

# Pennsylvania Department of Health Office of Medical Marijuana Report

July 2022



**pennsylvania**  
DEPARTMENT OF HEALTH

## Table of Contents

Introduction	3
Section 1105(b)(1)	4
Section 1105(b)(2)	16
Section 1105(b)(3)	17

# 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.

## 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 Medical Marijuana Act was signed into law on April 17, 2016, and amended by Act 44 of 2021 on June 30, 2021, which made a number of enhancements to the state's program. The Department administers and enforces this Act, as amended, issues medical marijuana ID cards to certified patients and approved caregivers, and issues permits to grower/processors, dispensaries, and Clinical Registrants 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 may obtain medical marijuana product at Commonwealth dispensaries holding a valid permit issued by the Department. 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.

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 a Medical Marijuana Advisory Board (Board) recommendation included in The Board's final report as authorized by the Act, approval by the Secretary, and implementation through temporary regulations, dry leaf, or plant form for administration by vaporization became an acceptable form of medical marijuana for use by Pennsylvania patients, effective May 17, 2018. Dry leaf was made available for purchase by certified patients and approved caregivers in permitted dispensaries in August of 2018.

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 through 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 has initially issued 25 grower/processor permits. Pursuant to a court order, an additional permit was ordered by the court and awarded to a 26<sup>th</sup> grower/processor. 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.
  - A diversity plan.
- 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.
  - 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, as required by the Act.

The Department released Phase I permit applications for grower/processors on January 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. As stated above, on June 29, 2021, an additional permit was awarded by the court. Currently, 23 grower/processors are operational and actively growing and processing medical marijuana. Of the remaining grower/processors: one is operational and actively growing and preparing to process; one is operational and actively growing, but not yet processing; and one is not yet operational.

### **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.
  - A diversity plan.
- 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.
  - 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, as required by the Act.

Act 44 of 2021, which amended the Medical Marijuana Act, enacted several changes to the manner in which dispensaries operate. After the enactment of Act 44, a dispensary shall have either a physician or pharmacist available for synchronous interaction 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 available at other locations in lieu of the physician.

The Department released Phase I permit applications for dispensaries on January 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 December 18, 2018. Currently, 161 dispensary sites, of which

includes Clinical Registrant dispensaries, have been deemed operational and are actively dispensing medical marijuana products to certified patients and approved caregivers.

Dispensing activities to certified patients and approved caregivers began on February 15, 2018. As of May 15, 2022, there have been 61,647,200 products sold during 21,687,632 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, both grower/processors and dispensaries, to inspect and ensure that those medical marijuana organizations are complying with all statutory and regulatory requirements. To date, 1,603 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**

Laboratories testing medical marijuana are also overseen by the Department. The Department's Office of Medical Marijuana has issued guidance for testing and sampling of medical marijuana by a Department-approved laboratory. An approved laboratory collects samples for testing after harvesting the medical marijuana and again after processing it into a medical marijuana product. Additionally, Act 44 amended the Medical Marijuana Act to require stability testing at established intervals. 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.

The Department has approved the following laboratories:

- ACT Laboratories of Pennsylvania LLC
- Keystone State Testing LLC
- Steep Hill Pennsylvania
- MCR Labs, LLC
- US Cannalytics LLC
- Coral Reef Labs
- Budding Analytical Laboratories, LLC

As of May 6, 2022, Budding Analytical Laboratories, LLC did not renew its application and is no longer an approved laboratory.

### **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.

On July 25, 2017, the Department began registering physicians for the Program. As of May 15, 2022, 2,439 physicians have registered, 1,812 have been approved to certify patients to use medical marijuana product. 1,068,111 patient certifications have been issued by approved practitioners since the Program began.

### **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 by an approved practitioner as having at least one of the 23 serious medical conditions; and (3) Purchase a medical marijuana identification (ID) card. Once a patient is issued a medical marijuana ID card, the individual can obtain medical marijuana product at a permitted dispensary.

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 an unlimited number of certified patients. This change was initially implemented pursuant to a waiver provided during the COVID-19 pandemic. This change was codified by Act 44 of 2021, and is now part of the Medical Marijuana Act.

