# CHAPTER 1211a. CLINCIAL REGISTRANTS AND ACADEMIC CLINICAL RESEARCH CENTERS

Sec.


**Authority**

The provisions of this Chapter 1211a added under section 301(a)(3) and (b) of the Medical Marijuana Act (35 P.S. § 301(a)(3) and (b)), unless otherwise noted.

**Source**

The provisions of this Chapter 1211a added March 3, 2023, effective March 4, 2023, 53 Pa.B. 1275, unless otherwise noted.

## § 1211a.22. Clinical registrants generally.

(a) The qualifications that a clinical registrant shall meet to be approved by the Department are continuing qualifications.

(b) An applicant that has already been issued a grower/processor permit or a dispensary permit by the Department under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616) who wishes to become an approved clinical registrant shall:

(1) Submit a request to the Department under § 1211a.28 (relating to request for conversion of an existing permit) with the application for approval of a clinical registrant.

(2) Not be required to apply for, or be eligible to receive, an additional grower/processor permit or dispensary permit under the act, this chapter, Chapter 1141a, Chapter 1151a or Chapter 1161a (relating to general provisions; growers/processors; and dispensaries), as applicable.

(c) The Department will not approve more than ten clinical registrants.

(d) An approved clinical registrant may not dispense or offer to dispense, as a clinical registrant, any medical marijuana products at the clinical registrant dispensary location until:

(1) The clinical registrant's grower/processor and dispensary facilities have been inspected and deemed operational by the Department.

(2) The approved clinical registrant demonstrates to the satisfaction of the Department that it will be able to begin an approved research program or research study within 6 months following the date the Department determines the approved clinical registrant's dispensary to be operational.

(e) An approved 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 an approved clinical registrant under this chapter regardless of whether the patient is a participant in a research study.

## § 1211a.23. Limitation on permits.

(a) An approved clinical registrant may not hold more than one grower/processor permit and one dispensary permit.

(b) A dispensary permit held by an approved clinical registrant for use under this chapter may be used to dispense medical marijuana products at no more than six separate locations as approved in its application or under § 1161a.40 (relating to additional dispensary locations), each of which shall be dispensing medical marijuana for the purpose of conducting research.

(c) An approved clinical registrant may not locate more than three of its approved dispensaries in the same medical marijuana region or in the same county.

## § 1211a.24. Capital requirements.

An applicant shall provide all of the following information with its application under § 1211a.27 (relating to application for approval of a clinical registrant):

(1) An affidavit, on a form prescribed by the Department, stating that the applicant has at least $15 million in capital, which must include evidence that the applicant meets the capital requirements of a medical marijuana organization under § 1141a.30 (relating to capital requirements).

(2) A release sufficient to obtain information from a State governmental agency, financial institutions, an employer or any other person to verify the requirements of paragraph (1). Failure to provide a release will result in the rejection of the application for approval of a clinical registrant.

**Cross References**

This section cited in 28 Pa. Code § 1211a.27 (relating to application for approval of a clinical registrant).

## § 1211a.25. Certifying ACRCs.

(a) The qualifications that an ACRC shall meet to be approved by the Department are continuing qualifications.

(b) An accredited medical school may file an application with the Department to be certified as an ACRC using a form prescribed by the Department. The Department will publish a notice in the *Pennsylvania Bulletin* announcing the availability of the application and the time period during which the Department will accept applications.

(c) An application submitted under subsection (b) must include all of the following information:

(1) The legal name, address and telephone number of the accredited medical school and the name, telephone number and professional e-mail address of an individual at the accredited medical school who will be the primary contact for the Department during the Department's review of the application.

(2) The legal name, address and telephone number of the acute care hospital that is operated by or partnered with the accredited medical school and the name, telephone number and professional e-mail address of an individual at the accredited medical school who will be the primary contact for the Department during the Department's review of the application.

(3) An affidavit, on a form prescribed by the Department, disclosing any payments to the accredited medical school or any of its affiliates made by a person with whom the accredited medical school intends to enter into a research contract for purposes of operating as an approved clinical registrant or by any principal or financial backer of the person, up to and including the date of the submission of the application. The affidavit must include the amount and purpose of each payment made.

