# RULES AND REGULATIONS

## Title 28—HEALTH AND SAFETY

### DEPARTMENT OF HEALTH

### [ 28 PA. CODE CH. 1210 ]

### Medical Marijuana; Clinical Registrants; Temporary Regulations

### PART IX. MEDICAL MARIJUANA PROGRAM

### CHAPTER 1210 CLINICAL REGISTRANTS

**§ 1210.21. Definitions.**

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

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

*Accredited medical school*—An institution that is:

(a) Located within the Commonwealth.

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

*Applicant*—A person who wishes to submit or submits to the Department an application for registration to operate as a clinical registrant under the act and this part.

*Business entity*—An entity that is a sole proprietorship, general or limited partnership, limited liability corporation, corporation or combination thereof.

*Hospital*—A facility having an organized medical staff and providing equipment and services primarily for inpatient care to persons who require definitive diagnosis or treatment, or both, for injury, illness, pregnancy, or other disability.

*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.

*Institutional review board or IRB*—Any board, committee, or group designated by an academic clinical research center that reviews the anticipated scope of a clinical registrant's research study, the types of subject populations likely to be involved in a research study, the

appropriateness of the proposed initial and continuing review procedures under the research study compared to probable risks, and the size and complexity of the research study in relation to the resources provided by the clinical registrant.

*IRB approval*—The determination of the IRB that a research study has been reviewed and may be conducted by the clinical registrant within any constraints set forth by the IRB, an academic clinical research center, or the Department.

*Medical marijuana product*—The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary.

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

**§ 1210.22. Clinical registrants generally.**

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

(b) A clinical registrant shall not apply for a grower/processor permit and a dispensary permit until the clinical registrant has registered and been approved by the Department under § 1210.25 (relating to registration of clinical registrants).

(c) A clinical registrant shall not engage in the business of growing, processing, possessing, or selling medical marijuana or medical marijuana products until the Department approves both a grower/processor and dispensary permit for the clinical registrant.

(d) A clinical registrant shall not engage in the business of dispensing or offering to dispense medical marijuana products at a dispensary location until the clinical registrant begins a research study approved by the Department.

(e) A dispensary permit issued to a clinical registrant shall list on the permit the research studies that have been approved by the Department to be conducted at that dispensary.

**§ 1210.23. Limitation on permits.**

(a) Notwithstanding the limitations in section 616 of the act, the Department will not initially issue grower/processor and dispensary permits to more than eight clinical registrants. The following apply:

(1) The Department will not issue more than one individual grower/processor permit to more than one clinical registrant.

(2) The Department will not issue more than one individual dispensary permit to more than one clinical registrant.

(b) A dispensary permit may be used to provide medical marijuana products for research studies at no more than six separate locations as approved by the Department.

(c) A clinical registrant may choose its primary dispensary location and any additional locations based on the following:

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

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

**§ 1210.24. Capital requirements.**

(a) A clinical registrant 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 with its registration application under § 1210.25 (relating to registration of clinical registrants):

(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 governmental agency, financial institutions, an employer or any other person. Failure to provide a release will result in the rejection of the registration application.

**§ 1210.25. Registration of clinical registrants.**

(a) An applicant shall register with the Department using a form prescribed by the Department.

(b) A registration application shall contain the following information:

(1) The applicant's legal business name, address, telephone number, and professional email address.

(2) The legal business name, address, telephone number and professional email address of any individual, business entity or institution of higher education that is contracting or will be contracting with the applicant or will be involved in any research study that will be conducted by the applicant.

(3) The applicant's state and federal tax identification numbers.

(4) Evidence that the applicant is responsible and capable of successfully operating as a clinical registrant, including the following:

(i) A statement that the applicant will have a contract with an academic clinical research center before the applicant will engage in the business of growing, processing, possessing, selling, dispensing or offering to dispense medical marijuana or medical marijuana products.

(ii) A statement that the applicant, along with the academic clinical research center, will not engage in the business of growing, processing, or selling medical marijuana or medical marijuana products to a dispensary until a research study is approved by the Department.

