Pennsylvania's Medical Marijuana Act

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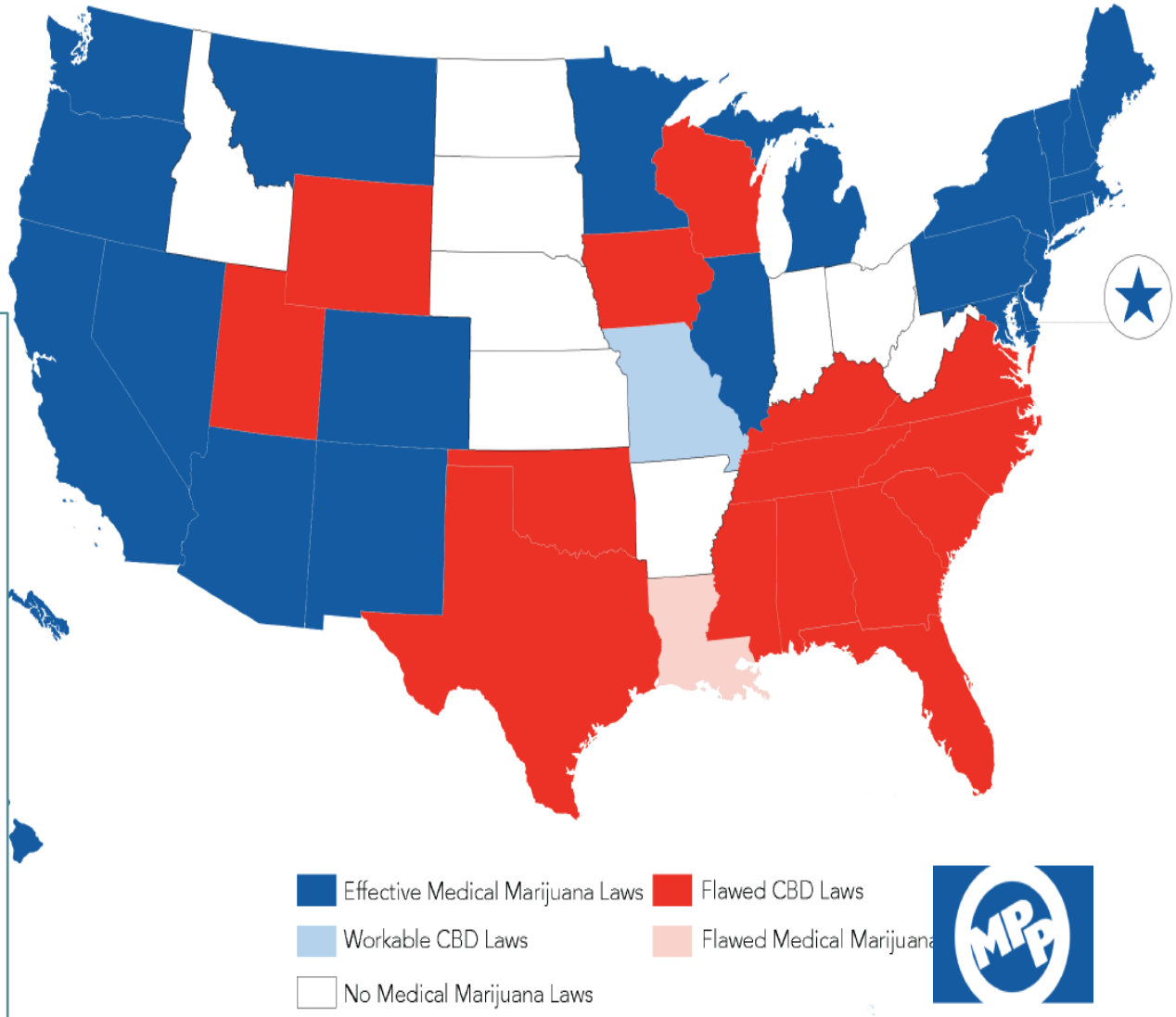
MEDICAL MARIJUANA (MMJ) IN THE U.S.

24 States, D.C. & Guam currently allow some form of MMJ

Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Guam, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Washington

17 Other States currently allow very limited MMJ

Alabama, Florida, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, Wyoming



CHAPTER 3: WHO RUNS THE PA MMJ PROGRAM?

PA Department of Health

- Director of Medical Marijuana
- Advisory Board – 15 Members (7 from State Govt. & 8 At-Large Members)

POWERS OF THE PA DEPARTMENT OF HEALTH

- Issue Permits
- Register Practitioners
- Regulatory and Enforcement
- Establish and Maintain Database
- Maintain a Directory

WHAT MEDICAL CONDITIONS WILL QUALIFY?

