Pennsylvania Department of Health Bureau of Medical Marijuana Report

May 2024

pennsylvania
DEPARTMENT OF HEALTH

ABBREVIATION LIST

- **ACRC**- Academic Clinical Research Center
- **Act**- Medical Marijuana Act, 35 P.S. § § 10231.101-10231.2110
- **ACT 44**- Act 44 of 2021
- **ACT 63**- Act 63 of 2023
- **BMM**- Bureau of Medical Marijuana
- **Bulletin**- *Pennsylvania Bulletin*
- **CHIP**- Children's Health Insurance Program
- **CR**- Clinical Registrant
- **CRD**- Customer Relations Division
- **DEA**- Drug Enforcement Agency
- **Department**- Pennsylvania Department of Health
- **E-card**- Electronic Medical Marijuana ID Card
- **FCD**- Facility Compliance Division
- **FDA**- United States Food and Drug Administration
- **Fund**- Medical Marijuana Program Fund
- **G/P**- Grower/Processor
- **ID-** Medical Marijuana Identification Card
- **LECOM**- Lake Erie College of Medicine
- **Minors**- Certified patients under the age of 18
- **MMAB**- Medical Marijuana Advisory Board
- **MMAP**- Medical Marijuana Assistance Program
- **MMO**- Medical Marijuana Organization
- **OMM**- Office of Medical Marijuana
- **PACE/PACENET**- Pharmaceutical Assistance Contract for the Elderly
- **PCARD**- Product Compliance and Research Division
- **PCOM**- Philadelphia College of Osteopathic Medicine
- **Program**- Pennsylvania Medical Marijuana Program
- **PSOM**- Perelman School of Medicine
- **Secretary**- Secretary of Health
- **SNAP**- Supplemental Nutrition Assistance Program
- **SOP**- Standard Operating Procedure
- **Summit**- Medical Marijuana Research Summit
- **TJU**- Thomas Jefferson University
- **USPS**- United States Postal Service
- **WIC**- Pennsylvania Special Supplemental Nutrition Program for Women, Infants and Children

PART 1 – KEY MESSAGING

Purpose of Report

The purpose of this report is to inform the legislative and executive branch on how they can assist the Bureau of Medical Marijuana (BMM) to make the administration of medical marijuana to the residents of Pennsylvania as safe, effective, and efficient as possible.

The General Assembly has been extremely supportive since the inception of the Pennsylvania Medical Marijuana Program (Program). However, there are still opportunities to close regulatory, availability, and efficiency gaps. The first seven pages of this report outline the Program's progress since the publishing of the 2022 Biennial Report and its recommendations for amendments to the current law. The remainder of the report explains in detail, for those who may be less familiar, the history and current state of BMM and associated benefits and risks of medical marijuana.

Legislative Requirement

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. § § 10231.101-10231.2110, 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.

35 P.S. § 10231.1105(a).

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.

35 P.S. § 10231.1105(b).

Major Accomplishments

We are proud to present some of BMM's major accomplishments since the publishing of its last report. These accomplishments are described more fully in other areas of this report.

