pennsylvania
DEPARTMENT OF HEALTH

Official Report

This two-year report of the Pennsylvania Department of Health's Office of Medical Marijuana is to comply with 35 P.S. § 10231.1105

May 15, 2020

Introduction

This document, the official report of the Pennsylvania Department of Health (Department), serves to comply with the requirements of Section 1105 of the Medical Marijuana Act (Act), 35 P.S. § 10231.1105, which requires the Department to issue a written report every two years, beginning May 17, 2018, to:

- The Governor;
- The President *pro tempore* of the Senate;
- The Majority Leader and the Minority Leader of the Senate;
- The Speaker of the House of Representatives;
- The Majority Leader and the Minority Leader of the House of Representatives;
- The chairman and minority chairman of the Judiciary Committee of the Senate;
- The chairman and minority chairman of the Public Health and Welfare Committee of the Senate;
- The chairman and minority chairman of the Judiciary Committee of the House of Representatives;
- The chairman and minority chairman of the Health Committee of the House of Representatives; and
- The Attorney General of the Commonwealth.

In accordance with the Act, this report includes:

(1) An assessment of the use of medical marijuana as a result of the enactment of the Act;

(2) An assessment of the benefits and risks to patients using medical marijuana under the Act, including adverse events; and

(3) Recommendations for amendments to the Act for reasons of patient safety or to aid the general welfare of the citizens of this Commonwealth.

I. Section 1105(b)(1)

An assessment of the use of medical marijuana as a result of the enactment of the Act.

Pennsylvania Medical Marijuana Program (Program)
The Act was signed into law on April 17, 2016. The Department administers and enforces the Act, issues medical marijuana ID cards to certified patients and approved caregivers, and issues permits to grower/processors and dispensaries within the commonwealth.

The Department's vision is to have a high quality, efficient and compliant medical marijuana program for commonwealth residents afflicted with a serious medical condition as defined by the Act. The Program provides access to medical marijuana to these patients through a safe and effective method of distribution and promotes high quality research into the effectiveness of medical marijuana in treating a patient's serious medical condition.

Under the Program, patients, who are residents of the commonwealth and who have a serious medical condition as certified by a physician, may obtain medical marijuana product at commonwealth dispensaries holding a valid permit issued by the Department.

Under the Act, the forms of medical marijuana available in Pennsylvania were initially limited to the following:

- A form medically appropriate for administration by vaporization or nebulization (excluding dry leaf or plant form);
- Pill;
- Topical forms, including gel, creams or ointments;
- Tinctures;
- Liquid; and
- Oil.

As a result of Medical Marijuana Advisory Board (Board) recommendation in the final report authorized by the Act, approval by the secretary, and implementation by temporary regulations, dry leaf or plant form for administration by vaporization became an acceptable form of medical marijuana for Pennsylvania patients, effective May 17, 2018. Dry leaf was made available for purchase by certified patients and approved caregivers in permitted dispensaries in August 2018. An individual must satisfy three qualifications to be a patient in the Program: (1) be a resident of the Commonwealth of Pennsylvania; (2) have a serious medical condition; and (3) obtain a certification by a practitioner who is registered with, and approved by, the Program.

There were initially 17 serious medical conditions covered under the Act. The Act defined a "serious medical condition" as any one of the following:

- Amyotrophic lateral sclerosis;
- Autism;
- Cancer;
- Crohn's disease;

- Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity;
- Epilepsy;
- Glaucoma;
- Huntington's disease;
- Inflammatory bowel disease;
- Intractable seizures;
- Multiple sclerosis;
- Neuropathies;
- Parkinson's disease;
- Positive status for human immunodeficiency virus or acquired immune deficiency syndrome;
- Post-traumatic stress disorder;
- Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or ineffective; and
- Sickle cell anemia.

As a result of Board recommendations in the final report authorized by the Act, approval by the secretary, and implementation by temporary regulations, effective May 17, 2018, the list of serious medical conditions for which a patient may be certified to use medical marijuana has been modified/expanded to include: cancer, including remission therapy; neurodegenerative diseases; terminal illness; dyskinetic and spastic movement disorders; severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain; and opioid use disorder for which conventional therapeutic interventions are contraindicated or ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions.

Additionally, pursuant to the process for reviewing and approving new serious medical conditions adopted by the Board in its final report, effective July 20, 2019, the Board recommended, and the secretary approved, the following new serious medical conditions as qualifying for the use of medical marijuana upon proper certification by an approved practitioner: Anxiety disorders and Tourette Syndrome.