Serious medical conditions, including:

- Cancer
- HIV / AIDS
- ALS
- Parkinson's Disease
- Multiple Sclerosis
- Spinal Cord Nerve Injuries
- Epilepsy
- Inflammatory Bowel Disease
- Neuropathies
- Huntington's Disease
- Crohn's Disease
- Post Traumatic Stress Disorder (PTSD)
- Intractable Seizures
- Glaucoma
- Sickle Cell Anemia
- Severe Chronic or Intractable Neuropathic Pain
- Chronic or Intractable Pain *(resistant to opioid or other therapeutic treatments)*
- Autism

HOW WILL MEDICAL MARIJUANA BE DISPENSED/ ADMINISTERED?

- Pills
- Oils
- Topical Forms (i.e. gel, creams, ointments)
- Vaporization
- Tinctures
- Liquid
- **NO** Dry Leaf or Plant Forms.
- **NO** Sales of Edibles

CHAPTER 4: PRACTITIONERS

- Physicians must apply / credentials
- Physicians must complete a 4-hour course
- Subject to annual review
- Affirmative obligation to notify Dept. of Health regarding a patient's status

RESTRICTIONS ON PARTICIPATING DOCTORS

- Examination fee only
- Can hold no ownership in an Medical Marijuana Organization (MMO)
- Cannot advertise Medical Marijuana services
- Subject to disciplinary action by State Board of Medicine or State Board of Osteopathic Medicine
- Cannot recommend for themselves or family members

WHAT HAPPENS WHEN A DOCTOR SEES A PATIENT?

- Issues certification
- Can only recommend for ***serious*** medical conditions
- Continuing care of practitioner
- Patient to receive therapeutic or palliative benefit for use of MMJ
- Any requirement or limitation as to the form of MMJ
- Must review Rx Drug monitoring program before issuing a certification

CHAPTER 5: HOW DOES THE MMJ LAW APPLY TO PATIENTS?

- Certification
- ID Card to patient or Caregiver
- $50 application fee
- Valid for only One Year
- ONLY a 30-day supply

Medical Marijuana Organizations
Overview

- Department to issue permits to two types of entities:
  - Grower/Processors
  - Dispensaries
- Both addressed in Chapters 6 and 7.
- Chapter 8 provides further restrictions on dispensaries.

Chapter 6 - Medical Marijuana Organizations

- Applications for Permits must include items identified in § 602, including:
  - Criminal history record check
  - Description of business activities
  - A statement that the applicant "possesses the ability to obtain in an expeditious manner the right to use sufficient land, buildings and other premises and equipment to properly carry on the activity described in the application and any proposed location for a facility."

Chapter 6 - Medical Marijuana Organizations

- 602 Application Requirements (cont'd):
  - Maintenance of adequate security
  - Information from all financial backers and principals of the applicant, including identifying all involvement with the manufacturing or distribution of controlled substances in and outside of the Commonwealth.

Medical Marijuana Organizations
Zoning Information

- Section 2107 is the only insight the Act provides for zoning considerations

- A grower/processor shall meet the same municipal zoning and land use requirements as other manufacturing, processing and production facilities that are located in the same zoning district.

- A dispensary shall meet the same municipal zoning and land use requirements as other commercial facilities that are located in the same zoning district.

Medical Marijuana Organizations Controls

- Both growers/processors and dispensaries must implement an electronic seed-to-sale tracking system. *S. 701(a)*

- Both entities must also submit quarterly accounting reports concerning sales and inventory. *S. 701(d)*

Medical Marijuana Organizations Controls

- Department to promulgate regulations concerning the storage and transportation of medical marijuana. *S. 703*
  - Use of GPS systems for transportation. *S. 703(4).*
- All grower/processors must contract with a certified laboratory to test the medical marijuana at harvest and at final processing. *S. 704*

Chapter 6 – Medical Marijuana Organizations Grower/Processors

- The Department may not initially permit more than 25 Growers/Processors. *S. 616(1).*
- Initial nonrefundable application fee of $10,000. *S. 607(1)(i).*
- Permit fee of $200,000. Must be included with application, returned if permit is denied. *S. 607(1)(ii).*
- $2,000,000 in capital; $500,000 on deposit with financial institution. *S. 607(1)(vi).*

Medical Marijuana Organizations: Grower/Processor Cont'd

- Medical marijuana must be grown in an indoor, enclosed, secure facility. *S. 702(b)(1).*

- Regulations will be promulgated enabling growers/ processors to obtain seed from outside the Commonwealth in order to initially grow medical marijuana. *S. 702(a)(1).*

- The Department may not issue more than one individual grower/processor permit to one person. *S. 616(4).*

Medical Marijuana Organizations: Dispensary

- The Department may not initially permit more than 50 dispensaries. Each dispensary may operate no more than 3 locations. *S. 616(2)*
- Initial nonrefundable application fee of $5,000. *S. 607(2)(i).*
- Permit fee of $30,000. Must be included with application, returned if permit is denied. *S. 607(2)(ii)*
- $150,000 in capital and on deposit with financial institution. *S. 607(2)(vi)*

Medical Marijuana Organizations: Dispensary Cont'd

- Medical marijuana may only be dispensed in an indoor, enclosed, secure facility. *S. 802(a)(1))*.
- Dispensary may not operate on the same site as growing/processing facility. *S. 802(a)(2)*.
- May not operate within 1,000 feet of public, private or parochial school or a day-care center, unless waiver obtained from Department. *S. 802(a)(3) and 802(b)*
- No single person may hold more than five individual dispensary permits. *S. 616(3)*.