- Dispensing events to certified patients and approved caregivers began on February 15, 2018, and by March 1, 2024, over $5.8 billion worth of medical marijuana products have been dispensed through approximately 42,000,000 dispensing events.
- In October 2022, BMM received permission to electronically process caregiver fingerprints and receive criminal history records. This resulted in substantially faster application processing times for caregivers and a reduction in administrative time.
- In November 2022, Medical Marijuana Assistance Program (MMAP) phase 3 was implemented to provide a $50 monthly benefit to assist eligible patients in purchasing medical marijuana products. Over $470,000 has been distributed at the point of sale to patients to assist with the costs of their medication.
- BMM published its first Diversity Goal report in 2023. To improve upon the information gathering for the 2024 report, BMM created a reporting template to better capture data for the 2024 report.
- Final-form regulations were published on March 4, 2023.
- In fall 2023, BMM created the "Program Data" section on its publicly accessible website that includes aggregate data of Medical Marijuana Organization (MMO) transaction data, serious medical condition data, and the updated Program metrics shared at the Medical Marijuana Advisory Board (MMAB) meetings.
- In January 2024, the Office of Medical Marijuana (OMM) was transitioned to a bureau (BMM), which is comprised of 3 divisions: Customer Relations Division (CRD), Facility Compliance Division (FCD) and Product Compliance and Research Division (PCARD). Leading up to the reorganization, BMM reclassified 12 positions and filled a total of 16 staff vacancies to be able to more efficiently respond to the medical marijuana organizations and patients.
- PCARD updated its processes, including weekly discussion meetings and developed new Standard Operating Procedures (SOPs), to allow staff to review and make determinations for submission requests consistently and efficiently. These improvements brought the total pending product related requests from an average of 900 pending requests (December 2022) to an average of 75 pending requests. Pending request turnaround time for decisions is most often less than two weeks.
- FCD worked collaboratively with the Department of Agriculture to implement an application that allows for real time updates to Pennsylvania's hemp grower licensing information that is also stored in the seed-to-sale system.

Recommendations for Legislative Amendments

Recommendations for amendments to the Act for reasons of patient safety or to aid the general welfare of the citizens of this Commonwealth (35 P.S. § 10231.1105(b)(3)).

Regulatory Authority Over Laboratories

Currently, the Department lacks meaningful oversight over laboratories approved to test medical marijuana (approved laboratories) on behalf of the Grower/Processors (G/Ps). The Act does not provide the Department the same type of regulatory oversight of approved laboratories as it does for the MMOs. Meaningful regulatory oversight of the approved laboratories would allow the Department to be better positioned to prevent potentially adulterated or contaminated products as well as potentially inflated THC numbers from being released into the market for patient consumption and increased product prices. Meaningful oversight would also ensure approved laboratories are utilizing fair business operations and identical testing procedures for all G/Ps. Increased regulatory oversight of the approved laboratories is critical for the Department to ensure additional levels of patient safety and protection.

The Department supports laboratory oversight that would allow BMM to conduct announced and unannounced inspections or investigations to determine an approved laboratory's compliance. This would include giving the Department and its authorized agents free access to review and, if necessary, make copies of all materials related to an approved laboratory's testing of medical marijuana and related operations (accreditation assessments, financial data, employee data, and corporate structure). Failure to provide the Department and its authorized agents immediate access to any of this material, the approved laboratory facility location, or an individual, should also result in a citation as these laboratories are the last stop before potentially contaminated product goes into the market for utilization by patients with serious medical conditions.

Any legislation addressing these compliance inspections and audits should also:

- Provide the Department the authority to apply the same penalties to approved laboratories as it does with MMOs;
- Provide the Department sole discretion to audit test all medical marijuana, including products for sale at the dispensary. In light of monetary and resource constraints, the ability to conduct audit testing should allow the Department the flexibility to establish its own testing laboratory, to work with a public, state-operated or private laboratory that tests medical marijuana products for the Department only, and to submit samples to approved laboratories to test until the more desired options are feasible; and
- Provide the Department the ability to initiate recalls, not just to instruct G/Ps of a risk to public health and safety which then requires the G/Ps to initiate recalls.

The Department also supports laboratory oversight requiring two separate and distinct laboratories to conduct the testing required under 35 P.S. § 10231.704(a): one approved laboratory conducts the required harvest lot test, and a different approved laboratory conducts the product lot test. Furthermore, interlaboratory testing, or more commonly known in the industry as "round-robin testing," should be mandatory to ensure quality assurance of the approved laboratories' ability to be compliant with the testing standards and methods

established by BMM. The goal of both the two-lab test and the round-robin testing is to deter unscrupulous business dealings and ensure the ability to assess the reproducibility and consistency of testing standards and methods.

