

Maryland Medical Cannabis Commission

Joy A. Strand, MHA
Executive Director

Ehsan Abdeslahian, MD
Commissioner

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Discussion Topics

- Legislative Timeline
- MMCC Overview
- Industry Overview
 - Registration Databases
 - Industry Partners
- Current Statistics
- Medical Cannabis Efficacy
- Guidelines for the Recommendation of Cannabis in Patient Care
- Legal Protections for Certifying Physicians

MMCC Mission

*The Maryland Medical Cannabis Commission (MMCC) develops policies, procedures, and regulations to implement programs that ensure medical cannabis is available to qualifying patients in a safe and effective manner. The MMCC oversees all **licensing, registration, inspection, and testing measures** pertaining to Maryland's medical cannabis program and provides relevant program information to patients, providers, caregivers, growers, processors, dispensaries, and testing laboratories.*



Legislative Timeline

2011 - GA enacts protection for Use of medical cannabis for patients and recommending physicians

2013 – The MD GA created the MMCC for investigational use of medical cannabis

2014 – legislation expands MMCC role to register physicians, and conduct research medicinal use cannabis.

2015 – MMCC receives high volume of applications

2017 - Bill proposed MMCC changes & prohibition of cannabis use in public

2012 – 3 bills introduced for medical cannabis in MD. All 3 fail but set the precedent for 2013 legislative victories

2013 – law expanded to include caregiver protection

2015 - Authorizes MMCC to license growers, processors, register ITLs, & inspect facilities.

2016 - Dentists, podiatrists and certified nurse midwives added to certifying providers

December 1, 2017 – Product on the shelves for Maryland patients.



MMCC Core Competencies

Licensing – ensuring that growers, processors, dispensaries, and independent-testing lab facilities are in compliance with COMAR 10.62.

Registration – oversee the process of adding patients, caregivers, and providers to participate in the program.

Compliance – team of inspectors ensures that facilities are adhering to the safety and security measures before initiating sales and during the operational stage.

Safety & Quality – Commission and ITLs work together to test product for potency and purity, stability, contaminants, the product's cannabinoid profile, and other measures that provide consumer safety and confidence.



Qualified Patient, Certifying Provider or Caregiver



MMCC Registry Databases

- Patient Registry
 - Registered Patient
 - Certified Patient
- Caregiver Registry
- Provider Registry

Patient Registration

- Online registration – mmcc.Maryland.gov
- Upload personal information and recent photo
- MMCC issues unique patient identifier via email



Patient Certification

- Patient visits certifying provider and presents MMCC registration number
- Provider enters recommendation for patient into MMCC data base
- Patient is now able to purchase cannabis from licensed MD dispensary
- Patient may purchase medical cannabis card (\$50) – pending changes



Provider Registration

- Be a licensed provider in good standing in Maryland
Physician, NP, Cert. Nurse Mid-Wife, Podiatrist, Dentist
- Online registration – mmcc.Maryland.gov
- Renew registration every two (2) years
- Specify conditions they will or will not certify for



Provider Responsibility

- Access patient medical history and patient examination to determine if cannabis treatment is appropriate
- Establish a bona fide provider-patient relationship
- Issue patient a “written certification” via the MMCC Registry
- Follow up with the patient at medically appropriate intervals
- Terminate certification under certain circumstances
- Conduct an in person evaluation every 365 days

Caregiver

- Caregiver – defined
 - (a) ‘Caregiver’ means an individual 21 years old or older designated by a patient who has agreed to assist with a qualifying patient’s medical use of medical cannabis.
 - (b) ‘Caregiver’ means for a qualifying patient younger than 18 years old, a parent or legal guardian.

