Contents

I. GENERALLY

The Pennsylvania Department of Health (Department) became responsible for administering Pennsylvania's Medical Marijuana Program with the enactment of the Medical Marijuana Act (Act).

Act 63 of 2023 allows for:

(1) an independent grower/processor that applies and meets the requirements under section 618 shall be issued one dispensary permit.
(2) an independent dispensary that applies and meets the requirements under section 618 shall be issued one grower/processor permit.

Act 63 requires that the permit granted as part of this application to be issued to the business entity that holds the original permit (the permittee). Therefore, the permit will not be issued to a separate, distinct legal entity.

The Department's use of "applicant" refers to the current Medical Marijuana Organization (MMO) applying for an additional permit under Act 63 of 2023.

Upon approval by the Department, the permits issued under this section shall carry the same rights, privileges and obligations as permits issued under this chapter.

An independent grower/processor or an independent dispensary may not enter into a change of control transaction with any person, which as defined in the regulations includes entities, for a duration of one year from the date the first dispensary location or the grower/processor location of the permit issued under Act 63 is deemed operational by the department, unless the change of control transaction occurs between an independent grower/processor or independent dispensary and a diverse group (securities sale prohibition period). The Department interprets the securities sale prohibition period to be a blackout period, wherein the independent MMO is restricted from soliciting, negotiating, or selling securities.

Applicants should understand the Act and its accompanying regulations at 28 Pa. Code Chapters 1141a, 1151a, 1161a, 1171a, 1181a, 1191a and 1211a (permanent regulations) and are advised to read these instructions and any guidance before beginning work on any application. These instructions apply to both the grower/processor and dispensary permit applications unless otherwise noted.

Completing the Application

An applicant seeking approval from the Department must complete all sections of the Application for Approval of an Act 63 of 2023 Permit, including information on the individual who will be the primary contact for the applicant during the Department's review of the application. The primary contact will be the business contact of record for the applying MMO. The application and any required supporting documentation must be saved as PDF files on a single USB drive.

An area is provided for all answers unless it is specified that additional documents must be attached. Please restrict your answers to the fields provided ( ). Each answer area is supplied with three blank lines. Feel free to copy and paste to make additional answer lines should more room be needed. Additional documents may also be attached.

The applicant must provide the requested documentation and answer ALL affirmations unless directed to move on to the next section. All documentation (either specifically requested or if more space is necessary for your answer) must be attached to the application in the form of PDF files.

Please make sure the Application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

Medical Marijuana Regions

The Commonwealth is divided into six Medical Marijuana Regions, comprised of the counties listed below. A map of the Medical Marijuana Regions is available online.

Region 1 Southeast	**Region 2 Northeast**	**Region 3 Southcentral**	**Region 4 Northcentral**	**Region 5 Southwest**	**Region 6 Northwest**
Berks	Carbon	Adams	Bradford	Allegheny	Cameron
Bucks	Lackawanna	Bedford	Centre	Armstrong	Clarion
Chester	Lehigh	Blair	Clinton	Beaver	Clearfield
Delaware	Luzerne	Cumberland	Columbia	Butler	Crawford
Lancaster	Monroe	Dauphin	Montour	Cambria	Elk
Montgomery	Northampton	Franklin	Northumberland	Fayette	Erie
Philadelphia	Pike	Fulton	Sullivan	Greene	Forest
Schuylkill	Susquehanna	Huntingdon	Snyder	Indiana	Jefferson
	Wayne	Juniata	Tioga	Somerset	Lawrence
	Wyoming	Lebanon	Union	Washington	McKean
		Mifflin	Lycoming	Westmoreland	Mercer
		Perry	Potter		Venango
		York			Warren

Fees

Application Fees and Permit Fees must be submitted in the form of separate, certified checks or money orders made payable to “Commonwealth of Pennsylvania.” Each fee must be enclosed in a separate, sealed envelope within the application package. Application Fees are non- refundable. Permit Fees will be refunded if the applicant is not issued a permit. Permit fees will not be refunded until the applicant has exhausted the opportunities to resubmit a failed application within 15 days (“retry”) and resubmit an application not meeting minimum criteria within 15 days (“cure”). Refunds will be issued to the business name provided in the permit application, in care of the primary contact, and mailed to the primary contact’s mailing address.

Please note: a refund cannot be processed without the applicant’s Federal Employer ID Number.

The following fees must be submitted with each application:

Grower/Processor Permit Applications:

Application Fee: $10,000
Permit Fee: $200,000

Dispensary Permit Applications:

Application Fee: $5,000
Permit Fee: $30,000 per dispensary location identified in the application, up to $90,000

Application Timetable

Applicants must be aware of and conform to the following dates and deadlines:

April 12, 2024:
The Application for Approval of an Act 63 of 2023, Grower Processor Permit Application, Dispensary Permit Application, associated attachments, and instructions will be available on Pennsylvania's Medical Marijuana website.

May 12, 2024:
The earliest date for which the Department will accept Act 63 of 2023 Applications. (See Section IV below, "Preparing and Submitting Your Application").

June 12, 2024:
The latest date for which the Department will accept Act 63 of 2023 Applications. (See Section IV below, "Preparing and Submitting Your Application").

Definitions for Terms Within Application Documents

Certain relevant and newly enacted definitions are included here for the Applicant's convenience. All words and phrases shall have the meanings given to them in the Medical Marijuana Act and regulations, and applicants are encouraged to familiarize themselves with all defined terms. See 35 PS. § 10231.103 and 28 Pa. Code § 1141a.21:

Change of control transaction - the consolidation, merger or acquisition by a person or group of persons acting in concert of more than 20% of:

(1) a medical marijuana organization's securities or other ownership interests, with the exception of any ownership interest of the person that existed:

(i) at the time of the issuance of the initial medical marijuana organization's permit and payment of the initial permit; or

(ii) prior to the effective date of this subparagraph; or

(2) the securities or other ownership interests of a corporation or other form of business entity which owns directly or indirectly 20% of the securities or other ownership interests of the medical marijuana organization.

Diverse group - A disadvantaged business, minority-owned business, women-owned business, service-disabled veteran-owned small business or veteran-owned small business that has been certified by a third-party certifying organization.

Independent dispensary - A dispensary issued a permit to operate in this Commonwealth and that meets all of the following:

(1) Has not had the dispensary's permit revoked.

(2) Has not entered into a change of control transaction with any other person that was issued a grower/processor permit, dispensary permit or clinical registrant permit in this Commonwealth.

(3) Is not materially the same as another medical marijuana organization in this Commonwealth through a parent company, subsidiary or shared affiliation with another entity that holds a permit from the department under this act or through the sharing of principals, officers or directors, employees, facilities, equipment, finances or capital.

Independent grower/processor - a grower/processor awarded a permit to operate in this Commonwealth that meets all of the following criteria as of the effective date of this definition:

(1) Has not had its permit revoked.

(2) Has not entered into a change of control transaction with any other person that was issued a grower/processor permit, dispensary permit or clinical registrant permit in this Commonwealth.

(3) Is not materially the same as another medical marijuana organization in this Commonwealth through a parent company or subsidiary of another entity that holds a permit from the department under this act or through the sharing of principals, officers or directors, employees, facilities, equipment, finances or capital.

Materially the same - A person who shares any of the following with another person:

(1) Profits or losses.

(2) Common valuation, in the case of a publicly traded company.

(3) Common ownership of more than 5%, including subsidiaries.

(4) Common ownership of 5% or less if the persons with voting rights to elect or appoint one or more members of the board of directors or other governing board.

(5) Common management, policies, principals, officers, directors, employees, equipment, finances or capital.

Operator - An individual who directly oversees or manages the day-to-day business functions for an applicant or permittee and has the ability to direct employee activities onsite and offsite or within a facility for which a permit is sought or has been issued under this part

Parent company - A company which directly or indirectly controls any other permittee under this act.

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.

The terms “you” and “your” generally refer to the applicant applying for the permit. The term “Department” refers to the Pennsylvania Department of Health.

II. DISCLOSURE OF APPLICATION INFORMATION

Information Subject to Disclosure

Applications submitted to the Department, including all attachments, are public records and are subject to disclosure under the Right-to-Know Law (RTKL), 65 P.S. §§ 67.101-67.3104.

Accordingly, under 28 Pa. Code § 1141a.29 (a)(2), to the extent that your application package contains trade secret or confidential proprietary information, an applicant also must submit a redacted application in an electronic format.

Definition of Trade Secret and Confidential Proprietary Information

“Trade secret” is defined under the RTKL as: “Information, including a formula, drawing, pattern, compilation, including a customer list, program, device, method, technique or process that: (1) derives independent economic value, actual or potential, from not being generally known to and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use; and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. The term includes data processing software obtained by an agency under a licensing agreement prohibiting disclosure.” 65 P.S. § 65.102.

“Confidential proprietary information” is defined under the RTKL as: “Commercial or financial information received by an agency: (1) which is privileged or confidential; and (2) the disclosure of which would cause substantial harm to the competitive position of the person that submitted the information.” 65 P.S. § 65.102.

You must **SUBMIT A SEPARATE REDACTED APPLICATION** in an electronic format that complies with the following:

Redact ONLY trade secret or confidential proprietary information *as defined under the RTKL*.

1. Redaction marks must be BLACK on WHITE background, must be marked “RTKL 708(b)(11),” and must cover only exempt material. Section headings and content descriptors on the permit application and attachments must remain exposed.

PROPERLY REDACTED:

C. PLEASE ALSO PROVIDE A DETAILED SUMMARY OF THE METHODS AND PROCEDURES THAT WILL BE USED FOR THE GROWING OF MEDICAL MARIJUANA AT THE PROPOSED GROWER/PROCESSOR FACILITY. FOR EXAMPLE: THE INCLUSION OF GROWING MEDIUMS OR HYDROPONICS, THE PHYSICAL CONDITION FOR MAINTAINING THE IMMATURE MEDICAL MARIJUANA PLANTS AND MEDICAL MARIJUANA PLANTS, NUTRIENT PRACTICE, PARTICULAR LIGHTING STRATEGIES, ETC.

ABC Corporation will utilize the following proprietary methods:

RTKL 708(b)(11)

IMPROPERLY REDACTED:

RTKL 708(b)(11)

2. All redactions must be marked. Do not withhold or delete portions of the redacted application.
3. Do not lock, password protect, or otherwise secure the redacted copy from editing, organizing and printing.
4. Include all sections of application and attachments in the redacted application (even if no redaction is made to some portions), as the redacted and unredacted applications must match page for page.
5. Include a written statement signed by an applicant representative stating that all redactions made by the applicant constitute trade secret or confidential proprietary information as defined under the RTKL.

In accordance with section 707(b) of the Right-to-Know Law, 65 P.S. 67.707(b), the Department will make an independent determination as to whether to release the information marked as confidential proprietary or trade secret.

Other Information Exempt From Disclosure

Should the Department receive a RTKL request for an application, the Department will redact any other information exempt from disclosure under the RTKL, the Act and the regulations prior to providing records to the requester.

Defense of Applicant Redactions

An applicant must defend its own redactions in any administrative or court proceeding, including any appeals. You must maintain the email address you submit as your primary contact in Section 1 of the application, even if you do not receive a permit, so that the Department may keep you informed of RTKL requests and any litigation involving your redacted permit application. Any information not adequately defended by the applicant may result in full disclosure of the information in un-redacted form.

III. CONSENT TO INVESTIGATION AND BACKGROUND CHECKS

By submitting an application to the Department, an applicant consents to any investigation, to the extent deemed appropriate by the Department, of the applicant's ability to meet the requirements of the Act and regulations.

Individuals with Controlling Interest

In the application, questions relating to principals and financial backers must be answered only for those individuals with a "controlling interest," which is defined as follows:

- For a publicly traded company, voting rights that entitle a person to elect or appoint one or more of the members of the board of directors or other governing board or the ownership or beneficial holding of 5% or more of the securities of the publicly traded company.
- For a privately held entity, the ownership of 5% or more of the business.

Background Checks

To provide the criminal history record check required, an applicant must submit fingerprints of its principals, financial backers, operators and employees to the Pennsylvania State Police. The Pennsylvania State Police or its authorized agent will submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the individuals whose fingerprints have been submitted and obtaining a current record of criminal arrests and convictions.

The Department may only use criminal history background check information to determine the character, fitness and suitability to serve in the designated capacity of the principal, financial backer, operator and employee.

The requirement of obtaining a background check applies to individual owners of securities in a publicly traded company only where the individual holds a controlling interest.

A financial backer, principal or employee may not hold a volunteer position, position for remuneration or otherwise be affiliated with a MMO if the individual has been convicted of a criminal offense relating to the sale or possession of illegal drugs, narcotics or controlled substances.

Background Check Process

All individuals who are listed as financial backers, principals, operators and employees in Part C, Section 4 of the grower/processor permit application or the dispensary permit application must complete a federal background check as part of their permit application. The Commonwealth's vendor for digital fingerprinting is IdentoGO.

Pre-enrollment with IdentoGO is required. Once enrolled, you may either schedule an appointment or "walk-in" during the location's posted hours of operation. Scheduling an appointment is recommended.

IdentoGO uses service codes that are unique to the agency requiring the background check. These codes ensure that applicants are processed for the proper purpose and that the results are forwarded to the appropriate agency. The Department uses the Service Name and Code listed below. DO NOT use the code for any other purpose. All background check results will be transmitted directly to the Department. Please use the following steps to obtain the required federal background check:

1. Each individual financial backer, principal, operator and employee begins the Federal Criminal Background Check process by visiting the IdentoGO website at the following link:

   https://uenroll.identogo.com

2. Enter the service code (also referred to as Authorization or Coupon Code) no matter the individual's affiliation with the organization.
   - PA Medical Marijuana Organization – 1KGBJG

3. If you are able to visit a Pennsylvania location to get your digital fingerprinting, click on the "Schedule or Manage Appointment" tab and complete the requested information.

4. If you are outside of the Commonwealth and not able to visit a physical location in Pennsylvania, click on the "Submit A Fingerprint Card by Mail" tab and complete the requested information.

IV. PREPARING AND SUBMITTING YOUR APPLICATION

The Application Package

The application package consists of the following:

1. The completed Act 63 of 2023 Permit Application.
2. The completed Medical Marijuana Grower/Processor Permit Application if the applicant is already in possession of a Pennsylvania Medical Marijuana dispensary permit OR the completed Medical Marijuana Dispensary Permit Application if the applicant is already in possession of a Pennsylvania Medical Marijuana grower/processor permit.
3. Completed Attachments 1 through 7 for the Act 63 of 2023 Permit Application submitted.
4. Completed Attachments A through J for any Medical Marijuana Grower/Processor or Dispensary Permit Application submitted.
5. Any additional attachments referenced in a narrative section of the applications.
6. Redacted version of each completed application and all accompanying attachments, redacted according to the instructions provided in Section II.
7. Appropriate Application Fees and Permit Fees for each application submitted, in the form of certified checks or money orders, made payable to "Commonwealth of Pennsylvania." Each fee must be enclosed in its own separate, sealed envelope within the application package.
8. The Department will consider any application sent by mail as long as the United States Postal Service postmark on the outside of the package is clear and legible. The Department will return a permit application that is postmarked after the June 12, 2024 deadline.

Completing the Application

Complete every section of each required application. For sections that require a written answer, please limit your response to no more than 5,000 words per section. If a question or item does not apply, place "Not Applicable" or "N/A" within that line or box. Do not leave the answer space blank.

The application form and all attachments must be saved in an electronic format as PDF files on a single USB drive, CD-ROM, or DVD, in accordance with the following file naming format: *Applicant Name_Application Type_Document Title.pdf*.

Examples:

- Jane Doe LLC_Act 63 of 2023_Application.pdf
- Jane Doe LLC_Act 63 of 2023_Attachment 4.pdf
- Jane Doe LLC_Grower-Processor_Application.pdf
- Jane Doe LLC_Grower-Processor_Attachment G.pdf
- Jane Doe LLC_Dispensary_Application.pdf
- Jane Doe LLC_Dispensary_Redacted Application.pdf

If you are submitting more than one application on a single USB drive, CD-ROM, or DVD, add a numerical suffix to clearly identify which application the file is associated with:

- Jane Doe LLC_Grower-Processor_Application-2.pdf

- Jane Doe LLC_Dispensary_Attachment G-3.pdfXxx

Please note:

- Do not lock, password protect, or otherwise secure any file.
- Paper submittals will not be considered.
- Letters of Recommendation or Support should not be submitted and will not be considered.

Submitting Your Application Package

Application packages must be mailed to the following address:

Bureau of Medical Marijuana
Department of Health
Room 628, Health and Welfare
Building 625 Forster Street
Harrisburg, PA 17120

V. AFTER YOU SUBMIT YOUR APPLICATION

If the Department deems corrected or additional information is needed to make a determination, the Department will request, in writing, the information and documentation required. The applicant will have 15 days from the mailing date of the notice to respond. If the Department deems that the application does not meet minimum scores in any section, the Department will notify the applicant of the deficiency(s). The applicant will have an additional 15 days from the mailing date of the notice to respond. Failure to provide the requested information to the Department by the deadline may be grounds for denial of the issuance of a permit.

An application is deemed to be incomplete if any of these occur, but not limited to: missing signatures; attachments referenced in narrative section but not actually included; lack of complete notarization; all checkboxes not appropriately marked; failure to include required dispensary and/or grower/processor application; failure to included complete required attachments; Electronic media not containing the complete application package will be deemed incomplete and rejected.

An application package that is postmarked after the June 12, 2024 deadline will be rejected by the Department and returned to the applicant without further consideration, along with the Application Fee and Permit Fee.

Changes During Application Process or Permit Term

During the application process, while the application is under review or at any time during the permit term, if a permit is issued, the medical marijuana organization must notify the Department, in writing, of the following:

- Any change in facts or circumstances reflected in the application, or any newly discovered or occurring fact or circumstance which the Department requires to be included in the application, including a change in control.
- Any proposed modification of its plan of operation, including any change to any information provided in the application.

Please note: the Department will only take into consideration the application and attachments that are received on or after May 12, 2024, and postmarked on or before June 12, 2024. Documentation received outside of this submission window unless part of the "retry" or "cure" process will not be considered in the scoring of your application submission.

VI. SCORING METHODOLOGY

The Act permits the Department to grant or deny a permit to an applicant based upon the criteria specified in section 603(a.1) of the Act:

(1) The applicant will maintain effective control of and prevent diversion of medical marijuana.
(2) The applicant will comply with all applicable laws of this Commonwealth.
(3) The applicant is ready, willing and able to properly carry on the activity for which a permit is sought.
(4) The applicant possesses the ability to obtain in an expeditious manner sufficient land, buildings and equipment to properly grow, process or dispense medical marijuana.
(5) It is in the public interest to grant the permit.
(6) The applicant, including the financial backer or principal, is of good moral character and has the financial fitness necessary to operate.
(7) The applicant is able to implement and maintain security, tracking, recordkeeping and surveillance systems relating to the acquisition, possession, growth, manufacture, sale, delivery, transportation, distribution or the dispensing of medical marijuana as required by the Department.
(8) The applicant meets the minimum acceptable scoring requirements set forth in 28 Pa. Code § 1211a.27a.