Electronic Medical Marijuana ID Cards (E-cards)

BMM proposes that the Act be amended to allow E-cards in addition to physical medical marijuana ID cards. A primary barrier for patients and caregivers is the wait time required to process and receive the physical ID card. The ID card is required to enter a dispensary and purchase medical marijuana. Currently, medical marijuana ID cards are printed by a third-party vendor and mailed directly to the patient or caregiver via the United States Postal Service (USPS). E-cards will provide patients and caregivers with quicker access to medication and increase their satisfaction. Furthermore, an E-card would not only eliminate the time associated with mailing a physical medical marijuana ID card but would also be helpful to patients and caregivers that may have their physical medical marijuana ID card lost, stolen or damaged.

The allowance of E-cards would also reduce the amount of money spent on printing costs for physical medical marijuana ID cards. Since the 2022 report, the third-party vendor increased the amount each physical medical marijuana ID card costs to produce from $9.50 to $15.50 per card. With the costs to mail directly to the patient or caregiver, BMM pays the third-party vendor approximately $450,000 to $600,000 per month.

Additionally, E-cards can be as secure as physical medical marijuana ID cards. The Act requires a medical marijuana ID card to have certain content, including a photograph of the individual being issued the card, as well as to be scanned by a dispensary to enter. Like a physical card, the E-card could be scanned from a mobile phone display, or it could be printed and scanned. While the scan of the E-card will allow the system to identify the patient or caregiver, the photograph requirement can be addressed by also requiring a valid form of government-issued photo identification be presented to the dispensary for entrance.

BMM does not recommend completely discontinuing the physical medical marijuana ID cards, because it sees the value and it supports patients and caregivers having the option to decide and utilize their preference as appropriate for their circumstances.

PART 2- BENEFITS AND RISKS OF MEDICAL MARIJUANA

An assessment of the benefits and risks to patients using medical marijuana under the Act, including adverse events (35 P.S. § 10231.1105(b)(2)).

Medical Marijuana Ch. 20 Research

The benefits to patients are evidenced by them continuing to visit permitted dispensaries to purchase medical marijuana products to treat their serious medical conditions. Chapter 20 of the Act, 35 P.S. §§ 10231.2000-2003, allows research to be conducted by Academic Clinical Research Centers (ACRCs), which has enhanced 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 are carefully observed and documented by research teams, who continue to publish their findings. Below is a description of the relationship of Pennsylvania's ACRCs and Clinical Registrants (CRs) as provided by them.

After receiving approval by the Department to conduct research on medical marijuana with its CR partner, the Chester-based Agronomed Biologics LLC, Drexel University opened a new Medical Cannabis Research Center to begin conducting evidenced-based research on the effects medical marijuana has on patients with specific medical and behavioral maladies.

In June 2019, the Penn State College of Medicine ACRC, in a relationship with PA Options for Wellness, was one of the first three centers approved by the Commonwealth. Their center's goal is to support the development of medical marijuana pre-clinical and clinical research and provide scientific evidence on the utility of medical marijuana. Currently, there are more than 30 researchers engaged in cannabis research within the ACRC; these researchers are divided into two divisions, a basic science division and a clinical science division.

The Sidney Kimmel College of Medicine at Thomas Jefferson University (TJU) became a certified ACRC in 2018 in partnership with Ethos. TJU is currently enrolling patients for medical marijuana studies related to cancer and chronic pain. TJU is also planning an upcoming observational study for patients receiving medical marijuana for generalized anxiety disorder.

Along with their former partnered CR, the University of Pittsburgh School of Medicine conducted observational research on the effects of medical marijuana on acute pain, chronic pain, and inflammation in adult patients with sickle cell disease. They also completed a sophisticated retrospective analysis of the effects of medical marijuana on chronic pain, overall well-being, sleep, and opioid use with the UPMC Department of Anesthesiology.

