CHAPTER 1211. CLINCIAL REGISTRANTS AND ACADEMIC CLINICAL RESEARCH CENTERS—TEMPORARY REGULATIONS

Sec.

Authority

The temporary provisions of this Chapter 1211 issued and readopted under the Medical Marijuana Act (35 P.S. §§ 10231.101—10231.2110), as amended by the act of June 22, 2018 (P.L. 322, No. 43), unless otherwise noted.

Source

The temporary provisions of this Chapter 1211 adopted August 17, 2018, effective August 18, 2018, expired March 18, 2020, 48 Pa.B. 5027; readopted January 14, 2022, effective January 15, 2022, expire on January 15, 2024, 52 Pa.B. 359, unless otherwise noted. Immediately preceding text appears at serial pages (395023) to (395037).

§ 1211.21. 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.

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.

IRB—Institutional review board—A board, committee, RAC or group designated by a certified ACRC that reviews and approves the anticipated scope of an approved clinical registrant's research study involving human subjects under the criteria in 45 CFR 46.111 (relating to criteria for IRB approval of research) and 21 CFR 56.111 (relating to criteria for IRB approval of research).

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

RAC—Research approval committee—A board, committee or group created or designated by a certified ACRC to review and approve the scope and research protocols of a research program proposed by an approved clinical registrant.

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 program or research study 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. This term shall include a letter of intent to enter into an agreement for purposes of a clinical registrant application.

Research program—Research on the therapeutic or palliative efficacy of medical marijuana limited to the serious medical conditions defined by the act and this part.

Research project or study—Any other research on medical marijuana or its effectiveness in treating a medical or psychological condition.

Research protocol—A written procedure for conducting a research program or research study 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 program or research study:

(A) Title of the research program or research study.

(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 program or research study.

(E) The locations of the dispensaries that will be participating in the research program or research study.

Authority

The temporary provisions of this § 1211.21 amended under the Medical Marijuana Act (35 P.S. §§ 10231.101—10231.2110).

Source

The temporary provisions of this § 1211.21 amended December 21, 2018, effective December 22, 2018, 48 Pa.B. 7778. Immediately preceding text appears at serial pages (393535) to (393537).

§ 1211.22. 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 § 1211.28 (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, as a clinical registrant, any medical marijuana products at the clinical registrant 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 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.

§ 1211.23. 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, 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.

§ 1211.24. Capital requirements.

An applicant shall provide all of the following information with its application under § 1211.27 (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 § 1141.30 (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 § 1211.27 (relating to application for approval of a clinical registrant).

§ 1211.25. 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 § 1211.27 (relating to application for approval of a clinical registrant).

§ 1211.26. 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.

§ 1211.27. 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 § 1211.25 (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 program or research study.

(6) An affidavit and release under § 1211.24 (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 program or research study 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 as a clinical registrant until the clinical registrant dispensary is ready, willing and able to dispense medical marijuana products.

(8) Except as provided in § 1211.28 (relating to request for conversion of an existing permit), an application for a grower/processor permit under Chapters 1141 and 1151 (relating to general provisions—temporary regulations; and growers/processors—temporary regulations).

(9) Except as provided in § 1211.28, an application for a dispensary permit under Chapter 1141 and Chapter 1161 (relating to dispensaries—temporary regulations).

(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) 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) A certified ACRC's intellectual property.

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

Cross References

This section cited in 28 Pa. Code § 1211.24 (relating to capital requirements); 28 Pa. Code § 1211.28 (relating to request for conversion of an existing permit); 28 Pa. Code § 1211.30 (relating to approval or denial of an application for approval of a clinical registrant); and 28 Pa. Code § 1121.32 (relating to revocation of approval of a clinical registrant).

§ 1211.27a. 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 a certified 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 certified ACRCs.

(c) A certified 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 certified ACRC, the Department shall follow the following process in approving the applications:

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

(i) Is complete;

(ii) Complies with the Act and the Department's temporary regulations, and

(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

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

ment. 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.

Authority

The temporary provisions of this § 1211.27a issued under the Medical Marijuana Act (35 P.S. §§ 10231.101—10231.2110).

Source

The temporary provisions of this § 1211.27a adopted December 21, 2018, effective December 22, 2018, expire on December 22, 2020, 48 Pa.B. 7778.

§ 1211.28. 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 § 1211.27 (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—temporary regulations) and Chapter 1151 or Chapter 1161 (relating to growers/processors—temporary regulations; and dispensaries—temporary regulations), 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 § 1211.22 (relating to clinical registrants generally); and 28 Pa. Code § 1211.27 (relating to application for approval of a clinical registrant).

§ 1211.29. 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, at a minimum, ensure that each research program, project or study addresses all of the following:

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

§ 1211.30. 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 § 1211.27 (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 § 1211.27(b)(4) violate the prohibition in § 1211.34 (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 § 1211.34. 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—temporary regulations; growers/processors—temporary regulations; and dispensaries—temporary regulations), 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.

§ 1211.31. 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 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 certified 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 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 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.

§ 1211.32. 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 § 1211.27 (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.

§ 1211.33. 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 program or research study.

§ 1211.34. 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 § 1211.30 (relating to approval or denial of an application for approval of a clinical registrant).

§ 1211.35. 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 certified 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, certified ACRCs or any other person it determines would benefit from the findings.

Cross References

This section cited in 28 Pa. Code § 1211.36 (relating to sale or exchange).

§ 1211.36. 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 only sell its medical marijuana products to either its own approved dispensaries or any other approved dispensaries of an approved clinical registrant.

(c) Notwithstanding subsection (b), 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 (35 P.S. §§ 10231.601—10231.616).

(d) A petition filed under subsection (c) must include either the report or manuscript required under § 1211.35 (relating to reporting requirements). If a clinical registrant fails to provide the report or manuscript required under § 1211.35, the petition will be denied.

§ 1211.37. 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).

[Next page is 1230-1.]