Scoring Rubric

Each section of the application is assigned a maximum number of points, as shown in the tables below. The total possible number of points for a grower/processor permit application and a dispensary permit application is 1,000. The Scoring Matrices for the diversity plan and community impact sections are also attached.

Act 63 of 2023 Permit Application Scoring	Pass/ Fail	Points per section	Minimum Acceptable Score	Subtotal
Section 1 – General Information	✓			
Section 2 – Qualifying as an Independent	✓			
Section 3 – Change of Control	✓			
Section 4 – Current Permit Status	✓			
Section 5 – Significant Changes	✓			
Section 6 – Release Authorization	✓			

Grower/Processor Permit Application Scoring	Pass/ Fail	Points per section	Minimum Acceptable Score	Subtotal
PART A – Applicant Identification and Facility Information				
2 – Facility Information	✓			
PART B – Diversity Plan				
3 – Diversity Plan		100		100
PART C – Applicant Information				
4 – Principals, Financial Backers, Operators and Employees	✓			
6 – Compliance with Applicable Laws and Regulations	✓			
7 – Civil and Administrative Action	✓			
PART D – Plan of Operation				
8 – Operational Timetable		75	31	
9 – Employee Qualifications, Description of Duties and Training		25	11	
10 – Security and Surveillance		50	21	
11 – Transportation of Medical Marijuana		25	11	
12 – Storage of Medical Marijuana		25	11	
13 – Packaging and Labeling of Medical Marijuana		25	11	
14 – Inventory Management		25	11	
15 – Management and Disposal of Medical Marijuana Waste		25	11	
16 – Diversion Prevention		50	21	
17 – Growing Practice		100	41	
18 – Nutrient and Additive Practices		100	41	
19 – Processing and Extraction		100	41	
20 – Sanitation and Safety		25	11	
21 – Quality Control and Testing for Potential Contamination	✓			
22 – Recordkeeping		25	11	
Subtotal				675
PART E – Applicant Organization, Ownership, Capital and Tax Status				
23 – Organizational Structure	✓			
24 – Business History and Capacity to Operate		75	31	

27 – Capital Requirements	✓			
Subtotal				75
PART F – Community Impact				
28 – Community Impact		100		100
ATTACHMENTS				
Attachment A: Signature Page	✓			
Attachment C: Property Title, Lease, or Option to Acquire Property Location	✓			
Attachment D: Site and Facility Plan		50	21	
Attachment E: Personal Identification	✓			
Attachment F: Affidavit of Business History	✓			
Attachment G: Affidavit of Criminal Offense	✓			
Attachment H: Tax Clearance Certificates	✓			
Attachment I: Affidavit of Capital Sufficiency	✓			
Attachment J: Sample Medical Marijuana Product Label	✓			
Subtotal				50
TOTAL POSSIBLE POINTS				1,000

Dispensary Permit Application Scoring	Pass/ Fail	Points per section	Minimum Acceptable Score	Subtotal
PART A – Applicant Identification and Dispensary Information				
2 – Dispensary Information	✓			
PART B - Diversity Plan				
3 – Diversity Plan		100		100
PART C - Applicant Information				
4 – Principals, Financial Backers, Operators and Employees	✓			
6 – Compliance with Applicable Laws and Regulations	✓			
7 – Civil and Administrative Action	✓			
PART D – Plan of Operation				
8 – Operational Timetable		100	41	
9 – Employee Qualifications, Description of Duties and Training		50	21	
10 – Security and Surveillance		100	41	
11 – Transportation of Medical Marijuana		50	21	
12 – Storage of Medical Marijuana		75	31	
13 – Labeling of Medical Marijuana Products	✓			
14 – Inventory Management		75	31	
15 – Diversion Prevention		100	41	
16 – Sanitation and Safety		50	21	
17 – Recordkeeping		75	31	
Subtotal				675
PART E – Applicant Organization, Ownership, Capital and Tax Status				
18 – Organizational Structure	✓			
19 – Business History and Capacity to Operate		75	31	

22 – Capital Requirements	✓			
Subtotal				75
PART F – Community Impact				
23 – Community Impact		100		100
ATTACHMENTS				
Attachment A: Signature Page	✓			
Attachment C: Property Title, Lease, or Option to Acquire Property Location	✓			
Attachment D: Site and Facility Plan		50	21	
Attachment E: Personal Identification	✓			
Attachment F: Affidavit of Business History	✓			
Attachment G: Affidavit of Criminal Offense	✓			
Attachment H: Tax Clearance Certificates	✓			
Attachment I: Affidavit of Capital Sufficiency	✓			
Subtotal				50
TOTAL POSSIBLE POINTS				1,000

Diversity Plan Scoring Matrix

1) **Diversity Plan – Equal Opportunity and Access in Employment (maximum of 75 points).** The following point allocations are in regard to the applicant's internal business makeup, including ownership, management, and employment, as well as efforts taken in the community or otherwise to increase its diversity and support workforce development.

Points	Applicant's commitment to diversity	Diversity Practices and Goals
61-75	**Exemplary commitment to diversity.**	• High percentage of diverse participant principals, operators, financial backers, or owners. • High percentage of diverse participant employees in management or other leadership roles. • Plans to use diverse participant employees, including at least one in a leadership role. • Multiple diverse participants represented across the business. • Official affirmative action plan to recruit, utilize, and promote diverse participants. • Adopted internal diversity goals and regularly tracks its progress toward their achievement. • Consistent efforts to promote diversity such as providing community outreach, mentoring, training or professional development programs or other opportunities to cultivate diversity. • Regularly participating in outside organizations, i.e., civic and professional groups, that promote diversity.

46-60	**Significant commitment to diversity**.	• Moderate percentage of diverse participant principals, operators, financial backers, or owners. • High percentage of diverse participant employees. • Plans to use diverse participant employees, including at least one in a leadership role. • Official affirmative action plan to recruit, utilize, and promote diverse participants. • Internal diversity goals with tracked progress toward their achievement. • Regular efforts to promote diversity such as providing or planning to provide community outreach, mentoring, training or professional development programs or other opportunities to cultivate diversity. • Participating in outside organizations, i.e., civic and professional groups, that promote diversity.
31-45	**Moderate commitment to diversity**.	• Few diverse participant principals, operators, financial backers, or owners. • Moderate percentage of diverse participant employees. • Plans to use some diverse participant employees. • Official affirmative action plan to recruit, utilize, and promote diverse participants. • Internal diversity goals. • Moderate efforts to promote diversity such as such as providing or planning to provide community outreach, mentoring, training or professional development programs or other opportunities to cultivate diversity. • Occasionally participates in outside organizations, i.e., civic and professional groups, that promote diversity.
16-30	**Some commitment to diversity**.	• No diverse participant principals, operators, financial backers, or owners. • Some diverse participant employees. • Plans to use some diverse participant employees. • No official affirmative action plan to recruit, utilize, and promote diverse participants. • No internal diversity goals. • Sporadic efforts to promote diversity. • Limited participation in outside organizations, i.e., civic and professional groups, that promote diversity.

1-15	**Nominal commitment to diversity**.	• No diverse participant principals, operators, financial backers, or owners. • Few diverse participant employees. • No plans to use diverse participant employees. • No official affirmative action plan to recruit, utilize, and promote diverse participants. • No internal diversity goals. • Minimal efforts to promote diversity. • Limited or no participation in outside organizations, i.e., civic and professional groups, that promote diversity.
0	**No commitment to diversity**.	• No diverse participant principals, operators, financial backers, or owners. • No diverse participant employees. • No plans to use diverse participant employees. • No official affirmative action plan to recruit, utilize, and promote diverse participants. • No internal diversity goals. • No efforts to promote diversity. • No participation in outside organizations, i.e., civic and professional groups, that promote diversity.

Total Score for Equal Opportunity and Access in Employment (maximum 75 points) _____

2) **Equal Opportunity and Access in Contracting (maximum 25 points).** The following section is in regard to the applicant's plan to utilize Diverse Groups in contracting. Diverse Groups include Disadvantaged businesses, Minority-owned businesses, Women-owned businesses, Service-disabled veteran-owned small businesses, and Veteran-owned small businesses that have been certified by a third-party certifying organization (Unified Certification Program (UCP), Woman's Business Enterprise National Council (WBENC), National Minority Supplier Development Council (NMSDC), United States Small Business Administration (SBA) 8(a) Program, and Vets First Verification Program (vetbiz.gov)) or that have been verified by the Department of General Services' Bureau of Diversity, Inclusion and Small Business Opportunities. **Applicants must provide proof of current Diverse Group status.**

Total available points are based upon percentage of revenues to be paid to Diverse Groups for the full permit term.

Total percentage of revenues to be paid to Diverse Groups for the full permit term: _____ ÷ 4 = _____

Total Score for Equal Opportunity and Access in Contracting (maximum 25 points) _____

Total overall Diversity Plan score: _____ /100 total points

Community Impact Scoring Matrix

Category	Score
Job Creation (maximum of 20 points) This category will be scored based on the level of impact on the municipality in which the site and facility is located, depending on the following factors: Size of the Municipality Size of the Site and Facility Number of Jobs Created (or Projected to be Created) The Number of Jobs Created (or Projected to be Created) is Reasonable Based on the Proposed Site and Facility Potential for Future Growth The Potential for Future Growth is Reasonable Based on the Proposed Site and Facility	_____/ 20
Site Selection (maximum of 40 points) This category will be scored based on the following factors: Whether the site and facility will be located in an Act 47 financially distressed municipality as of February 2020(see attached list) Whether the site and facility are the redevelopment of a brownfield or a vacant, previously utilized site or building	_____/ 40
Need for Economic Development (maximum of 15 points) This category will be scored based on the unemployment rate in the municipality (or the unemployment rate of the county if the municipality unemployment rate is unavailable) in which the site and facility is located. The unemployment rate will be compared to the Pennsylvania state unemployment average of 4.2%. Unemployment rates may be found at the following website: https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml This category will be scored as follows:	

Municipality in which the site and facility is located has an unemployment rate 25% or greater than the state average: 11-15 points Municipality in which the site and facility is located has an unemployment rate from 1% to 24% above the state average: 6-10 points Municipality in which the site and facility is located has an unemployment rate equal to or lower than the state average: 0-5 points	**_____/ 15**
Priority Points (maximum of 25 points) This category will be scored based on community initiatives that include, but are not limited to, the following factors: Charitable Giving Community events University-community partnerships Job training in the medical marijuana field Existence of a Labor Peace Agreement	**_____/ 25** **TOTAL SCORE:** **_____/100 points**

Currently Underserved Counties

(As of March 2024)

- Adams
- Beaver
- Bedford
- Bradford
- Clinton
- Fayette
- Juniata
- Northumberland
- Pike
- Schuylkill
- Tioga
- Venango
- Warren

MEDICAL MARIJUANA ACT - ENACTMENT

Act of Apr. 17, 2016, P.L. 84, No. 16 Cl. 35

An Act

Establishing a medical marijuana program; providing for patient and caregiver certification and for medical marijuana organization registration; imposing duties on the Department of Health; providing for a tax on medical marijuana organization gross receipts; establishing the Medical Marijuana Program Fund; establishing the Medical Marijuana Advisory Board; establishing a medical marijuana research program; imposing duties on the Department of Corrections, the Department of Education and the Department of Human Services; and providing for academic clinical research centers and for penalties and enforcement.

TABLE OF CONTENTS

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

CHAPTER 1
PRELIMINARY PROVISIONS

Section 101. Short title.

This act shall be known and may be cited as the Medical Marijuana Act.

Section 102. Declaration of policy.

The General Assembly finds and declares as follows:

(1) Scientific evidence suggests that medical marijuana is one potential therapy that may mitigate suffering in some patients and also enhance quality of life.

(2) The Commonwealth is committed to patient safety. Carefully regulating the program which allows access to medical marijuana will enhance patient safety while research into its effectiveness continues.

(3) It is the intent of the General Assembly to:

(i) Provide a program of access to medical marijuana which balances the need of patients to have access to the latest treatments with the need to promote patient safety.

(ii) Provide a safe and effective method of delivery of medical marijuana to patients.

(iii) Promote high quality research into the effectiveness and utility of medical marijuana.

(4) It is the further intention of the General Assembly that any Commonwealth-based program to provide access to medical marijuana serve as a temporary measure, pending Federal approval of and access to medical marijuana through traditional medical and pharmaceutical avenues.

Section 103. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Advisory board." The advisory board established under section 1201.

"Caregiver." The term includes the following entities designated to deliver medical marijuana:

(1) An individual designated by a patient.

(2) If the patient is under 18 years of age, an individual under section 506(2).

(3) Individuals designated in writing, for purposes of section 502, by an organization that provides hospice, palliative or home health care services and:

(i) are employed by an organization that is licensed under the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act;

(ii) have significant responsibility for managing the health care and well-being of a patient; and

(iii) were designated by the organization to provide care to a patient who has provided authorization for the designation.

(4) Individuals designated in writing, for purposes of section 502, by a residential facility, including a long-term care nursing facility, a skilled nursing facility, an assisted

living facility, a personal care home, an independent long-term care facility or an intermediate care facility for individuals with intellectual disabilities that:

(i) are licensed by the department or the Department of Human Services;

(ii) have significant responsibility for managing the health care and well-being of the patient; and

(iii) were designated by the residential facility to provide care to a patient who has provided authorization for the designation.

(Def. amended June 30, 2021, P.L.210, No.44)

"Certified medical use." The acquisition, possession, use or transportation of medical marijuana by a patient, or the acquisition, possession, delivery, transportation or administration of medical marijuana by a caregiver, for use as part of the treatment of the patient's serious medical condition, as authorized in a certification under this act, including enabling the patient to tolerate treatment for the serious medical condition.

"Certified registered nurse practitioner." As defined in section 2 of the act of May 22, 1951 (P.L.317, No.69), known as The Professional Nursing Law.

"Change in control." The acquisition by a person or group of persons acting in concert of a controlling interest in an applicant or permittee either all at one time or over the span of a 12-consecutive-month period.

"Change of control transaction." The consolidation, merger or acquisition by a person or group of persons acting in concert of more than 20% of:

(1) a medical marijuana organization's securities or other ownership interests, with the exception of any ownership interest of the person that existed:

(i) at the time of the issuance of the initial medical marijuana organization's permit and payment of the initial permit; or

(ii) prior to the effective date of this subparagraph; or

(2) the securities or other ownership interests of a corporation or other form of business entity which owns directly or indirectly 20% of the securities or other ownership interests of the medical marijuana organization.

(Def. added Dec. 14, 2023, P.L. , No.63)

"Continuing care." Treating a patient, in the course of which the practitioner has completed a full assessment of the patient's medical history and current medical condition, including a consultation with the patient. (Def. amended June 30, 2021, P.L.210, No.44)

"Controlling interest." As follows:

(1) For a publicly traded entity, voting rights that entitle a person to elect or appoint one or more of the members of the board of directors or other governing board or the ownership or beneficial holding of 5% or more of the securities of the publicly traded entity.

(2) For a privately held entity, the ownership of any security in the entity.

"Department." The Department of Health of the Commonwealth.

"Dispensary." A person, including a natural person, corporation, partnership, association, trust or other entity, or any combination thereof, which holds a permit issued by the department to dispense medical marijuana. The term does not include a health care medical marijuana organization under Chapter 19.

"Diverse group." The term shall mean the same as under section 615(d). (Def. added Dec. 14, 2023, P.L. , No.63)

"Excipients." Solvents, chemicals or materials reported by a medical marijuana organization and approved by the department for use in the processing of medical marijuana. (Def. added June 30, 2021, P.L.210, No.44)

"Family or household member." As defined in 23 Pa.C.S. § 6102 (relating to definitions).

"Financial backer." An investor, mortgagee, bondholder, note holder or other source of equity, capital or other assets, other than a financial institution.

"Financial institution." A bank, a national banking association, a bank and trust company, a trust company, a savings and loan association, a building and loan association, a mutual savings bank, a credit union or a savings bank.

"Form of medical marijuana." The characteristics of the medical marijuana recommended or limited for a particular patient, including the method of consumption and any particular dosage, strain, variety and quantity or percentage of medical marijuana or particular active ingredient.

"Fund." The Medical Marijuana Program Fund established in section 902.

"Grower/processor." A person, including a natural person, corporation, partnership, association, trust or other entity, or any combination thereof, which holds a permit from the department under this act to grow and process medical marijuana. The term does not include a health care medical marijuana organization under Chapter 19.

"Harvest batch." A specifically identified quantity of medical marijuana plant that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time and at the same location and cured under uniform conditions. (Def. added June 30, 2021, P.L.210, No.44)

"Harvest lot." A specifically identified quantity of medical marijuana plant taken from a harvest batch. (Def. added June 30, 2021, P.L.210, No.44)

"Identification card." A document issued under section 501 that authorizes access to medical marijuana under this act.

"Independent dispensary." A dispensary issued a permit to operate in this Commonwealth and that meets all of the following:

(1) Has not had the dispensary's permit revoked.

(2) Has not entered into a change of control transaction with any other person that was issued a grower/processor permit, dispensary permit or clinical registrant permit in this Commonwealth.

(3) Is not materially the same as another medical marijuana organization in this Commonwealth through a parent company, subsidiary or shared affiliation with another entity that holds a permit from the department under this act or through the sharing of principals, officers or directors,

employees, facilities, equipment, finances or capital.
(Def. added Dec. 14, 2023, P.L. , No.63)

"Independent grower/processor." A grower/processor awarded a permit to operate in this Commonwealth that meets all of the following criteria as of the effective date of this definition:

(1) Has not had its permit revoked.

(2) Has not entered into a change of control transaction with any other person that was issued a grower/processor permit, dispensary permit or clinical registrant permit in this Commonwealth.

(3) Is not materially the same as another medical marijuana organization in this Commonwealth through a parent company or subsidiary of another entity that holds a permit from the department under this act or through the sharing of principals, officers or directors, employees, facilities, equipment, finances or capital.

(Def. added Dec. 14, 2023, P.L. , No.63)

"Individual dose." A single measure of medical marijuana.

"Materially the same." A person who shares any of the following with another person:

(1) Profits or losses.

(2) Common valuation, in the case of a publicly traded company.

(3) Common ownership of more than 5%, including subsidiaries.

(4) Common ownership of 5% or less if the persons with voting rights to elect or appoint one or more members of the board of directors or other governing board.