Lake Erie College of Medicine (LECOM) became a certified ACRC in 2018 and has been conducting medical marijuana research with their CR: CannTech PA LLC doing business as Ayr Wellness. Thus far, they have conducted studies on the quality of life in patients using medical marijuana, and they continued to study the effects of medical marijuana on patients

with inflammatory bowel disease, anxiety, and post-traumatic stress disorder, as well as the effects on opioid use and pain management.

Philadelphia College of Osteopathic Medicine (PCOM), in collaboration with its CR partner Organic Remedies has developed a multi-study research program that will gather and share data and insights into the use and processing of medical marijuana and its impact on behavior, quality of life, cognition, chronic pain and opioid management.

The Geisinger Commonwealth School of Medicine was authorized by the Department as an ACRC in September of 2021 and became operational in the summer of 2022, with their CR partner, Story of PA LLC. With increasing numbers of residents registered to use medical marijuana and leveraging Geisinger's close community relations and aim to make better health easier for our patients, the Geisinger ACRC is conducting research to evaluate the impact of medical marijuana on patients cared for within the Geisinger Health System.

Temple University is a certified ACRC with Laurel Harvest as the CR for medical marijuana research. Their ongoing studies focus on the therapeutic potential of medical marijuana for applications in chronic obstructive pulmonary disease, post incisional pain and eosinophilic esophagitis. Most recently, Temple and Laurel Harvest have been working on clinical studies to focus on medical marijuana efficacy for neuropathic pain, and for sleep troubles arising from chronic pain.

The Perelman School of Medicine (PSOM) at the University of Pennsylvania has partnered with Curaleaf as its CR to advance science through medical marijuana research. Researchers at PSOM are currently working to assess medical marijuana for patients with epilepsy and evaluating medical marijuana as part of an outpatient palliative treatment plan for patients with cancer.

Every year, a Medical Marijuana Research Summit (Summit) is held to discuss current and future medical marijuana studies. Attendees include ACRCs, CRs, BMM, physicians, students and stakeholders interested in the future of medical marijuana. Since the last Biennial Report, two Summits were held. The first Summit was held in April of 2023 and hosted by the Penn State College of Medicine. 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. The most recent Summit was held in April of 2024 and was hosted in Erie, by the LECOM. For more information regarding their research, please refer to the Chapter 20 webpage found on the BMM website.

Adverse Event Reports

As required by 28 Pa. Code § 1151.42(a), G/Ps must investigate adverse event reports sent to them by the BMM. An adverse event is defined in 28 Pa. Code § 1141a.21 as “an injury resulting from the use of medical marijuana dispensed at a dispensary. An injury includes physical harm, mental harm or loss of function.” Between January 1, 2022, and March 1, 2024, there were 84 adverse events reported, investigated by G/Ps, and reviewed by BMM. Of those events, no product recalls were initiated by the G/Ps nor did BMM determine the products posed a risk to public health and safety. BMM noted most adverse events were known side effects from using medical marijuana, such as tiredness.

PART 3 – DETAILED INFORMATION

Program History and Current State

An assessment of the use of medical marijuana as a result of the enactment of the Act (35 P.S. § 1105(b)(1)).

Pennsylvania Medical Marijuana Program History

The Act was signed into law on April 17, 2016. Since its enactment, the Act has been amended by Act 44 of 2021 (Act 44) and by Act 63 of 2023, both of which have made numerous enhancements to the Program. The Department established the OMM to administer and enforce the Act, to issue medical marijuana ID cards to certified patients and approved caregivers, and to issue and regulate permits to G/Ps and dispensaries within the Commonwealth. In January 2024, OMM was redesignated as BMM.

The Department's vision is to have a high quality, efficient and compliant Program for Commonwealth residents with a serious medical condition as defined by the Act. The Program ensures access to medical marijuana for 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 products at dispensaries by holding a valid medical marijuana ID card issued by the Department. To be a patient in the Program, an individual must satisfy three qualifications: (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, BMM.

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.

