CHAPTER 1210. CLINICAL REGISTRANTS AND ACADEMIC CLINICAL RESEARCH CENTERS—TEMPORARY REGULATIONS

Sec.

Authority

The temporary provisions of this Chapter 1210 issued under the Medical Marijuana Act (35 P.S. §§ 10231.101—10231.2110), unless otherwise noted.

Source

The temporary provisions of this Chapter 1210 adopted March 16, 2018, effective March 17, 2018, expire on March 17, 2010, 48 Pa.B. 1508, unless otherwise noted.

§ 1210.21. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

ACRC—An accredited medical school in this Commonwealth that operates or partners with an acute care hospital licensed and operating in this Commonwealth.

Accredited medical school—An institution that is:

(i) Located in this Commonwealth.

(ii) Accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation.

Acute care hospital—A facility having an organized medical staff that provides equipment and services primarily for inpatient medical care and other related services to persons who require definitive diagnosis or treatment, or both, for injury, illness, pregnancy or other disability and is licensed by the Department to operate as a hospital in this Commonwealth under the Health Care Facilities Act (35 P.S. §§ 448.101—448.904b) and the regulations promulgated thereunder.

Applicant—A person who submits an application to the Department to become an approved clinical registrant.

Approved clinical registrant—An entity that applied for and received the approval of the Department to do all of the following:

(i) Hold a permit as both a grower/processor and a dispensary.

(ii) Enter into a research contract with a certified ACRC.

Approved research project—A research project that has been approved by an institutional review board and submitted by an approved clinical registrant to the Department.

Certified ACRC—An ACRC that has applied for and has been certified by the Department to enter into a research contract with an approved clinical registrant.

Institution of higher education—A community college, State-owned institution, State-related institution, or private college or university approved by the Department of Education.

Institutional review board—Any board, committee or group designated by a certified ACRC that reviews and evaluates the anticipated scope of an approved clinical registrant's research involving patients or patient data.

Research—Any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research contract—A written agreement between an approved clinical registrant and a certified ACRC that contains the responsibilities and duties of each party with respect to the research project that the approved clinical registrant and the certified ACRC intend to conduct under this chapter and under which the certified ACRC will provide medical advice to the approved clinical registrant regarding, among other areas, patient health and safety, medical applications, and dispensing and management of controlled substances.

Research project—A distinct plan for research.

Research protocol—A written procedure for conducting a research project that includes all of the following information:

(i) With respect to the investigator:

(A) Name and address.

(B) Institutional affiliation.

(C) Qualifications, including a curriculum vitae and list of publications, if any.

(ii) With respect to the research project:

(A) Title of the project.

(B) Statement of the purpose.

(C) Type of medical marijuana product involved and the amount needed.

(D) Description of the research to be conducted, including the number and type of medical marijuana product, the dosage, the route and method of administration, and the duration of the research project.

(E) The locations of the dispensaries that will be participating in the research project.

§ 1210.22. 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 § 1210.28 (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 1141, Chapter 1151 or Chapter 1161, as applicable.

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

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

(1) The Department has determined that an approved clinical registrant is ready, willing and able to operate as a grower/processor and a dispensary.

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

§ 1210.23. 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 by the Department. 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.

(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.

Cross References

This section cited in 28 Pa. Code § 1210.27 (relating to application for approval of a clinical registrant).

§ 1210.24. Capital requirements.

(a) An applicant is not required to meet the same capital requirements as a medical marijuana organization under § 1141.30 (relating to capital requirements).

(b) An applicant shall provide all of the following information with its application under § 1210.27 (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.

(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 § 1210.27 (relating to application for approval of a clinical registrant).

§ 1210.25. 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 approved as a certified 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 State and Federal 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).

(8) Any other information deemed necessary by the Department.

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

Cross References

This section cited in 28 Pa. Code § 1210.27 (relating to application for approval of a clinical registrant).

§ 1210.26. 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.

§ 1210.27. 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 certified ACRC under § 1210.25 (relating to certifying ACRCs).

(3) The applicant's State and Federal 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 a certified ACRC or any affiliates of a certified 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 project.

(6) An affidavit and release under § 1210.24 (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 certified ACRC.

(ii) A description of the research projects the applicant and the certified 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 until the dispensary is ready, willing and able to dispense medical marijuana products.