(4) A statement that the accredited medical school is currently accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation.

(5) A statement that the acute care hospital designated by the accredited medical school under paragraph (2) holds a valid license from the Department.

(6) The Federal and State tax identification numbers of the accredited medical school.

(7) A statement that a false statement made by the accredited medical school submitting the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

(d) The Department will publish a list containing the name and address of each ACRC on its publicly-accessible web site and in the *Pennsylvania Bulletin*.

**Cross References**

This section cited in 28 Pa. Code § 1211a.27 (relating to application for approval of a clinical registrant).

## § 1211a.26. Revocation of a certification of an ACRC.

(a) The certification of an ACRC will be revoked by the Department upon the occurrence of any of the following:

(1) The ACRC is no longer accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation, as applicable.

(2) The ACRC no longer operates or is partnered with the acute care hospital listed in its application for certification.

(3) The ACRC is no longer located in this Commonwealth.

(b) If the Department intends to revoke the certification of an ACRC under this section, the Department will provide written notice of its intention to the ACRC. Upon receipt of a notice under this subsection, the ACRC shall have 90 days from the date of the notice to provide the Department with evidence satisfactory to the Department that it has received reaccreditation by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation, as applicable, that it operates or is partnered with another acute care hospital or that it has relocated within this Commonwealth. If the ACRC does not comply with this subsection within 90 days from the date of the notice, the Department may revoke the certification of the ACRC.

## § 1211a.27. Application for approval of a clinical registrant.

(a) An applicant shall file an application for approval of a clinical registrant with the Department on a form prescribed by the Department. The Department will publish a notice in the *Pennsylvania Bulletin* announcing the availability of applications and the time period during which the Department will accept applications.

(b) An application for approval of a clinical registrant submitted under this section must include all of the following information:

(1) The legal name, address and telephone number of the applicant and the name, telephone number and professional e-mail address of an individual who will be the primary contact for the Department during the Department's review of the application.

(2) The name of the ACRC under § 1211a.25 (relating to certifying ACRCs).

(3) The applicant's Federal and State tax identification numbers.

(4) An affidavit, on a form prescribed by the Department, disclosing any payments made by the applicant, a principal or financial backer of the applicant to an ACRC or any affiliates of an ACRC, up to and including the date of the submission of the application. The affidavit must include the amount and purpose of each payment made.

(5) The name of an institution of higher education, if any, that will be participating in an approved research program or research study.



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(6) An affidavit and release under § 1211a.24 (relating to capital requirements).

(7) Evidence that the applicant is responsible and capable of successfully operating as an approved clinical registrant, including all of the following:

(i) A copy of the research contract between the applicant and the ACRC.

(ii) A description of the research program or research study the applicant and the ACRC intend to conduct.

(iii) A statement that the applicant may not engage in the business of selling, dispensing or offering to dispense medical marijuana products at an applicant's dispensary as a clinical registrant until the clinical registrant's grower/processor and dispensary facilities have been inspected and deemed operational by the Department.

(8) Except as provided in § 1211a.28 (relating to request for conversion of an existing permit), an application for a grower/processor permit under Chapters 1141a and 1151a (relating to general provisions; and growers/processors).

(9) Except as provided in § 1211a.28, an application for a dispensary permit under Chapter 1141a and Chapter 1161a (relating to dispensaries).

(10) A statement that a false statement made by the applicant is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

(c) An applicant may only include one ACRC in its application for approval of a clinical registrant.

(d) The following documents provided to the Department under this chapter are confidential and not subject to disclosure under the Right-to-Know Law (65 P.S. §§ 67.101—67.3104):

(1) A research contract.

(2) A description of a research program or research study.

(3) An ACRC's intellectual property.

(4) An approved clinical registrant's intellectual property.

**Cross References**

This section cited in 28 Pa. Code § 1211a.24 (relating to capital requirements); 28 Pa. Code § 1211a.28 (relating to request for conversion of an existing permit); 28 Pa. Code § 1211a.30 (relating to approval or denial of an application for approval of a clinical registrant); and 28 Pa. Code § 1211a.32 (relating to revocation of approval of a clinical registrant).

