

MEDICAL MARIJUANA ORGANIZATION PERMIT APPLICATION, CLINICAL REGISTRANTS

Instructions

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I. CLINICAL REGISTRANTS 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), which includes a research program component, 35 P.S. §§ 10231.101-10231.2110.

In order to facilitate research programs, the Department intends to approve up to 8 clinical registrants.

An applicant who does not already hold a grower/processor permit, a dispensary permit, or both, must apply for the appropriate permit(s). Each unique permit application must be accompanied by the appropriate fees.

An applicant who has already been issued a grower/processor permit or a dispensary permit and who wishes to become a clinical registrant, shall submit, with the application for approval as a clinical registrant, a request for conversion of an existing permit pursuant to 28 Pa. Code 1211.28.

Applicants should understand the Act and its accompanying temporary regulations at 28 Pa. Code Chapters 1141, 1151, 1161, 1171, 1181, 1191 and 1211 (temporary 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.

Please note: Permit applications that were previously submitted in Phase I or Phase II will not be considered for approval as a clinical registrant. An applicant must submit a new, timely application package with the required fees to be considered .

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



A dispensary permit held by an approved clinical registrant may be used to dispense medical marijuana at no more than six separate locations as approved by the Department, no more than three of which shall be located in the same region or in the same county.

FEES

Initial Application Fees and Initial 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. Initial Application Fees are non-refundable. Initial Permit Fees will be refunded if the applicant is not issued a permit. Refunds will be issued to the business name provided in Section 1 of 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:

Initial Application Fee: \$10,000

Initial Permit Fee: \$200,000

Dispensary Permit Applications:

Initial Application Fee: \$5,000

Initial Permit Fee: \$30,000 per dispensary location identified in the application, up to \$180,000

APPLICATION TIMETABLE

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

October 4, 2018:

Clinical registrant permit applications and accompanying attachments as well as application instructions will be available on Pennsylvania’s Medical Marijuana [website](#).

November 8, 2018:

The latest date for which the Department will accept permit application packages. (See Section IV below, “Preparing and Submitting Your Application”).

DEFINITIONS FOR TERMS WITHIN APPLICATION DOCUMENTS

The definitions for the words and terms used in the permit application documents are set forth in the Act and its temporary regulations.

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

II. DISCLOSURE OF APPLICATION INFORMATION

INFORMATION SUBJECT TO DISCLOSURE

Permit 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 § 1141.29 (a)(2), to the extent that your application package contains trade secret or confidential proprietary information, an applicant also must submit a redacted application.

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:

1. Redact **ONLY** trade secret or confidential proprietary information *as defined under the RTKL*.
2. 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)

3. All redactions must be marked. Do not withhold or delete portions of the redacted application.
4. Do not lock, password protect, or otherwise secure the redacted copy from editing, organizing and printing.
5. 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.
6. 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.
7. Failure to include a redacted application will result in disclosure to the public of any trade secret or confidential proprietary information contained within your application.

OTHER INFORMATION EXEMPT FROM DISCLOSURE

Should the Department receive a RTKL request for a permit application, the Department will redact any other information exempt from disclosure under the RTKL, the Act and the temporary 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 permit 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 a permit 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 temporary regulations.

INDIVIDUALS WITH CONTROLLING INTEREST

In the permit 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 any security in the entity.

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 does not apply to an owner of securities in a publicly traded company if the Department determines that the owner is not substantially involved in the activities of the medical marijuana organization.

A financial backer, principal or employee may not hold a volunteer position, position for remuneration or otherwise be affiliated with a medical marijuana organization or a clinical registrant 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 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.

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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 Names and Codes listed below. DO NOT use these codes for any other purpose.

All background check results will be mailed 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 corresponding service code (also referred to as Authorization or Coupon Code) based on the individual’s affiliation with the organization.
 - Financial Backer – 1KG8GT
 - Employee – 1KG8JR
 - Operator – 1KG8H7
 - Principal – 1KG8F9
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 application for a grower/processor permit or a dispensary permit.
2. The completed checklist and signed signature page (Attachment A).
3. Completed attachments B through L.
4. Redacted version of the completed permit application and all accompanying attachments, redacted according to the instructions provided in Section II.
5. Appropriate Initial Application Fees and Initial Permit Fees, 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.