Dry leaf, or "flower," form became an acceptable form of administration by vaporization in May 2018. The approval came about through a recommendation made by the Medical Marijuana Advisory Board (MMAB) and then approved by the Secretary of Health (Secretary). Temporary regulations were published May 17, 2018, implementing the dry leaf form. Dry leaf was first made available for dispensing to certified patients and approved caregivers in August 2018.

Initially, the Act identified 17 serious medical conditions. However, the Act also grants the MMAB the authority to make recommendations, in pertinent part, "whether to change, add or

reduce the types of medical conditions which qualify as serious medical conditions under this Act." 35 P.S. § 10231.1201(j)(5)(ii). MMAB recommendations are provided to the Secretary for a final determination as to whether or not to approve the medical condition as an additional serious medical condition. If approved, the additional serious medical condition and rationale are published in the *Pennsylvania Bulletin* (Bulletin). The serious medical condition is effective upon its publication in the Bulletin. As a result, the list of qualifying serious medical conditions has expanded over the years.

The following represents the current list of approved serious medical conditions:

1. Amyotrophic lateral sclerosis.
2. Anxiety disorders.
3. Autism.
4. Cancer, including remission therapy.
5. Chronic hepatitis C.
6. Crohn's disease.
7. Damage to the nervous tissue of the central nervous system (brain-spinal cord) with objective neurological indication of intractable spasticity, and other associated neuropathies;
8. Dyskinetic and spastic movement disorders.
9. Epilepsy.
10. Glaucoma.
11. Huntington's disease.
12. Inflammatory bowel disease.
13. Intractable seizures.
14. Multiple sclerosis.
15. Neurodegenerative diseases.
16. Neuropathies.
17. 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.
18. Parkinson's disease.
19. Positive status human immunodeficiency virus or acquired immune deficiency syndrome;
20. Post-traumatic stress disorder.
21. Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.
22. Sickle cell anemia.
23. Terminal illness.
24. Tourette syndrome.

BMM's Organization

OMM was redesignated as the Bureau of Medical Marijuana in January 2024. BMM has three distinct divisions: Facility Compliance Division (FCD), the Customer Relations Division (CRD) and Product Compliance and Research Division (PCARD). In total, BMM has a total of 34 positions. Most of the employees work in FCD.

FCD oversees all aspects of G/P, dispensary and/or CR compliance. The division primarily composes of field staff who conduct on-site inspections of the facilities and investigate complaints. FCD also processes applications for alterations, laboratory approvals to test medical marijuana, additional dispensary locations, change of facility locations, closures of facility locations, and permit renewals.

CRD is responsible for the application and registration of patients, caregivers, and practitioners, including the processing of patient and caregiver medical marijuana ID cards. CRD also reviews and addresses inquiries from patients, caregivers, practitioners, legislators, and the public. CRD also reviews and approves training courses as well as manages the MMAP and BMM publicly-accessible website.

The Act and regulations require pre-approval for new medical marijuana products and formulations, related devices, labeling, packaging, strain names, product marketing, advertising, and promotional materials and events. PCARD reviews each of these submission requests and makes determinations on the regulatory compliance. Additionally, PCARD oversees and supports the Chapter 20 research done by the ACRCs and reviews medical professional training required under the Act.

Final-Form Regulations

In March 2023, BMM published its final-form regulations. The following are highlights of the final-form regulation provisions:

- In determining whether to approve an added substance into medical marijuana products, the Department added two additional considerations, in addition to those minimum requirements by law: (1) whether the added substance is permitted by the FDA for the applicable route of administration and dosage; and (2) whether the added substance has known drug interactions.
- The labeling requirements were expanded to require that labels:
    - list the percentages of all cannabinoids and individual terpenes;
    - be firmly affixed to the container directly holding medical marijuana as well as the outer packaging;
    - list THC as the first number in a THC:CBD ratio; and
    - list known allergens.
- G/Ps can apply solvent-based extraction methods and processes to medical marijuana plants that have failed an approved laboratory test for yeast and mold and be processed into a topical form.
- Each distinct dispensary facility location is required to have no less than one dedicated medical professional present, either physically or by synchronous interaction, who is prohibited from covering more than one dispensary facility location regardless of whether in person coverage or synchronous interaction is used.