Act 44 also amended the term “caregiver” to include the following entities:

- Individuals designated in writing, for the purpose of section 502, by an organization that provides hospice, palliative or home health care services and are employed by an organization that is licensed under the act of July 19, 1979, known as the Healthcare Facilities Act, or have significant responsibility for managing the healthcare and well-being of a patient and were designated by the organization to provide care to a patient who has provided authorization for the designation.
- Individuals designated in writing, for the purpose of section 502, by a residential facility, including a long-term care nursing facility, a skilled nursing facility, an assisted living facility,

personal care home, an independent long-term care facility or an intermediate care facility for individuals with intellectual disabilities that are licensed by the Department or the Department of Human Services or have significant responsibility for managing the healthcare and well-being of the patient and were designated by the residential facility to provide care to a patient who has provided authorization for the designation.

On November 1, 2017, the Department opened the patient and caregiver registry. As of May 15, 2022, there are 712,421 patients and 37,221 caregivers registered in the Program.

Patients who are issued a medical marijuana ID card (ID card) by the Department are responsible for an annual card fee of \$50. ID cards are valid for the same amount of time of the patient certification authorized by an approved practitioner, up to a maximum of 1 year. Certified patients may now qualify to have their annual card fee eliminated if they participate in any of the following programs: CHIP, Medicaid, PACE/PACENET, SNAP or WIC. As of May 15, 2022, 1,117,500 medical marijuana ID cards have been issued to certified patients and approved caregivers.

### **Medical Marijuana Assistance Program (MMAP)**

The Medical Marijuana Act created the Medical Marijuana Program Fund as a special fund in the State Treasury. The Office of Medical Marijuana was tasked with assisting patients by using an allotted percentage of this Fund to establish:

1. A program to assist with the cost of providing medical marijuana to patients who demonstrate financial hardship or need.
2. A program to assist patients and caregivers with the cost associated with the waiver or reduction of fees for identification card.
3. A program to provide for the cost of background checks for caregivers.

The Office of Medical Marijuana has been providing patient assistance since December of 2017. Act 44 allowed the Office to expand on and implement the Medical Marijuana Assistance Program, or MMAP.

From December of 2017, the following measures have been in place:

- Patients and caregivers who are registered with an existing Commonwealth financial hardship program are provided a 50% discount on their annual identification card fee, and
- 65% of background check fees for eligible caregivers are covered.

The expansion of MMAP is occurring in three phases:

- Phase 1 eliminated annual card fees for eligible participants registered in an existing Commonwealth financial hardship program;
- Phase 2 eliminated all background check fees for eligible caregivers; and
- Phase 3 will distribute a to-be-determined benefit amount per funding period per eligible patient.

Phases 1 and 2 were implemented on March 1, 2022. Phase 3 implementation is in process as the Department designs the infrastructure and support system that is required.

## **Chapter 20**

Chapter 20 of the Act, 35 P.S. §§ 10231.2001-2003.1, 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.

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 certified 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 September 5, 2019, and four CRs were awarded on February 20, 2020. The Department released Phase IV applications to become approved as a CR on February 27, 2020. Applications were due to be mailed to the Department and postmarked no later than March 26, 2020. An eighth CR was awarded on August 5, 2020.

Act 44 of 2021 added opportunities for two ACRC and CRs to be added to the program. The Geisinger Commonwealth School of Medicine became the ninth certified ACRC in Pennsylvania on September 23, 2021, and on March 4, 2022, a ninth CR was approved to work with that ACRC.

## **The Medical Marijuana Advisory Board**

Chapter 12 of the Act identifies the membership, organizational structure and duties of the Medical Marijuana Advisory Board (Board). The 15-member board is established within the Department of Health and consists of the following members:

- The Secretary of Health or a designee, who also serves as chairperson of the Board;
- The Commissioner of the Pennsylvania State Police or a designee;
- The Chairman of the State Board of Pharmacy or a designee;
- The Commissioner of Professional and Occupational Affairs or a designee;
- The Physician General or a designee;
- The President of the Pennsylvania Chiefs of Police Association or a designee;

- The President of the Pennsylvania District Attorneys Association or a designee;

One member to be appointed by each of the following:

- The Governor;
- The President pro tempore of the Senate;
- The Majority Leader of the Senate;
- The Minority Leader of the Senate;
- The Speaker of the House of Representatives;
- The Majority Leader of the House of Representatives;
- The Minority Leader of the House of Representatives; and
- One appointee by the Governor shall be a patient, a family or household member of a patient, or a patient advocate.