Medical Marijuana Organizations: Dispensary Cont'd

- No more than five growers/processors may be permitted as dispensaries. *S. 616(5)*
- Dispensaries must have a physician or pharmacist onsite at all times. *S. 801(b)*
- Onsite physician may not certify patients to receive treatment at the dispensary. *S. 801(b)*

Chapter 11: Regulatory Promulgation

Temporary Regulations

- **Mandatory Publication -** DOH must being promulgating temporary regulations within six months of the Effective Date. §1107 (c).

- **Mandatory Expiration -** Temporary regulations shall expire **not later than two years** following the publication of the temporary regulation, which will not be subject to: (1) the Commonwealth documents law; (2) regulatory review act; or (3) the Commonwealth attorneys act. §1107 (a).

- **Time Limit** - the DOH's shall have the ability to promulgate temporary regulations for two years after the Effective Date. Regulations adopted after this period shall be promulgated as provided by law. §1107 (b).

- **Practical Implications -** DOH must begin promulgating temporary regulations on November 17, 2016, and may continue to do so until May 17, 2018, which temporary regs may not expire later than two years following the publication. Such timing essentially allows for temporary regulations to remain in effect as late as May 17, 2020.

Chapter 11: Regulatory Promulgation

Permanent Regulations

- The DOH will presumably need to begin to establish promulgate permanent regulations no later than two years from the effective date (May 17, 2018).

- There is uncertainty as to whether full regulatory review will unfold during the temporary promulgation process.

- There is uncertainty as to whether the temporary regulations will be intended for conversion to permanent regulations.

Chapter 12: Advisory Board

Medical Marijuana Advisory Board is Established

- The Board will consist of the following individuals, or their chosen designee:
  - Secretary pf the Department of Health
  - State Police Commissioner
  - State Board of Pharmacy Chairman
  - Commissioner of Professional and Occupational Affairs
  - Physician General
  - President of PA Chiefs of Police
  - President of PA District Attorneys Association
  - A designee with knowledge and experience “in issues relating to care and treatment of individuals with a serious medical condition, geriatric or pediatric medicine or clinical research” appointed by each of the following:
    - Governor
    - President pro tempore of the Senate
    - Majority Leader of the Senate
    - Speaker of the House of Representatives
    - Minority Leader of the House of Representatives
    - Governor selected patient advocate §1201 (a).

Chapter 12: Advisory Board - Powers

The advisory board shall have the power to prescribe, amend and repeal bylaws, rules and regulations governing the advisory board. The advisory board may delegate supervision of the administration of advisory board activities to an administrative secretary and other employees of the department. §1201 (f).

(1-2) examine/analyze statutory/ regulatory law of Medical Marijuana in PA and in other jurisdictions;
(3) accept/ review written comments about Medical Marijuana;
(4) issue on May 17, 2018 a report ("Report") to the governor, senate, and house, which will be a public record;
(5) the Report shall be written and include recommendations and findings as to whether to change:

(i) the types of medical professionals permitted to certify Patients;
(ii) the list of Serious Medical Conditions;
(iii) the form of permitted Medical Marijuana;
(iv) the number of growers/processors or dispensaries;
(v) Patient access to Medical Marijuana and affordability of access; and
(vi) the regulations on dispensing dry leaf or plant. §1201 (j).

Chapter 19: Research Program and Health Care Medical Marijuana Organization "HCMMO"

- Section 1902 of the Act calls for the establishment of a Research Program to study Medical Marijuana "MMJ."
- The Act indicates that the DOH will create a database of medical conditions cited by Practitioners with respect to each Serious Medical Condition.
- When the database reaches 25 Patients for a particular medical condition, the DOH **shall** petition the FDA for approval to study MMJ treatment of said condition.
- Upon application to the USDA, the FDA will publicly announce the proposed study, upon which notice a Vertically Integrated Health System ("VIHS") and University within the Commonwealth may request to participate.

Research Program and Health Care Medical Marijuana Organization "HCMMO" - continued

- Upon approval from the FDA and DEA, the DOH will select a VIHS to conduct the study.
- Such approved VIHS is then considered a HCMMO, which is defined in the preamble of Section 1902 in part as a VIHS approved…to dispense or grow and process, or both, MMJ.
- The Act requires that HCMMOs only dispense MMJ received from an approved Grower or an HCMMO approved to Grow and Process. The statement that HCMMOs must only dispense MMJ obtained by "approved" parties, which may be an "approved" HCMMO, indicates that some HCMMOs may apply for growing licenses.
- The application process for such license is not outlined in the Act and will thus be subject to regulation.