Caregiver

- Online registration – mmcc.Maryland.gov
- Upload personal information and recent photo
- Patient designate caregivers during registration process
- Two (2) maximum caregivers per patient
- Five (5) maximum patients per caregiver
- Caregivers must be 21 years or older



Sample MMCC ID Card

FRONT



BACK



*Caregiver cards look like Patient cards, but they have a **Red** stripe, rather than a **Purple** stripe.
The cards for minor patients have a **Green** stripe.*



Limits on Medical Cannabis

- Patients limited to a combination of 120 grams of flower or 36 grams of THC in a 30 day period.
- Certifications that are not used to obtain medical cannabis within 120 days of issuance become null and void.
- Patient may only have 1 provider and 1 written recommendation at a time.
- Patient must renew certification by visiting a provider at least once per 365 days.



Patient/Provider Statistics



Statewide Cannabis Patient Statistics

3.28.18

Registered Patients	29,391
Certified Patients	19,794
Pending Patients	10,264

Registered Caregivers	1,636
Pending Caregiver	240



Statewide Cannabis Patient Statistics

3.28.18

Minor Patients

Registered	107
Certified	65

Hospice

Registered	108
Certified	64

Statewide Cannabis Provider Statistics

3.28.18

Physicians 534

Nursing (NP & CNMW) 193

Dentists 42

Podiatrist 6

Industry Categories

- Grower
- Processor
- Dispensary
- Independent Testing Laboratory (ITL)

Grower – 14 licensed in MD

Grows several varieties of cannabis

Ships cannabis material to processor, dispensaries or ITL



Processor – 12 licensed in MD

Transforms cannabis into another product or extract



Dispensary – 39 licensed in MD (2.22.18)

Storefront where patient purchase medical cannabis flower or infused products



Medical Cannabis Products in MD

- Flower/ Pre-rolls
- Extracts, Oils & Tinctures
- Vape Cartridges
- Capsules & Patches
- Salves, Lotions, Ointments
- Cannabis- infused edible food products ARE NOT approved in Maryland



Tinctures



Pre-rolls



Extracts



Oils

Guidelines and Regulation for Safe and Effective Product

Product Testing Requirements



Independent Testing Laboratories

- Sampling and product testing is done at every step where the cannabis is changed.
- Independent of locations that grow, process, or dispense medical cannabis.
- Must register with Commission.
- Must be accredited by a third-party accreditation body that adheres to 17025 ISO/IEC requirements.



Current Registered ITLs



Steep Hill[™]



Quales

Defining Standards

ADVENT LABORATORIES, INC.



ATLANTIC
TEST LABS, INC.



MARYLAND
Department of Health

Contaminant Testing

Pesticide Analysis

Microbiological Impurities

Water Activity

Residual Solvent Testing

Heavy Metal Screen

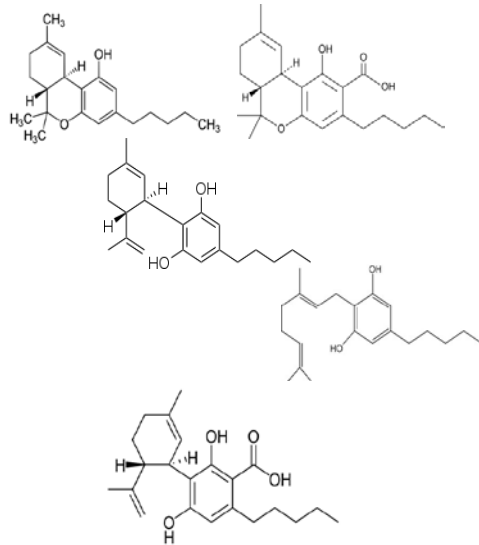
Moisture Content

Foreign Matter Inspection



Potency Testing

Cannabinoids



CERTIFICATE OF ANALYSIS

Concentrations of the following:

THC

THCA

CBD

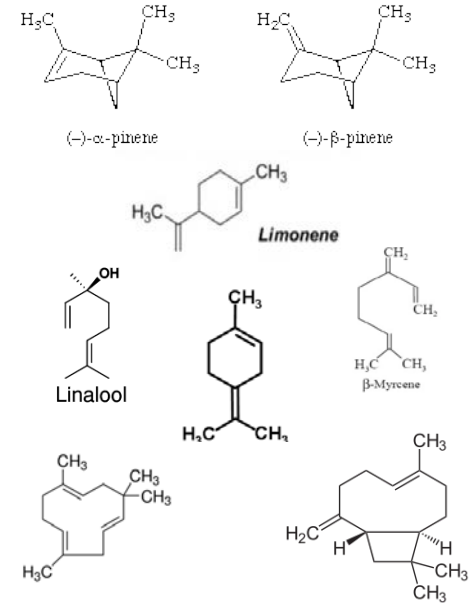
CBDA

CBG

CBN

Terpenes (*alpha/beta –Pinene, beta-Myrcene, Limonene, Terpinolene, cis-Ocimene, Linalool, beta-Caryophyllene, Humulene, beta-Eudesmol, Caryophyllene oxide, trans-Nerolidol*)

Terpenes



Guidelines and Regulation for a Safe and Effective Product

Seed-to-Sale Tracking System





- Purpose of METRC Software: Public Health and Public Safety.
- Metrc™ is a compliance management solution used by regulatory bodies for the oversight of the cannabis industry.
- Metrc is a cloud hosted on-line software tracking & reporting system.
- MD licensed medical cannabis businesses are required to track and report supply chain activities from ‘seed to sale’.

<https://www.metrc.com>



METRC™

- Total tracking of cannabis; immature plant → finalized product sale
- Integrated with MMCC Registry to track the amount of medical cannabis per patient
- Facility reports – transfers, transactions, testing procedures per facility
- Testing results recorded in Metrc
- Control product recall by placing administrative holds
- Real-time transaction oversight
- Industry must document activity in METRC for state regulatory purposes