## § 1211a.27a. Research contracts.

(a) An applicant for approval as a clinical registrant shall provide, with its application, either an executed agreement or a letter of intent to enter into an agreement, with an ACRC, the effective date of which shall be on or after the effective date of the ACRC certification.

(b) A clinical registrant applicant may submit more than one application, with separate applications identifying distinct ACRCs.

(c) An ACRC may enter into a letter of intent with more than one clinical registrant applicant but may only execute a research contract with one approved clinical registrant.

(d) If more than one applicant for approval as a clinical registrant submits an application that includes a letter of intent with the same ACRC, the Department shall follow the following process in approving the applications:

(1) Determine initially that the CR application meets all of the following qualifications:

(i) Is complete.

(ii) Complies with the act and this part.

(iii) Meets the following minimum scoring requirements in each of the following application sections:

| *Grower Processor Application* | *Max Points/ Section* | *Minimum Acceptable Score* |
|---|---|---|
| 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 |
| 22—Recordkeeping | 25 | 11 |
| 24—Business History and Capacity to Operate | 75 | 31 |

| *Grower Processor Application* | *Max Points/ Section* | *Minimum Acceptable Score* |
|---|---|---|
| Attachment D: Site and Facility Plan | 50 | 21 |

| *Dispensary Application* | *Max Points/ Section* | *Minimum Acceptable Score* |
|---|---|---|
| 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 |
| 14—Inventory Management | 75 | 31 |
| 15—Diversion Prevention | 100 | 41 |
| 16—Sanitation and Safety | 50 | 21 |
| 17—Recordkeeping | 75 | 31 |
| 19—Business History and Capacity to Operate | 75 | 31 |
| Attachment D: Site and Facility Plan | 50 | 21 |

(2) The Department shall approve clinical registrant applicants that meet the standards of paragraph (1) in the following order:

(i) A clinical registrant applicant that holds a grower/processor permit and a dispensary permit, both of which are in good standing, and both medical marijuana organizations have been deemed operational by the Department. In applying this preference, the Department will look at the clinical registrant's primary dispensary location only.

(ii) A clinical registrant applicant that holds a grower/processor permit only that is in good standing and the applicant's medical marijuana organization has been deemed operational by the Department.

(iii) A clinical registrant applicant that holds a dispensary permit only that is in good standing and the applicant's primary dispensary location has been deemed operational by the Department.

(iv) A clinical registrant applicant that holds a grower/processor permit only that is in good standing, but has not been deemed operational by the Department.

(v) A clinical registrant applicant that holds a dispensary permit only that is in good standing, but has not had its primary location deemed operational by the Department.

(vi) A clinical registrant applicant that is applying for both a grower/processor permit and dispensary permit under this chapter. Awarding of approval to these clinical registrant applications shall be prioritized by ranking the sum of the grower/processor permit and dispensary permit application scores highest to lowest.

## § 1211a.28. Request for conversion of an existing permit.

(a) An applicant holding a grower/processor permit or a dispensary permit, or both, under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616), shall submit a request for conversion of an existing permit under this section on a form prescribed by the Department when submitting an application for approval of a clinical registrant under § 1211a.27 (relating to application for approval of a clinical registrant).

(b) Upon approval of a clinical registrant under subsection (a), the clinical registrant shall surrender its grower/processor permit or dispensary permit, or both, previously issued under sections 601—616 of the act.

(c) A grower/processor permit or dispensary permit, or both, surrendered under subsection (b) will increase the number of grower/processor permits or dispensary permits, as applicable, available to other persons applying for permits under sections 601—616 of the act, Chapter 1141a (relating to general provisions) and Chapter 1151a or Chapter 1161a (relating to growers/processors; and dispensaries), as applicable.

(d) An applicant may include additional dispensary locations in its request for conversion of an existing permit or may request additional dispensary locations at a later date under § 1161a.40 (relating to application for additional dispensary locations).

**Cross References**

This section cited in 28 Pa. Code § 1211a.22 (relating to clinical registrants generally); and 28 Pa. Code § 1211a.27 (relating to application for approval of a clinical registrant).