The final-form regulations are available at 28 Pa. Code Part IXA. Medical Marijuana (pacodeandbulletin.gov).

Act 63 of 2023

On December 14, 2023, Governor Shapiro signed Act 63 that became effective on April 12, 2024. Act 63 allows qualified independent MMOs to apply for either a G/P permit or

dispensary permit: an independent G/P has the opportunity to obtain a dispensary permit and an independent dispensary has the opportunity to obtain a G/P permit. Effectively, this creates further vertical integration of the market. Furthermore, applications for additional permits will be available starting in May 2024. The number of additional G/Ps and dispensaries will depend on the number of MMOs that qualify as an independent as well as the number of applications submitted.

Under Chapter 6, the Act established that the Department may issue up to 25 G/P permits, not associated with Chapter 20, to grow medical marijuana plants and process them into acceptable forms of medical marijuana products for distribution to dispensaries. An additional G/P permit was ordered to be awarded by the court, for a total of 26 G/P permits not associated with Chapter 20. The Act also established that the Department may issue up to 50 dispensary permits, not associated with Chapter 20, to dispense medical marijuana products to certified patients and approved caregivers. Each dispensary permit may have up to three separate locations, for a total of up to 150 dispensary locations. Prior to Act 63, no more than five Chapter 6 G/Ps were to be issued a dispensary permit and be considered vertically integrated. Vertical integration is the combination in one permittee of two stages of production normally operated by separate permittees.

Under Chapter 20, a CR holds a G/P permit and a dispensary permit, which may have up to six separate locations, and is in a research contract with a certified ACRC. The Act allows the Department to approve up to 10 CRs, in addition to the Chapter 6 permits, that are vertically integrated. Currently, there are 8 CR permits. There are 8 Chapter 20 G/P locations and 45 Chapter 20 dispensary locations.

G/P Application Process and History of Permits

The application process requires an applicant to:

- Apply for, and be awarded, a permit with the Department before growing or 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.
- 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, as required by the Act.

The Department released Phase I permit applications for G/Ps on January 17, 2017, and it awarded 12 permits to successful applicants on June 20, 2017. Phase II permit applications for GPs were released on April 5, 2018, and 13 permits were awarded to successful

applicants on July 31, 2018. After litigation, on June 29, 2021, an additional permit was awarded by the court.

As of March 1, 2024, 33 G/Ps are operational and actively growing and processing medical marijuana. This includes 8 of the 10 potential G/Ps allowed pursuant to Chapter 20.

Dispensary Application Process and History of Permits

The application process requires an applicant 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.
- 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, as required by the Act.

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.

As of March 1, 2024, 180 dispensary sites have been deemed operational and are actively dispensing medical marijuana products to certified patients and approved caregivers. This includes dispensaries allowed pursuant to Chapter 20.

Chapter 20, ACRCs and CRs History

Chapter 20 allows research to be conducted at Pennsylvania academic medical institutions. An “accredited medical school” found within the Commonwealth operates or partners with an acute care hospital licensed in Pennsylvania and applies to the Department to be certified as an ACRC. Upon certification by the Department, the ACRC must then partner with an CR.

Applications to become an approved ACRC were first 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 medical schools that are certified ACRCs in Pennsylvania. The eight medical schools were:

- 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 (TJU), Philadelphia;
- Perelman School of Medicine (PSOM) 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 (PCOM), 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. An eighth CR was awarded on August 5, 2020.

Act 44 added opportunities for two additional ACRCs and CRs 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 them. In October 2023, one of the eight original CR permits was surrendered to the Department, which means that there is a CR permit available.

Act 63 amended the definition of “accredited medical school” to include medical institutions that have gained pre-accreditation or provisional accreditation. The Department anticipates that this change will result in the tenth permitted ACRC to be certified. If certified, an additional CR permit will be available.

