ANALYSIS OF PA DEPT. OF HEALTH
DRAFT MEDICAL MARIJUANA REGULATIONS

In August 2016, the Pennsylvania Department of Health ("the Department") released draft regulations to govern Pennsylvania's recently created Medical Marijuana Program ("MMP"). The draft regulations are divided into two main chapters: Chapter 1141 - General; and, Chapter 1151 - Growers/Processors and Medical Marijuana Organizations. In short, the draft regulations define how medical marijuana will be cultivated, protected and tracked within the state.

The following memorandum summarizes the draft rules with a focus on the specific provisions that will directly impact those seeking permits to cultivate and process medical marijuana in Pennsylvania. The draft regulations span 90 pages and specific provisions should be consulted before relying upon this summary.

CHAPTER 1141 - GENERAL

§ 1141.21. Definitions

Employee - An individual who is hired to perform work for a medical marijuana organization. The term includes contractors or subcontractors working for a medical marijuana organization. This broad definition could affect future tort or workers compensation claims that make a liability distinction when it comes to employees and independent contractors.

Serious Medical Condition - Any of the following: cancer, HIV/AIDS, ALS (amyotrophic lateral sclerosis), Parkinson's disease, MS (multiple sclerosis), intractable neurological spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, Crohn's disease, PTSD (post-traumatic stress disorder), intractable seizures, glaucoma, sickle cell anemia, severe chronic pain in which conventional therapies are ineffective, or autism.

§ 1141.23. Limitations on number of permits.

Grower/processor - 25 permits (limit of 1 per applicant)
Dispensary - 50 permits (limit of 5 permits per applicant; each permit is good for 3 separate locations)
§ 1141.24. General requirements for permits.

No medical marijuana organization can operate out of a personal residence or other location where law enforcement has limited access.

A permit issued to a medical marijuana organization is valid for one year and is non-transferable.

§ 1141.27. Fees.

- Grower/processor - $10,000 - Initial Permit Application Fee
  - $200,000 - Initial Permit Fee (refunded if unsuccessful)
  - $10,000 - Permit Renewal Fee

§ 1141.28. Initial permit application.

The initial permit application must include the following:

- The physical address of the organization’s proposed site, including:
  - evidence of the applicant’s clear legal title, current lease (with consent of landlord to operate a medical marijuana organization) or other evidence of authority to use the site for the cultivation or sale of medical marijuana.

- Copies of applicable zoning ordinances affecting the use of the proposed site as a medical marijuana organization and a certification that the applicant has/will comply with all local zoning requirements.

- A Plan of Operation that describes how the applicant will comply with regulations relating to:
  - Security
  - Employee qualifications and training
  - Transportation of medical marijuana
  - Storage of medical marijuana
  - Labeling of medical marijuana
  - Inventory management
  - Quality control and testing for contamination
  - Recordkeeping
  - Preventing of loss/diversion of medical marijuana
  - Growing/cultivating of medical marijuana, and
  - All financial information including capital requirements
• An agreement that the applicant has actual notice of:
  
  o Marijuana is a Schedule I controlled substance under federal law.
  
  o Growing, distributing or possessing marijuana in any capacity, outside a federally-approved research program, is a violation of federal law.
  
  o Participation in the Medical Marijuana Program does not authorize any violation of federal law or state law, and does not provide immunity from or an affirmative defense to arrest or prosecution.

Applicants consent to site visits by the Department to determine the appropriateness of the site or the applicant’s readiness to participate in the medical marijuana program and compliance with local zoning requirements.

§ 1141.29. Capital requirements.

Grower/processor must submit an affidavit it has at least $2,000,000 in capital, $500,000 of which must be in cash or on deposit with a financial institution

Dispensary must submit an affidavit that it has at least $150,000 in cash or on deposit with a financial institution

§ 1141.30. Background checks.

Permit applicants must submit for fingerprinting of its principals, financial backers, operators and employees to the Pennsylvania State Police and the FBI to verify identity and obtain record of criminal history.

An individual who has been convicted of a criminal offense relating to the sale or possession of illegal drugs is barred from volunteering or being employed by a medical marijuana organization as a principal, financial backer or employee.

