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SUMMARY OF CHANGES TO FINAL MEDICAL MARIJUANA REGULATIONS
CHAPTER 1181a. PHYSICIANS AND PRACTITIONERS
CHAPTER 1191a. PATIENTS AND CAREGIVERS
CHAPTER 1141a. GENERAL PROVISIONS

CHAPTER 1181a. PHYSICIANS AND PRACTITIONERS

Sec.
1181a.22. Practitioners generally.
1181a.23. Medical professionals generally.
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This chapter, which tracks sections 401—405 of the act (35 P.S. §§ 10231.401—10231.405), pertains to practitioner registration, training requirements and prohibitions, issuance, and revocation of patient certifications. This chapter replaces temporary Chapter 1181 (relating to physicians and practitioners—temporary regulations). New sections and amendments to sections of the temporary regulations are discussed more fully as follows.

Since the terms "practitioner" and "physician" appear to be used interchangeably in the regulations, the Department of Health (Department) was asked to review the use of both terms throughout this final-form rulemaking to ensure usage is clear and appropriate.

The term "practitioner" is defined in section 103 of the act as "a physician who is registered with the department under section 401." (See 35 P.S. § 10231.103.) Since "physician" is not defined in the act, it is defined in § 1141a.21 of these regulations as "the term as defined in section 2 of the Medical Practice Act of 1985 or section 2 of the Osteopathic Medical Practice Act." Careful review of each term used throughout this final-form rulemaking reveals that the terms are not used interchangeably. Rather, "physician" is used when referring to the individual who has not yet registered under section 401 of the act. "Practitioner" is used when referring to an individual who has already registered under section 401 of the act.

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§ 1181a.22. Practitioners generally

This section requires that a practitioner must meet continuing qualifications to be registered with the Department and may not issue patient certifications prior to becoming registered. This section also requires a practitioner to notify the dispensing dispensary of a patient's adverse reaction to medical marijuana. Further, this section permits a practitioner to petition the Board to review any proposed change to the currently listed serious medical conditions for which medical marijuana could be beneficial.

Summary of Changes:

- Other than amending a citation and name chang in subsection (b), deleting reference to the statute in subsection (d) in order to refer to this new chapter, and deleting the last sentence of subsection (d), since the Board has already created a process, no substantial changes were made to this section.

§ 1181a.22 Practitioners generally.

…

(b) A physician may not issue a patient certification without being registered by the Department as a practitioner in accordance with § 1181a.24 (relating to ~~physician~~ practitioner registration).

(c) A practitioner shall notify a dispensary by telephone of a patient's adverse reaction to medical marijuana products dispensed by that dispensary immediately upon becoming aware of the reaction.

(d) ~~Under section 1201(j)(5)(iv) of the act (35 P.S. §10231.1201(j)(5)(iv)),~~ A practitioner may petition the Medical Marijuana Advisory Board (Board) for the Board to review on a continuing basis, and recommend to the Secretary for approval, that serious medical conditions be changed, reduced or added to those conditions for which medical marijuana is likely to provide therapeutic or palliative benefit to a patient. ~~The Board will establish a procedure to effectuate this subsection.~~

§ 1181a.23. Medical professionals generally

This section provides that, like the requirements for a registered practitioner, the requirements to be a registered medical professional are an ongoing responsibility to maintain. The section also provides that a medical professional may not assume any duties at a dispensary until all requirements are satisfied. This section further requires that a medical professional notify the practitioner listed on the patient certification of any adverse reaction suffered by the patient due to use of a medical marijuana product purchased at the dispensary.

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Summary of Changes:

- Other than amending a citation in subsection (b), no substantial changes were made to this section.

Changes to Final § 1181a.23. Medical professionals generally.

…

(b) A medical professional may not assume any duties at a dispensary until the training required under § 1181a.32 (relating to training) and any other requirements for medical professionals under the act and this part are completed.

…

§ 1181a.24. Practitioner registration

This section details the requirements for practitioner registration.

Summary of Changes:

- The physician licensing requirement in temporary subsection (a)(1) was relocated to subsection (a).
- Temporary regulation subsection (a)(2) was deleted, and subsection (c) was amended to clarify that the Department determines approval to issue patient certifications based on the information submitted in the application.
- Temporary regulation subsection (c) was amended to be subsection (d).
- This section further provides that the Department may only list a physician on the practitioner registry after the physician has completed the training course required in § 1181a.32 (relating to training) and met all other requirements for registration.
- The Department amended the title of this section to mirror the title of practitioner registration, the title of section 401 of the act. See 35 P.S. § 10231.401.
- The phrase "at a minimum" was deleted from subsection (b) and "all of the following" was added to (b)(4).