The Medical Marijuana Act, as amended by Act 44 of 2021, identifies the Board's duties as follows:

- 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.
- 4) To issue written reports to the Governor, the Senate and the House of Representatives.
- 5) The written reports under paragraph (4) shall include recommendations and findings as to the following:
  - (i) Whether to change the types of medical professionals who can issue certifications to patients;
  - (ii) Whether to change, add or reduce the types of medical conditions which qualify as serious medical conditions under this Act;
  - (iii) Whether to change the form of medical marijuana permitted under this Act; and
  - (iv) How to ensure affordable patient access to medical marijuana.

The Chair of the Board assigned each of these four items to the Board's already existing subcommittees for additional visibility and review. Additionally, the Board was asked to establish policies to help guide its work. As such, a reports policy was presented and approved at the November 16, 2021 board meeting. The policy requires a report to be produced after any meeting where a recommendation is approved by the Board regarding any of the four items previously mentioned. The report shall then be presented, at the next regularly scheduled board meeting, for approval and adoption by the Board, before it can be submitted to the Secretary of Health for consideration.

After receiving a report from the Board under section 1201(j)(4), at the discretion of the Secretary of Health, the Department may effectuate recommendations made by the Board by

transmitting a notice to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin.

Since Act 44 was passed on June 30, 2021, and as a result of the reports policy, the Board has submitted one report to the Secretary of Health for consideration. After a “Qualifying Medical Conditions for Medical Marijuana Usage Application”, labeled SMC21-0004, requesting to add chronic hepatitis as an approved serious medical condition was submitted, presented to and approved by the Board, a report was compiled. The report was presented, adopted and approved at the March 22, 2022, board meeting and it has been sent to the Secretary, the Governor and the Legislature. The Secretary has 12 months from the receipt of the report to determine if she is going to effectuate the recommendation.

### **Temporary Regulations**

Under the authority of the Medical Marijuana Act regarding temporary regulations, the Department promulgated temporary regulations to facilitate the prompt implementation of the Act. Under section 1107 of the Act, the Department's authority to adopt temporary regulations was to expire May 12, 2018, 2 years after the effective date of section 1107 of the Act. Prior to the expiration of its authority to adopt temporary regulations, the Department promulgated a second set of temporary regulations, with an expiration date of May 12, 2020, published in the May 12, 2018, *Pennsylvania Bulletin*. Act 10 of 2020, section 1736-A.1, extended the expiration date of the temporary regulations to November 20, 2021.

On June 22, 2018, the General Assembly amended Chapter 20 of the Act and provided the Department with authority to issue new temporary regulations to implement the revised Chapter 20. Under section 2004 of the Act, the Department's authority to issue Chapter 20 temporary regulations was to expire 2 years after initial publication of the amended Chapter 20 temporary regulations. The Department rescinded the initial Chapter 20 temporary regulations on July 28, 2018, and promulgated revised Chapter 20 temporary regulations on August 18, 2018, and on December 22, 2018. On June 30, 2021, Act 44 of 2021 was enacted, which further extended the Department's authority to promulgate temporary regulations until May 31, 2022. As a result, the Department published a notice extending the deadline for expiration of the temporary medical marijuana regulations to January 15, 2024, by republishing and readopting the temporary regulations.

### **Act 44 of 2021**

Act 44 amended the Medical Marijuana Act, specifically, amending the definitions of “caregiver”, “continuing care”, and “serious medical condition” and adding new definitions for “excipients”, “harvest batch”, “harvest lot”, “medical marijuana product”, “process lot”, “research initiative”, and “synchronous interaction”.

These changes were initially implemented through waivers under the Governor’s Proclamation of Disaster Emergency, and then were codified under Act 44. To date, the following provisions have been implemented:

1. Remove the cap providing that an individual may not act as a caregiver for more than five patients.
2. Increase the allowable supply of medical marijuana to be dispensed from 30-day to 90-day.