Examples of RFID Tags for Cannabis Plants



Medical Cannabis Efficacy

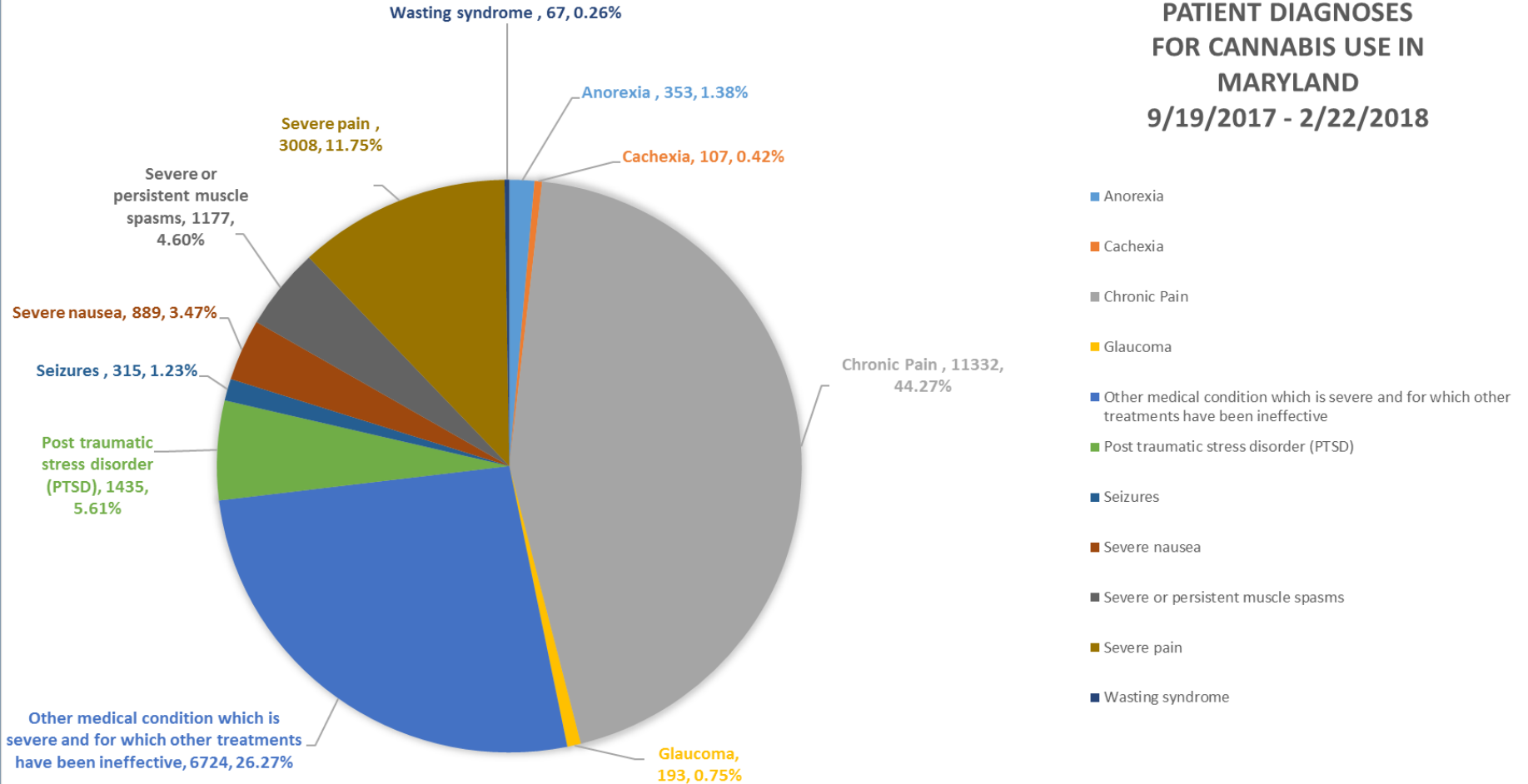
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Qualifying Medical Conditions in Maryland

- Cachexia
- Anorexia
- Wasting syndrome
- Severe or chronic pain
- Severe nausea
- Seizures
- Severe or persistent muscle spasms
- Glaucoma
- Post Traumatic Stress Disorder (PTSD)
- Any condition which is severe and for which other medical treatments have been ineffective

PATIENT DIAGNOSES FOR CANNABIS USE IN MARYLAND 9/19/2017 - 2/22/2018



Medical Cannabis Cannabinoids

- Plant contains over sixty (60) cannabinoids
- Main cannabinoids: THC and CBD – ratio determines therapeutic vs. Psychoactive effects
- Receptors located in spine and brain – comprise endocannabinoid system
- Activation causes various responses depending on dose and cannabinoid ratios

Administration and Formulations

**Inhalation by
Smoking or
Vaporization**



(herbal
cannabis,
resin,
concentrates)

Oral



(prescription
cannabinoids,
edibles,
Tinctures)

**Oro-mucosal
or Sublingual**



(lollipops,
lozenges,
nabiximols)

**Topical or
Rectal**



(herbal
cannabis,
resin,
concentrates)

Potential Adverse Effects of Medical Cannabis

Minor side effects of cannabis consumption

- **Dizziness**
 - **Dry mouth**
 - **Nausea/ Vomiting**
 - **Drowsiness**
 - **Sedation**
 - **Fatigue**
 - **Reduced coordination**
 - **Euphoria**
 - **Confusion or disorientation**
- Major side effects are rare
 - All side effects should be weighed against potential benefits on a patient-by-patient basis

Guidelines for the Recommendation of Cannabis in Patient Care

Ehsan Abdeshahian, MD
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Policy Guidelines

- FSMB appointed a work group on cannabis and medical regulation to develop guidelines regarding cannabis and patient care
 - Includes conditions, diseases or indications