The following represents the most up-to-date list of the 23 approved serious medical conditions:

- Amyotrophic lateral sclerosis;
- Anxiety disorders;
- Autism;
- Cancer, including remission therapy;
- Crohn's disease;
- Damage to the nervous tissue of the central nervous system (brain-spinal cord) with objective neurological indication of intractable spasticity, and other associated neuropathies;
- Dyskinetic and spastic movement disorders;
- Epilepsy;
- Glaucoma;

- Huntington's disease;
- Inflammatory bowel disease;
- Intractable seizures;
- Multiple sclerosis;
- Neurodegenerative diseases;
- Neuropathies;
- Opioid use disorder for which conventional therapeutic interventions are contraindicated or ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions;
- Parkinson's disease;
- Positive status human immunodeficiency virus or acquired immune deficiency syndrome;
- Post-traumatic stress disorder;
- Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain;
- Sickle cell anemia;
- Terminal illness; and
- Tourette syndrome.

Grower/Processors

Grower/processors grow medical marijuana plants and process those plants into acceptable forms of medical marijuana products for distribution to dispensaries.

The Department may issue permits to no more than 25 grower/processors. No more than five grower/processors may also be issued a dispensary permit. The application process requires an applicant – at a minimum – to:

- Apply for, and be awarded, a permit with the Department before growing/processing medical marijuana;
- Provide information or evidence in the permit application, including, but not limited to:
    - Their ability to maintain effective security and control to prevent diversion, abuse or other illegal conduct;
    - Their compliance with municipality zoning requirements; and
    - A diversity plan that establishes a goal of opportunity and access in employment and contracting;
- Submit a permit application with:
    - Initial non-refundable fee of $10,000;
    - Permit fee of $200,000, which is refundable if the permit is not granted; and
    - Proof of $2 million in capital ($500,000 of which must be on deposit in a financial institution).

The applicants who receive a permit, including their employees, must complete a two-hour training course that was developed by the Department, with subject matter including methods to recognize and report unauthorized activity, diversion of medical marijuana for unlawful

purposes, falsification of identification cards, proper handling of medical marijuana, and recordkeeping, as required by the Act.

The Department released Phase I permit applications for grower/processors on Jan. 17, 2017, and it awarded 12 permits to successful applicants on June 20, 2017. Phase II permit applications for grower/processors were released on April 5, 2018, and 13 permits were awarded to successful applicants on July 31, 2018. Currently, 22 grower/processors are operational and actively growing and processing medical marijuana. The permit held by one grower/processor, AGRiMED Industries of PA LLC, was not renewed in 2019 and the status of their permit is currently the subject of active litigation.

Dispensaries

Dispensaries dispense medical marijuana products to certified patients and approved caregivers for the treatment of serious medical conditions. Dispensaries are charged with maintaining clean, efficient, and secure facilities and ensuring that medical marijuana products are dispensed only to certified patients and approved caregivers.

The Department may issue permits for no more than 50 dispensaries. Each dispensary may have up to three separate locations, for a total of up to 150 dispensary locations in the commonwealth. The application process requires an applicant – at a minimum – to:

- Apply for, and be awarded, a permit with the Department before dispensing medical marijuana product;
- Provide information or evidence in the permit application, including, but not limited to:
    - A description of business organization and activities;
    - Their ability to maintain effective security and control to prevent diversion, abuse or other illegal conduct;
    - Their compliance with municipality zoning requirements; and
    - A diversity plan that establishes a goal of opportunity and access in employment and contracting;
- Submit a permit application with:
    - Initial non-refundable fee of $5,000;
    - Permit fee of $30,000, which is refundable if the permit is not granted; and
    - Proof of $150,000 in capital.

The applicants who receive a permit, including their employees, must complete a two-hour training course that was developed by the Department, with subject matter including methods to recognize and report unauthorized activity, diversion of medical marijuana for unlawful purposes, falsification of identification cards, proper handling of medical marijuana, and recordkeeping, as required by the Act.

A dispensary shall have either a physician or pharmacist onsite at all times when medical marijuana products are being dispensed to certified patients and approved caregivers. If a dispensary has more than one location, a physician assistant or a certified registered nurse practitioner may be onsite at other locations in lieu of the physician.

The Department released Phase I permit applications for dispensaries on Jan. 17, 2017, and awarded permits to 27 primary dispensaries, on June 29, 2017. Phase II permit applications for dispensaries were released on April 5, 2018, and 23 permits were awarded to successful applicants on Dec. 18, 2018. Currently, 80 dispensary sites have been deemed operational and are actively dispensing medical marijuana products to certified patients and approved caregivers. Two dispensary permittees decided not to pursue their permits and, therefore, those permits will be made available in the future during a Phase III.