(8) Except as provided in subsection (d), an application for a grower/processor permit under Chapters 1141 and 1151 (relating to general provisions; and growers/processors).

(9) Except as provided in subsection (d), an application for a dispensary permit under Chapter 1141 and Chapter 1161 (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).

(11) Any other information deemed necessary by the Department.

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

(d) Subject to the limitations in § 1210.23 (relating to limitation on permits), an applicant that already holds 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 include in its application for approval of a clinical registrant a request for conversion of an existing permit under § 1210.28 (relating to request for conversion of an existing permit).

(e) 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 project.

(3) A certified ACRC's intellectual property.

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

Cross References

This section cited in 28 Pa. Code § 1210.24 (relating to capital requirements); 28 Pa. Code § 1210.28 (relating to request for conversion of an existing permit); 28 Pa. Code § 1210.30 (relating to approval or denial of an application for approval of a clinical registrant); and 28 Pa. Code § 1210.32 (relating to revocation of approval of a clinical registrant).

§ 1210.28. 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), may 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 § 1210.27 (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 1141 (relating to general provisions) and Chapter 1151 or 1161 (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 § 1161.40 (relating to application for additional dispensary locations).

Cross References

This section cited in 28 Pa. Code § 1210.22 (relating to clinical registrants generally); and 28 Pa. Code § 1210.27 (relating to application for approval of a clinical registrant).

§ 1210.29. Practices and procedures of institutional review boards.

An institutional review board shall adopt practices and procedures regarding research projects which, at a minimum, address all of the following:

(1) Protecting the rights and welfare of patients involved in research projects 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 projects 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 project.

(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.

§ 1210.30. 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 § 1210.27 (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 § 1210.27(b)(4) violate the prohibition in § 1210.34 (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 certified 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 § 1210.34. 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.

(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 1141, 1151 and 1161 (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.

§ 1210.31. 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 § 1141.36 (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 projects 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 projects being conducted under the research contract, including preliminary findings, if applicable, and any expectations and projections the approved clinical registrant and the certified ACRC have for future research projects over the course of the 2 years following the date of submission of the report.

(4) A description of proposed research projects 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 institutional review board approval for each research project.

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

(6) Any other information deemed necessary by the Department.

(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 project and the approved clinical registrant does not intend to commence any additional approved research projects within the first 6 months following the approval of its application for renewal.

§ 1210.32. 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 § 1210.27 (relating to application for approval of a clinical registrant).

(3) The research contract between the approved clinical registrant and the certified 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 certified 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 certified 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.

§ 1210.33. Dispensing and tracking medical marijuana products.

In addition to the information to be entered in the electronic tracking system under § 1161.39 (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 project.

§ 1210.34. Prohibition.

Except for reasonable remuneration specifically in a research contract for the services to be performed or costs to be incurred by a certified ACRC, a certified 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 a certified ACRC under a research contract to defray start-up and ongoing costs of the certified 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 a certified ACRC established 1 year or more prior to the effective date of the act.

Cross References

This section cited in 28 Pa. Code § 1210.30 (relating to approval or denial of an application for approval of a clinical registrant).

§ 1210.35. Reporting requirements.

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

(b) In the event the approved clinical registrant or its certified ACRC intends to submit a manuscript of the results of an approved research project 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, certified ACRCs or any other person it determines would benefit from the findings.

Cross References

This section cited in 28 Pa. Code § 1210.36 (relating to sale or exchange).

§ 1210.36. Sale or exchange.

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

(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 or exchange the following items to another grower/processor holding a permit under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616):

(1) Seeds.

(2) Immature medical marijuana plants.

(3) Medical marijuana plants.

(4) Medical marijuana products

(c) The grower/processor of an approved clinical registrant may only sell its medical marijuana products to either its own approved dispensaries or any other approved dispensaries of an approved clinical registrant.

(d) Notwithstanding subsection (c), an approved clinical registrant may petition the Department, on a form prescribed by the Department, to sell its medical marijuana products to a dispensary holding a permit under sections 601—616 of the act.

(e) A petition filed under subsection (d) must include either the report or manuscript required under § 1210.35 (relating to reporting requirements). If a clinical registrant fails to provide the report or manuscript required under § 1210.35, the petition shall be denied.

§ 1210.37. Appeals.

Chapter 5 of 2 Pa.C.S. (relating to practice and procedure) applies to actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).