Grower/Processor and Dispensary Inspections

BMM’s FCD employs a team of safety inspection supervisors and safety inspectors who visit all permitted MMOs at least once a year to inspect and ensure that G/Ps and dispensaries are complying with all statutory and regulatory requirements. From January 1, 2022, through December 31, 2023, 467 regulatory inspections were completed. These statutory and regulatory requirements were designed to protect patients from unsafe medical marijuana products and deter diversion of product to unqualified persons. Failure to comply with these requirements may result in a MMO 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

Grower/processors are required to contract with a laboratory approved by the Department to test medical marijuana. An approved laboratory is required to collect samples for testing of harvest lots and process lots as well as stability testing at established intervals to monitory quality of the finished medical marijuana in the market. The testing conducted checks for contaminants, potency, and cannabinoid and terpene profiles. This testing is paramount for patient safety and product transparency. As part of the regulatory requirements, BMM issued guidance for testing and sampling of medical marijuana by approved laboratories.

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

- ACT Laboratories of Pennsylvania LLC.
- Keystone State Testing LLC.
- Steep Hill Pennsylvania.
- US Cannalytics LLC.
- Coral Reef Labs.

As mentioned in Part 1, comprehensive Department regulatory oversight of approved laboratories is necessary.

Practitioners

Under the law, Pennsylvania physicians who have an active medical license in this Commonwealth, in accordance with the Medical Practice Act of 1985 (63 P.S. §§ 422.1—422.51a) or the Osteopathic Medical Practice Act (63 P.S. §§ 271.1—271.18), are eligible to apply to be included on the registry of practitioners who can certify patients for medical marijuana. 28 Pa. Code § 1181a.24(a). A practitioner is a physician who has registered and been approved by the Department to certify a patient as having one or more of the 24 qualifying serious medical conditions for which they may recommend treatment using medical marijuana.

A physician may register and apply to become an approved practitioner if they meet 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 they are qualified in treating serious medical conditions, and (3) successfully complete the required four-hour training course approved by the Department.

On July 25, 2017, the Department began registering physicians for the Program. As of March 1, 2024, 1,929 physicians have been approved to certify patients to use medical marijuana products, and 440,949 patient certifications have been issued by approved practitioners since the Program began.

Patients and Caregivers Medical Marijuana ID Cards

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 24 serious medical conditions; and (3) pay the required annual medical marijuana ID card fee. Once a patient or caregiver has their physical medical marijuana ID card, they can obtain medical marijuana products at a permitted dispensary.

Certified patients under the age of 18 (minors) are not issued a medical marijuana ID card. Minors must have a designated caregiver, who may be a parent, legal guardian, or a designee approved by the Department, to obtain medical marijuana product for them.

Certified adult patients who are unable to obtain medical marijuana product independently are not issued medical marijuana ID cards. These patients can designate up to two caregivers to obtain their medical marijuana products for them. A caregiver must be at least 21 years old, registered with the Department, and complete a criminal history background

check. An approved caregiver may be designated by an unlimited number of certified patients. On November 1, 2017, the Department opened the patient and caregiver registry. As of March 1, 2024, there are 939,382 patients and 45,962 caregivers registered for the Program.

Patients, who are issued a medical marijuana ID card, are responsible for an annual card processing fee of $50. The cards are valid for the same amount of time as the patient certification authorized by an approved practitioner, not to exceed 1 year. As of March 1, 2022, certified patients may be eligible for a waiver of the $50 processing fee if they qualify for assistance under MMAP. As of March 1, 2024, medical marijuana ID cards have been issued to 441,188 certified patients and 9,203 approved caregivers.

Medical Marijuana Assistance Program (MMAP)

With the passage of the Act, the Medical Marijuana Program Fund was created as a special fund in the State Treasury. The Department was tasked with establishing:

1. A program that assists with the cost of providing medical marijuana to patients who demonstrate financial hardship or need;
2. A program that assists patients and caregivers with the cost associated with their medical marijuana ID cards; and
3. A program that provides for the cost of background checks for caregivers.