(5) Common management, policies, principals, officers, directors, employees, equipment, finances or capital.

(Def. added Dec. 14, 2023, P.L. , No.63)

"Medical marijuana." Marijuana for certified medical use as set forth in this act.

"Medical marijuana organization." A dispensary or a grower/processor. The term does not include a health care medical marijuana organization under Chapter 19.

"Medical marijuana product." The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary. (Def. added June 30, 2021, P.L.210, No.44)

"Parent company." A company which directly or indirectly controls any other permittee under this act. (Def. added Dec. 14, 2023, P.L. , No.63)

"Patient." An individual who:

(1) has a serious medical condition;

(2) has met the requirements for certification under this act; and

(3) is a resident of this Commonwealth.

"Permit." An authorization issued by the department to a medical marijuana organization to conduct activities under this act.

"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. (Def. added Dec. 14, 2023, P.L. , No.63)

"Physician assistant." As defined in section 2 of the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985, and section 2 of the act of October 5, 1978 (P.L.1109, No.261), known as the Osteopathic Medical Practice Act.

"Practitioner." A physician who is registered with the department under section 401.

"Prescription drug monitoring program." The Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP).

"Principal." An officer, director or person who directly owns a beneficial interest in or ownership of the securities of an applicant or permittee, a person who has a controlling interest in an applicant or permittee or who has the ability to elect the majority of the board of directors of an applicant or permittee or otherwise control an applicant or permittee, other than a financial institution.

"Process lot." An amount of a medical marijuana product of the same type and processed using the same medical marijuana extract, standard operating procedures and the same or combination of different harvest lots. (Def. added June 30, 2021, P.L.210, No.44)

"Registry." The registry established by the department for practitioners.

"Research initiative." A nonpatient investigation not subject to Institutional Review Board or Research Approval Committee approval requirements of a patient-based research program, project or study, conducted by an academic clinical research center and its contracted clinical registrant. (Def. added June 30, 2021, P.L.210, No.44)

"Secretary." The Secretary of Health of the Commonwealth.

"Security." As defined in section 102(t) of the act of December 5, 1972 (P.L.1280, No.284), known as the Pennsylvania Securities Act of 1972.

"Serious medical condition." Any of the following:

(1) Cancer, including remission therapy.

(2) Positive status for human immunodeficiency virus or acquired immune deficiency syndrome.

(3) Amyotrophic lateral sclerosis.

(4) Parkinson's disease.

(5) Multiple sclerosis.

(6) Damage to the nervous tissue of the central nervous system (brain-spinal cord) with objective neurological indication of intractable spasticity and other associated neuropathies.

(7) Epilepsy.

(8) Inflammatory bowel disease.

(9) Neuropathies.

(10) Huntington's disease.

(11) Crohn's disease.

(12) Post-traumatic stress disorder.

(13) Intractable seizures.

(14) Glaucoma.

(15) Sickle cell anemia.

(16) Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.

(17) Autism.

(18) Other conditions that are recommended by the advisory board and approved by the secretary under section 1202.

(Def. amended June 30, 2021, P.L.210, No.44)

"Synchronous interaction." A two-way or multiple-way exchange of information between a patient and a health care provider that occurs in real time via audio or video conferencing. (Def. added June 30, 2021, P.L.210, No.44)

"Terminally ill." A medical prognosis of life expectancy of approximately one year or less if the illness runs its normal course.

Compiler's Note: Section 9 of Act 44 of 2021 provided that the amendment of the definition of "serious medical condition" shall apply retroactively to May 18, 2016.

CHAPTER 3
PROGRAM

Section 301. Program established.

(a) Establishment.--A medical marijuana program for patients suffering from serious medical conditions is established. The program shall be implemented and administered by the department. The department shall:

(1) Issue permits to medical marijuana organizations to authorize them to grow, process or dispense medical marijuana and ensure their compliance with this act.

(2) Register practitioners and ensure their compliance with this act.

(3) Have regulatory and enforcement authority over the growing, processing, sale and use of medical marijuana in this Commonwealth.

(4) Establish and maintain an electronic database to include activities and information relating to medical marijuana organizations, certifications and identification cards issued, practitioner registration and electronic tracking of all medical marijuana as required under this act to include:

(i) Ensurance that medical marijuana is not diverted or otherwise used for unlawful purposes by a practitioner or medical marijuana organization.

(ii) Ability to establish the authenticity of identification cards.

(iii) Recording recommended forms of medical marijuana provided in a certification filed by the practitioner.

(iv) Monitoring all growth, transfer, possession, processing, testing and dispensing of medical marijuana in this Commonwealth.

(v) The tracking system under section 701 must include information under section 801(a) and any other information required by the department to be used by the department and dispensaries to enable a dispensary to lawfully provide medical marijuana. The tracking system and database shall be capable of providing information in real time. The database shall be capable of receiving information from a dispensary regarding the disbursement of medical marijuana to patients and caregivers. This information shall be immediately accessible to the department and other dispensaries to inhibit diversion and ensure compliance with this act.

(5) Maintain a directory of patients and caregivers approved to use or assist in the administration of medical marijuana within the department's database.

(6) Develop a four-hour training course for physicians, pharmacists, certified registered nurse practitioners and physician assistants regarding the latest scientific research on medical marijuana, including the risks and benefits of medical marijuana, and other information deemed necessary by the department. Successful completion of the course shall be approved as continuing education credits as determined by:

(i) The State Board of Medicine and the State Board of Osteopathic Medicine.

(ii) The State Board of Pharmacy.

(iii) The State Board of Nursing.

(7) Develop a two-hour course for the principals and employees of a medical marijuana organization who either have direct contact with patients or caregivers or who physically handle medical marijuana. Employees must successfully complete the course no later than 90 days after commencing employment. Principals must successfully complete the course prior to commencing initial operation of the medical marijuana organization. The subject matter of the course shall include the following:

(i) Methods to recognize and report unauthorized activity, including diversion of medical marijuana for unlawful purposes and falsification of identification cards.

(ii) Proper handling of medical marijuana and recordkeeping.

(iii) Any other subject required by the department.

(8) Develop enforcement procedures, including announced and unannounced inspections of facilities of the grower/processors and dispensaries and all records of the medical marijuana organizations.

(9) Establish a program to authorize the use of medical marijuana to conduct medical research relating to the use of medical marijuana to treat serious medical conditions, including the collection of data and the provision of research grants.

(10) Establish and maintain public outreach programs about the medical marijuana program, including:

(i) A dedicated telephone number for patients, caregivers and members of the public to obtain basic information about the dispensing of medical marijuana under this act.

(ii) A publicly accessible Internet website with similar information.

(11) Collaborate as necessary with other Commonwealth agencies or contract with third parties as necessary to carry out the provisions of this act.

(12) Determine the minimum number and type of medical marijuana products to be produced by a grower/processor and dispensed by a dispensary.

(13) Develop recordkeeping requirements for all books, papers, any electronic database or tracking system data and other information of a medical marijuana organization.

Information shall be retained for a minimum period of four years unless otherwise provided by the department.

(14) Restrict the advertising and marketing of medical marijuana, which shall be consistent with the Federal regulations governing prescription drug advertising and marketing.

(b) Regulations.--The department shall promulgate all regulations necessary to carry out the provisions of this act.

Section 302. Confidentiality and public disclosure.

(a) Patient information.--The department shall maintain a confidential list of patients and caregivers to whom it has issued identification cards. All information obtained by the department relating to patients, caregivers and other applicants shall be confidential and not subject to public disclosure, including disclosure under the act of February 14, 2008 (P.L.6, No.3), known as the Right-to-Know Law, including:

(1) Individual identifying information about patients and caregivers.

(2) Certifications issued by practitioners.

(3) Information on identification cards.

(4) Information provided by the Pennsylvania State Police under section 502(b).

(5) Information relating to the patient's serious medical condition.

(b) Public information.--The following records are public records and shall be subject to the Right-to-Know Law:

(1) Applications for permits submitted by medical marijuana organizations.

(2) The names, business addresses and medical credentials of practitioners authorized to provide certifications to patients to enable them to obtain and use medical marijuana in this Commonwealth. All other practitioner registration information shall be confidential and exempt from public disclosure under the Right-to-Know Law.

(3) Information relating to penalties or other disciplinary actions taken against a medical marijuana organization or practitioner by the department for violation of this act.

Section 303. Lawful use of medical marijuana.

(a) General rule.--Notwithstanding any provision of law to the contrary, use or possession of medical marijuana as set forth in this act is lawful within this Commonwealth.

(b) Requirements.--The lawful use of medical marijuana is subject to the following:

(1) Medical marijuana may only be dispensed to:

(i) a patient who receives a certification from a practitioner and is in possession of a valid identification card issued by the department; and

(ii) a caregiver who is in possession of a valid identification card issued by the department.

(2) Subject to regulations promulgated under this act, medical marijuana may only be dispensed to a patient or caregiver in the following forms:

(i) pill;

(ii) oil;

(iii) topical forms, including gels, creams or

ointments;

(iv) a form medically appropriate for administration by vaporization or nebulization, excluding dry leaf or plant form until dry leaf or plant forms become acceptable under regulations adopted under section 1202;

(v) tincture; or

(vi) liquid.

(3) Unless otherwise provided in regulations adopted by the department under section 1202, medical marijuana may not be dispensed to a patient or a caregiver in dry leaf or plant form.

(4) ((4) deleted by amendment June 30, 2021, P.L.210, No.44).

(5) A patient may designate up to two caregivers at any one time.

(6) Medical marijuana that has not been used by the patient shall be kept in the original package in which it was dispensed.

(7) A patient or caregiver shall possess an identification card whenever the patient or caregiver is in possession of medical marijuana.

(8) Products packaged by a grower/processor or sold by a dispensary shall only be identified by the name of the grower/processor, the name of the dispensary, the form and species of medical marijuana, the percentage of tetrahydrocannabinol and cannabinol contained in the product and any other labeling required by the department.

Section 304. Unlawful use of medical marijuana.

(a) General rule.--Except as provided in section 303, section 704, Chapter 19 or Chapter 20, the use of medical marijuana is unlawful and shall, in addition to any other penalty provided by law, be deemed a violation of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

(b) Unlawful use described.--It is unlawful to:

(1) Smoke medical marijuana.

(2) Except as provided under subsection (c), incorporate medical marijuana into edible form.

(3) Grow medical marijuana unless the grower/processor has received a permit from the department under this act.

(4) Grow or dispense medical marijuana unless authorized as a health care medical marijuana organization under Chapter 19.

(5) Dispense medical marijuana unless the dispensary has received a permit from the department under this act.

(c) Edible medical marijuana.--Nothing in this act shall be construed to preclude the incorporation of medical marijuana into edible form by a patient or a caregiver in order to aid ingestion of the medical marijuana by the patient.

CHAPTER 4
PRACTITIONERS

Section 401. Practitioner registration.

(a) Eligibility.--A physician included in the registry is authorized to issue certifications to patients to use medical

marijuana. To be eligible for inclusion in the registry:

(1) A physician must apply for registration in the form and manner required by the department.

(2) The department must determine that the physician is, by training or experience, qualified to treat a serious medical condition. The physician shall provide documentation of credentials, training or experience as required by the department.

(3) The physician must have successfully completed the course under section 301(a)(6).

(b) Department action.--

(1) The department shall review an application submitted by a physician to determine whether to include the physician in the registry. The review shall include information maintained by the Department of State regarding whether the physician has a valid, unexpired, unrevoked, unsuspended Pennsylvania license to practice medicine and whether the physician has been subject to discipline.

(2) The inclusion of a physician in the registry shall be subject to annual review to determine if the physician's license is no longer valid, has expired or been revoked or the physician has been subject to discipline. If the license is no longer valid, the department shall remove the physician from the registry until the physician holds a valid, unexpired, unrevoked, unsuspended Pennsylvania license to practice medicine.

(3) The Department of State shall report to the department the expiration, suspension or revocation of a physician's license and any disciplinary actions in a timely fashion.

(c) Practitioner requirements.--A practitioner included in the registry shall have an ongoing responsibility to immediately notify the department in writing if the practitioner knows or has reason to know that any of the following is true with respect to a patient for whom the practitioner has issued a certification:

(1) The patient no longer has the serious medical condition for which the certification was issued.

(2) Medical marijuana would no longer be therapeutic or palliative.

(3) The patient has died.

Section 402. Practitioner restrictions.

(a) Practices prohibited.--The following apply with respect to practitioners:

(1) A practitioner may not accept, solicit or offer any form of remuneration from or to a prospective patient, patient, prospective caregiver, caregiver or medical marijuana organization, including an employee, financial backer or principal, to certify a patient, other than accepting a fee for service with respect to the examination of the prospective patient to determine if the prospective patient should be issued a certification to use medical marijuana.

(2) A practitioner may not hold a direct or economic interest in a medical marijuana organization.

(3) A practitioner may not advertise the practitioner's services as a practitioner who can certify a patient to receive medical marijuana.

(b) Unprofessional conduct.--A practitioner who violates

subsection (a) shall not be permitted to issue certifications to patients. The practitioner shall be removed from the registry.

(c) Discipline.--In addition to any other penalty that may be imposed under this act, a violation of subsection (a) or section 403(e) shall be deemed unprofessional conduct under section 41(8) of the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985, or section 15(a)(8) of the act of October 5, 1978 (P.L.1109, No.261), known as the Osteopathic Medical Practice Act, and shall subject the practitioner to discipline by the State Board of Medicine or the State Board of Osteopathic Medicine, as appropriate.

Section 403. Issuance of certification.

(a) Conditions for issuance.--A certification to use medical marijuana may be issued by a practitioner to a patient if all of the following requirements are met:

(1) The practitioner has been approved by the department for inclusion in the registry and has a valid, unexpired, unrevoked, unsuspended Pennsylvania license to practice medicine at the time of the issuance of the certification.

(2) The practitioner has determined that the patient has a serious medical condition and has included the condition in the patient's health care record.

(3) The patient is under the practitioner's continuing care for the serious medical condition.

(4) In the practitioner's professional opinion and review of past treatments, the practitioner determines the patient is likely to receive therapeutic or palliative benefit from the use of medical marijuana.

(b) Contents.--The certification shall include:

(1) The patient's name, date of birth and address.

(2) The specific serious medical condition of the patient.

(3) A statement by the practitioner that the patient has a serious medical condition and the patient is under the practitioner's continuing care for the serious medical condition.

(4) The date of issuance.

(5) The name, address, telephone number and signature of the practitioner.

(6) Any requirement or limitation concerning the appropriate form of medical marijuana and limitation on the duration of use, if applicable, including whether the patient is terminally ill.

(c) Consultation.--A practitioner shall review the prescription drug monitoring program prior to:

(1) Issuing a certification to determine the controlled substance history of a patient.

(2) Recommending a change of amount or form of medical marijuana.

(c.1) Other access by practitioner.--A practitioner may access the prescription drug monitoring program to do any of the following:

(1) Determine whether a patient may be under treatment with a controlled substance by another physician or other person.

(2) Allow the practitioner to review the patient's controlled substance history as deemed necessary by the

practitioner.

(3) Provide to the patient, or caregiver on behalf of the patient if authorized by the patient, a copy of the patient's controlled substance history.

(d) Duties of practitioner.--The practitioner shall:

(1) Provide the certification to the patient.

(2) Provide a copy of the certification to the department, which shall place the information in the patient directory within the department's electronic database. The department shall permit electronic submission of the certification.

(3) File a copy of the certification in the patient's health care record.

(e) Prohibition.--A practitioner may not issue a certification for the practitioner's own use or for the use of a family or household member.

Section 404. Certification form.

The department shall develop a standard certification form, which shall be available to practitioners upon request. The form shall be available electronically. The form shall include a statement that a false statement made by a practitioner is punishable under the applicable provisions of 18 Pa.C.S. Ch. 49 (relating to falsification and intimidation).

Section 405. Duration.

Receipt of medical marijuana by a patient or caregiver from a dispensary may not exceed a 90-day supply of individual doses. During the last seven days of any 30-day period during the term of the identification card, a patient may obtain and possess a 90-day supply for the subsequent 30-day period. Additional 90-day supplies may be provided in accordance with this section for the duration of the authorized period of the identification card unless a shorter period is indicated on the certification.

(405 amended June 30, 2021, P.L.210, No.44)

CHAPTER 5
PATIENTS

Section 501. Identification cards.

(a) Issuance.--The department may issue an identification card to a patient who has a certification approved by the department and to a caregiver designated by the patient. An identification card issued to a patient shall authorize the patient to obtain and use medical marijuana as authorized by this act. An identification card issued to a caregiver shall authorize the caregiver to obtain medical marijuana on behalf of the patient.

(b) Procedure for issuance.--The department shall develop and implement procedures for:

(1) Review and approval of applications for identification cards.

(2) Issuance of identification cards to patients and caregivers.

(3) Review of the certification submitted by the practitioner and the patient.

(c) Application.--A patient or a caregiver may apply, in a form and manner prescribed by the department, for issuance or renewal of an identification card. A caregiver must submit a separate application for issuance or renewal. Each application

must include:

(1) The name, address and date of birth of the patient.

(2) The name, address and date of birth of a caregiver.

(3) The certification issued by the practitioner.

(4) The name, address and telephone number of the practitioner and documentation from the practitioner that all of the requirements of section 403(a) have been met.

(5) A $50 processing fee. The department may waive or reduce the fee if the applicant demonstrates financial hardship.

(6) The signature of the applicant and date signed.

(7) Other information required by the department.

(d) Forms.--Application and renewal forms shall be available on the department's publicly accessible Internet website.

(e) Expiration.--An identification card of a patient or caregiver shall expire within one year from the date of issuance, upon the death of the patient, or as otherwise provided in this section.

(f) Separate cards to be issued.--The department shall issue separate identification cards for patients and caregivers as soon as reasonably practicable after receiving completed applications, unless it determines that an application is incomplete or factually inaccurate, in which case it shall promptly notify the applicant.

(g) (Reserved).

(h) Change in name or address.--A patient or caregiver who has been issued an identification card shall notify the department within 10 days of any change of name or address. In addition, the patient shall notify the department within 10 days if the patient no longer has the serious medical condition noted on the certification.

(i) Lost or defaced card.--In the event of a lost, stolen, destroyed or illegible identification card, the patient or caregiver shall apply to the department within 10 business days of discovery of the loss or defacement of the card for a replacement card. The application for a replacement card shall be on a form furnished by the department and accompanied by a $25 fee. The department may establish higher fees for issuance of second and subsequent replacement identification cards. The department may waive or reduce the fee in cases of demonstrated financial hardship. The department shall issue a replacement identification card as soon as practicable. A patient or caregiver may not obtain medical marijuana until the department issues the replacement card.

Section 502. Caregivers.