Dispensing activities to certified patients and approved caregivers began on Feb. 15, 2018. To date, there have been 12,606,458 products sold during 4,432,579 dispensing events.

Grower/Processor and Dispensary Inspections
The Department employs a team of safety inspection supervisors and safety inspectors who visit all permitted medical marijuana organizations to inspect and ensure that grower/processors and dispensaries are complying with all statutory and regulatory requirements. To date, 476 regulatory inspections have been completed.

These statutory and regulatory requirements were designed to protect patients and the commonwealth's residents. Failure to comply with these requirements may result in a medical marijuana organization receiving one or more of the following penalties: suspension or revocation of operating permit, civil penalties of up to $10,000 for each violation, order of restitution of funds or property unlawfully obtained or retained, or issuance of a cease and desist order of some or all operations.

Laboratories
As part of the regulatory requirements, the Department's Office of Medical Marijuana issued guidance for testing and sampling of medical marijuana by a Department-approved laboratory. A commonwealth approved laboratory collects samples for testing after harvesting the medical marijuana and again after processing it into a medical marijuana product. Approved medical marijuana laboratories test for contaminants and potency to ensure that medical marijuana adheres to its chemical labeling. This is done so that patients receive the correct form and dosage to treat their serious medical conditions.

There are currently six approved laboratories in Pennsylvania. These laboratories are:

- ACT Laboratories of Pennsylvania LLC;
- Keystone State Testing LLC;
- Steep Hill Pennsylvania;
- PCR Labs LLC;
- US Cannalytics LLC; and
- Budding Analytical Laboratory, LLC.

Physicians and Practitioners
A practitioner is a physician who has registered and been approved by the Department to certify a patient as having a serious medical condition that qualifies for treatment with medical marijuana. A physician may register as a practitioner by meeting the following criteria: (1) hold a valid, unexpired, unrevoked, unsuspended Pennsylvania license to practice medicine, (2)

demonstrate to the Department by training or expertise that he or she is qualified in treating serious medical conditions, (3) apply to the Department to be registered with the program, and (4) successfully complete the required four-hour course, established by the Department, regarding the latest scientific research on medical marijuana, including the risks and benefits of medical marijuana.

On July 25, 2017, the Department began registering physicians for the Program. To date, 1,889 physicians have registered, and 1,349 have been approved to certify patients to use medical marijuana product. Also, to date, 306,291 patient certifications have been issued by approved practitioners since the Program began.

As a result of Board recommendations in the final report authorized by the Act, approval by the secretary, and implementation by temporary regulations, the Department will require that patients under 18 years of age be certified by a practitioner who is board eligible/certified in pediatrics or pediatric specialties, neurology with special qualifications in child neurology, child and adolescent psychiatry or adolescent medicine (whether through pediatrics, internal medicine or family practice). Because of the potential effects of medical marijuana use on a developing brain, a practitioner with specialized knowledge relating to minor patients is preferred; however, the number of registered practitioners meeting these qualifications and accepting new patients is, at present, too limited to effectuate this requirement without delaying much needed medicine to a vulnerable population of patients. Therefore, the provision will not become effective until there are a sufficient number of practitioners who meet these qualifications and who are registered with the Department to provide certification services to patients under 18 years of age.

Patients and Caregivers

Before obtaining medical marijuana products at a dispensary, patients must complete the following steps: (1) register online with the Department; (2) be certified as a patient by an approved practitioner who will assess if medical marijuana is appropriate for their serious medical condition and ensure that there are no contraindications with any existing treatments; and (3) purchase a medical marijuana ID card. Once a patient is issued a medical marijuana ID card, the individual can obtain medical marijuana product in accordance with the recommendation on their patient certification.

Certified patients who are age 18 and older and do not require a caregiver will be issued an ID card that they can use at a dispensary to obtain medical marijuana product.

No certified patient under the age of 18 will be issued an ID Card. Minors will have a designated caregiver who may be a parent, legal guardian, or a designee approved by the Department, who will obtain medical marijuana product for them.

Certified patients unable to obtain medical marijuana product independently will not be issued an ID card. Certified patients who are minors, homebound, or individuals who typically rely on a caregiver will have a designated caregiver to obtain their medical marijuana product.

A caregiver must be at least 21 years old, register with the Department, and complete a federal background check (FBI fingerprints). A certified patient can designate up to two caregivers and

an approved caregiver may be designated by up to five certified patients.

On Nov. 1, 2017, the Department opened the patient and caregiver registry. To date, there are 297,317 patients and 29,040 caregivers registered in the Program.