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Changes to Final § 1181a.24. Practitioner registration.

(a) A physician who has an active and unrestricted medical license in this Commonwealth in accordance with the Medical Practice Act of 1985 (63 P.S. §§ 422.1-4 22.51a) or the Osteopathic Medical Practice Act (63 P.S. §§ 271.1- 271.18) may file an application for registration with the Department as a practitioner on a form prescribed by the Department. ~~if the physician meets both of the following qualifications:~~

~~(1) Has an active medical license in this Commonwealth in accordance with the Medical Practice Act of 1985 (63 P.S. § § 422.1—422.51a) or the Osteopathic Medical Practice Act (63 P.S. § § 271.1—271.18) applicable to the physician.~~

~~(2) Is qualified, as determined by the Department from information provided by the physician under subsection (b), to treat patients with one or more serious medical conditions.~~

(b) An application for registration must include~~, at a minimum,~~ the following requirements:

…

(4) A certification by the physician that states all of the following:

…

(c) Based on the information provided by the physician under subsection (b), the Department will determine whether to approve the physician to issue patient certifications.

(d) The Department may list a physician on the practitioner registry only after the physician has successfully completed the training course required under § 1181a.32 (relating to training) and any other requirements for registration under the act and this part.

§ 1181a.25. Practitioner registry

This section provides that the Department will maintain a practitioner registry for use by patients or caregivers, and that inclusion in the registry is subject to annual review by the Department to ensure that the practitioner remains qualified.

Summary of Changes:

- Other than moving language from subsection (b) to subsection (a), no substantial changes were made to this section.

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Changes to Final § 1181a.25. Practitioner registry.

(a) The Department will maintain a practitioner registry for use by a patient or caregiver registered by the Department. The practitioner registry will include only the practitioner's name, business address and medical credentials.

~~(b) The practitioner registry will include only the practitioner's name, business address and medical credentials.~~

§ 1181a.26. Denial, revocation or suspension of a practitioner registration

This section provides the grounds upon which the Department may deny, revoke, or suspend a practitioner's registration. The section also prohibits a physician who has been denied registration or has had that registration revoked or suspended from accessing, issuing, modifying, or copying a patient's certification. Further, this section provides that a physician may reapply if the circumstances leading to registration denial, revocation or suspension have resolved.

Summary of Changes:

- Removal of duplicative language in subsection (a).
- Adding clarifying language in subsection (b).
- Amending a citation and title in subsection (c) to refer to this new chapter.
- Amending subsection (d) to clarify the intent and to provide an example of when the exception would apply.

Changes to Final § 1181a.26. Denial, revocation or suspension of a practitioner registration.

(a) A practitioner registration will be denied, revoked or suspended if the practitioner's medical license is inactive, expired, suspended, revoked, limited or otherwise restricted by the applicable Medical Board.~~, or if the physician has been subject to professional disciplinary action, including an immediate temporary action.~~

(b) A practitioner registration may be denied, revoked or suspended if the practitioner is or has been the subject of professional disciplinary action, including an immediate temporary action.

(c) A physician who has been denied registration or whose practitioner registration has been revoked or suspended may reapply to the Department for inclusion in the practitioner registry in accordance with §1181a.24 (relating to ~~physician~~ practitioner registration) if the event that led to

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the physician's denial, revocation or suspension has been resolved and the physician's medical license is designated as active without limitation by the applicable Medical Board. The physician's application for registration under this subsection must include evidence of the resolution.

(d)

…

(3) Provide a copy of an existing patient certification to any person, including a patient or a caregiver, except ~~in accordance with applicable law.~~ where a patient is entitled by law to obtain copies of their own medical records, such as in 42 Pa. C.S. §6155(b)(1) (relating to rights of patients).

…

§ 1181a.27. Issuing patient certifications

This section specifies the conditions under which a practitioner may issue a patient certification, as well as specifying the information that is required on a patient certification. This section also requires a practitioner to provide a copy of a completed patient certification to the patient or the patient's caregiver and to the Department, as well as to retain a copy in the patient's file. At the proposed rulemaking stage, this section mirrored temporary § 1181.27 (relating to issuing patient certifications).

Summary of Changes:

- The phrase "and any other factor deemed relevant by the practitioner" is deleted from subsection (a)(1). In its place, subsection (a)(1.1) is added to include the statutory requirement for the patient to be under the practitioner's continuing care for the serious medical condition. (See 35 P.S. §§ 10231.403 and 10231.103.)
- The Department additionally deletes the phrase "at a minimum" from subsection (c) as it constitutes non-regulatory language.
- Minor language changes in subsection (c)(9) and subsection (d).