(a) Requirements.--

(1) If the patient designates a caregiver, the application shall include the name, address and date of birth of the caregiver, and other individual identifying information required by the department and the following:

(i) Federal and Commonwealth criminal history record information as set forth in subsection (b).

(ii) If the caregiver has an identification card for the caregiver or another patient, the expiration date of the identification card.

(iii) Other information required by the department.

(2) The application shall be accompanied by a fee of $50. The department may waive or reduce the fee in cases of demonstrated financial hardship.

(3) The department may require additional information for the application.

(4) The application shall be signed and dated by the applicant.

(b) Criminal history.--A caregiver who has not been previously approved by the department 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. Any criminal history record information relating to a caregiver obtained under this section by the department may be interpreted and used by the department only to determine the applicant's character, fitness and suitability to serve as a caregiver under this act. The criminal history record information provided under this subsection may not be subject to the limitations under 18 Pa.C.S. § 9121(b)(2) (relating to general regulations). The department shall also review the prescription drug monitoring program relating to the caregiver. The department shall deny the application of a caregiver who has been convicted of a criminal offense that occurred within the past five years relating to the sale or possession of drugs, narcotics or controlled substances. The department may deny an application if the applicant has a history of drug abuse or of diverting controlled substances or illegal drugs. ((b) amended June 30, 2021, P.L.210, No.44)

Section 503. Notice.

An application for an identification card shall include notice that a false statement made in the application is punishable under the applicable provisions of 18 Pa.C.S. Ch. 49 (relating to falsification and intimidation).

Section 503.1. Verification.

The department shall verify the information in a patient or caregiver's application and on any renewal form.

Section 504. Special conditions.

The following apply:

(1) If the practitioner states in the certification that, in the practitioner's professional opinion, the patient would benefit from medical marijuana only until a specified earlier date, then the identification card shall expire on that date.

(2) If the certification so provides, the identification card shall state any requirement or limitation by the practitioner as to the form of medical marijuana for the patient.

Section 505. (Reserved).

Section 506. Minors.

If a patient is under 18 years of age, the following shall apply:

(1) The patient shall have a caregiver.

(2) A caregiver must be one of the following:

(i) A parent or legal guardian of the patient.

(ii) An individual designated by a parent or legal

guardian.

(iii) An appropriate individual approved by the department upon a sufficient showing that no parent or legal guardian is appropriate or available.

Section 507. Caregiver authorization and limitations.

(a) Age.--An individual who is under 21 years of age may not be a caregiver unless a sufficient showing, as determined by the department, is made to the department that the individual should be permitted to serve as a caregiver.

(b) Changing caregiver.--If a patient wishes to change or terminate the designation of the patient's caregiver, for whatever reason, the patient shall notify the department as soon as practicable. The department shall issue a notification to the caregiver that the caregiver's identification card is invalid and must be promptly returned to the department.

(c) Denial in part.--If an application of a patient designates an individual as a caregiver who is not authorized to be a caregiver, that portion of the application shall be denied by the department. The department shall review the balance of the application and may approve that portion of it.

Section 508. Contents of identification card.

An identification card shall contain the following:

(1) The name of the caregiver or the patient, as appropriate. The identification card shall also state whether the individual is designated as a patient or as a caregiver.

(2) The date of issuance and expiration date.

(3) An identification number for the patient or caregiver, as appropriate.

(4) A photograph of the individual to whom the identification card is being issued, whether the individual is a patient or a caregiver. The method of obtaining the photograph shall be specified by the department by regulation. The department shall provide reasonable accommodation for a patient who is confined to the patient's home or is in inpatient care.

(5) Any requirement or limitation set by the practitioner as to the form of medical marijuana.

(6) Any other requirements determined by the department, except the department may not require that an identification card disclose the patient's serious medical condition.

Section 509. Suspension.

If a patient or caregiver intentionally, knowingly or recklessly violates any provision of this act as determined by the department, the identification card of the patient or caregiver may be suspended or revoked. The suspension or revocation shall be in addition to any criminal or other penalty that may apply.

Section 510. Prohibitions.

The following prohibitions shall apply:

(1) A patient may not operate or be in physical control of any of the following while under the influence with a blood content of more than 10 nanograms of active tetrahydrocannabis per milliliter of blood in serum:

(i) Chemicals which require a permit issued by the Federal Government or a state government or an agency of the Federal Government or a state government.

(ii) High-voltage electricity or any other public

utility.

(2) A patient may not perform any employment duties at heights or in confined spaces, including, but not limited to, mining while under the influence of medical marijuana.

(3) A patient may be prohibited by an employer from performing any task which the employer deems life-threatening, to either the employee or any of the employees of the employer, while under the influence of medical marijuana. The prohibition shall not be deemed an adverse employment decision even if the prohibition results in financial harm for the patient.

(4) A patient may be prohibited by an employer from performing any duty which could result in a public health or safety risk while under the influence of medical marijuana. The prohibition shall not be deemed an adverse employment decision even if the prohibition results in financial harm for the patient.

CHAPTER 6
MEDICAL MARIJUANA ORGANIZATIONS

Section 601. Medical marijuana organizations.

The following entities shall be authorized to receive a permit to operate as a medical marijuana organization to grow, process or dispense medical marijuana:

(1) Grower/processors.

(2) Dispensaries.

Section 602. Permits.

(a) Application.--An application for a grower/processor or dispensary permit to grow, process or dispense medical marijuana shall be in a form and manner prescribed by the department and shall include:

(1) Verification of all principals, operators, financial backers or employees of a medical marijuana grower/processor or dispensary.

(2) A description of responsibilities as a principal, operator, financial backer or employee.

(3) Any release necessary to obtain information from governmental agencies, employers and other organizations.

(4) A criminal history record check. Medical marijuana organizations applying for a permit shall submit fingerprints of principals, financial backers, operators and employees to the Pennsylvania State Police 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 principals, financial backers, operators and employees and obtaining a current record of any criminal arrests and convictions. Any criminal history record information relating to principals, financial backers, operators and employees obtained under this section by the department may be interpreted and used by the department only to determine the principal's, financial backer's, operator's and employee's character, fitness and suitability to serve as a principal, financial backer, operator and employee under this act. The criminal history record information provided under this subsection may not be subject to the limitations under 18

Pa.C.S. § 9121(b)(2) (relating to general regulations). After submission of required documentation to the department, medical marijuana organizations may allow employees to work in a supervised capacity until the department formally approves the employee's affiliation with the medical marijuana organization. Any employee who the department determines to be unable to meet the affiliation requirements under section 614 shall be terminated by the medical marijuana organization immediately. This paragraph shall not apply to an owner of securities in a publicly traded corporation or an owner of 5% or less in a privately held business entity if the department determines that the owner of the securities is not substantially involved in the activities of the medical marijuana organization. ((4) amended June 30, 2021, P.L.210, No.44)

(5) Details relating to a similar license, permit or other authorization obtained in another jurisdiction, including any suspensions, revocations or discipline in that jurisdiction.

(6) A description of the business activities in which it intends to engage as a medical marijuana organization.

(7) A statement that the applicant:

(i) ((i) deleted by amendment June 30, 2021, P.L.210, NO.44).

(ii) Possesses the ability to obtain in an expeditious manner the right to use sufficient land, buildings and other premises and equipment to properly carry on the activity described in the application and any proposed location for a facility.

(iii) Is able to maintain effective security and control to prevent diversion, abuse and other illegal conduct relating to medical marijuana.

(iv) Is able to comply with all applicable Commonwealth laws and regulations relating to the activities in which it intends to engage under this act.

((7) amended June 30, 2021, P.L.210, No.44)

(8) The name, residential address and title of each financial backer and principal of the applicant. Each individual, or lawful representative of a legal entity, shall submit an affidavit with the application setting forth:

(i) Any position of management or ownership during the preceding 10 years of a controlling interest in any other business, located inside or outside this Commonwealth, manufacturing or distributing controlled substances.

(ii) Whether the person or business has been convicted of a criminal offense graded higher than a summary offense or has had a permit relating to medical marijuana suspended or revoked in any administrative or judicial proceeding.

(9) Any other information the department may require.

(b) Notice.--An application shall include notice that a false statement made in the application is punishable under the applicable provisions of 18 Pa.C.S. Ch. 49 (relating to falsification and intimidation).

Section 603. Granting of permit.

(a) General rule.--The department may grant or deny a permit to a grower/processor or dispensary.

(a.1) Determination.--In making a decision under subsection (a), the department shall determine that:

(1) The applicant will maintain effective control of and prevent diversion of medical marijuana.

(2) The applicant will comply with all applicable laws of this Commonwealth.

(3) The applicant is ready, willing and able to properly carry on the activity for which a permit is sought.

(4) The applicant possesses the ability to obtain in an expeditious manner sufficient land, buildings and equipment to properly grow, process or dispense medical marijuana.

(5) It is in the public interest to grant the permit.

(6) The applicant, including the financial backer or principal, is of good moral character and has the financial fitness necessary to operate.

(7) The applicant is able to implement and maintain security, tracking, recordkeeping and surveillance systems relating to the acquisition, possession, growth, manufacture, sale, delivery, transportation, distribution or the dispensing of medical marijuana as required by the department.

(8) The applicant satisfies any other conditions as determined by the department.

(b) Nontransferability.--A permit issued under this chapter shall be nontransferable.

(c) Privilege.--The issuance or renewal of a permit shall be a revocable privilege.

(d) Regions.--The department shall establish a minimum of three regions within this Commonwealth for the purpose of granting permits to grower/processors and dispensaries and enforcing this act. The department shall approve permits for grower/processors and dispensaries in a manner which will provide an adequate amount of medical marijuana to patients and caregivers in all areas of this Commonwealth. The department shall consider the following when issuing a permit:

(1) Regional population.

(2) The number of patients suffering from serious medical conditions.

(3) The types of serious medical conditions.

(4) Access to public transportation.

(5) Any other factor the department deems relevant.

Section 604. Notice.

When the boundaries under section 603(d) are established, the department shall publish notice of the determination in the Pennsylvania Bulletin. The department may adjust the boundaries as necessary every two years. Notice of any adjustment to the boundaries shall be published in the Pennsylvania Bulletin.

Section 605. (Reserved).

Section 606. Application and issuance.

(a) Duty to report.--An applicant to be a grower/processor or to operate a dispensary is under a continuing duty to:

(1) Report to the department any change in facts or circumstances reflected in the application or any newly discovered or occurring fact or circumstance which is required to be included in the application, including a change in control or change of control transaction of the medical marijuana organization. ((1) amended Dec. 14, 2023, P.L. , No.63)

(2) Report to law enforcement, within 24 hours, any loss

or theft of medical marijuana.

(3) Submit to announced or unannounced inspections by the department of the facilities for growing, processing, dispensing or selling medical marijuana, including all records of the organization.

(b) Additional information.--If the department is not satisfied that the applicant should be issued a permit, the department shall notify the applicant in writing of the factors for which further documentation is required. Within 30 days of the receipt of the notification, the applicant may submit additional material to the department.

Section 607. Fees and other requirements.

The following apply:

(1) For a grower/processor:

(i) An initial application fee in the amount of $10,000 shall be paid. The fee is nonrefundable.

(ii) A fee for a permit as a grower/processor in the amount of $200,000 shall be paid. The permit shall be valid for one year. Applicants shall submit the permit fee at the time of submission of the application. The fee shall be returned if the permit is not granted.

(iii) A renewal fee for the permit as a grower/processor in the amount of $10,000 shall be paid and shall cover renewal for all locations. The renewal fee shall be returned if the renewal is not granted.

(iv) An application to renew a permit must be filed with the department not more than six months nor less than four months prior to expiration.

(v) All fees shall be paid by certified check or money order.

(vi) Before issuing an initial permit under this paragraph, the department shall verify that the applicant has at least $2,000,000 in capital, $500,000 of which must be on deposit with a financial institution.

(2) For a dispensary:

(i) An initial application fee in the amount of $5,000 shall be paid. The fee is nonrefundable.

(ii) A permit fee for a dispensary shall be $30,000 for each location. The period of the permit is one year. An applicant shall submit the permit fee at the time of submission of the application. The fee shall be returned if the application is not granted.

(iii) A renewal fee for the permit as a dispensary in the amount of $5,000 shall be paid. The fee shall be returned if the renewal is not granted and shall cover renewal for all locations.

(iv) An application to renew a permit must be filed with the department not more than six months nor less than four months prior to expiration.

(v) All fees shall be paid by certified check or money order.

(vi) Before issuing an initial permit under this paragraph, the department shall verify that the applicant has at least $150,000 in capital, which must be on deposit with a financial institution.

(3) A fee of $250 shall be required when amending the

application to indicate relocation within this Commonwealth or the addition or deletion of approved activities by the medical marijuana organization.

(4) Fees payable under this section shall be deposited into the fund.

Section 608. Issuance.

A permit issued by the department to a medical marijuana organization shall be effective only for that organization and shall specify the following:

(1) The name and address of the medical marijuana organization.

(2) The activities of the medical marijuana organization permitted under this act.

(3) The land, buildings, facilities or location to be used by the medical marijuana organization.

(4) Any other information required by the department.

Section 609. Relocation.

(a) Authorization.--The department may approve an application from a medical marijuana organization to relocate within this Commonwealth or to add or delete activities or facilities.

(b) Designations.--Notwithstanding the provisions of subsection (a), a dispensary may interchange the designation of a primary, secondary or tertiary location at any time, including the period before a location becomes operational, by providing written notice to the department at least 14 days before the change in designation. A change in designation under this subsection may not be subject to approval by the department.

(609 amended June 30, 2021, P.L.210, No.44)

Section 610. Terms of permit.

A permit issued by the department shall be valid for one year from the date of issuance.

Section 611. (Reserved).

Section 612. Permit renewals.

(a) Renewal.--An application for renewal shall include the following information:

(1) Any material change in the information provided by the medical marijuana organization in a prior application or renewal of a permit.

(2) Any charge or initiated, pending or concluded investigation, during the period of the permit, by any governmental or administrative agency with respect to:

(i) any incident involving the theft, loss or possible diversion of medical marijuana grown, processed or dispensed by the applicant; and

(ii) compliance by the applicant with the laws of this Commonwealth with respect to any substance listed in section 4 of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

(b) Approval.--The department shall renew a permit unless the department determines that:

(1) The applicant is unlikely to maintain or be able to maintain effective control against diversion of medical marijuana.

(2) The applicant is unlikely to comply with all laws of this Commonwealth applicable to the activities in which it may

engage under the permit.

(c) Nonrenewal decision.--The denial or nonrenewal shall specify in detail how the applicant has not satisfied the department's requirements for renewal. Within 30 days of the department's decision, the applicant may submit additional material to the department or demand a hearing, or both. If a hearing is demanded, the department shall fix a date as soon as practicable.

Section 613. Suspension or revocation.

The department may suspend or revoke a medical marijuana organization permit if:

(1) The department has evidence that the medical marijuana organization has failed to maintain effective control against diversion of medical marijuana.

(2) The organization violates any provision of this act or a regulation of the department.

(3) The organization has intentionally, knowingly, recklessly or negligently failed to comply with applicable laws of this Commonwealth relating to medical marijuana.

Section 614. Convictions prohibited.

(a) Prohibitions.--The following individuals may not hold volunteer positions or positions with remuneration in or be affiliated with a medical marijuana organization, including a clinical registrant under Chapter 20, in any way if the individual has been convicted of any felony criminal offense related to the manufacture, delivery or possession with intent to manufacture or deliver a controlled substance in violation of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, or similar law in any other jurisdiction:

(1) Financial backers.

(2) Principals.

(3) Employees.

(b) Exclusion.--This section shall not apply to an individual for whom it has been 10 or more years since the entry of a final disposition of a felony conviction related to the manufacture, delivery or possession with intent to manufacture or deliver a controlled substance in violation of The Controlled Substance, Drug, Device and Cosmetic Act, or similar law in any other jurisdiction, or one year since the individual's release from imprisonment for the felony conviction, whichever is later.

(614 amended June 30, 2021, P.L.210, No.44)

Section 615. Diversity goals.

(a) Goals.--It is the intent and goal of the General Assembly that the department promote diversity and the participation by diverse groups in the activities authorized under this act. In order to further this goal, the department shall adopt and implement policies ensuring the following:

(1) That diverse groups are accorded equal opportunity in the permitting process.

(2) That permittees promote the participation of diverse groups in their operations by affording equal access to employment opportunities.

(b) Duties of department.--To facilitate participation by diverse groups in the activities authorized under this act, the department shall:

(1) Conduct necessary and appropriate outreach including, if necessary, consulting with other Commonwealth agencies to identify diverse groups who may qualify for participation in activities under this act.

(2) Provide sufficient and continuous notice of the participation opportunities afforded under this act by publishing notice on the department's publicly accessible Internet website.

(3) Include in the applications for permit under this act language to encourage applicants to utilize and give consideration to diverse groups for contracting or professional services opportunities.

(c) Reports.--No later than March 1, 2018, and each March 1 thereafter, the department shall submit a report to the chairperson and minority chairperson of the Public Health and Welfare Committee of the Senate and the chairperson and minority chairperson of the Health Committee of the House of Representatives summarizing the participation and utilization of diverse groups in the activities authorized under this act. The report shall include:

(1) The participation level, by percentage, of diverse groups in the activities authorized under this act.

(2) A summary of how diverse groups are utilized by permittees, including in the provision of goods or services.

(3) Any other information the department deems appropriate.

(d) Definitions.--The following words and phrases when used in this section shall have the meanings given to them in this subsection unless the context clearly indicates otherwise:

"Disadvantaged business." As defined in 74 Pa.C.S. § 303(b) (relating to diverse business participation).

"Diverse group." A disadvantaged business, minority-owned business, women-owned business, service-disabled veteran-owned small business or veteran-owned small business that has been certified by a third-party certifying organization.

"Minority-owned business." As defined in 74 Pa.C.S. § 303(b).

"Service-disabled veteran-owned small business." As defined in 51 Pa.C.S. § 9601 (relating to definitions).

"Third-party certifying organization." As defined in 74 Pa.C.S. § 303(b).

"Veteran-owned small business." As defined in 51 Pa.C.S. § 9601.

"Women-owned business." As defined in 74 Pa.C.S. § 303(b).

Section 616. Limitations on permits.

The following limitations apply to approval of permits for grower/processors and dispensaries:

(1) The department may not initially issue permits to more than 25 growers/processors.

(2) The department may not initially issue permits to more than 50 dispensaries. Each dispensary may provide medical marijuana at no more than three separate locations.

(3) The department may not issue more than five individual dispensary permits to one person.

(4) The department may not issue more than one individual grower/processor permit to one person.

