RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 1210]

Medical Marijuana; Clinical Registrants and Academic Clinical Research Centers; Temporary Regulations

PART IX. MEDICAL MARIJUANA

CHAPTER 1210 CLINICAL REGISTRANTS AND ACADEMIC CLINICAL RESEARCH CENTERS

§ 1210.34. Sale or exchange.

§ 1210.35. Appeals.

§ 1210.21. Definitions.

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

Academic clinical research center or ACRC—An accredited medical school within this Commonwealth that operates or partners with an acute care hospital licensed within this Commonwealth.

Accredited medical school—An institution that is:

(i) Located within 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 and 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 act of July 19, 1979 (P.L. 130, No.48), known as the Health Care Facilities Act, and the regulations promulgated pursuant thereto.

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:

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

(ii) Contract with a certified ACRC under which the certified ACRC 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.

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 academic clinical research center that has applied for and has been certified by the Department to contract with an approved clinical registrant.

Institutional review board or IRB—Any board, committee, research approval committee, or group designated by a certified academic clinical research center that reviews and evaluates the anticipated scope of an approved clinical registrant's research study involving human subjects under the criteria set forth in 45 CFR § 46.111 and 21 CFR § 56.111.

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

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

Research approval committee or RAC—An Institutional Review Board or any internal board, committee, or group created or designated by a certified academic clinical research center to review and approve the scope and research protocols of a research project proposed by an approved clinical registrant.

Research contract—A written agreement between an approved clinical registrant and a certified academic clinical research center that contains the responsibilities and duties of each party with respect to the research project(s) that the approved clinical registrant and the certified academic clinical research center intend to conduct under this chapter and under which the certified academic clinical research center or its affiliate 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 that includes a patient.

Research protocol— A protocol to conduct research with Schedule I Controlled Substances in the form described in 21 CFR § 1301.18.

§ 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 and desires to become an approved clinical registrant shall:

(1) Submit a request to the Department under § 1210.27 (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 this chapter.

(c) The Department will not approve more than eight (8) clinical registrants.

(d) An approved clinical registrant shall 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 commence an approved research project within six months following the date the approved clinical registrant commences operations at a dispensary location listed in its dispensary permit.

§ 1210.23. Limitation on permits.

(a) The Department will not issue more than one grower/processor permit and one dispensary permit to an approved clinical registrant.

(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.

(c) An approved clinical registrant shall choose its primary dispensary location and any additional locations based on the following criteria:

(1) The primary dispensary location, and no more than two additional dispensary locations, may be located in the same medical marijuana region.

(2) The primary dispensary location and one additional dispensary location may be located in the same county.

§ 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 the following information with its application under § 1210.26 (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. Failure to provide a release will result in the rejection of the application for approval of a clinical registrant.

§ 1210.25. Certifying academic clinical research centers.

(a) An accredited medical school may file an application with the Department to be approved as a certified academic clinical research center 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.

(b) An application submitted under subsection (a) shall include the following information:

(1) The legal name, address and telephone number of the accredited medical school and the name, telephone number and professional email 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 any acute care hospital that will be affiliated with the accredited medical school and the name, telephone number and professional email 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 contract for purposes of operating as an approved clinical registrant or by any principal of the person, up to and including the date of the submission of the application. The affidavit shall 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 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.

(c) The Department shall publish a list containing the name and address of each certified academic clinical research center on its publicly accessible Internet website and in the *Pennsylvania Bulletin.*

§ 1210.26. 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 shall include the following information:

(1) The legal name, address and telephone number of the applicant and the name, telephone number and professional email 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 academic clinical research center under § 1210.25 (relating to certifying academic clinical research centers).

(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 or a principal 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 shall include the amount and purpose of each payment made.

(5) The name of any institution of higher education that will be contracting with the applicant to review and approve a 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 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, which dispensary location will be associated with each research project and a copy of the research approval committee approval with respect to each research project.

(iii) A statement that the applicant will not engage in the business of growing, processing, or selling medical marijuana or medical marijuana products to a dispensary until a research project has been approved by the research approval committee for that dispensary and submitted to the Department.

(iv) A statement that the applicant will 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 for the research project being conducted at that dispensary.

(8) An application for a grower/processor permit under 28 Pa. Code Ch. 1141 (relating to general provisions) and 28 Pa. Code Ch. 1151 (relating to growers/processors).

(9) An application for a dispensary permit under 28 Pa. Code Ch. 1141 (relating to general provisions) and 28 Pa. Code Ch. 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 academic clinical research center in its application for approval of a clinical registrant.

