example: how many plan members have claims that would indicate they are treating chronic nerve pain?

  Disease State Profile: Long-Term Exposure Risk

- How many plan members appear to have trialed first- and second-line treatment options for chronic nerve pain? (1 in 1,000? 5 in 1,000?)

  Severity Index: Short-Term Exposure Risk

REGIONAL TAXATION CONSIDERATIONS

State	Taxation on Recreational	Taxation on Medical	Tax Deductible Expense*
CO	15% State retail excise tax + 15% State retail sales tax + local sales tax	2.9% State sales tax	NO
CA	As of Jan 1, 2018, 15% excise tax + 7.25% - 9.25% State & local sales tax	Only 15% excise tax will be applied. No sales tax.	NO
OR	State tax of 17%, and municipalities can enact an additional tax of 3%	Senate Bill 1601: medical cannabis cardholders are not subject to taxation.	NO

*IRS Sec 502: cannot include medical expenses you pay for controlled substances (such as marijuana) that aren't legal under federal law, even if such substances are legal by state law.

REGIONAL ACCESS & DISTRIBUTION

	Colorado	New York
Medical Cannabis Legalization	2001	2014
Product Regulation	Few restrictions on medical cannabis products	Department of Health (DOH) authorized non-smoke oils for vaporization and capsules. Ingested Doses <10mg THC
Medical Cannabis Producers	Over 700 licensed cultivation sites in Colorado & home growing is permitted	5 state-selected producers (expanding to 10) and products must be tested by an independent lab
Distribution	Over 500 licensed medical marijuana centres	Medical cannabis is dispensed by trained pharmacists in state-selected dispensaries, DOH regulates pricing
Clinical Considerations	Physicians provide certifications to patients with 9 qualifying medical conditions	Physician must register with DOH & receive training to issue certificates to patients with 12 qualifying conditions

Coverage programs in these 2 states would require very different approaches & safeguards. OH will fall in between these 2 extremes.

WORKPLACE SAFETY

- **Written policies** need to be in place requiring employees to disclose use of substances that may impair the ability to safely perform duties. These policies again need to be very region specific

- Need to communicate risk and policies to mitigate impaired driving (variability in driving laws)

- Policies around eligible dosage forms and medical marijuana products at work vs. at home (**CBD dominant strains** & non-smoked products more compatible with workplace administration)

- **Any program needs to be accompanied by member education and workplace policies & procedures**

WORKPLACE ACCOMODATION

- ADA prohibits employers from discriminating against qualified individuals on the basis of disability. Requirement to provide reasonable accommodations to disabled employees, provided there is no undue hardship on the employer.

- Section 12114(a) states that duty to accommodate does not apply to an employee engaging in the illegal use of drugs.

- “Illegal use of drugs” is defined as use/possession/distribution which is unlawful under the Controlled Substance Act (CSA) but excludes use of a drug taken under the supervision of a medical professional.

- Room for interpretation of this legislation & definition of “under supervision of a medical professional” - different states have developed different policies on duty to accommodate.

WORKPLACE ACCOMODATION

Plan Sponsors and HR leaders should consider the following steps to determine responsibilities surrounding accommodation of medical cannabis:

1) Determine if workplace is regulated by **Drug Free Workplace Act**

2) Obtain legal opinion to determine if State-level statutes have addressed accommodation of medical cannabis. In states where statutes do not address the issue, courts generally determined that employers are not required to accommodate (e.g. Emerald Steel vs. Bureau of Labor and Industries in OR)

3) In states that have enacted laws related to medical cannabis accommodation, legal opinion will be required to determine the approach and how to address those plan members who are in safety-sensitive positions