(5) Except as provided under section 617, no more than

five grower/processors may be issued permits as dispensaries.
((5) amended Dec. 14, 2023, P.L. , No.63)
(6) A dispensary may only obtain medical marijuana from a grower/processor holding a valid permit under this act.
(7) A grower/processor may only provide medical marijuana to a dispensary holding a valid permit under this act.

Section 617. Additional dispensary and grower/processor permits authorized.

(a) Authorization.--
(1) An independent grower/processor that applies and meets the requirements under section 618 shall be issued one dispensary permit.
(2) An independent dispensary that applies and meets the requirements under section 618 shall be issued one grower/processor permit.

(b) Rights and privileges.--The permits issued under this section shall carry the same rights, privileges and obligations as permits issued under this chapter.

(c) Suspension or revocation prohibited.--The department may not suspend or revoke the permit of an entity that receives a permit under this section due to the entity entering into a change of control transaction with any person at least one year after the holder of the dispensary permit becomes operational in this Commonwealth. Nothing in this section shall prohibit the department from taking action for a violation of section 618(a)(4).

(d) Permit for clinical registrant.--Notwithstanding subsection (c) or section 619, an independent grower/processor or independent dispensary that applies for a permit to convert to a clinical registrant under section 2002 shall surrender a grower/processor permit or dispensary permit, or both, previously issued to the independent grower/processor or independent dispensary.

(617 added Dec. 14, 2023, P.L. , No.63)

Section 618. Application and issuance of additional permits.

(a) Applications.--
(1) The department shall develop a standard application form and open applications for permits authorized under section 617 within 30 days of the effective date of this paragraph.
(2) Applicants under this section shall submit applications for permits authorized under section 617.
(3) The department shall review applications for permits authorized under section 617 within 45 days of receipt of an application under paragraph (1) from an eligible independent grower/processor or independent dispensary.
(4) An application for a permit authorized under section 617 shall require:
(i) Supporting documentation and certification to the department that the applicant qualifies as an independent grower/processor or independent dispensary.
(ii) Certification to the department that the applicant will not enter into a change of control transaction with any other person for a duration of one year from the date the first dispensary location or grower/processor location is deemed operational by the department, unless the change of control transaction occurs

after the holder of the permit becomes operational and is between the applicant and a diverse group.

(iii) Any information required under section 602 that has significantly changed since the applicant received an initial permit.

(b) Issuance.--

(1) Except as provided under paragraph (3), the department shall issue permits under section 617 within 60 days of the application submission deadline under subsection (a)(2) to all applicants that meet the minimum requirements for permitting under this chapter. The department shall notify an applicant for permits authorized under section 617 of the approval of an application by certified mail or email.

(2) If an application under this section is incomplete, the following apply:

(i) The department shall, within 15 days of reviewing the application, notify the applicant by certified mail or email of the missing application materials.

(ii) An applicant shall have 15 days from when the notice is received under this paragraph to provide missing materials to the department.

(iii) An applicant's failure to complete the application by the deadline under subparagraph (ii) shall be grounds for denial of a permit.

(3) If an application under this section is complete but does not meet the minimum criteria for a permit, the department shall notify the applicant by certified mail or email of the deficiencies in the application and the following apply:

(i) An applicant shall have 30 days from the date the notice is received under this paragraph to provide supplemental application materials to the department.

(ii) An applicant's failure to provide the supplemental application materials to the department by the deadline will be grounds for denial of the issuance of a permit.

(iii) An applicant's failure to meet the minimum criteria for a permit after providing supplemental application materials to the department shall be grounds for denial of the issuance of a permit.

(iv) The department may use up to 30 additional days to issue dispensary permits to applicants that meet the minimum criteria for a permit after providing supplemental application materials to the department.

(4) If the department denies an application for a dispensary permit authorized under section 617, the department shall notify the applicant of the denial by certified mail or email. The notice shall include each deficiency in the application that does not meet the minimum criteria to be issued a dispensary permit.

(5) If an independent grower/processor or independent dispensary receives a denial under paragraph (4), the independent grower/processor or independent dispensary may reapply for a permit authorized under section 617 30 days after receiving notice of a denial.

(6) Appeals to the issuance or denials of dispensary permits under this section must be responded to by the

department within 45 days of submittal.

(7) An independent grower/processor or independent dispensary issued a permit under section 617 shall notify the department when the independent grower/processor or independent dispensary location is operational.

(8) Upon notification under paragraph (7), the department shall schedule an inspection to determine if the medical marijuana organization facility is operational to the satisfaction of the department. Nothing in this section shall prohibit the department from determining that the inspected location fails to be operational.

(c) Fees.--

(1) An independent grower/processor applying for a dispensary permit shall pay:

(i) An initial application fee in the amount of $5,000. The fee is nonrefundable.

(ii) A permit fee of $30,000 for each dispensary location. The period of the permit shall be one year. An applicant shall submit the permit fee at the time of submission of the application. The fee shall be returned if the application is not granted.

(iii) A renewal fee for the permit as a dispensary in the amount of $5,000. The fee shall be returned if the renewal is not granted and shall cover renewal for all locations. An application to renew a permit must be filed with the department not more than six months nor less than four months prior to expiration.

(iv) A fee of $250 when amending the application to indicate relocation within this Commonwealth or the addition or deletion of approved activities by the medical marijuana organization.

(2) An independent dispensary applying for a grower/processor permit shall pay:

(i) An initial application fee in the amount of $10,000. The fee is nonrefundable.

(ii) A permit fee of $200,000. The period of the permit is one year. An applicant shall submit the permit fee at the time of submission of the application. The fee shall be returned if the application is not granted.

(iii) A renewal fee for the permit as a grower/processor in the amount of $10,000. The fee shall cover the renewal for all locations. The renewal fee shall be returned if the renewal is not granted. An application to review a permit must be filed with the department not more than six months nor less than four months prior to expiration.

(iv) A fee of $250 when amending the application to indicate relocation within this Commonwealth or the addition or deletion of approved activities by the medical marijuana organization.

(3) All fees under this subsection shall be paid by certified check or money order.

(4) Fees payable under this subsection shall be deposited into the fund.

(d) Regions.--An independent grower/processor may apply for a dispensary permit under this section in any region established

under section 603(d).

(e) Certification violation.--If an independent grower/processor or independent dispensary enters into a change of control transaction with another entity in violation of this act, the contract or agreement executed with the other entity for the change of control transaction shall be void, unless the change of control transaction occurs at least one year after the permittee becomes operational or the merger is between a permit holder and a diverse group.

(618 added Dec. 14, 2023, P.L. , No.63)

Section 619. Limitations on other additional permits or licenses.

Notwithstanding the provisions of section 617 or 618, nothing in section 617 or 618 shall be construed to limit an entity that qualifies as an independent grower/processor or independent dispensary from applying for and receiving additional permits or licenses under any other provisions of this act upon the release of additional permits or licenses by the department or the Commonwealth.

(619 added Dec. 14, 2023, P.L. , No.63)

CHAPTER 7
MEDICAL MARIJUANA CONTROLS

Section 701. Electronic tracking.

(a) Requirement.--A grower/processor or dispensary must implement an electronic inventory tracking system which shall be directly accessible to the department through its electronic database that electronically tracks all medical marijuana on a daily basis. The system shall include tracking of all of the following:

(1) For a grower/processor, a seed-to-sale tracking system that tracks the medical marijuana from seed to plant until the medical marijuana is sold to a dispensary.

(2) For a dispensary, medical marijuana from purchase from the grower/processor to sale to a patient or caregiver and that includes information that verifies the validity of an identification card presented by the patient or caregiver.

(3) For a grower/processor and a dispensary, a daily log of each day's beginning inventory, acquisitions, amounts purchased and sold, disbursements, disposals and ending inventory. The tracking system shall include prices paid and amounts collected from patients and caregivers.

(4) For a grower/processor and a dispensary, a system for recall of defective medical marijuana.

(5) For a grower/processor and a dispensary, a system to track the plant waste resulting from the growth of medical marijuana or other disposal, including the name and address of any disposal service.

(b) Additional requirements.--In addition to the information under subsection (a), each medical marijuana organization shall track the following:

(1) Security and surveillance.

(2) Recordkeeping and record retention.

(3) The acquisition, possession, growing and processing of medical marijuana.

(4) Delivery and transportation, including amounts and

method of delivery.

(5) Dispensing, including amounts, pricing and amounts collected from patients and caregivers.

(c) Access.--Information maintained in electronic tracking systems under subsection (a) shall be confidential and not subject to the act of February 14, 2008 (P.L.6, No.3), known as the Right-to-Know Law.

(c.1) Application programming interface.--The department or the department's contracted seed-to-sale vendor shall allow two-way communication, automation and application-programming interface of a medical marijuana organization's enterprise resource planning, inventory, accounting and point-of-sale software with the software of the department or the department's contracted seed-to-sale vendor. The department or the department's contracted seed-to-sale vendor shall provide for the development and use of a seed-to-sale cannabis tracking system, which shall include a secure application program interface capable of accessing all data required to be transmitted to the advisory board to ensure compliance with the operational reporting requirements established under this act and the regulations of the department. ((c.1) added June 30, 2021, P.L.210, No.44)

(d) Reports.--Within one year of the issuance of the first permit to a grower/processor or dispensary, and every three months thereafter in a form and manner prescribed by the department, the following information shall be provided to the department, which shall compile the information and post it on the department's publicly accessible Internet website:

(1) The amount of medical marijuana sold by a grower/processor during each three-month period.

(2) The price of amounts of medical marijuana sold by grower/processors as determined by the department.

(3) The amount of medical marijuana purchased by each dispensary in this Commonwealth.

(4) The cost of amounts of medical marijuana to each dispensary in amounts as determined by the department.

(5) The total amount and dollar value of medical marijuana sold by each dispensary in the three-month period.

Section 702. Grower/processors.

(a) Authorization.--Subject to subsection (b), a grower/processor may do all of the following in accordance with department regulations:

(1) Obtain and transport seed and immature plant material from outside this Commonwealth during at least one 30-day period per year as designated by the department to grow and process medical marijuana.

(2) Obtain seed and plant material from another grower/processor within this Commonwealth to grow medical marijuana.

(2.1) Obtain and transport bulk postharvest medical marijuana plant material from another grower/processor within this Commonwealth to process medical marijuana. As used in this paragraph, the term "postharvest plant material" includes all unfinished plant and plant-derived material, whether fresh, dried, partially dried, frozen or partially frozen, oil, concentrate or similar byproducts derived or processed from medical marijuana or medical marijuana plants.

(3) Apply solvent-based extraction methods and processes to medical marijuana plants that have failed a test conducted by an approved laboratory at harvest, subject to the following:

(i) The test failure shall be limited to yeast and mold.

(ii) The extracted material shall be processed into a topical form.

(iii) The medical marijuana product must pass a final processed test under section 704.

(iv) The medical marijuana product shall be labeled as remediated.

(v) This paragraph shall expire upon the publication in the Pennsylvania Bulletin of a notice of the secretary's approval of the recommendations relating to a research initiative, as prescribed in section 2003.1.

(4) Obtain harvested hemp from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp under the 3 Pa.C.S. Ch. 15 (relating to controlled plants and noxious weeds) if the hemp received by a grower/processor is subject to the laboratory testing requirements of section 704.

(5) Add excipients or hemp or hemp-derived additives obtained or cultivated in accordance with paragraph (4). Excipients must be pharmaceutical grade, unless otherwise approved by the department. In determining whether to approve an added substance, the department shall consider the following:

(i) Whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under Federal guidelines.

(ii) Whether the added substance constitutes a known hazard such as diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6.

(b) Limitations.--

(1) A grower/processor may only grow, store, harvest or process medical marijuana in an indoor, enclosed, secure facility which:

(i) includes electronic locking systems, electronic surveillance and other features required by the department; and

(ii) is located within this Commonwealth.

(2) For the purpose of paragraph (1), a grower/processor shall maintain continuous video surveillance. A grower/processor is required to retain the recordings onsite or offsite for a period of no less than 180 days, unless otherwise required for investigative or litigation purposes.

(c) Pesticides.--The following shall apply:

(1) A grower/processor may use a pesticide that is registered by the Department of Agriculture under the act of March 1, 1974 (P.L.90, No.24), known as the Pennsylvania Pesticide Control Act of 1973, and designated by the Secretary of Agriculture in consultation with the secretary for use by a grower/processor.

(2) The Secretary of Agriculture shall, within 30 days of the effective date of this subsection, transmit to the

Legislative Reference Bureau for publication in the Pennsylvania Bulletin an initial list of pesticides which may be used by grower/processors. The list shall be posted on the department's publicly accessible Internet website and shall be reviewed and updated by the Secretary of Agriculture, in consultation with the secretary, at least once annually and transmitted to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin.

(702 amended June 30, 2021, P.L.210, No.44)

Section 703. Storage and transportation.

The department shall develop regulations relating to the storage and transportation of medical marijuana among grower/processors, testing laboratories and dispensaries which ensure adequate security to guard against in-transit losses. The tracking system developed by the department shall include all transportation and storage of medical marijuana. The regulations shall provide for the following:

(1) Requirements relating to shipping containers and packaging.

(2) The manner in which trucks, vans, trailers or other carriers will be secured.

(3) Security systems that include a numbered seal on the trailer.

(4) Obtaining copies of drivers' licenses and registrations and other information related to security and tracking.

(5) Use of GPS systems.

(6) Number of drivers or other security required to ensure against storage or in-transit losses.

(7) Recordkeeping for delivery and receipt of medical marijuana products.

(8) Requirements to utilize any electronic tracking system required by the department, which shall allow for the two-way communication, automation and application-programming interface between a medical marijuana organization's enterprise resource planning, inventory, accounting and point-of-sale software and the software of the department or the department's vendor. ((8) amended June 30, 2021, P.L.210, No.44)

(9) Transporting medical marijuana to a grower/processor, approved laboratory or dispensary.

Section 704. Laboratory.

(a) General testing.--A grower/processor shall contract with one or more independent laboratories to test the medical marijuana produced by the grower/processor. The department shall approve a laboratory under this subsection and require that the laboratory report testing results in a manner as the department shall determine, including requiring a test at harvest and a test at final processing. The possession by a laboratory of medical marijuana shall be a lawful use.

(b) Stability testing.--A laboratory shall perform stability testing to ensure the medical marijuana product's potency and purity. A grower/processor shall retain a sample from each medical marijuana product derived from a harvest batch and request that a sample be identified and collected by a laboratory approved under subsection (a) from each process lot to perform stability testing under the following conditions:

(1) The medical marijuana product is still in inventory at a dispensary in this Commonwealth as determined by the seed-to-sale system.

(2) The stability testing is done at six-month intervals for the duration of the expiration date period as listed on the medical marijuana product and once within six months of the expiration date.

(704 amended June 30, 2021, P.L.210, No.44)

Section 705. Prices.

The department and the Department of Revenue shall monitor the price of medical marijuana sold by grower/processors and by dispensaries, including a per-dose price. If the department and the Department of Revenue determine that the prices are unreasonable or excessive, the department may implement a cap on the price of medical marijuana being sold for a period of six months. The cap may be amended during the six-month period. If the department and the Department of Revenue determine that the prices become unreasonable or excessive following the expiration of a six-month cap, additional caps may be imposed for periods not to exceed six months.

CHAPTER 8
DISPENSARIES

Section 801. Dispensing to patients and caregivers.

(a) General rule.--A dispensary that has been issued a permit under Chapter 6 may lawfully dispense medical marijuana to a patient or caregiver upon presentation to the dispensary of a valid identification card for that patient or caregiver. The dispensary shall provide to the patient or caregiver a receipt, as appropriate. The receipt shall include all of the following:

(1) The name, address and any identification number assigned to the dispensary by the department.

(2) The name and address of the patient and caregiver.

(3) The date the medical marijuana was dispensed.

(4) Any requirement or limitation by the practitioner as to the form of medical marijuana for the patient.

(5) The form and the quantity of medical marijuana dispensed.

(b) Requirements.--A dispensary shall have a physician or a pharmacist available, either in person or by synchronous interaction, to verify patient certifications and to consult with patients and caregivers at all times during the hours the dispensary is open to receive patients and caregivers. If a dispensary has more than one separate location, a physician assistant or a certified registered nurse practitioner may verify patient certifications and consult with patients and caregivers, either in person or by synchronous interaction, at each of the other locations in lieu of the physician or pharmacist. A physician, a pharmacist, a physician assistant or a certified registered nurse practitioner shall, prior to assuming duties under this paragraph, successfully complete the course established in section 301(a)(6). A physician may not issue a certification to authorize patients to receive medical marijuana or otherwise treat patients at the dispensary. ((b) amended June 30, 2021, P.L.210, No.44)

(c) Filing with department.--Prior to dispensing medical marijuana to a patient or caregiver, the dispensary shall file the receipt information with the department utilizing the electronic tracking system. When filing receipts under this subsection, the dispensary shall dispose of any electronically recorded certification information as provided by regulation.

(d) Limitations.--No dispensary may dispense to a patient or caregiver:

(1) a quantity of medical marijuana greater than that which the patient or caregiver is permitted to possess under the certification; or

(2) a form of medical marijuana prohibited by this act.

(e) Supply.--When dispensing medical marijuana to a patient or caregiver, the dispensary may not dispense an amount greater than a 90-day supply until the patient has exhausted all but a seven-day supply provided pursuant to a previously issued certification until additional certification is presented under section 405. ((e) amended June 30, 2021, P.L.710, No.44)

(f) Verification.--Prior to dispensing medical marijuana to a patient or caregiver, the dispensary shall verify the information in subsections (e) and (g) by consulting the electronic tracking system included in the department's electronic database established under section 301(a)(4)(v) and the dispensary tracking system under section 701(a)(2).

(g) Form of medical marijuana.--Medical marijuana dispensed to a patient or caregiver by a dispensary shall conform to any requirement or limitation set by the practitioner as to the form of medical marijuana for the patient.

(h) Safety insert.--When a dispensary dispenses medical marijuana to a patient or caregiver, the dispensary shall provide to that patient or caregiver, as appropriate, a safety insert. The insert shall be developed and approved by the department. The insert shall provide the following information:

(1) Lawful methods for administering medical marijuana in individual doses.

(2) Any potential dangers stemming from the use of medical marijuana.

(3) How to recognize what may be problematic usage of medical marijuana and how to obtain appropriate services or treatment for problematic usage.

(4) How to prevent or deter the misuse of medical marijuana by minors or others.

(5) Any other information as determined by the department.

(i) Sealed and labeled package.--Medical marijuana shall be dispensed by a dispensary to a patient or caregiver in a sealed and properly labeled package. The labeling shall contain the following:

(1) The information required to be included in the receipt provided to the patient or caregiver, as appropriate, by the dispensary.

(2) The packaging date.

(3) Any applicable date by which the medical marijuana should be used.

(4) A warning stating:

"This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the

advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children."