## § 1211a.29. Practices and procedures of research programs, projects or studies.

(a) Medical marijuana dispensed as part of a research program shall be dispensed only in a form permitted by the act or this part and only from a dispensary to a patient or to a caregiver.

(b) Marijuana dispensed under a research project or study may be dispensed, in any form deemed medically safe by an IRB, from a clinical registrant dispensary directly to an ACRC.

(c) A RAC or IRB shall adopt research procedures and shall review and approve each research program in accordance with the RAC or IRB established practices and procedures.

(d) An IRB shall review each proposed research project or study in accordance with the IRB's practices, procedures and protocols.

(e) A RAC or IRB shall ensure that each research program, project or study addresses all of the following:

(1) Protecting the rights and welfare of patients involved ia)(2.1))n research programs conducted under this chapter.

(2) Minimizing the risk to patients by using procedures that are consistent with sound research design and that do not unnecessarily expose patients to risk being performed on subjects for diagnosis or treatment purposes.

(3) Determining that the risks to patients involved in research programs are reasonable in relation to the anticipated benefits (if any) to the patients, and the importance of the knowledge that may be expected to result from the research program.

(4) Guaranteeing that informed consent will be sought from each prospective patient or the patient's legally authorized representative and is properly documented.

(5) Protecting the privacy of every patient.

## § 1211a.29a. Research initiative.

(a) An ACRC, 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) An ACRC 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 submission. 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 6 months from the start date of the research initiative.

(2) Research initiative findings shall be provided to the Department by the ACRC within 15 days of the research initiative's conclusion.

(3) An ACRC and its contracted clinical registrant shall present research initiative findings to the Medical Marijuana Advisory Board (Board) and the Board's research subcommittee for the Board's review and consideration under sections 1201 and 1202 of the act (35 P.S. §§ 10231.1201 and 10231.1202). The Board shall issue a written report, with recommendations and findings regarding the use of solvent-based extraction methods and processes on micro-

bial 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.

## § 1211a.30. Approval or denial of an application for approval of a clinical registrant.

(a) An applicant shall be an approved clinical registrant upon the Department's approval of an application under § 1211a.27 (relating to application for approval of a clinical registrant).

(b) The Department may deny the application for approval of a clinical registrant if the payments disclosed in the affidavit submitted under § 1211a.27(b)(4) violate the prohibition in § 1211a.34 (relating to prohibition).

(c) Before the Department denies an application for approval of a clinical registrant under subsection (b), the Department will provide the applicant with written notice specifying the violation. The applicant may submit to the Department, within 10 days following receipt of the Department's written notice, a supplemental affidavit indicating that the ACRC or its affiliate has refunded to the applicant or a principal or financial backer of the applicant that portion of payments in violation of § 1211a.34. Upon receipt of the supplemental affidavit, the Department may approve the application for approval of a clinical registrant. If the applicant fails to provide a supplemental affidavit within 10 days of the Department's written notice, the Department will deny the application for approval of a clinical registrant.

(c.1) The Department shall not approve an applicant for a grower/processor permit if the applicant has previously had a contractual relationship with an ACRC whereby the ACRC 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.

(d) An approved clinical registrant shall have the same rights and obligations as a medical marijuana organization that holds a grower/processor permit or a dispensary permit under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616) and Chapters 1141a, 1151a and 1161a (relating to general provisions; growers/processors; and dispensaries), as applicable, subject to any modifications or limitations in sections 2001—2003 of the act (35 P.S. §§ 10231.2001—10231.2003) and this chapter.

(e) A grower/processor permit and a dispensary permit issued to an approved clinical registrant will expire upon the nonrenewal, revocation or suspension by the Department of the approved clinical registrant's approval.

## § 1211a.31. Renewal of approval of a clinical registrant.

(a) The term of an approval of a clinical registrant will coincide with the term of the clinical registrant's grower/processor permit and dispensary permit.

(b) An approved clinical registrant shall renew its approval as part of the renewal for a grower/processor permit and a dispensary permit under § 1141a.36 (relating to permit renewal applications). The renewal application must be on a form prescribed by the Department and include all of the following:

(1) A copy of the research contract.