(d) An applicant that already holds a grower/processor permit or a dispensary permit, or both, under sections 601—616 of the act, shall include in its application for approval of a clinical registrant a request for conversion of an existing permit under § 1210.27 (relating to request for conversion of an existing permit).

§ 1210.27. Request for conversion of an existing permit.

(a) An applicant holding a grower/processor permit, a dispensary permit, or both, under sections 601—616 of the act, may submit a request for conversion of an existing permit under § 1210.27 (relating to request for conversion of an existing permit) on a form prescribed by the Department when submitting an application for approval of a clinical registrant under § 1210.26 (relating to application for approval of a clinical registrant).

(b) An approved clinical registrant submitting a request for conversion of an existing grower/processor permit shall pay the following fees:

(1) An application fee of $10,000, which is nonrefundable.

(2) A permit fee of $200,000.

(c) An approved clinical registrant submitting a request for conversion of an existing dispensary permit shall pay the following fees:

(1) An application fee of $5,000, which is nonrefundable.

(2) A permit fee of $30,000 for each dispensary location listed under the permit.

(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).

§ 1210.28. Research approval committees.

The primary purposes of a research approval committee shall include, at a minimum, the following:

(1) Protecting the rights and welfare of human subjects involved in research activities being conducted under this chapter.

(2) Minimizing the risk to human research subjects by using procedures that are consistent with sound research design and that do not unnecessarily expose the research participants to risk, and whenever appropriate, by using procedures already 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 individual, 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 and maintaining confidentiality of data.

§ 1210.29. 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 § 1210.26 (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 § 1210.26(b)(4) violate the prohibition in § 1210.32 (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 academic clinical research center or its affiliate has refunded to the applicant or a principal of the applicant that portion of such payments in violation of § 1210.32. 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.

§ 1210.30. Renewal of clinical registrant approval.

(a) The approval of a clinical registrant shall be for a term of one year from the date of the Department's approval of an application for approval of a clinical registrant filed under § 1210.26(b)(4) (relating to application for approval of a clinical registrant).

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

(1) The Department revokes or suspends the grower/processor permit or dispensary permit held by the approved clinical registrant.

(2) The Department revokes the certification of the ACRC listed in the clinical registrant's application under § 1210.26 (relating to application for approval of a clinical registrant).

(3) The research contract between the approved clinical registrant and the certified ACRC expires or is terminated by either party.

(4) The Department does not approve the renewal of a grower/processor permit or dispensary permit held by the approved clinical registrant.

(c) If the Department revokes the certification of an ACRC under subsection (b)(2), the approved clinical registrant shall have 60-days from the date of revocation to contract with another certified ACRC. If the approved clinical registrant does not contract with another certified ACRC within 60-days from the date of revocation, the Department may revoke the clinical registrant's approval.

(d) 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.

(e) 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 shall be on a form prescribed by the Department and shall include 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 all 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 two years following the date of submission of the report.

(4) A description of any 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 research approval committee 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.

(e) The Department will not renew an approval for a clinical registrant under this section if the Department determines either of the following:

(1) A research project is not being conducted in conjunction with any of the dispensary locations under the dispensary permit held by the approved clinical registrant.

(2) The approved clinical registrant does not intend to commence any additional research projects within the first six months after the approval of its application for approval of a clinical registrant.

§ 1210.31. Dispensing and tracking medical marijuana products.

(a) In addition to the information to be entered in the electronic tracking system under § 1161.39 (relating to electronic tracking system), the dispensary of an approved clinical registrant

shall enter information into the electronic tracking system as required by the Department listing the medical marijuana products dispensed to a patient enrolled in an approved research project, or to the patient's caregiver, if applicable.

(b) Notwithstanding anything to the contrary contained in this part, an approved clinical registrant may dispense medical marijuana products to its certified ACRC for purposes of an approved research project.

§ 1210.32. Prohibition.

Except for reasonable remuneration specifically set forth in a research contract for the services to be performed or costs to be incurred by a certified ACRC or its affiliate, a certified ACRC shall not solicit or accept anything of value from an approved clinical registrant or a principal 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 costs of the certified ACRC in connection with the establishment of the contractual relationship set forth in the research contract.

§ 1210.33. 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 thirty (30) days following publication.

(c) The Department may post the findings received under this section on its publicly accessible Internet website and share them with other approved clinical registrants, certified academic clinical research centers or any other person it determines would benefit from the findings.

§ 1210.34. 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.

(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:

(1) Seeds.

(2) Immature medical marijuana plants.

(3) Medical marijuana plants.

(4) Medical marijuana products

(c) An approved clinical registrant's grower/processor may only sell its medical marijuana products to those dispensaries that are permitted to the same approved clinical registrant.

§ 1191.35 Appeals.

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