(5) The amount of individual doses contained within the package and the species and percentage of tetrahydrocannabinol and cannabidiol.

(6) A warning that the medical marijuana must be kept in the original container in which it was dispensed.

(7) A warning that unauthorized use is unlawful and will subject the person to criminal penalties.

(8) Any other information required by the department.

Section 802. Facility requirements.

(a) General rule.--

(1) A dispensary may dispense medical marijuana in an indoor, enclosed, secure facility located within this Commonwealth or in accordance with a curbside delivery protocol as determined by the department. ((1) amended June 30, 2021, P.L.210, No.44)

(1.1) For the purposes of paragraph (1), a dispensary shall maintain continuous video surveillance. The dispensary is required to retain the recordings onsite or offsite for a period of no less than 180 days, unless otherwise required for investigative or litigation purposes. ((1.1) added June 30, 2021, P.L.210, No.44)

(2) A dispensary may not operate on the same site as a facility used for growing and processing medical marijuana.

(3) A dispensary may not be located within 1,000 feet of the property line of a public, private or parochial school or a day-care center.

(4) A dispensary may sell medical devices and instruments which are needed to administer medical marijuana under this act.

(5) A dispensary may sell services approved by the department related to the use of medical marijuana.

(b) Adjustment or waiver of prohibition.--The department may amend a prohibition under subsection (a)(3) if it is shown by clear and convincing evidence that the amendment is necessary to provide adequate access to patients. An amendment may include additional security, physical plant of a facility or other conditions necessary to protect children.

Section 803. Posting.

A dispensary shall post a copy of its permit in a location within its facility in a manner that is easily observable by patients, caregivers, law enforcement officers and agents of the department.

CHAPTER 9
TAX ON MEDICAL MARIJUANA

Section 901. Tax on medical marijuana.

(a) Tax imposed.--A tax is imposed on the gross receipts of a grower/processor received from the sale of medical marijuana by a grower/processor to a dispensary, to be paid by the grower/processor, at the rate of 5%. The tax shall be charged against and be paid by the grower/processor and shall not be added

as a separate charge or line item on any sales slip, invoice, receipt or other statement or memorandum of the price paid by a dispensary, patient or caregiver.

(b) Payment of tax and reports.--The tax imposed under subsection (a) shall be administered in the same manner as the tax imposed under Article XI of the act of March 4, 1971 (P.L.6, No.2), known as the Tax Reform Code of 1971, except that estimated tax payments under section 3003.2 of the Tax Reform Code of 1971 shall not be required. A grower/processor shall make quarterly payments under this section for each calendar quarter at the rate prescribed in subsection (a) on the gross receipts for the calendar quarter. The tax shall be due and payable on the 20th day of January, April, July and October for the preceding calendar quarter on a form prescribed by the Department of Revenue.

(c) (Reserved).

(d) Deposit of proceeds.--All money received from the tax imposed under subsection (a) shall be deposited into the fund.

(e) Exemption.--Medical marijuana shall not be subject to the tax imposed under section 202 of the Tax Reform Code of 1971.

(f) Information.--A grower/processor that sells medical marijuana shall provide to the Department of Revenue information required by the department.

Section 902. Medical Marijuana Program Fund.

(a) Fund established.--The Medical Marijuana Program Fund is established as a special fund in the State Treasury. Money in the fund is appropriated as set forth in subsection (c). Any amount unspent at the end of a fiscal year shall be appropriated to the department for its operations.

(b) Source of funds.--Fees and taxes payable under this act shall be deposited into the fund. The money deposited into the fund may only be used for the purposes set forth in this section. Any interest accrued shall be deposited into the fund.

(c) Use of proceeds.--After any repayment made under subsection (d), money in the fund is appropriated in accordance with the following percentages:

(1) To the department, 55% of the revenue in the fund. Forty percent of the revenue in the fund shall be expended for operations of the department, including outreach efforts and other projects, as required by this act. Fifteen percent of the amount in the fund shall be used by the department to establish the following:

(i) a program to assist patients with the cost of providing medical marijuana to patients who demonstrate financial hardship or need under this act, and the department shall develop guidelines and procedures to ensure maximum availability to individuals with financial need;

(ii) a program to assist patients and caregivers with the cost associated with the waiver or reduction of fees for identification cards under sections 501(c)(5) and 502(a)(2); and

(iii) a program to reimburse caregivers for the cost of providing background checks for caregivers.

(2) To the Department of Drug and Alcohol Programs, for drug abuse prevention and counseling and treatment services, 10% of the revenue in the fund.

(3) To the department, for further research related to the use of medical marijuana, including the research program established under Chapter 19, 30% of the revenue in the fund. Funding shall be provided for research into the treatment of those serious medical conditions for which medical marijuana is available for treatment within this Commonwealth and for research into the use of medical marijuana to treat other medical conditions for which medical marijuana may have legitimate medicinal value. Money shall be used to subsidize the cost of, or provide, medical marijuana to patients participating in the program. However, money in the fund may not be expended on activity under Chapter 20.

(4) To the Pennsylvania Commission on Crime and Delinquency, for distribution to local police departments which demonstrate a need relating to the enforcement of this act, 5% of the revenue in the fund.

(d) Repayment of initial funding.--The department shall repay from the fees, taxes and investment earnings of the fund to the General Fund any money appropriated for the initial planning, organization and administration by the department with respect to the establishment of the program at the time of the original enactment of this act. ((d) amended June 30, 2021, P.L.210, No.44)

CHAPTER 11
ADMINISTRATION

Section 1101. Governing practice and procedure.

The provisions of 2 Pa.C.S. (relating to administrative law and procedure) shall apply to all actions of the department under this act constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

Section 1102. Reports by medical marijuana organizations.

A medical marijuana organization shall periodically file reports related to its activities. The department shall determine the information required in and the frequency of filing the reports.

Section 1103. Law enforcement notification.

Notwithstanding any provision of this act or any other law to the contrary, the department may notify any appropriate law enforcement agency of information relating to any violation or suspected violation of this act. In addition, the department shall verify to law enforcement personnel in an appropriate case whether a certification, permit, registration or an identification card is valid, including release of the name of the patient.

Section 1104. Evaluation.

The department may provide for an analysis and evaluation of the implementation and effectiveness of this act, including whether the intent and stated policy of the General Assembly have been achieved. The department may enter into agreements with one or more persons for the performance of an evaluation of the implementation and effectiveness of this act.

Section 1105. Report.

(a) Report required.--The department shall submit a written report under subsection (b) every two years, beginning two years after the effective date of this section, to the following:

(1) The Governor.

(2) The President pro tempore of the Senate.
(3) The Majority Leader and the Minority Leader of the Senate.
(4) The Speaker of the House of Representatives.
(5) The Majority Leader and the Minority Leader of the House of Representatives.
(6) The chairman and minority chairman of the Judiciary Committee of the Senate.
(7) The chairman and minority chairman of the Public Health and Welfare Committee of the Senate.
(8) The chairman and minority chairman of the Judiciary Committee of the House of Representatives.
(9) The chairman and minority chairman of the Health Committee of the House of Representatives.
(10) The Attorney General of the Commonwealth.

(b) Contents of report.--The following information shall be included in the report:
(1) An assessment of the use of medical marijuana as a result of the enactment of this act.
(2) An assessment of the benefits and risks to patients using medical marijuana under this act, including adverse events.
(3) Recommendations for amendments to this act for reasons of patient safety or to aid the general welfare of the citizens of this Commonwealth.

Section 1106. (Reserved).

Section 1107. Temporary regulations.

(a) Promulgation.--In order to facilitate the prompt implementation of this act, the department may promulgate temporary regulations that shall expire not later than two years following the publication of the temporary regulation. The department may promulgate temporary regulations not subject to:
(1) Sections 201, 202, 203, 204 and 205 of the act of July 31, 1968 (P.L.769, No.240), referred to as the Commonwealth Documents Law.
(2) The act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act.
(3) Sections 204(b) and 301(10) of the act of October 15, 1980 (P.L.950, No.164), known as the Commonwealth Attorneys Act.

(b) Expiration.--Notwithstanding any other provision of law, the department's authority to adopt temporary regulations under subsection (a) shall expire May 31, 2022. Regulations adopted after this period shall be promulgated as provided by law. ((b) amended June 30, 2021, P.L.210, No.44)

(c) Publication.--The department shall begin publishing temporary regulations in the Pennsylvania Bulletin no later than six months after the effective date of this section.

CHAPTER 12
MEDICAL MARIJUANA ADVISORY BOARD

Section 1201. Advisory board.

(a) Establishment.--The Medical Marijuana Advisory Board is established within the department. The advisory board shall consist of the following members:

(1) The secretary or a designee.
(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.
(8) One member to be appointed by each of the following, which members shall be knowledgeable and experienced in issues relating to care and treatment of individuals with a serious medical condition, geriatric or pediatric medicine or clinical research:
(i) The Governor.
(ii) The President pro tempore of the Senate.
(iii) The Majority Leader of the Senate.
(iv) The Minority Leader of the Senate.
(v) The Speaker of the House of Representatives.
(vi) The Majority Leader of the House of Representatives.
(vii) The Minority Leader of the House of Representatives.
(9) One member appointed by the Governor, who shall be a patient, a family or household member of a patient or a patient advocate.

(b) Terms.--Except as provided under subsection (g), the members appointed under subsection (a)(8) and (9) shall serve a term of four years or until a successor has been appointed and qualified, but no longer than six months beyond the four-year period.

(c) Chair.--The secretary, or a designee, shall serve as chair of the advisory board.

(d) Voting; quorum.--The members under subsection (a)(1), (2), (3), (4), (5), (6) and (7) shall serve ex officio and shall have voting rights. A majority of the members shall constitute a quorum for the purpose of organizing the advisory board, conducting its business and fulfilling its duties. A vote of the majority of the members present shall be sufficient for all actions of the advisory board unless the bylaws require a greater number.

(e) Attendance.--A member of the advisory board appointed under subsection (a)(8) or (9) who fails to attend three consecutive meetings shall forfeit his seat unless the secretary, upon written request from the member, finds that the member should be excused from a meeting for good cause. A member who cannot be physically present may attend meetings via electronic means, including video conference.

(f) Governance.--The advisory board shall have the power to prescribe, amend and repeal bylaws, rules and regulations governing the manner in which the business of the advisory board is conducted and the manner in which the duties granted to it are fulfilled. The advisory board may delegate supervision of the administration of advisory board activities to an administrative

secretary and other employees of the department as the secretary shall appoint.

(g) Initial terms.--The initial terms of members appointed under subsection (a)(8) and (9) shall be for terms of one, two, three or four years, the particular term of each member to be designated by the secretary at the time of appointment. All other members shall serve for a term of four years.

(h) Vacancy.--In the event that any member appointed under subsection (a)(8) or (9) shall die or resign or otherwise become disqualified during the member's term of office, a successor shall be appointed in the same way and with the same qualifications as set forth in this section and shall hold office for the unexpired term. An appointed member of the advisory board shall be eligible for reappointment.

(i) Expenses.--A member appointed under subsection (a)(8) or (9) shall receive the amount of reasonable travel, hotel and other necessary expenses incurred in the performance of the duties of the member in accordance with Commonwealth regulations, but shall receive no other compensation for the member's service on the board.

(j) Duties.--The advisory board shall have the following 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.

(4) To issue written reports to the Governor, the Senate and the House of Representatives. ((4) amended June 30, 2021, P.L.210, No.44)

(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.

(iv) ((iv) deleted by amendment).

(v) How to ensure affordable patient access to medical marijuana.

(vi) ((vi) deleted by amendment).

((5) amended June 30, 2021, P.L.210, No.44)

(6) The written reports under this section shall be adopted at a public meeting. The reports shall be a public record under the act of February 14, 2008 (P.L.6, No.3), known as the Right-to-Know Law. ((6) amended June 30, 2021, P.L.210, No.44)

Section 1202. Effectuating recommendations of advisory board.

After receiving a report of the advisory board under section 1201(j)(4), at the discretion of the secretary, the department may effectuate recommendations made by the advisory board by transmitting a notice to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin. The secretary shall

transmit notice to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin within 12 months of the receipt of a report of the advisory board. The notice shall include the recommendations of the advisory board and shall state the specific reasons for the decision of the secretary on whether or not to effectuate each recommendation.

(1202 amended June 30, 2021, P.L.210, No.44)

CHAPTER 13
OFFENSES RELATED TO MEDICAL MARIJUANA

Section 1301. Criminal diversion of medical marijuana by practitioners.

In addition to any other penalty provided by law, a practitioner commits a misdemeanor of the first degree if the practitioner intentionally, knowingly or recklessly certifies a person as being able to lawfully receive medical marijuana or otherwise provides medical marijuana to a person who is not lawfully permitted to receive medical marijuana.

Section 1302. Criminal diversion of medical marijuana.

In addition to any other penalty provided by law, an employee, financial backer, operator or principal of any of the following commits a misdemeanor of the first degree if the person intentionally, knowingly or recklessly sells, dispenses, trades, delivers or otherwise provides medical marijuana to a person who is not lawfully permitted to receive medical marijuana:

(1) A medical marijuana organization.

(2) A health care medical marijuana organization or university participating in a research study under Chapter 19.

(3) A clinical registrant or academic clinical research center under Chapter 20.

(4) A laboratory utilized to test medical marijuana under section 704.

Section 1303. Criminal retention of medical marijuana.

In addition to any other penalty provided by law, a patient or caregiver commits a misdemeanor of the third degree if the patient or caregiver intentionally, knowingly or recklessly possesses, stores or maintains an amount of medical marijuana in excess of the amount legally permitted.

Section 1304. Criminal diversion of medical marijuana by patient or caregiver.

(a) Offense defined.--In addition to any other penalty provided by law, a patient or caregiver commits an offense if the patient or caregiver intentionally, knowingly or recklessly provides medical marijuana to a person who is not lawfully permitted to receive medical marijuana.

(b) Grading.--A first offense under this section constitutes a misdemeanor of the second degree. A second or subsequent offense constitutes a misdemeanor of the first degree.

Section 1305. Falsification of identification cards.

(a) Offense defined.--In addition to any other penalty provided by law, a person commits an offense if, knowing he is not privileged to hold an identification card, the person:

(1) possesses an identification card and either attempts to use the card to obtain medical marijuana or obtains medical marijuana;

(2) possesses an identification card which falsely identifies the person as being lawfully entitled to receive medical marijuana and either attempts to use the card to obtain medical marijuana or obtains medical marijuana; or

(3) possesses an identification card which contains any false information on the card and the person either attempts to use the card to obtain medical marijuana or obtains medical marijuana.

(b) Grading.--A first offense under this section constitutes a misdemeanor of the second degree. A second or subsequent offense under this section constitutes a misdemeanor of the first degree.

Section 1306. Adulteration of medical marijuana.

(a) General rule.--In addition to any other penalty provided by law, a person commits an offense if the person adulterates, fortifies, contaminates or changes the character or purity of medical marijuana from that set forth on the patient's or caregiver's identification card.

(b) Grading.--A first offense under this section constitutes a misdemeanor of the second degree. A second or subsequent offense under this section constitutes a misdemeanor of the first degree.

Section 1307. Disclosure of information prohibited.

(a) Offense defined.--In addition to any other penalty provided by law, an employee, financial backer, operator or principal of any of the following commits a misdemeanor of the third degree if the person discloses, except to authorized persons for official governmental or health care purposes, any information related to the use of medical marijuana:

(1) A medical marijuana organization.

(2) A health care medical marijuana organization or university participating in a research study under Chapter 19.

(3) A clinical registrant or academic clinical research center under Chapter 20.

(4) An employee or contractor of the department.

(b) Exception.--Subsection (a) shall not apply where disclosure is permitted or required by law or by court order. The department, including an authorized employee, requesting or obtaining information under this act shall not be subject to any criminal liability. The immunity provided by this subsection shall not apply to any employee of the department who knowingly and willfully discloses prohibited information under this act.

(1307 amended June 30, 2021, P.L.210, No.44)

Section 1308. Additional penalties.

(a) Criminal penalties.--In addition to any other penalty provided by law, a practitioner, caregiver, patient, employee, financial backer, operator or principal of any medical marijuana organization, health care medical organization or university participating in a research study under Chapter 19, and an employee, financial backer, operator or principal of a clinical registrant or academic clinical research center under Chapter 20, who violates any of the provisions of this act, other than those specified in section 1301, 1302, 1303, 1304, 1305, 1306 or 1307, or any regulation promulgated under this act:

(1) For a first offense, commits a misdemeanor of the third degree and shall, upon conviction, be sentenced to pay a fine of not more than $5,000, or to imprisonment for not more than six months.

(2) For a second or subsequent offense, commits a misdemeanor of the third degree and shall, upon conviction, be sentenced to pay a fine of not more than $10,000, or to imprisonment for not less than six months or more than one year, or both.

(b) Civil penalties.--In addition to any other remedy available to the department, the department may assess a civil penalty for a violation of this act, a regulation promulgated under this act or an order issued under this act or regulation as provided in this subsection. The following shall apply:

(1) The department may assess a penalty of not more than $10,000 for each violation and an additional penalty of not more than $1,000 for each day of a continuing violation. In determining the amount of each penalty, the department shall take the following factors into consideration:

(i) The gravity of the violation.

(ii) The potential harm resulting from the violation to patients, caregivers or the general public.

(iii) The willfulness of the violation.

(iv) Previous violations, if any, by the person being assessed.

(v) The economic benefit to the person being assessed for failing to comply with the requirements of this act, a regulation promulgated under this act or an order issued under this act or regulation.

(2) If the department finds that the violation did not threaten the safety or health of a patient, caregiver or the general public and the violator took immediate action to remedy the violation upon learning of it, the department may issue a written warning in lieu of assessing a civil penalty.

(3) A person who aids, abets, counsels, induces, procures or causes another person to violate this act, a regulation promulgated under this act or an order issued under this act or regulation shall be subject to the civil penalties provided under this subsection.

(c) Sanctions.--

(1) In addition to the penalties provided in subsection (b) and any other penalty authorized by law, the department may impose the following sanctions:

(i) Revoke or suspend the permit of a person found to be in violation of this act, a regulation promulgated under this act or an order issued under this act or regulation.

(ii) Revoke or suspend the permit of a person for conduct or activity or the occurrence of an event that would have disqualified the person from receiving the permit.

(iii) Revoke or suspend the registration of a practitioner for a violation of this act or a regulation promulgated or an order issued under this act or for conduct or activity which would have disqualified the practitioner from receiving a registration.

(iv) Suspend a permit or registration of a person pending the outcome of a hearing in a case in which the permit or registration could be revoked.

(v) Order restitution of funds or property unlawfully obtained or retained by a permittee or registrant.

(vi) Issue a cease and desist order.