3. Remove the background check requirement for a caregiver who has been previously approved by the Department of Health.
4. Permit medical professionals to consult with patients from a remote location.
5. Allow a dispensary to dispense medical marijuana in accordance with a department-approved curbside delivery protocol.
6. Extend the authority to adopt medical marijuana temporary regulations until May 31, 2022.
7. Empower the Medical Marijuana Advisory Board to issue written reports to the Governor and General Assembly addressing whether to change the types of medical professionals who can issue certifications, whether to change, add or reduce the qualifying serious medical conditions; to adopt the reports in public meetings, and to effectuate them by publishing a notice in the *Pennsylvania Bulletin*.
8. Prohibit a contractor of the Department from disclosing confidential information and provides immunity to the Department and its employees for obtaining confidential information.
9. Provide that an academic clinical research center (ACRC) may only contract with one clinical registrant.
10. Increases the number of clinical registrants (CR) from 8 to 10 and clinical registrant dispensaries from 48 to 60.
11. Permits a CR GP to sell its medical marijuana products to any dispensary.
12. Requires the Department to open applications for ACRCs and issue approvals within 90 days and open applications for CRs within 120 days and issue approvals within 180 days.
13. Removes background check requirement for a less than 5% owner of a privately held business.
14. Allows employees of medical marijuana organizations to begin work while awaiting background checks, subject to supervision and immediate removal if background check reveals a prohibitive criminal record.
15. Reduces criminal convictions preventing an individual from holding a position with a medical marijuana organization from any conviction related to the sale or possession of illegal drugs to only felony convictions less than ten years old.
16. Removes the requirement to include with a permit application a statement that each financial backer, operator, employee and principal of the medical marijuana organization is of good moral character.
17. Prohibits the Department from issuing a grower/processor permit to an applicant who previously had a contractual relationship with a ACRC to provide advice to the applicant regarding enumerated issues.
18. Allows grower/processors to import seed and immature plants during one 30-period per year, as designated by the Department.
19. Allows a grower/processor to use a pesticide that is registered by the Department of Agriculture under the Pesticide Control Act, published in the *Pennsylvania Bulletin*, and updated annually.
20. Requires permittees to maintain continuous video surveillance and retain it for 180 days or longer if needed for investigative or litigation purposes.
21. Permits a dispensary to switch the designation of its primary, secondary, and tertiary locations by providing written notice to the Department.

22. Provides for research initiatives studying the efficacy of applying solvent-based extraction methods and processes to remediate microbial contamination of medical marijuana plants and products.
23. Removes the requirement to delay start-up of the patient financial hardship fund until after the permanent regulations are published. (See MMAP section)
24. Remove the provision that eliminates medical marijuana dispensaries after marijuana is rescheduled.
25. Remove the requirement for in-person patient and practitioner interactions.
26. Allows for “ENTERPRISE RESOURCE PLANNING” (ERP) application programming interface with the seed-to-sale tracking system.
27. Allows grower/processors to obtain from other grower/processors post-harvest material, including dry leaf and oil, for processing.

The following amendments included in Act 44 required revisions to regulations, processes, forms, applications and are not yet fully effectuated.

1. Allows the Department to receive background checks via electronic means.
2. Allows grower/processors to apply solvent-based extraction methods and processes to plants that have failed a harvest test for yeast or mold, limited to processing for topical use only, labeling as remediated, and passing a final process test.
3. Allows grower/processors to obtain harvested hemp from a Department of Agriculture permit holder, subject to harvest and process lab testing, and to add pharmaceutical grade hemp-based excipients and other excipients if approved by the Department.
4. Require stability testing at established intervals.

## 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 them continuing to visit permitted dispensaries to purchase medical marijuana products to treat their serious medical conditions. As of May 15, 2022, there have been 61,647,200 products sold during 21,687,632 dispensing events.

The implementation of Chapter 20 of the Act, 35 P.S. §§ 10231.2001-2003.1, which allows research to be conducted at Pennsylvania academic institutions, will enhance efforts to determine how medical marijuana can be 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.

Three Medical Marijuana Research Summits have been held by the department to discuss the progress regarding Chapter 20. Those in attendance discussed their plans to identify the benefits and risks to patients using medical marijuana under the Act. At the most recent summit, in March of 2022, nine ACRCs and each of their CR partners were able to participate and share updates on their current and future projects as well as learned best practices.