§ 1141.31. Diversity goals.

The Medical Marijuana Program seeks to promote and ensure that medical marijuana organizations foster participation of diverse groups in all aspects of their operations.

Each medical marijuana organization must include in its initial permit application a Diversity Plan that establishes a goal of diversity in employment by, and ownership and management of, the medical marijuana organization.
A medical marijuana organization may demonstrate achievement of its diversity goals through:

- contracting or transacting business with diverse groups,
- contracting with a business enterprise under terms and conditions that establish a participation plan
- employing diverse individuals in all job classifications

§ 1143.43. Inspection and investigation.

The Department may conduct announced or unannounced inspections or investigations to determine compliance with any application, permit or the Act. The Department or its agents have free access to all books, records, papers, financial records or other physical or electronic information that relates to the business of the grower/processor.

CHAPTER 1151 – GROWERS/PROCESSORS AND MEDICAL MARIJUANA ORGANIZATIONS


- All employees of growers/processors must be at least 21.
- No person under 21 may enter or remain on growers/processor site.

§ 1151.22. Grower/processor regions.

The Department will divide the available grower/processor permits into three regions (see Figure 1):

- Region 1: Department's NW and SW Health Districts
- Region 2: Department's NC and SC Health Districts
- Region 3: Department's NE and SE Health Districts
The Department may change the number of regions or adjust the boundaries of existing regions.

Pennsylvania Department of Health
Community Health Districts

Figure 1

§ 1151.23. Plans of operation.

As part of the initial permit application, grower/processors must submit a Plan of Operation that includes the following:

- Employment policies and procedures
- Security policies and protocols
- Process for receiving, processing, packaging, labeling, tracking, transporting, storing, disposing and recalling medical marijuana products and waste in accordance with all local, state and federal law
- Workplace safety
- Maintenance, cleaning and sanitation of the worksite and equipment
• Proper handling and storage of any chemicals
• Inventory maintenance including reporting of adverse loss
• Investigative complaints from dispensaries, patients or practitioners


Marijuana must be grown and processed in an enclosed, locked facility approved by the Department.

Growing and production areas should be designed so they can be easily observed and inventoried.

Loading/unloading of medical marijuana should be conducted in a secure dock out of public sight.

§ 1151.25. Start-up inventory.

A grower/processor may obtain marijuana seeds (but not plants) from outside of Pennsylvania for the purpose of securing its start-up inventory within 30 days after becoming operational.

Within 24 hours of receipt, a grower/processor must record and track each marijuana seed that enters the site.

Thirty days after becoming operational, a grower/processor may only grow medical marijuana from seeds or clones located physically on the permitted site, or purchased seeds or clones from another grower/processor within the state.

§ 1151.27. Security and surveillance.

Each grower/processor must have a commercial-grade security system that incorporates the following elements:

• Coverage of all facility entrances and exits, including all windows, storage areas and the perimeter of the facility.

• A duress alarm – silent security feature that signals the alarm user is being forced to turn off the system.

• A panic alarm – an audible alarm to signal an emergency situation requiring law enforcement response.

• A holdup alarm – a silent alarm designed to signal a robbery in progress.

• An automatic voice dialer – a security feature capable of being programmed to send a prerecorded message requesting dispatch to law enforcement.
• A failure notification system to alert of any failures in the surveillance system.

• A smoke and fire alarm.

• Auxiliary power sufficient to maintain operation for 48 hours.

• The ability to ensure all access doors are not controlled by a single electronic panel to ensure locks are not release during power outages.

• Motion detectors may be used.

Each grower/processor facility must have a surveillance system that records all activity in images of digital quality and resolution capable of revealing facial detail. The system must incorporate the following:

• Fixed cameras in limited access areas of the facility, including:
  • Areas where marijuana is grown, processed, labeled, stored and transported
  • Areas storing the surveillance system storage device
  • All facility entrances and exits
  • All rooms with exterior windows and walls
  • All storage rooms that contain safes
  • Twenty feet of the exterior of the perimeter of the facility

• Auxiliary power sufficient to maintain operation for 48 hours.

