Medical Cannabis in the U.S. and Canada: What’s New and What’s Next?

Michael Sullivan, RPh, BSP, MBA
Chief Executive Officer
Cubic Health Inc.
Toronto, Ontario
Disclaimer

- Speaker has no conflicts to disclose
- Speaker has no relationship with and/or investment in any medical or recreational cannabis entity or related stakeholder
- Speaker neither encouraging nor discouraging coverage of medical cannabis under benefit plans—intent of this presentation is simply to provide objective information for consideration
**Key Messages**

- Growth in clinical research and global investment and legislative reforms in number of States will make medical cannabis an issue every plan will face.
- Wait-and-see approach to coverage justified today but plans are advised to start building a framework for coverage if zero-tolerance is not a consideration.
Key Messages

• Any coverage today needs to be **regionally based** because of conflict between Federal and State laws and big differences in State programs

• For plans not looking to cover cannabis—value in building criteria for assessing exceptional cases and accommodation considerations in States that require accommodation
Key Messages

• For plans not governed by zero tolerance regulation (highly safety sensitive industries) every situation is unique:
  – Risk exposure to medical cannabis claims
  – Geographic distribution
  – Financial means to afford comprehensive coverage
  – Therefore plan designs need to be unique as well
Lessons Learned from Canada

- Medical cannabis legal federally for 18 years
- Recreational cannabis legal federally Oct 2018
- Given the head start that Canada has had Federally in both areas, what are lessons that can be learned for U.S. plan sponsors?
Lessons Learned from Canada

• Since legalization of recreational cannabis there has been virtually nothing happening with respect to plan coverage for medical cannabis
• Coverage under Canadian plans is very rare outside of use of Healthcare Spending Accounts
• Demand for plan coverage has been non-existent
Lessons Learned from Canada

Medical Cannabis registrations in Canada – Source: Government of Canada
Lessons Learned from Canada

• We don’t expect much to change until we see:
  – Products with Health Canada approval and DIN (NDC)
  – Workplace impairment testing issues resolved
  – Supply stabilization in medical cannabis market
  – Entrance of edibles into the market in late 2019
  – Landmark clinical trials published that impact clinical practice guidelines
Lessons Learned from Canada

• **Measuring impairment—not possible today**
• Positive test indicates past use not impairment
• Current “precedent” in Canada is Lower Churchill Transmission vs IBEW Local 1620
  – Since employers can’t measure impairment, they can’t manage safety risk and in safety-sensitive position that amounts to undue hardship on employer
Lessons Learned from Canada

- Safety sensitive employers requiring employees to abstain from recreational cannabis for up to 28 days before returning to work
- No accommodation required for rec use
- In Q1 2019, Statistics Canada reported 17.5% of Canadians 15+ had cannabis use in last 90 days
**Science Behind Cannabinoids**

<table>
<thead>
<tr>
<th><strong>Tetrahydrocannabinol (THC)</strong></th>
<th><strong>Cannabidiol (CBD)</strong></th>
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</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="THC structure" /></td>
<td><img src="image2.png" alt="CBD structure" /></td>
</tr>
<tr>
<td>- Cannabis is composed of 750 different chemicals, more than 100 are active cannabinoids</td>
<td>- Mainly non-psychoactive</td>
</tr>
<tr>
<td>- THC most well known, main psychoactive component, causes many of physical and psychotropic effects</td>
<td>- CBD of greatest interest to plan sponsors because of opportunity to mitigate impairing effects of TBD</td>
</tr>
<tr>
<td>- Level of THC can vary widely among strains</td>
<td>- May be synergistic or antagonistic to THC effects depending on dose and ratio</td>
</tr>
<tr>
<td>- Effective in pain, spasms, and nausea</td>
<td>- Anti-inflammatory, analgesic, anti-emetic, anxiolytic and anticonvulsant properties</td>
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Science Behind Cannabinoids

- June 2018—FDA approved Epidiolex for 2 rare forms of childhood-onset epilepsies
- Epidiolex is CBD oral solution
- Resulting in rescheduling of CBD

What does this mean moving forward?
What Does Evidence Say Today?

- The evidence base has not materially changed in recent years despite ongoing research.
- **Substantial clinical evidence** to support use of medical cannabis in the following 3 conditions:
  - **Chronic Pain**
  - **CINV** (Chemotherapy Induced Nausea and Vomiting)
  - **Spasticity** (related to Multiple Sclerosis)
What Does Evidence Say Today?

• Growing body of clinical evidence to support its use in the following areas but evidence is still considered “Moderate”:
  – Pediatric Treatment-Resistant Epilepsy
  – Post-Traumatic Stress Disorder (PTSD)
  – Short-Term Sleep Disturbance (related to Apnea, Fibromyalgia, Chronic Pain and MS)
  – Opioid Dose Reduction in Chronic Pain
What Does Evidence Say Today?