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6. The Department will consider any application sent by mail to have been received on the date it is deposited in the 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 November 8, 2018 deadline.

COMPLETING THE APPLICATION

Complete every section of the permit 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.

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_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 permit 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.pdf

Please note:

- Do not lock, password protect, or otherwise secure any file.
- Paper submittals will be returned to the applicant without further consideration.
- 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:

Office 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 an application is complete but the Department needs additional information to make a determination, the Department will request, in writing, the information and documentation it requires. The applicant will have 30 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 that is not considered to be complete will be rejected by the Department and returned to the applicant, without further consideration, and the Initial Permit Fee will be refunded. The Initial Application Fee, however, is non-refundable.

An application package that is postmarked after the November 8, 2018 deadline will be rejected by the Department and returned to the applicant without further consideration, along with the Initial Application Fee and Initial Permit Fee.

CHANGES DURING APPLICATION PROCESS OR PERMIT TERM

During the application process, while the permit 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 initial permit application.

Please note: the Department will only take into consideration the permit application and attachments that are received on or before the November 8, 2018 deadline. Documentation that is postmarked after the November 8, 2018 deadline 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):

- (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.

The Department may also consider the following factors about each Medical Marijuana Region in its determination to grant or deny a permit:

- Regional population
- The number of patients suffering from a serious medical condition
- The types of serious medical conditions in the region
- Access to public transportation
- The health care needs of rural and urban areas
- Areas with recognized need for economic development

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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.

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

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27 – Capital Requirements	✓		
Subtotal			75
PART F – Community Impact			
28 – Community Impact		100	100
ATTACHMENTS			
Attachment A: Signature Page	✓		
Attachment B: Organizational Documents	✓		
Attachment C: Property Title, Lease, or Option to Acquire Property Location	✓		
Attachment D: Site and Facility Plan		50	
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	✓		
Attachment K: Release Authorization	✓		
Attachment L: Applicant Priorities for Multiple Applications	n/a	n/a	
Subtotal			50
TOTAL POSSIBLE POINTS			1,000

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Dispensary Permit Application Scoring	Pass/ Fail	Points per section	Subtotal
PART A – Applicant Identification and Dispensary Information			
1 – Applicant Name, Address and Contact Information	✓		
2 – Dispensary Information	✓		
PART B - Diversity Plan			
3 – Diversity Plan		100	100
PART C - Applicant Information			
4 – Principals, Financial Backers, Operators and Employees	✓		
5 – Moral Affirmation	✓		
6 – Compliance with Applicable Laws and Regulations	✓		
7 – Civil and Administrative Action	✓		
PART D – Plan of Operation			
8 – Operational Timetable		100	
9 – Employee Qualifications, Description of Duties and Training		50	
10 – Security and Surveillance		100	
11 – Transportation of Medical Marijuana		50	
12 – Storage of Medical Marijuana		75	
13 – Labeling of Medical Marijuana Products	✓		
14 – Inventory Management		75	
15 – Diversion Prevention		100	
16 – Sanitation and Safety		50	
17 – Recordkeeping		75	
Subtotal			675
PART E – Applicant Organization, Ownership, Capital and Tax Status			
18 – Organizational Structure	✓		
19 – Business History and Capacity to Operate		75	
20 – Current Officers	✓		
21 – Ownership	✓		
22 – Capital Requirements	✓		
Subtotal			75
PART F – Community Impact			
23 – Community Impact		100	100
ATTACHMENTS			
Attachment A: Signature Page	✓		
Attachment B: Organizational Documents	✓		
Attachment C: Property Title, Lease, or Option to Acquire Property Location	✓		
Attachment D: Site and Facility Plan		50	
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	✓		

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Attachment J: Sample Medical Marijuana Product Label	n/a	n/a	
Attachment K: Release Authorization	✓		
Attachment L: Applicant Priorities for Multiple Applications	n/a	n/a	
Subtotal			50
TOTAL POSSIBLE POINTS			1,000