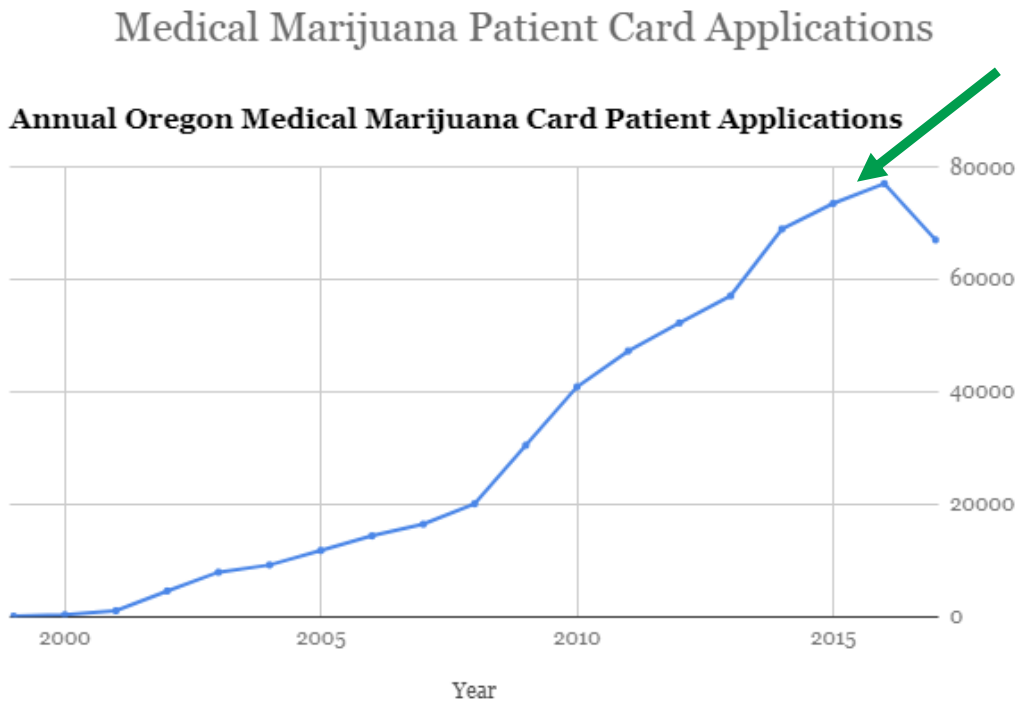
This could change based on the outcome of Sessions' Memo

WORKPLACE ACCOMODATION IN OH

- OH **does not** require employers to permit or accommodate an employee's use, possession, or distribution of medical marijuana
- An employer may choose to accommodate on-duty or off-duty medical marijuana use like any other accommodation
- Federal contractors working in OH must still maintain a Drug-Free Workplace and employees in certain safety-sensitive positions cannot be accommodated (e.g. DoT)
- Employers can take the necessary steps to prohibit employees from working when impaired
- Employers can make employment decisions based on marijuana use, OH's Medical Marijuana Law hasn't been tested in courts

IMPACT OF REC MARKETS

- Rec marijuana can have a dramatic impact on the effectiveness and legitimacy of medical marijuana market



- There was a 13% reduction in medical marijuana card applications in OR post-legalization, due to similar costs between medical & rec streams and $200 annual card fee

IMPACT OF REC MARKETS

Overall impact of legalization on medical marijuana markets will depend on **4 key variables by State**:

1) Comparative Pricing
2) Taxation
3) Accessibility to Specific Strains and Dosage Forms
4) Product Availability

- 8 States & DC have laws legalizing recreational use, the most recent being California (Jan 2018)

Sessions Memo could significantly impact the interplay between medical & rec markets

COVERAGE APPROACH

Any consideration of coverage under a plan should explore the following five (5) core elements:

1) Disease-state focused, clinically driven Prior Authorization
2) Limiting coverage to where evidence-base supports use
3) Limiting coverage to members who have failed previous therapies
4) Multiple levels of coverage based on safety-sensitivity
5) Regimens divided into Workplace vs. Non-Workplace to maximize effectiveness and safety

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