A medical marijuana ID card issued by the Department has a fee of $50 and is valid for the amount of time authorized by an approved practitioner, up to a maximum of one year. Certified patients may qualify for a reduced fee ID card if they participate in any of the following programs: CHIP, Medicaid, PACE/PACENET, SNAP or WIC. To date, 320,445 medical marijuana ID cards have been issued to certified patients and approved caregivers.

Chapter 20

Chapter 20 of the Act, 35 P.S. §§ 10231.2001-2003, allows research to be conducted at Pennsylvania academic institutions. An accredited medical school within the commonwealth that operates or partners with an acute care hospital licensed in Pennsylvania, applies to the Department to be certified as an academic clinical research center (ACRC). Upon certification by the Department, the ACRC must then partner with an approved clinical registrant (CR). An approved clinical registrant is defined as an entity that applied for, and received, the approval of the Department to: (1) hold a permit as both a grower/processor and a dispensary and (2) enter into a research contract with a certified ACRC.

Chapter 20 will enhance efforts to determine how medical marijuana can be best used to effectively treat various serious medical conditions.

Applications to become an approved ACRC were made available on April 5, 2018. The Department published the list of approved ACRCs in the Pennsylvania Bulletin on May 19, 2018. On May 14, 2018, Governor Tom Wolf announced eight universities that are approved, effective May 19, 2018, ACRCs in Pennsylvania. The eight universities include:

- Drexel University College of Medicine, Philadelphia;
- Lewis Katz School of Medicine at Temple University, Philadelphia;
- Penn State College of Medicine, Hershey;
- Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia;
- Perelman School of Medicine at the University of Pennsylvania, Philadelphia;
- University of Pittsburgh School of Medicine, Pittsburgh;
- Lake Erie College of Osteopathic Medicine (LECOM), Erie; and
- Philadelphia College of Osteopathic Medicine, Philadelphia.

The Department released Phase I applications to become approved as a CR on May 24, 2018. No CRs were approved during Phase I. The Department released Phase II applications to become approved as a CR on March 7, 2019, and three CRs were awarded on June 19, 2019. The Department released Phase III applications to become approved as a CR on Sept. 5, 2019, and four CRs were awarded on Feb. 20, 2020. The Department released Phase IV applications to become approved as a CR on Feb. 27, 2020. Applications were due to be mailed to the Department and postmarked no later than March 26, 2020. One ACRC is available to be partnered with an approved CR for Phase IV.

Two approved CRs held dispensary permits issued under Chapter 6 of the Act, which will be converted under Chapter 20 and will, therefore, be made available in the future during a Phase III.

The Medical Marijuana Advisory Board

Section 1201 of the Act, 35 P.S. § 10231.1201 established the Board. Section 1201(j) states that the Board has the following ongoing duties:

> (1) To examine and analyze the statutory and regulatory law relating to medical marijuana within this Commonwealth.
> (2) To examine and analyze the law and events in other states and the nation with respect to medical marijuana.
> (3) To accept and review written comments from individuals and organizations about medical marijuana.

The Board continues to meet on a quarterly basis in furtherance of these duties. Schedule dates and locations of these meeting can be found in the PA Bulletin.

Temporary Regulations

The Department began promulgating temporary regulations governing operation of the Program on Oct. 29, 2016, and added chapters on various dates through Dec. 2018. The bulk of the temporary regulations were initially set to expire on May 12, 2020. However, pursuant to Act 10 of 2020, the expiration date for the entirety of the temporary regulations has been extended until Nov. 20, 2021, or upon the publication of the final-form regulations by the Department, whichever is sooner.

II. Section 1105(b)(2)

An assessment of the benefits and risks to patients using medical marijuana under the Act, including adverse events.

The benefits to patients are evidenced by their continuing to visit permitted dispensaries to purchase medical marijuana products to treat their serious medical conditions. To date, there have been 12,606,458 products sold during 4,432,579 dispensing events.

The implementation of Chapter 20 of the Act, 35 P.S. §§ 10231.2001-2003, which allows research to be conducted at Pennsylvania academic institutions, will enhance efforts to determine how medical marijuana can be best used to effectively treat various serious medical conditions. Both benefits and risks to patients using medical marijuana under the Act will be realized once Chapter 20 of the Act is fully implemented and the research studies conclude.

A research summit was held in July 2019 to kick off the beginning of the implementation of Chapter 20. All approved ACRCs and three of the approved CRs were in attendance. The ACRCs discussed their planned research projects, and all in attendance had a robust discussion about identifying the benefits and risks to patients using medical marijuana under the Act.