(iii) A statement that the applicant, along with the academic clinical research center, will not engage in the business of selling, dispensing or offering to dispense medical marijuana products at an applicant's dispensary until a research study that has been approved by the Department is being conducted at that dispensary.

(5) The physical address of an existing or proposed site and facility to be used for a grower/processor facility and dispensary facility.

(6) An affidavit and release under § 1210.24 (relating to capital requirements).

(7) A timetable when the applicant, if approved, will submit a grower/processor permit application and a dispensary permit application.

(8) 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).

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

(c) The Department will publish a notice in the *Pennsylvania Bulletin* of the availability of clinical registrant registration applications.

(d) The Department will approve only one registration submitted by each applicant.

**§ 1210.26. Clinical registrant applying for a grower/processor permit.**

Notwithstanding § 1210.24 (relating to capital requirements), an applicant shall meet all the requirements under Chapter 1141 (relating to general provisions) and Chapter 1151 (relating to growers/processors) for the submission of an initial permit application for a grower/processor permit.

**§ 1210.27. Clinical registrant applying for a dispensary permit.**

(a) Notwithstanding § 1210.24 (relating to capital requirements), an applicant shall meet all the requirements under Chapter 1141 (relating to general provisions) and Chapter 1161 (relating to dispensaries) required for the submission of an initial permit application for a dispensary permit.

(b) In addition to the requirements under subsection (a), an applicant shall also submit with the initial permit application for a dispensary permit the following:

(1) A copy of the applicant's contract with an academic clinical research center.

(2) A statement that the applicant intends to conduct the research studies listed in the registration approved by the Department.

(3) The name and address of any institutions of higher education, if applicable, that the applicant has contracted with for assistance with each research study listed in the registration.

(4) The following information for each research study listed in the registration:

(i) The formal name of the research study.

(ii) A statement of its purpose, including the reason for the research study.

(iii) Each strain or variety of medical marijuana that is intended to be used in the research study.

(iv) The percentage of THC or CBD contained in the medical marijuana to be used in the research study.

(v) The date each research study will begin and its anticipated end date.

(vi) The anticipated number of patients that will be participating in the research study.

(vii) A statement on whether an applicant will allow the designation of a caregiver while the patient is participating in the research study.

(viii) The dispensary location that will dispense medical marijuana products for each research study.

(ix) The name, address, professional title and short version of a curriculum vitae for each individual involved in directing or overseeing the research study.

(x) Evidence that each research study has been reviewed and approved by an institutional review board.

(xi) Any other information required by the Department.

(5) A statement that the clinical registrant has a contractual relationship with an academic clinical research center under which the academic clinical research center or its affiliate shall provide medical advice to the clinical registrant regarding, at a minimum, the following areas:

(i) Patient health and safety.

(ii) Application of various forms of medical treatment related to medical marijuana use.

(iii) Dispensing and management of controlled substances while a patient is using medical marijuana.

**§ 1210.28. Amending clinical registrant registrations.**

(a) A clinical registrant may at any time and on a form provided prescribed by the Department, file an amendment to its registration under § 1210.25 (relating to registration of clinical registrants) to obtain approval for any of the following:

(1) To conduct a research study.

(2) To increase the number of patients covered by an approved research study in the registration.

(3) Modify the dates for which the research study was approved.

(b) If the amendment under subsection (a) is for approval of a new study under an existing registration, the amendment shall include the same information as provided under § 1210.27(b) (relating to clinical registrant applying for a dispensary permit).

**§ 1210.29. Dispensing medical marijuana products.**

(a) A dispensary may dispense medical marijuana products to a patient or caregiver who presents a valid identification card to an employee at the facility who is authorized to dispense medical marijuana products at the facility.

(b) A dispensary may dispense medical marijuana products to a patient who is participating in a research study, or the patient's caregiver, if applicable, at any location that lists the research study on the dispensary's permit under § 1210.22(e) (relating to clinical registrants generally).

(c) A dispensary that dispenses medical marijuana products to patients or caregivers who are not participating in a research study shall maintain the following:

(1) A separate counter area for the dispensing of medical marijuana products.

(2) A separate shelf area for displaying medical marijuana products.