(2) A list of the approved research programs or research studies that are continuing or, if any of them are concluded, the dates they were concluded.

(3) A report of the current status of active research programs or research studies being conducted under the research contract, including preliminary findings, if applicable, and any expectations and projections the approved clinical registrant and the ACRC have for future research programs or research studies over the course of the 2 years following the date of submission of the report.

(4) A description of proposed research programs or research studies covered by the research contract that the approved clinical registrant intends to conduct within the next year following submission of the renewal application including evidence of IRB approval for each research program or research study.

(5) A statement that a false statement made by the approved clinical registrant or the ACRC is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

(c) The Department will not renew an approval for a clinical registrant under this section if the Department determines that none of the dispensary locations under the dispensary permit held by the approved clinical registrant are participating in an approved research program or research study and the approved clinical registrant does not intend to begin any additional approved research programs or research studies within the first 6 months following the approval of its application for renewal.

## § 1211a.32. Revocation of approval of a clinical registrant.

(a) The approval of a clinical registrant will be revoked immediately by the Department upon the occurrence of any of the following:

(1) The Department revokes, suspends or does not renew the grower/processor permit or dispensary permit held by the approved clinical registrant.

(2) Subject to subsection (b), the Department revokes the certification of the ACRC listed in the clinical registrant's application under § 1211a.27 (relating to application for approval of a clinical registrant).

(3) The research contract between the approved clinical registrant and the ACRC expires without being renewed or is terminated by either party.

(b) If the Department intends to revoke the certification of the ACRC under subsection (a)(2), the Department will provide written notice of its intention to the approved clinical registrant. Upon receipt of a notice under this subsection, the approved clinical registrant shall have 90 days from the date of the notice to contract with another ACRC that is not already a party to a research contract with another approved clinical registrant and to provide the Department with all relevant information relating to the ACRC. If the approved clinical registrant does not comply with this subsection within 90 days from the date of the notice, the Department may revoke the clinical registrant's approval.

## § 1211a.33. Dispensing and tracking medical marijuana products.

In addition to the information to be entered in the electronic tracking system under § 1161a.39 (relating to electronic tracking system) with respect to medical marijuana products dispensed to all patients and caregivers, the dispensary of an approved clinical registrant shall enter information into the electronic tracking system as required by the Department that identifies patients that are enrolled in an approved research program or research study.

## § 1211a.34. Prohibition.

Except for reasonable remuneration specifically in a research contract for the services to be performed or costs to be incurred by an ACRC, an ACRC may not solicit or accept anything of value from an approved clinical registrant or a principal or financial backer of an approved clinical registrant. Reasonable remuneration may include up-front deposits or other payments to an ACRC under a research contract to defray start-up and ongoing costs of the ACRC in connection with the establishment of the contractual relationship in the research contract. This section does not apply to charitable contributions that are part of a history of giving to an ACRC established 1 year or more prior to the effective date of the act.

**Cross References**

This section cited in 28 Pa. Code § 1211a.30 (relating to approval or denial of an application for approval of a clinical registrant).

## § 1211a.35. Reporting requirements.

(a) Except as provided in subsection (b), an approved clinical registrant shall provide a written report of the findings of its research program or research study to the Department within 365 days of the completion of an approved research program or research study.

(b) In the event the approved clinical registrant or its ACRC intends to submit a manuscript of the results of an approved research program or research study to a peer-reviewed medical journal for publication, the written report required under subsection (a) shall be provided to the Department within 30 days following publication.

(c) The Department may post the findings received under this section on its publicly-accessible web site and share them with other approved clinical registrants, ACRCs or any other person it determines would benefit from the findings.

## § 1211a.36. Sale or exchange.

(a) The grower/processor of an approved clinical registrant may sell or exchange the following items to another grower/processor:

(1) Seeds.

(2) Immature medical marijuana plants.

(3) Medical marijuana plants.

(4) Medical marijuana products.

(b) The grower/processor of an approved clinical registrant may sell its medical marijuana products to any dispensary.

## § 1211a.37. Appeals.

Sections 501—508 of 2 Pa.C.S. (relating to practice and procedure of Commonwealth agencies) and its accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure), apply to actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

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