(2) A person who aids, abets, counsels, induces, procures or causes another person to violate this act shall be subject to the sanctions provided under this subsection.

(d) Costs of action.--The department may assess against a person determined to be in violation of this act the costs of investigation of the violation.

(e) Minor violations.--Nothing in this section shall be construed to require the assessment of a civil penalty or the imposition of a sanction for a minor violation of this act if the department determines that the public interest will be adequately served under the circumstances by the issuance of a written warning.

Section 1309. Other restrictions.

This act does not permit any person to engage in and does not prevent the imposition of any civil, criminal or other penalty for the following:

(1) Undertaking any task under the influence of medical marijuana when doing so would constitute negligence, professional malpractice or professional misconduct.

(2) Possessing or using medical marijuana in a State or county correctional facility, including a facility owned or operated or under contract with the Department of Corrections or the county which houses inmates serving a portion of their sentences on parole or other community correction program. Nothing in this paragraph shall be construed to apply to employees of the facilities set forth in this paragraph. The Department of Corrections shall adopt a written policy no later than 18 months from the effective date of this section regarding the possession and use of medical marijuana by employees in State correctional facilities. The governing authority of a county may adopt a resolution no later than 18 months from the effective date of this section regarding the possession and use of medical marijuana by employees in a county correctional facility.

(3) Possessing or using medical marijuana in a youth detention center or other facility which houses children adjudicated delinquent, including the separate, secure State-owned facility or unit utilized for sexually violent delinquent children under 42 Pa.C.S. § 6404 (relating to duration of inpatient commitment and review). As used in this paragraph, the term "sexually violent delinquent children" shall have the meaning given to it in 42 Pa.C.S. § 6402 (relating to definitions). Nothing in this paragraph shall be construed to apply to employees of the facilities set forth in this paragraph.

CHAPTER 19
RESEARCH PROGRAM

Section 1901. Definitions.

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Health care medical marijuana organization." A vertically integrated health system approved by the department to dispense

medical marijuana or grow and process medical marijuana, or both, in accordance with a research study under this chapter.

"Vertically integrated health system." A health delivery system licensed under the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act, in which the complete spectrum of care, including primary and specialty care, hospitalization and pharmaceutical care, is provided within a single organization.

Section 1902. Establishment of medical marijuana research program.

(a) Program to be established.--The department shall establish and develop a research program to study the impact of medical marijuana on the treatment and symptom management of serious medical conditions. The program shall not include a clinical registrant or academic clinical research center under Chapter 20.

(b) Department duties.--The department shall:

(1) Review all serious medical conditions which are cited by a practitioner upon the practitioner's certification that a patient be granted an identification card.

(2) Create a database of all serious medical conditions, including comorbidities, which are cited by practitioners in the certifications of patients. The database shall also include the form of medical marijuana certified to treat each serious medical condition.

(3) When the database contains 25 or more patients with the same serious medical condition, petition the United States Food and Drug Administration and the United States Drug Enforcement Administration for approval to study the condition and the impact of medical marijuana on the condition.

(4) Concurrent with the request to the United States Food and Drug Administration and United States Drug Enforcement Administration, publicly announce the formation of a research study to which a vertically integrated health system and a university within this Commonwealth may submit a request to participate.

(5) Upon approval of a research study by the United States Food and Drug Administration and the United States Drug Enforcement Administration, select a vertically integrated health system or systems to conduct the research study and designate the form or forms of medical marijuana which will be used to treat the serious medical condition.

(6) Notify a patient who has been issued an identification card:

(i) that the patient has been selected to participate, at the patient's option, in a research study to study medical marijuana as a treatment; and

(ii) where the patient may secure medical marijuana through a health care medical marijuana organization at no cost to the patient in accordance with subsection (c).

(7) If the United States Food and Drug Administration and the United States Drug Enforcement Administration reject the proposal for the research study, take all reasonable steps to collect and collate data on the serious medical condition and the use of medical marijuana as a treatment for the serious medical condition and consider submitting an additional request to the United States Food and Drug Administration and United

States Drug Enforcement Administration for a research study on the same condition.

(c) Costs.--The cost of the medical marijuana which is dispensed to patients in accordance with an approved research study shall be paid for by the fund.

(d) Geographic accessibility.--The department shall take into consideration the geographic location of the health care medical marijuana organization when assigning a patient to a health care medical marijuana organization. The department shall make an effort to assign a patient to a health care medical marijuana organization that is located within 50 miles of the patient's residence.

(e) Data.--Data collected by the health care medical marijuana organization shall be provided to the university participating in the research study for analysis.

Section 1903. Medical marijuana research program administration.

(a) General rule.--The department shall establish a research study for each serious medical condition. The department shall engage universities within this Commonwealth to participate in the collection, collation, analysis and conclusive findings of the research studies. The department shall, by regulation, establish the procedure to be used by health care medical marijuana organizations with respect to:

(1) Real time inventory tracking.

(2) Real time tracking of the medical marijuana dispensed.

(3) Recall of defective medical marijuana.

(b) Request for distributions.--The department shall establish a form and procedure for universities selected to participate in a research study to request distributions from the fund to conduct research on medical marijuana, including administrative costs. These distributions shall also be used to pay for the cost of the medical marijuana so that it is not borne by the patient participating in the research study. The forms shall include, at a minimum, the following:

(1) The form or forms of medical marijuana to be studied.

(2) The serious medical condition to be studied.

(c) Research reports.--

(1) A vertically integrated health system shall report on the effectiveness of the use of medical marijuana for the treatment of the serious medical condition studied and all counterindications and noted side effects.

(2) The department shall notify the vertically integrated health system and the university participating in the research study of the data which is required to meet the United States Food and Drug Administration's and the United States Drug Enforcement Administration's approval for the research study.

(3) The first report, including the data required under paragraph (2), shall be submitted to the department and made publicly available within 180 days of the initiation of a research study for a specific serious medical condition.

(4) An annual report of the data required under paragraph (2) shall be submitted to the department beginning one year after the initiation of a research study for a specific serious medical condition and each year thereafter.

Section 1904. Approval.

A vertically integrated health system located in this

Commonwealth may petition the department to participate in a research study to study a serious medical condition under section 1903. Approval of the vertically integrated health system as a health care medical marijuana organization by the department shall authorize access within a region under section 603(d) to medical marijuana for all patients included in an approved research study.

Section 1905. Requirements.

(a) Dispensing.--A health care medical marijuana organization that dispenses medical marijuana shall:

(1) Maintain licensure with the department as required under the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

(2) Secure the medical marijuana within the associated pharmacies of the health care medical marijuana organization in a manner and method prescribed by the department.

(3) Keep a daily log of the medical marijuana dispensed and the research study with which the patient and the medical marijuana are associated. Reports shall be delivered to the department and the university participating in the research study on a weekly basis.

(4) Report to the Pennsylvania Health Care Cost Containment Council the utilization rates of those patients participating in the research of medical marijuana and treatment options.

(5) Only dispense medical marijuana received from a grower/processor or a health care medical marijuana organization that is approved to grow and process medical marijuana.

(6) Provide all patients or caregivers with the safety insert, prepared by the department, which includes potential dangers, recognition and correction of problematic dosage and any other information required by the department or which the department deems relevant for patient safety.

(b) Growing and processing.--A health care medical marijuana organization that grows and processes medical marijuana shall:

(1) Maintain licensure with the department as required under the Health Care Facilities Act.

(2) Only make available medical marijuana to health care medical marijuana organizations that dispense medical marijuana.

(3) Keep a daily log of medical marijuana intended for ultimate use by patients participating in a research study.

Section 1906. Restrictions.

A health care medical marijuana organization may not participate in a research study of any kind, including the program established under this chapter, or dispense or grow and process medical marijuana if it has violated its licensure requirements under the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

Section 1907. Regulations.

The department shall, by regulation, establish the procedure to be used by a health care medical marijuana organization that grows and processes medical marijuana with respect to:

(1) Real time inventory tracking, including a seed-to-dispensing tracking system that tracks medical marijuana from seed or immature plant stage until the medical marijuana is

provided to a patient in a research study.

(2) Security, recordkeeping, record retention and surveillance systems relating to every stage of growing and processing medical marijuana.

(3) A daily log of each day's beginning inventory, acquisitions, disbursements, disposals and ending inventory.

(4) A system to recall defective medical marijuana.

(5) A system to track the plant waste resulting from the growth of medical marijuana.

(6) Testing of medical marijuana by an independent laboratory to test the medical marijuana produced by the health care medical marijuana organization, including requiring a test at harvest and a test at final processing.

(7) Any other procedure deemed necessary by the department.

Section 1908. Nonentitlement.

Nothing in this chapter shall be construed to create an entitlement or right of a patient to receive medical marijuana or to participate in a research study.

CHAPTER 20
ACADEMIC CLINICAL RESEARCH CENTERS AND CLINICAL REGISTRANTS
(Ch. hdg. amended June 22, 2018, P.L.322, No.43)

Section 2000. Legislative findings and declaration of policy.

(a) Legislative findings.--It is determined and declared as a matter of legislative finding:

(1) Patients suffering from serious medical conditions deserve the benefit of research conducted in conjunction with the Commonwealth's medical schools to determine whether medical marijuana will improve their conditions or symptoms.

(2) The Commonwealth has an interest in creating a mechanism whereby the Commonwealth's medical schools and hospitals can help develop research programs and studies in compliance with applicable law.

(b) Declaration of policy.--The General Assembly declares as follows:

(1) It is the intention of the General Assembly to create a mechanism whereby this Commonwealth's medical schools and hospitals may provide advice to grower/processors and dispensaries in the areas of patient health and safety, medical applications and dispensing and management of controlled substances, among other areas. It is the further intention of the General Assembly to create a mechanism whereby the Commonwealth may encourage research associated with medical marijuana.

(2) It is the policy of the Commonwealth to allow, in addition to the 25 grower/processors and 50 dispensaries initially authorized under section 616, the operation of additional grower/processors and dispensaries which will be approved by the department as clinical registrants. A clinical registrant is a grower/processor and a dispensary which has a contractual relationship with a medical school that operates or partners with a hospital to provide advice about medical marijuana so that patient safety may be enhanced.

(2000 added June 22, 2018, P.L.322, No.43)

Section 2001. Definitions.

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Academic clinical research center." An accredited medical school within this Commonwealth that operates or partners with an acute care hospital licensed within this Commonwealth that has been approved and certified by the department to enter into a contract with a clinical registrant.

"Accredited medical school." An institution located within this Commonwealth that is accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation or has gained pre-accreditation or provisional accreditation so that the institution is authorized to enroll students and is affiliated with an accredited institution of higher education located within this Commonwealth. (Def. added Dec. 14, 2023, P.L. , No.63)

"Clinical registrant." An entity that:

(1) is approved by the department as a clinical registrant;

(2) has a contractual relationship with an academic clinical research center under which the academic clinical research center or its affiliate provides advice to the entity, regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances; and

(3) is approved by the department to hold a permit as both a grower/processor and a dispensary.

(2001 amended June 22, 2018, P.L.322, No.43)

Section 2001.1. Academic clinical research centers.

(a) General rule.--An academic clinical research center must be approved and certified by the department before the academic clinical research center may contract with a clinical registrant. An academic clinical research center shall only contract with one clinical registrant. The accredited medical school that is seeking approval and certification from the department as an academic clinical research center must provide all information required by the department, including information for the individual who will be the primary contact for the academic clinical research center during the department's review of the application. The accredited medical school must also provide all information required by the department for any licensed acute care hospital that the accredited medical school will operate or partner with during the time that it may be approved and certified as an academic clinical research center by the department. ((a) amended June 30, 2021, P.L.210, No.44)

(b) Posting and publication of list.--The department shall post a list containing the name and address of each certified academic clinical research center on the department's publicly accessible Internet website and publish the list in the Pennsylvania Bulletin.

(2001.1 added June 22, 2018, P.L.322, No.43)

Section 2002. Clinical registrants.

(a) Approval.--The department may approve up to 10 clinical registrants. Each clinical registrant may provide medical marijuana at not more than six separate locations. The total

number of locations authorized to dispense medical marijuana under this section shall not exceed 60. The grower/processor and dispensary permits issued to clinical registrants approved under this section shall be in addition to the 25 grower/processor and 50 dispensary permits issued by the department in accordance with section 616(1) and (2). The limitations relating to number and location in sections 616(1) and (2) and 603(d) do not apply. A clinical registrant may not hold more than one grower/processor and one dispensary permit. Once the department approves an entity as a clinical registrant, the entity shall comply with this chapter. The following shall apply:

(1) The department shall:

(i) Open applications for the approval of up to two additional academic clinical research centers and issue approvals to qualified academic clinical research centers within 90 days of the effective date of this paragraph.

(ii) Open applications for the approval of up to two additional clinical registrants within 120 days of the effective date of this paragraph and issue permits to qualified clinical registrants within 180 days from the date when applications are posted.

(2) If the statutory maximum number of approved academic clinical research centers or approved clinical registrants are not approved under paragraph (1), the department shall reopen the application process for the approval of academic clinical research centers and clinical registrants.

((a) amended June 30, 2021, P.L.210, No.44)

(b) Requirements.--The following shall apply to clinical registrants:

(1) An entity seeking approval as a clinical registrant shall submit an application to the department in such form and manner as the department prescribes. The department shall ensure that the applicant meets the requirements of this act before approving the application to become a clinical registrant.

(2) An entity may be issued a permit as a grower/processor or dispensary before seeking approval as a clinical registrant. An entity may also apply for a permit as a grower/processor or a dispensary at the same time the entity seeks approval from the department as a clinical registrant.

(3) An entity seeking approval as a clinical registrant that does not already hold a permit as a grower/processor or a dispensary shall submit the applications required under Chapter 6. In reviewing an application, the department shall ensure that the entity meets all of the requirements for the issuance of a grower/processor permit or a dispensary permit, as applicable.

(4) When the department issues a permit as a grower/processor or a dispensary to an entity seeking approval as a clinical registrant, the issuance shall not be construed to reduce the number of permits for growers/processors and dispensaries authorized under section 616(1) and (2).

(i) The department shall not approve an applicant for a grower/processor permit if the applicant has previously had a contractual relationship with an academic clinical research center whereby the academic clinical research

center or its affiliate provided advice to the applicant regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances and the applicant subsequently sold or assigned for profit to another entity their responsibility under the contractual relationship.

(ii) (Reserved).

((4) amended June 30, 2021, P.L.210, No.44)

(5) Except as provided in section 607(1)(vi) and (2)(vi), an entity seeking approval as a clinical registrant must pay the fees and meet all other requirements under this act for obtaining a permit as a grower/processor and a dispensary. Upon approval of the department, a clinical registrant shall be issued a grower/processor permit and a dispensary permit and shall be a medical marijuana organization. As a medical marijuana organization, a clinical registrant must comply with all the provisions of this act relating to medical marijuana organizations except as otherwise provided in this chapter.

(6) The clinical registrant must have a minimum of $15,000,000 in capital. The department shall verify the capital requirement.

(7) The clinical registrant shall have all of the same rights as a grower/processor permittee and must comply with all other requirements of this act regarding growing, processing and dispensing medical marijuana. ((7) amended June 30, 2021, P.L.210, No.44)

(8) A grower/processor facility owned by a clinical registrant may sell its medical marijuana products to all dispensary facilities. The facility may sell seeds, medical marijuana plants and medical marijuana products to, or exchange seeds, medical marijuana plants and medical marijuana products with, any other grower/processor facility holding a permit under Chapter 6 or this chapter. ((8) amended June 30, 2021, P.L.210, No.44)

(9) A clinical registrant may petition the department, on a form prescribed by the department, for approval to sell certain of the medical marijuana products grown and processed by its grower/processor facility to other medical marijuana organizations holding dispensary permits under Chapter 6. The petition must be accompanied by a written report of the clinical registrant's research findings with respect to the medical marijuana products which are the subject of the petition. The department shall approve the petition if it has been demonstrated that the medical marijuana products have a practical effect on patients which changes a recommendation within the medical field as indicated in the report submitted by the clinical registrant.

(10) A dispensary owned by a clinical registrant may dispense medical marijuana products to a patient or caregiver who presents a valid identification card to an employee who is authorized to dispense medical marijuana products at a dispensary location operated by the clinical registrant, regardless of whether the patient is a participant in a research study or program.

(2002 amended June 22, 2018, P.L.322, No.43)

Section 2003. Research study.

(a) Applicability.--The provisions of this section shall apply upon publication of the notice under section 2108.

(b) Procedures.--The department may, upon application, approve the dispensing of medical marijuana by a clinical registrant to the academic clinical research center for the purpose of conducting a research study. The department shall develop the application and standards for approval of such dispensing by the clinical registrant. The following apply to the research study:

(1) The clinical registrant shall disclose the following information to the department in its application:

(i) The reason for the research project, including the reason for the trial.

(ii) The strain and strength of medical marijuana to be used in the research study.

(iii) The anticipated duration of the study.

(iv) Evidence of approval of the trial by an accredited institutional review board and any other required regulatory approvals.

(v) Other information required by the department, except that the department may not require disclosure of any information that would infringe upon the academic clinical research center's exclusive right to intellectual property or legal obligations for patient confidentiality.

(2) The academic clinical research center shall provide its findings to the department within 365 days of the conclusion of the research study or within 365 days of publication of the results of the research study in a peer-reviewed medical journal, whichever is later.

(3) The department shall allow the exchange of medical marijuana seed between clinical registrants for the conduct of research.

(2003 amended June 22, 2018, P.L.322, No.43)

Section 2003.1. Research initiative.

(a) Authority.--An academic clinical research center, in coordination with its contracted clinical registrant, may conduct a research initiative on the antimicrobial effects of applying solvent-based extraction methods and processes to microbial contamination of immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.

(b) Procedure.--An academic clinical research center shall submit to the department for approval a completed written research protocol of the planned research initiative. The department shall grant approval or denial of the protocol within 15 days of its submissions. The following apply:

(1) The research initiative shall commence no later than 30 days from the date the department issues approval and shall be completed no later than six months from the start date of the research initiative.

(2) Research initiative findings shall be provided to the department by the academic clinical research center within 15 days of the research initiative's conclusion.

(3) An academic clinical research center and its contracted clinical registrant shall present research initiative findings to the advisory board and the board's research subcommittee for the board's review and consideration under sections 1201 and 1202. The board shall issue a written

report, with recommendations and findings regarding the use of solvent-based extraction methods and processes on microbial contamination by a clinical registrant or grower/processor. The secretary may approve the board's recommendation in accordance with section 1202.

(4) Prior to implementing a recommendation of the board under paragraph (3), as approved by the secretary, a clinical registrant or grower/processor shall seek approval from the department for a change in its grower/processor extraction process. The department shall inspect the site and facility equipment. Upon approval, the department shall issue a notice of final approval to implement the process.