(3) Proper signage that designates the areas to be used by patients and caregivers who are not participating in a research study.

(d) A dispensary shall use the electronic tracking system prescribed by the Department to track medical marijuana products that are dispensed to a patient or caregiver.

(e) A dispensary shall only dispense medical marijuana products to a patient or caregiver who is participating in a research study approved for that dispensary for that patient and caregiver.

**§ 1210.30. Limitations on dispensing.**

(a) A clinical registrant shall close a dispensary location that is no longer conducting all research studies approved by the Department for that dispensary and return any form of medical marijuana products to the grower/processor designated in the electronic tracking system.

(b) Upon the conclusion of a research study approved by the Department for a dispensary location, or closure of a dispensary location under subsection (a), the clinical registrant shall do the following:

(1) Notify the Department in writing that the research study has concluded.

(2) Cease dispensing the form of medical marijuana used in the research study to a patient or caregiver unless the same form of medical marijuana is being dispensed to a patient or caregiver under another research study approved by the Department at that same dispensary location.

(3) Direct the dispensary to return to the grower/processor designated in the electronic tracking system any form of medical marijuana that was designated for the research study, unless the same form of medical marijuana is being dispensed to patients or caregivers under another research study being conducted at the same dispensary location.

(c) Any time after the closure of a dispensary, the clinical registrant may reopen a dispensary location by filing an amendment under § 1210.28 (relating to amending clinical registrant registrations) to conduct a new research study.

(d) Nothing in this section shall prevent a clinical registrant from submitting an application under § 1141.40 (relating to application for approval of a change in location of a facility) while a research study is being conducted at a dispensary. -

**§ 1210.31. Prohibitions.**

(a) An applicant or clinical registrant may not accept, solicit or offer any form of consideration or remuneration from or to any individual, business entity, or institution of higher education to be part of a clinical registrant registration other than remuneration or consideration that will be listed by an applicant as being received from the individual, business entity, or institution of higher education to meet the capital requirements under § 1210.24 (relating to capital requirements).

(b) A clinical registrant may not sell or exchange medical marijuana products under § 1210.34 (relating to sale or exchange of medical marijuana) until the Department determines the clinical registrant's dispensary permit operational under § 1141.42 (relating to failure to be operational).

**§ 1210.32. Records subject to disclosure; confidentiality.**

(a) The following records are public records and shall be subject to disclosure under the Right-to-Know Law (65 P.S. §§ 67.101-67.3104):

(1) A clinical registrant's application for a grower/processor permit and dispensary permit.

(2) Information relating to penalties or other disciplinary actions taken against a clinical registrant's grower/processor and dispensary permits by the Department for a violation of the act.

(b) The following information is considered confidential, shall not be subject to the Right-to-Know Law, and shall not otherwise be released to any person unless pursuant to court order:

(1) Information provided in an application for registration including but not limited to:

(i) The name or other personal identifying information of a patient who is participating in a research study approved by the Department.

(ii) The name or other personal identifying information concerning a caregiver for a patient under subsection (1)(i).

(iii) Information relating to a patient's serious medical condition.

(2) Any other information regarding a patient, caregiver, or clinical registrant not listed in subsection (a) that falls within any exception to the Right-to-Know Law, or is otherwise considered to be confidential or proprietary information by other law.

(c) The Department may not require disclosure of any information that would infringe upon the academic clinical research center's exclusive right to intellectual property or legal obligations for patient confidentiality.

**§ 1210.33. Research findings.**

The academic clinical research center shall provide its findings to the Department within 365 days of the notice of completion of the research study under § 1210.30 (relating to limitations on dispensing), or within 365 days of publication of the results of the research study in a peer-reviewed medical journal, whichever is later.

**§ 1210.34. Sale or exchange of medical marijuana.**

Notwithstanding section § 1210.30 (relating to limitations on dispensing), a grower/processor of a clinical registrant may sell or exchange any of the following to another grower/processor under the act, with the prior written approval of the Department:

(1) Seeds.

(2) Immature medical marijuana plants.

(3) Medical marijuana plants.

(4) Medical marijuana products.