Due to the outstanding efforts of the ACRCs, several informative articles have been published on their research, such as: Delta-9-Tetrahydrocannabinol and Cannabidiol Drug-Drug Interactions, which was published after the conclusion of one of many studies conducted at the Department of Pharmacy and the Department of Pharmacology at Penn State College of Medicine. (Vrana K, Kocis P, [2020] Delta-9-Tetrahydrocannabinol and Cannabidiol Drug-Drug Interactions, *Med Cannabis Cannabinoids* 2020;3:61-73, DOI:10.1159/000507998)

Clinician Attitudes, Training, and Beliefs About Cannabis: An Interprofessional Assessment is one example of the work published by the team at Sidney Kimmel Medical College at Thomas Jefferson University. (Worster B, Ashare RL, Hajar E, Garber G, Smith K, Kelly EL [2021] Clinician attitudes, training, and beliefs about cannabis: an interprofessional assessment, *Cannabis and Cannabinoid Research* X:X, 1–10, DOI: 10.1089/can.2021.0022)

The Department continues to engage a Physician Workgroup (workgroup), led by the Physician General, which meets on a quarterly basis. This workgroup has representation from many areas of medicine who see patients with approved serious medical conditions. Additionally, each of the ACRCs participate in the workgroup. The workgroup continues to provide their medical expertise and advice while guiding the Medical Marijuana Program on the expansion of the program.

In the first quarter of 2022, the Department conducted a statewide review of all vaporized medical marijuana products containing added ingredients. After finishing this review, the Department determined that certain vaporized medical marijuana products contained some



added ingredients that have not been approved for inhalation by the United States Food and Drug Administration. Therefore, the Department directed grower/processors to follow mandatory recall procedures for all affected vaporized products in February of 2022.

As required by § 1161.38(a), the Department has received, from May 15, 2020, through May 15, 2022, 57 reports of adverse events from medical marijuana products dispensed from permitted dispensaries.

## **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:

Section 9 of the Medical Marijuana Act imposed a 5% tax to be charged against and paid by grower/processors. This tax and all fees that are collected are to establish the medical marijuana program fund. The money in this fund is appropriated, by law, for several initiatives. The department is given 55% of the total funds – 40% is to be expended for operations and 15% of the amount is used to establish the Medical Marijuana Assistance Program (MMAP), which is to assist patients with the cost of medical marijuana if they demonstrate a financial hardship. Additionally, MMAP is to assist with the cost for ID cards and to reimburse caregivers for the cost of their background checks.

Five percent of the total of the revenue in this fund is allocated to the Pennsylvania Commission on Crime and Delinquency for distribution to local police departments, and 10% of the fund goes to the Department of Drug and Alcohol Programs for drug use prevention in counseling and treatment services.

A large portion of this fund – 30% – is to be provided for research into the treatment of those serious medical conditions for which medical marijuana is available for treatment within Pennsylvania and for research to treat other medical conditions per Chapter 19 of the Medical Marijuana Act. This money is to be used to subsidize the cost of or provide medical marijuana to patients participating in the program however it may not be used for any research activity under Chapter 20.

Chapter 19 requires that the department establish and develop a research program to study the impact of medical marijuana and treatment and symptom management of medical conditions and would require a petition to and approval from both the FDA and DEA. Additionally, this program is not to include any of the Academic Clinical Research Centers under Chapter 20.

As stated in the MMAP section of this report, since the Medical Marijuana Program has been operational, the Department has given a reduced price for Medical Marijuana ID cards for patients and caregivers who demonstrate a financial hardship and has covered a large percentage of the background check fees for caregivers. More recently, we have begun to eliminate the cost of the identification cards for this population and move forward with plans to implement phase 3, assisting patients with paying for their medical marijuana products at the point of sale.

The 15% that has been allocated for MMAP, unfortunately, will do little to subsidize the needs of our most vulnerable patients who demonstrate financial hardship. The Department hopes to be able to offer substantial assistance to as many patients as possible. In order to effectively provide such assistance, we would ask that an amendment be made that would allow for the 30% allocated to the Chapter 19 research program be reappropriated to the existing 15% allocated to assisting patients with the cost of their medical marijuana. A total of 45% of the fund would help tremendously in ensuring the needs of qualifying patients are met.

Because medical marijuana remains a federally illegal, Schedule 1 drug, insurance companies do not cover it and the Act specifically states that no insurance or health plan is required to provide coverage for medical marijuana. One of the main concerns that many patients and their caregivers have is the cost of this medication. While many of the patients who demonstrate financial hardship are able to qualify for Medicaid, which covers many of their prescription drug costs, they are forced to pay out-of-pocket for medical marijuana and may not be able to afford to adequately treat their serious medical condition. This is not only concerning for their general welfare, but for their safety as well.

Additionally, the Department would like to have more statutory authority over laboratories that are approved for medical marijuana testing. The Department would be better positioned to ensure laboratories are designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of product results, are operating in compliance, and are offering fair business operations to all permittees.

Finally, the Department recommends amending the Act to 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.