• **Weak Evidence** (currently) to support its use as an effective therapeutic option in:
  – Appetite Stimulation and Weight-Loss in HIV/AIDS
  – Tourette Syndrome
  – Anxiety in Social Anxiety Disorders
What Does Evidence Say Today?

• Current evidence suggests that cannabis is ineffective in the treatment of:
  – Symptoms of Dementia
  – Glaucoma
  – Reducing depressive symptoms in patients with Chronic Pain or MS
What Does Evidence Say Today?

• **Insufficient clinical evidence available today** in the following areas:
  – General Depression
  – IBS, Crohn’s Disease and Ulcerative Colitis
  – Anorexia
  – Symptoms of Parkinson’s Disease or ALS
  – Dystonia
  – . . . as well as dozens of other conditions . . .
Legislative Considerations in U.S.

Federal law: Schedule 1 Drug under CSA meaning:
• MDs cannot “prescribe” can only “recommend”
• Not eligible as tax-exempt benefit
• FSAs cannot reimburse given that IRS doesn’t consider medical cannabis as medical care
• No NDC code (outside of Epidiolex)
Plan Coverage Considerations

Where does a plan start?

- Plan-specific risk exposure
- Develop financial limitations
- Determine eligible products and dosage forms
- Need to consider suppliers and distribution
Plan Coverage Considerations

- Regionally, need to consider safeguards (or lack of safeguards) of State-level programs:
  - Extent of eligible conditions
  - Availability of dosage forms and dosage restrictions
  - Equivalency Factors
  - Distribution model and product consistency
  - Cost considerations
Plan Coverage Considerations

- Consider new Ohio Medical Marijuana Control Program and its 21 qualifying conditions such as:
  - ALS, Alzheimer’s disease, Crohn’s disease, CTE, Glaucoma, Hepatitis C, HIV, IBD, Parkinson’s Disease, PTSD, Sickle Cell Anemia, Tourette’s Syndrome, Traumatic Brain Injury, and Ulcerative Colitis
  - Clinical evidence is not there today in these areas which could make claims management challenging
Plan Coverage Considerations

- Following core elements should form part of any coverage program today or moving forward:
  - Disease-state based, clinically driven Prior Authorization
  - Limit coverage to where evidence supports use
  - Limit coverage to those with past treatment failures
  - Different approaches based on safety sensitivity
  - Dosing is highly variable (start low, go slow)
Safety Considerations

• No definitive criteria for defining medical cannabis eligibility
• College of Family Physicians of Canada list that medical cannabis is generally inappropriate for patients who:
  – Are under the age of 25
  – Have personal history or strong family history of psychosis
  – Have current or past cannabis use/substance use disorder
  – Have cardiovascular (angina, arrhythmias) or respiratory disease
  – Are pregnant, planning to become pregnant or are breastfeeding
Safety Considerations

- THC is metabolized by CYP2C9, 2C19 and 3A4 in liver
- Some common antidepressants, PPIs, antibiotics, blood pressure meds, etc. can inhibit these enzymes
- Cannabinoids can inhibit CYP1A1, 1A2 and 1B1 which can impact metabolism of some Rx meds
Coverage Challenges

- Abacus survey (Jan 2019) asked medical cannabis users which conditions/symptoms being treated:
  - 66% of respondents included Pain
  - 58% Insomnia/Sleep
  - 58% Anxiety
  - 51% Stress
  - 22% Other Mental Health conditions
Coverage Challenges

• Same Abacus Data survey—when faced with access issues to medical cannabis:
  – 48% accessed cannabis via black market
  – 44% accessed cannabis via recreational market

What does this mean for plan sponsors?
Coverage Challenges

• When first considering using cannabis for medical purposes, which of the following did you consult:
  – **Doctors**—only 41% (ongoing = 36%)
  – Another Medical Cannabis User: 26% (ongoing 27%)
  – Friends or Family: 14% (ongoing 25%)
  – Internet 9% (ongoing 14%)

What does this mean for plan sponsors?
Coverage Challenges

• Financial impact of medical cannabis puts it in the category of a specialty drug for many patients:
  – $8.50/g for dried leaf @ 3g/day = $9,300
  – $20/g for CBD oil @ 2g/day = $14,600
• Pricing is highly variable based on potency, dosage form and supply
Key Takeaways

• For plans in non-zero tolerance workplaces value in proactively looking at framework for coverage—whether for broad coverage or exceptional cases only (i.e. therapy of last resort)

• Investment, broader legalization/expansion of medical programs, new products/dosage forms and increasing utilization rates indicate this will be an ongoing consideration in management of plans