MMAP was the program established to provide the required financial assistance to caregiver applicants and financial hardship eligible patients and caregivers. A financial hardship eligible patient or caregiver are those patients and caregivers who are enrolled in at least one of the following existing Commonwealth financial hardship programs: Children's Health Insurance Program (CHIP), Medicaid, Pharmaceutical Assistance Contract for the Elderly (PACE/PACENET), Supplemental Nutrition Assistance Program (SNAP) or the Pennsylvania Special Supplemental Nutrition Program for Women, Infants and Children (WIC).

From December of 2017 to April 30, 2022, patients and caregivers who were registered with an existing Commonwealth financial hardship program were provided a 50% discount on their annual identification card fee and caregiver applicants had 65% of background check fees covered.

With the passage of Act 44, MMAP financial assistance was expanded in a significant manner:

- The annual medical marijuana ID card fee may be completely waived for eligible participants who attest to being registered in an existing Commonwealth financial hardship program. Since March 1, 2022, this has saved nearly 160,000 eligible patients and caregivers more than $11.5 million.
- All background check fees were eliminated for caregivers. Since March 1, 2022, this has saved nearly 6,600 new caregivers approximately $143,000.
- A monthly benefit is distributed to eligible patients. Due to monetary constraints, this phase was launched in the form of a pilot in November of 2022 to provide a $50 monthly benefit for patients enrolled in PACE/PACENET. Since November 2022, over

$470,000 has been distributed at the point of sale to patients to assist with the costs of medication.

The Medical Marijuana Advisory Board (MMAB)

Chapter 12 of the Act, 35 P.S. §§ 10231.1201-10231.1202, identifies the membership, organizational structure, and duties of the MMAB. The 15-member board is established within the Department of Health and consists of the following members:

1. The Secretary of Health or a designee, who also serves as chairperson of the Board;
2. The Commissioner of the Pennsylvania State Police or a designee;
3. The Chairman of the State Board of Pharmacy or a designee;
4. The Commissioner of Professional and Occupational Affairs or a designee;
5. The Physician General or a designee;
6. The President of the Pennsylvania Chiefs of Police Association or a designee;
7. The President of the Pennsylvania District Attorneys Association or a designee; and
8. 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 Board's duties are 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.

To facilitate the amended reporting criteria as well as to ensure thorough visibility and review in drafting the written reports, the MMAB established policies to help guide its work and the

Chair of the Board assigned one of the four reporting topics previously mentioned to each of the MMAB subcommittees. The updated reports policy was presented and approved at the MMAB's November 16, 2021, meeting. The policy requires a report to be produced after any meeting where a recommendation is approved by the MMAB regarding any of the four reporting topics. The report shall then be presented, at the next regularly scheduled MMAB meeting, for approval and adoption by the MMAB, before it can be submitted to the Secretary for consideration.

After receiving a report from the MMAB under Section 1201(j)(4) of the Act, at the discretion of the Secretary, the Department may effectuate recommendations made by the MMAB by transmitting a notice to the Legislative Reference Bureau for publication in the *Pennsylvania Bulletin*.

Between July 2022 and December 2023, the MMAB submitted one report to the Secretary for consideration. At the September 2023 MMAB meeting, the MMAB approved a motion to allow Doctors of Podiatric Medicine to apply to be practitioners who can certify patients diagnosed with severe, chronic, or intractable pain of neuropathic origin, or severe, chronic, or intractable pain as designated within the scope of the Podiatric Practice Act. At the November 2023 MMAB meeting, the MMAB approved the report recommending the addition of Doctors of Podiatric Medicine to apply to be practitioners who can certify patients for medical marijuana. Pursuant to section 1202 of the Act, this report was sent to the Secretary, the Governor, and the General Assembly. The Secretary has 12 months from receipt of the report to determine whether to effectuate the recommendation.