To date, the Department has approved seven of the eight available CRs. The approved CRs are in the beginning stages of their operational status. Research studies have begun at one approved CR.

The Department also engages a physician workgroup, led by the Secretary of Health, that meets on a quarterly basis. This physician workgroup has representation from many areas of medicine who see patients with approved serious medical conditions. The physician workgroup provides their medical expertise and advice while guiding the Medical Marijuana Program on the implementation of the program.

As required by § 1161.38(a), since the last report, the Department has received 26 reports of adverse events from medical marijuana products dispensed from permitted dispensaries. None of these adverse events resulted in a product recall, as all were related to patient-specific issues.

III. Section 1105(b)(3)

Recommendations for amendments to the Act for reasons of patient safety or to aid the general welfare of the citizens of this Commonwealth.

The Department has the following recommendations for amendments to the Act for reasons of patient safety or to aid the general welfare of the citizens of this Commonwealth:

1. Remove 35 P.S. § 10231.2109(a). Applicability
   (a) Dispensaries.--The provisions of this act with respect to dispensaries shall not apply beginning 1,095 days from the effective date of an amendment to the Controlled Substances Act (Public Law 91-513, 84 Stat. 1236) removing marijuana from Schedule I of the Controlled Substances Act, allowing Pennsylvania's permitted medical marijuana dispensaries to remain open.

2. Re-empower the Board with all duties initially provided to them in issuing the final report under 35 P.S. §§ 10231.1201(j) and 10231.1202, and permit the Board to issue annual reports in order to make changes such as adding or reducing the number of grower/processor or dispensary permits. The Board's annual reports could be approved by the Secretary and implemented through final omitted regulation.

3. Change definition of caregiver to include an entity by changing "individual" to "person," which will allow long term care facilities, nursing homes, etc. to be approved as caregivers. Current definitions are:
   - "Caregiver." The individual designated by a patient or, if the patient is under 18 years of age, an individual under section 506(2), to deliver medical marijuana. 35 P.S. § 10231.103
   - "Person." A natural person, corporation, foundation, organization, business trust, estate, limited liability company, licensed corporation, trust, partnership, limited liability partnership, association or other form of legal business entity.

4. Revise the first sentence of 35 P.S. § 10231.502(b) to read "A caregiver not previously approved as a caregiver under this section shall submit fingerprints for the purpose of obtaining criminal history record checks, and the Pennsylvania State Police or its authorized agent shall submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the applicant and obtaining a current record of any criminal arrests and convictions." This would modify the background check requirement for the caregiver renewal process, allowing for expedited access for those caregivers previously approved within the Program. The Department will require state background checks under 35 P.S. § 10231.502(a)(3) for caregiver renewals.

5. Further revise 35 P.S. § 10231.502(b) to include the following language: "The information provided under this subsection shall not be limited by 18 Pa.C.S. § 9121(b)(2)," which would allow the Department to receive background checks in electronic form, expediting the caregiver approval process to allow for faster patient access for those requiring the assistance of a caregiver.

6. Revise 35 P.S. § 10231.602(a)(4) to include the following language: "The information provided under this subsection shall not be limited by 18 Pa.C.S. § 9121(b)(2)," which would allow the Department to receive background checks in electronic form, expediting the affiliation process for medical marijuana organization principals, financial backers, operators, and employees.

With the Governor's authorization in accordance with the Proclamation of Disaster Emergency (Proclamation) issued on March 6, 2020, operation of the following statutory provisions is temporarily suspended in order to respond to the COVID-19 emergency. Based on the successful operation of the Program under these temporary suspensions, the Department would like to request that the following statutory provisions be removed permanently:

1. The requirement in 35 P.S. § 10231.802(a)(1) that dispensing must occur in an indoor enclosed facility. The Department of Health (DOH) will allow dispensary employees to go out to the vehicle, retrieve their ID, go back inside and dispense product in accordance with regulatory dispensing requirements and then deliver to the vehicle. In all cases, the vehicle must be located on "site" (which is defined in 28 Pa. Code § 1161.23(a) as the total area contained within the facility's property line boundaries).

2. The limitation that only five patients may be assigned to one caregiver, which would provide more caregivers to patients in need. 35 P.S. § 10231.303(b)(4)

3. The phrase "in-person" from the definition of "continuing care" in 35 P.S. §10231.103 to allow for remote consultations for certifications. In all cases, patient records must be reviewed and evaluated.

4. The 30-day supply limit found in 35 P.S. § 10231.405d. DOH will require approved practitioners to notate on the patient's certification authorization to dispense a 90-day supply.