• Recorded images shall clearly display the date and time and be able to produce clear color still photos in a digital format.

§ 1151.28. Requirements for growing and processing medical marijuana.

Grower/processors must:

• Use good agricultural practices and only pesticides, fungicides or herbicides approved by the Department.

• Adopt a nutrient management plan prepared by a certified nutrient management consultant.

• Perform visual inspection of plants for mildew, mold, pests, rot or grey or black plant material.

• Install a system to monitor and regulate temperature, humidity, ventilation and lighting.
§ 1151.29. Forms of medical marijuana.

A grower/processor may only produce and dispense medical marijuana in the following forms:

- Pill
- Oil
- Topical forms (gel, cream or ointment)
- Form appropriate for vaporization or nebulization
- Tincture
- Liquid

A grower/processor may not produce medical marijuana in dry leaf or plant form.

§ 1151.30. Inventory

A grower/processor must maintain a real-time inventory including an accounting of:

- Seeds
- Marijuana plants
- Marijuana plant-clones in any stage of development
- Medical marijuana ready for sale
- All damaged, expired or contaminated marijuana awaiting disposal

A grower/processor must maintain inventory controls including monthly inventory of all marijuana in various stage of growth or processing.

A grower/processor must tag and track all marijuana seeds, plants and plant matter using a unique seed-to-sale technology as required by the MMP.

§ 1151.35. Packaging and labelling of medical marijuana.

A grower/processor must package the final form of medical marijuana at the manufacturing site in a package that is child-resistant, tamper-proof and tamper-evident, light-resistant and opaque, re-sealable and minimizes exposure to oxygen.

A grower/processor must label medical marijuana at the manufacturing site and indicate, among other things, the name/permit number of the grower/processor, the form of medical marijuana and information regarding the THC and CBD content.

§ 1151.36. Transportation of medical marijuana.

A grower/processor may contract for the delivery of medical marijuana to dispensaries.

A grower/processor must use a global tracking system to ensure safe, efficient delivery of medical marijuana.
Vehicles must be equipped with a locking cargo area and have no markings that would identify the vehicle as being used to transport medical marijuana.

Each delivery vehicle must be staffed with a delivery team of at least two employees (one of whom must remain with the vehicle at all times) and medical marijuana must not be visible from the outside of the vehicle.

§ 1151.38. Evidence of theft, diversion, or discrepancy during transport

Growerprocessors must immediately report evidence of theft or diversion of medical marijuana during transport to the Department and law enforcement.

Growerprocessors must investigate any discrepancies and send a report of the investigation to the Department.

§ 1151.39. Seed-to-sale tracking system.

All medical marijuana organizations shall implement a seed-to-sale tracking system as required by the Department.

§ 1151.41. Tax reporting.

All growerprocessors must submit quarterly reports to the Department and the Department of Revenue. Returns and payment are due on or before the twentieth day of the month following the close of the previous quarter.

All records must be maintained and available for review for a four-year period.

§ 1151.42. Recall of marijuana or medical marijuana.

A growerprocessor may withdraw medical marijuana from the market by its own determination for reasons that do not pose a risk to public health or safety, such as aesthetic reasons or other similar deficiencies, and notify the Department within 48 hours.

A growerprocessor must recall medical marijuana from the market if a condition poses a risk to public safety and immediately notify the Department of the recall.

§ 1151.43. Medical marijuana organization required training.

A principal of a medical marijuana organization must complete a Department-approved two-hour training course prior to operation of a medical marijuana organization.
All employees who have direct contact with patients/caregivers or who physically handle medical marijuana must complete a Department-approved two-hour training course within 90 days of employment.

The training course must provide information to principals and employees on:

- Applicable federal and state laws
- Standard operating procedures in the medical marijuana industry
- Proper handling of medical marijuana
- Detection and prevention of diversion of medical marijuana
- Security procedures
- Safety procedures, including response to fire, robbery, other emergency, etc.

The Department will make the two-hour training course available for free.

§ 1151.46. Insurance requirements.

Every grower/processor shall have insurance coverage for the buildings and equipment and comprehensive liability insurance, or an equivalent self-insurance plan, covering principals, officers and employees.