(2003.1 added June 30, 2021, P.L.210, No.44)

Section 2004. Temporary regulations.

(a) Promulgation.--In order to facilitate the prompt implementation of this chapter, the department shall promulgate temporary regulations that shall expire not later than two years following the publication of the temporary regulations. The temporary regulations shall not be subject to:

(1) Sections 201, 202, 203, 204 and 205 of the act of July 31, 1968 (P.L.769, No.240), referred to as the Commonwealth Documents Law.

(2) The act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act.

(3) Sections 204(b) and 301(10) of the act of October 15, 1980 (P.L.950, No.164), known as the Commonwealth Attorneys Act.

(b) Expiration.--The department's authority to adopt temporary regulations under subsection (a) shall expire six months after the effective date of this section. Regulations adopted after this period shall be promulgated as provided by law.

(c) Publication.--The department shall begin publishing temporary regulations in the Pennsylvania Bulletin no later than 90 days after the effective date of this section.

(2004 added June 22, 2018, P.L.322, No.43)

CHAPTER 21
MISCELLANEOUS PROVISIONS

Section 2101. Conflict.

The growth, processing, manufacture, acquisition, transportation, sale, dispensing, distribution, possession and consumption of medical marijuana permitted under this act shall not be deemed to be a violation of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act. If a provision of the Controlled Substance, Drug, Device and Cosmetic Act relating to marijuana conflicts with a provision of this act, this act shall take precedence.

Section 2101.1. Financial and employment interests.

(a) Financial interests.--Except as may be provided for the judiciary by rule or order of the Pennsylvania Supreme Court, an executive-level public employee, public official or party officer, or an immediate family member thereof, shall not intentionally or knowingly hold a financial interest in a medical marijuana organization or in a holding company, affiliate, intermediary or subsidiary thereof, while the individual is an executive-level

public employee, public official or party officer and for one year following termination of the individual's status as an executive-level public employee, public official or party officer.

(b) Employment.--Except as may be provided by rule or order of the Pennsylvania Supreme Court, no executive-level public employee, public official or party officer, or an immediate family member thereof, shall be employed by a medical marijuana organization or by any holding company, affiliate, intermediary or subsidiary thereof, while the individual is an executive-level public employee, public official or party officer and for one year following termination of the individual's status as an executive-level public employee, public official or party officer.

(c) Grading.--An individual who violates this section commits a misdemeanor and shall, upon conviction, be sentenced to pay a fine of not more than $1,000 or to imprisonment for not more than one year, or both.

(d) State Ethics Commission.--The State Ethics Commission shall do all of the following:

(1) Issue a written determination of whether a person is subject to subsection (a) or (b) upon the written request of the person or any other person that may have liability for an action taken with respect to such person. A person that relies in good faith on a determination made under this paragraph shall not be subject to any penalty for an action taken, provided that all material facts set forth in the request for the determination are correct.

(2) Publish a list of all State, county, municipal and other government positions that meet the definitions of "public official" or "executive-level public employee" as defined under 4 Pa.C.S. § 1512(b) (relating to financial and employment interests). The Office of Administration shall assist the State Ethics Commission in the development of the list, which shall be published by the State Ethics Commission in the Pennsylvania Bulletin biennially and posted by the department on the department's Internet website. Upon request, each public official shall have a duty to provide the State Ethics Commission with adequate information to accurately develop and maintain the list. The State Ethics Commission may impose a civil penalty under 65 Pa.C.S. § 1109(f) (relating to penalties) upon any individual, including any public official or executive-level public employee, who fails to cooperate with the State Ethics Commission under this subsection. A person that relies in good faith on the list published by the State Ethics Commission shall not be subject to any penalty for a violation of this section.

(e) Definitions.--As used in this section, the following words and phrases shall have the meanings given to them in this subsection:

"Financial interest." As defined in 4 Pa.C.S. § 1512(b).

"Immediate family." As defined in 4 Pa.C.S. § 1512(b).

"Party officer." As defined in 4 Pa.C.S. § 1512(b).

"Public official." The term shall include the following:

(1) The Governor, Lieutenant Governor, a member of the Governor's cabinet, Treasurer, Auditor General and Attorney General of the Commonwealth.

(2) A member of the Senate or House of Representatives of

the Commonwealth.

(3) An individual elected or appointed to any office of a county or municipality that directly receives a distribution of revenue from the fund.

(4) An individual elected or appointed to a department, agency, board, commission, authority or other governmental body not included in paragraph (1), (2) or (3) that directly receives a distribution of revenue from the fund.

(5) An individual elected or appointed to a department, agency, board, commission, authority, county, municipality or other governmental body not included in paragraph (1), (2) or (3) with discretionary power which may influence or affect the outcome of an action or decision and who is involved in the development of regulation or policy relating to a medical marijuana organization or who is involved in other matters under this act.

The term does not include a member of a school board or an individual who held an uncompensated office with a governmental body prior to January 1, 2017, and who no longer holds the office as of January 1, 2017.

Section 2102. Insurers.

Nothing in this act shall be construed to require an insurer or a health plan, whether paid for by Commonwealth funds or private funds, to provide coverage for medical marijuana.

Section 2103. Protections for patients and caregivers.

(a) Licensure.--None of the following shall be subject to arrest, prosecution or penalty in any manner, or denied any right or privilege, including civil penalty or disciplinary action by a Commonwealth licensing board or commission, solely for lawful use of medical marijuana or manufacture or sale or dispensing of medical marijuana, or for any other action taken in accordance with this act:

(1) A patient.

(2) A caregiver.

(3) A practitioner.

(4) A medical marijuana organization.

(5) A health care medical marijuana organization or university participating in a research study under Chapter 19.

(6) A clinical registrant or academic clinical research center under Chapter 20.

(7) An employee, principal or financial backer of a medical marijuana organization.

(8) An employee of a health care medical marijuana organization or an employee of a university participating in a research study under Chapter 19.

(9) An employee of a clinical registrant or an employee of an academic clinical research center under Chapter 20.

(10) A pharmacist, physician assistant or certified registered nurse practitioner under section 801(b).

(b) Employment.--

(1) No employer may discharge, threaten, refuse to hire or otherwise discriminate or retaliate against an employee regarding an employee's compensation, terms, conditions, location or privileges solely on the basis of such employee's status as an individual who is certified to use medical marijuana.

(2) Nothing in this act shall require an employer to make any accommodation of the use of medical marijuana on the property or premises of any place of employment. This act shall in no way limit an employer's ability to discipline an employee for being under the influence of medical marijuana in the workplace or for working while under the influence of medical marijuana when the employee's conduct falls below the standard of care normally accepted for that position.

(3) Nothing in this act shall require an employer to commit any act that would put the employer or any person acting on its behalf in violation of Federal law.

(c) Custody determination.--The fact that an individual is certified to use medical marijuana and acting in accordance with this act shall not by itself be considered by a court in a custody proceeding. In determining the best interest of a child with respect to custody, the provisions of 23 Pa.C.S. Ch. 53 (relating to child custody) shall apply.

Section 2104. Schools.

The Department of Education shall promulgate regulations within 18 months of the effective date of this section regarding the following:

(1) Possession and use of medical marijuana by a student on the grounds of a preschool, primary school and a secondary school.

(2) Possession and use of medical marijuana by an employee of a preschool, primary school and a secondary school on the grounds of such school.

Section 2105. Day-care centers.

The Department of Human Services shall promulgate regulations within 18 months of the effective date of this section regarding the following:

(1) Possession and use of medical marijuana by a child under the care of a child-care or social service center licensed or operated by the Department of Human Services.

(2) Possession and use of medical marijuana by an employee of a child-care or social service center licensed or operated by the Department of Human Services.

(3) Possession and use of medical marijuana by employees of a youth development center or other facility which houses children adjudicated delinquent, including the separate, secure State-owned facility or unit for sexually violent children, as set forth in section 1309(3).

Section 2106. Medical marijuana from other states (Expired).

Section 2107. Zoning.

The following apply:

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

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

Section 2108. Notice.

Upon amendment of the Controlled Substances Act (Public Law 91-513, 84 Stat. 1236) removing marijuana from Schedule I of the Controlled Substances Act, the department shall publish notice of

the effective date of the amendment in the Pennsylvania Bulletin.

Section 2109. Applicability.

(a) ((a) deleted by amendment June 30, 2021, P.L.210, No. 44)

(b) Issuance.--The issuance of permits and other authorizations shall begin upon publication of a notice by the department in the Pennsylvania Bulletin that adequate temporary or permanent regulations have been adopted to initiate the program under this act.

Section 2110. Effective date.

This act shall take effect in 30 days.

Pennsylvania Department of Health
Office of Medical Marijuana Report

July 2022

pennsylvania
DEPARTMENT OF HEALTH

Table of Contents

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 26th 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:101159/000507998)

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, Hajjar 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.

MEDICAL MARIJUANA ACT - LEGISLATIVE FINDINGS AND DECLARATION OF POLICY, ACADEMIC CLINICAL RESEARCH CENTERS, CLINICAL REGISTRANTS, RESEARCH STUDY AND TEMPORARY REGULATIONS

Act of Jun. 22, 2018, P.L. 322, No. 43 Cl. 35

Session of 2018
No. 2018-43

HB 2477

AN ACT

Amending the act of April 17, 2016 (P.L.84, No.16), entitled "An act establishing a medical marijuana program; providing for patient and caregiver certification and for medical marijuana organization registration; imposing duties on the Department of Health; providing for a tax on medical marijuana organization gross receipts; establishing the Medical Marijuana Program Fund; establishing the Medical Marijuana Advisory Board; establishing a medical marijuana research program; imposing duties on the Department of Corrections, the Department of Education and the Department of Human Services; and providing for academic clinical research centers and for penalties and enforcement," in academic clinical research centers, further providing for chapter heading, providing for legislative findings and declaration of policy, further providing for definitions, providing for academic clinical research centers, further providing for clinical registrants and for research study and providing for temporary regulations.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Chapter 20 heading of the act of April 17, 2016 (P.L.84, No.16), known as the Medical Marijuana Act, is amended to read:

CHAPTER 20

ACADEMIC CLINICAL RESEARCH CENTERS **AND CLINICAL REGISTRANTS**

Section 2. The act is amended by adding a section to read:

Section 2000. Legislative findings and declaration of policy.

(a) Legislative findings.--It is determined and declared as a matter of legislative finding:

(1) Patients suffering from serious medical conditions deserve the benefit of research conducted in conjunction with the Commonwealth's medical schools to determine whether medical marijuana will improve their conditions or symptoms.

(2) The Commonwealth has an interest in creating a mechanism whereby the Commonwealth's medical schools and hospitals can help develop research programs and studies in compliance with applicable law.

(b) Declaration of policy.--The General Assembly declares as follows:

(1) It is the intention of the General Assembly to create a mechanism whereby this Commonwealth's medical schools and hospitals may provide advice to grower/processors and

dispensaries in the areas of patient health and safety, medical applications and dispensing and management of controlled substances, among other areas. It is the further intention of the General Assembly to create a mechanism whereby the Commonwealth may encourage research associated with medical marijuana.

(2) It is the policy of the Commonwealth to allow, in addition to the 25 grower/processors and 50 dispensaries initially authorized under section 616, the operation of additional grower/processors and dispensaries which will be approved by the department as clinical registrants. A clinical registrant is a grower/processor and a dispensary which has a contractual relationship with a medical school that operates or partners with a hospital to provide advice about medical marijuana so that patient safety may be enhanced.

Section 3. Section 2001 of the act is amended to read:

Section 2001. Definitions.

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Academic clinical research center." An accredited medical school within this Commonwealth that operates or partners with an acute care hospital licensed within this Commonwealth **that has been approved and certified by the department to enter into a contract with a clinical registrant.**

"Clinical registrant." An entity that:

(1) [holds a permit as both a grower/processor and a dispensary; and] **is approved by the department as a clinical registrant;**

(2) has a contractual relationship with an academic clinical research center under which the academic clinical research center or its affiliate provides advice to the entity, regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances[.]; **and**

(3) is approved by the department to hold a permit as both a grower/processor and a dispensary.

Section 4. The act is amended by adding a section to read:

Section 2001.1. Academic clinical research centers.

(a) General rule.--An academic clinical research center must be approved and certified by the department before the academic clinical research center may contract with a clinical registrant. The accredited medical school that is seeking approval and certification from the department as an academic clinical research center must provide all information required by the department, including information for the individual who will be the primary contact for the academic clinical research center during the department's review of the application. The accredited medical school must also provide all information required by the department for any licensed acute care hospital that the accredited medical school will operate or partner with during the time that it may be approved and certified as an academic clinical research center by the department.

(b) Posting and publication of list.--The department shall post a list containing the name and address of each certified academic clinical research center on the department's publicly

accessible Internet website and publish the list in the Pennsylvania Bulletin.

Section 5. Sections 2002 and 2003 of the act are amended to read:

Section 2002. Clinical registrants.

[Notwithstanding the limitations in section 616, the] **(a) Approval.--The** department may [register] **approve** up to eight clinical registrants. Each [entity] **clinical registrant** may provide medical marijuana at not more than six separate locations. The total number of locations authorized to dispense medical marijuana under this section shall not exceed 48. [The following apply with respect to this category of clinical registrant:

(1) A] **The grower/processor and dispensary permits issued to clinical registrants approved under this section shall be in addition to the 25 grower/processor and 50 dispensary permits issued by the department in accordance with section 616(1) and (2). The limitations relating to number and location in sections 616(1) and (2) and 603(d) do not apply. A clinical registrant may not hold more than one grower/processor and one dispensary permit. Once the department approves the entity as a clinical registrant, the entity shall comply with this chapter.**

(b) Requirements.--The following shall apply to clinical registrants:

(1) An entity seeking approval as a clinical registrant shall submit an application to the department in such form and manner as the department prescribes. The department shall ensure that the applicant meets the requirements of this act before approving the application to become a clinical registrant.

(2) An entity may be issued a permit as a grower/processor or dispensary before seeking approval as a clinical registrant. An entity may also apply for a permit as a grower/processor or a dispensary at the same time the entity seeks approval from the department as a clinical registrant.

(3) An entity seeking approval as a clinical registrant that does not already hold a permit as a grower/processor or a dispensary shall submit the applications required under Chapter 6. In reviewing an application, the department shall ensure that the entity meets all of the requirements for the issuance of a grower/processor permit or a dispensary permit, as applicable.

(4) When the department issues a permit as a grower/processor or a dispensary to an entity seeking approval as a clinical registrant, the issuance shall not be construed to reduce the number of permits for growers/processors and dispensaries authorized under section 616(1) and (2).

(5) Except as provided in section 607(1)(vi) and (2)(vi), an entity seeking approval as a clinical registrant must pay the fees and meet all other requirements under this act for obtaining a permit as a grower/processor and a dispensary.[, except as provided under section 607(1)(vi) and (2)(vi).

(2)] **Upon approval of the department, a clinical registrant shall be issued a grower/processor permit and a dispensary permit and shall be a medical marijuana organization. As a medical marijuana organization, a clinical registrant must comply with all the provisions of this act relating to medical**

marijuana organizations except as otherwise provided in this chapter.

(6) The clinical registrant must have a minimum of $15,000,000 in capital. The department shall verify the capital requirement.

[(3)] **(7)** The clinical registrant must comply with all other requirements of this act regarding growing, processing and dispensing medical marijuana.

(8) A grower/processor facility owned by a clinical registrant may sell its medical marijuana products only to the clinical registrant's dispensary facilities and the dispensary facilities of other clinical registrants. The facility may sell seeds, medical marijuana plants and medical marijuana products to, or exchange seeds, medical marijuana plants and medical marijuana products with, any other grower/processor facility holding a permit under Chapter 6 or this chapter.

(9) A clinical registrant may petition the department, on a form prescribed by the department, for approval to sell certain of the medical marijuana products grown and processed by its grower/processor facility to other medical marijuana organizations holding dispensary permits under Chapter 6. The petition must be accompanied by a written report of the clinical registrant's research findings with respect to the medical marijuana products which are the subject of the petition. The department shall approve the petition if it has been demonstrated that the medical marijuana products have a practical effect on patients which changes a recommendation within the medical field as indicated in the report submitted by the clinical registrant.

(10) A dispensary owned by a clinical registrant may dispense medical marijuana products to a patient or caregiver who presents a valid identification card to an employee who is authorized to dispense medical marijuana products at a dispensary location operated by the clinical registrant, regardless of whether the patient is a participant in a research study or program.

Section 2003. Research study.

[Notwithstanding any provision of this act to the contrary, the] **(a) Applicability.--The provisions of this section shall apply upon publication of the notice under section 2108.**

(b) Procedures.--The department may, upon application, approve the dispensing of medical marijuana by a clinical registrant to the academic clinical research center for the purpose of conducting a research study. The department shall develop the application and standards for approval of such dispensing by the clinical registrant. The following apply to the research study:

(1) The clinical registrant shall disclose the following information to the department in its application:

(i) The reason for the research project, including the reason for the trial.

(ii) The strain **and strength** of medical marijuana to be used [and the strength of the medical marijuana to be used] in the research study.

(iii) The anticipated duration of the study.

(iv) Evidence of approval of the trial by an accredited institutional review board[, including] **and** any

other required regulatory approvals.

(v) Other information required by the department, except that the department may not require disclosure of any information that would infringe upon the academic clinical research center's exclusive right to intellectual property or legal obligations for patient confidentiality.

(2) The academic clinical research center shall provide its findings to the department within 365 days of the conclusion of the research study or within 365 days of publication of the results of the research study in a peer-reviewed medical journal, whichever is later.

(3) The department shall allow the exchange of medical marijuana seed between clinical registrants for the conduct of research.

Section 6. The act is amended by adding a section to read:

Section 2004. Temporary regulations.

(a) Promulgation.--In order to facilitate the prompt implementation of this chapter, the department shall promulgate temporary regulations that shall expire not later than two years following the publication of the temporary regulations. The temporary regulations shall not be subject to:

(1) Sections 201, 202, 203, 204 and 205 of the act of July 31, 1968 (P.L.769, No.240), referred to as the Commonwealth Documents Law.

(2) The act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act.

(3) Sections 204(b) and 301(10) of the act of October 15, 1980 (P.L.950, No.164), known as the Commonwealth Attorneys Act.

(b) Expiration.--The department's authority to adopt temporary regulations under subsection (a) shall expire six months after the effective date of this section. Regulations adopted after this period shall be promulgated as provided by law.

(c) Publication.--The department shall begin publishing temporary regulations in the Pennsylvania Bulletin no later than 90 days after the effective date of this section.

Section 7. This act shall take effect immediately.

APPROVED--The 22nd day of June, A.D. 2018.

TOM WOLF