Physician Patient Relationship

- Based on mutual understanding of shared responsibility to the patient's health
- Requires appropriate documentation
- Consistent with prevailing standard of care
- Physicians cannot recommend a test or otherwise authorized medical cannabis for themselves or family members

Patient Evaluation – must be in person

Must have a documented in person medical evaluation and collect relevant clinical history based on subjective and objective findings

- History of present illness
- Social history
- Past medical and surgical history
- Alcohol and substance abuse history
- Family history
- Physical examination
- Diagnoses
- Plan of care

Informed and Shared Decision-Making

- The decision to certify and recommend medical cannabis should be a shared decision between the physician and the patient.
- All risks and benefits must be discussed
 - No driving and operating heavy machinery while under the influence
- If patient is a minor or without decision-making capacity the physician should ensure the patient caregiver is involved in the treatment plan.

Treatment Agreement

- Healthcare provider should document a written treatment plan which includes:
 - Review of other measures
 - Advice about other options for managing the terminal or debilitating medical condition
 - Determination that the patient may benefit from the recommendation of cannabis
 - Advice about risk/use
 - Additional diagnostics or treatments
 - A specific duration for the cannabis authorization for a period no longer than twelve months
 - A specific ongoing treatment plan as medically appropriate

Medical Records

The physician should keep accurate and complete medical records
and remain a custodian of records



Ongoing Monitoring and Treatment Plan

- The provider should regularly assess the patient's response to the use of medical cannabis and the overall health and level of function at an interval appropriate to the individual patient.
- What is the efficacy, goals of treatment, and the progress toward those goals?

Consultation and Referral

- When needed, provider should seek consultation from:
 - Pain Management Specialist
 - Psychiatrist
 - Addiction Specialist
 - Mental Health Specialist

Physician Conflicts of Interest

COMAR 10.62.03.02

- A certifying provider may not receive compensation, *including promotion, recommendation, advertising, subsidized rent, or anything of value* from a licensed grower, processor, or a licensed dispensary unless the certifying provider submits an application to the Commission for approval for the compensation.



Legal Protections for Certifying Providers

Joy A. Strand, MHA
Executive Director



Maryland Law Protects Certifying Providers

Maryland law protects certifying physicians & providers.
Health-General Article, §13-3313, protects providers from “arrest, prosecution, or any civil or administrative penalty, including a civil penalty or *disciplinary action by a professional licensing board*” for their role in certifying patients, as long as complying with state law.



Federal law restricts use of federal funds to arrest or prosecute individuals complying with state medical cannabis laws

- Section 538 of the Consolidated Appropriations Act of 2018 (omnibus spending bill) contains protections for state medical cannabis programs. Courts have uniformly held these protections extend to individuals, businesses, and providers complying with state law. Section 538 was first adopted in 2014, and has been re-approved each year by Congress.



Physicians & providers have a First Amendment right to discuss and recommend cannabis to their patients

Conant v. Walters, 309 F.3d 629 (9th Cir. 2002) – A 1996 DOJ/HHS joint policy stating that recommending or prescribing a Schedule I substance would lead to revocation of a physician’s registration was struck down as a violation of physician and patient First Amendment free speech rights.

Court Decision: [t]he government may not initiate an investigation of a physician solely on the basis of a recommendation of marijuana within a bona fide doctor-patient relationship, unless the government in good faith believes that it has substantial evidence of criminal conduct. Because a doctor’s recommendation does not itself constitute illegal conduct, the portion of the injunction barring investigations solely on that basis does not interfere with the federal government’s ability to enforce its laws.



No documented case of medical malpractice for certifying a medical cannabis patient

No published court opinion has considered potential medical malpractice liability for a physician or other provider certifying or recommending



Questions?

joy.strand@maryland.gov

ehsan.abdeshahian@maryland.gov

Note: The information presented here are for informational purposes only and not for the purpose of providing legal advice. You should contact your attorney to obtain advice with respect to any particular subject.