Changes to Final § 1181a.27. Issuing patient certifications.

(a) A practitioner may issue a patient certification to a patient if the following conditions are met:

(1) The practitioner has determined, based upon a patient consultation ~~and any other factor deemed relevant by the practitioner,~~ that the patient has a serious medical condition and has included that condition in the patient's health care record.

(1.1) The patient is under the practitioner's continuing care for the serious medical condition.

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…

(c) A patient certification that is issued by a practitioner must include~~, at a minimum,~~ all of the following:

…

(9) ~~Any o~~Other information that the practitioner believes may be relevant to the patient's use of medical marijuana products.

…

(d) Upon completion of a patient certification, a practitioner shall do all of the following:

…

§ 1181a.28. Modifying a patient certification

This section provides for modifying a patient certification and requires a practitioner to provide a copy of a modified patient certification to the patient or the patient's caregiver and to the Department, as well as to retain a copy in the patient's file.

Summary of Changes:

- Subsection (a) is amended to delete the limitation pf a practitioner's modification of a patient certification within the first 30 days of issuance and allows modification of a patient certification at any time after issuance and before expiration.
- Minor language changes in subsection (b)

Changes to Final § 1181a.28. Modifying a patient certification.

(a) A practitioner may ~~not~~ modify ~~the form of medical marijuana products on~~ a patient certification ~~for 30 days from the date the receipt is entered into the electronic tracking system by the dispensary unless the practitioner notifies the Department of the intent to modify the patient certification.~~ at any time after issuance and before expiration.

(b) After modifying a patient certification, a practitioner shall do all of the following:

…

§ 1181a.29. Revocation of a patient certification

This section provides that a practitioner must immediately notify the Department that a patient's circumstances have changed in a manner that would affect the patient's certification. The section also provides that the Department will revoke the patient's certification upon receiving this notification. Further, this section provides that a practitioner may withdraw the issuance of a patient certification at any time. The section also provides that the Department will immediately notify the

medical marijuana cardholder of a certification revocation and enter the information into the electronic tracking system.

Summary of Changes:

- No changes were made to this section.

§ 1181a.30. Prescription drug monitoring program

This section requires a practitioner to review the Prescription Drug Monitoring Program prior to issuing or modifying a patient certification to determine whether the controlled substance history of the patient would impact the patient's use of medical marijuana products. The section also specifies the reasons for which a practitioner may access the Prescription Drug Monitoring Program.

Summary of Changes:

- No changes were made to this section.

§ 1181a.31. Practitioner prohibitions

This section lists the prohibitions for practitioners.

Summary of Changes:

- The Department added subsection (g) prohibiting a practitioner from charging patients excessive fees.

Changes to Final § 1181a.31. Practitioner prohibitions.
…
(g) A practitioner may not excessively charge a patient for any expense related to the certification and follow-up process.

§ 1181a.32. Training

This section specifies those individuals who must complete a 4-hour training course prescribed by the Department and the requirements of that training course. Further, this section provides that completion of the training course qualifies as continuing education credits by certain medical boards, and that individuals who completed the training course must submit documentation to that effect to the Department. Finally, this section provides that the Department will provide on its web site a list of approved training providers.

Summary of Changes:

- Amending a citation and title in subsection (a)(1) to refer to this new chapter.
- Minor language change in subsection (b)

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- Subsection (d)(1) is amended to reflect actual practice that the training providers submit proof of training completion to the Department, and that proof must be submitted within the time specified in subsection (a).
- Subsection (f) is added, which states that an application for approval to become an approved training provider is available on the Department's public web site and any application meeting the requirements of subsections (b) and (c) will be approved.

Changes to Final § 1181a.32. Training
(a) (1) A physician prior to being included in the practitioner registry under § 1181a.24 (relating to ~~physician~~ practitioner registration). … (b) The requirements of the training course required under subsection (a) must include~~, at a minimum,~~ all of the following: … (d) The individuals listed in subsection (a) shall ~~submit~~ ensure that the training provider submits documentation of the completion of the 4-hour training course to the Department within the time specified in subsection (a). … (f) An application for approval to become an approved training provider is available on the Department's public website. An application meeting the requirements of subsections (b) and (c) will be approved.

§ 1181a.33. Appeals

This section provides that all actions of the Department under this chapter are governed by 2 Pa. C.S. §§ 501—508 and its accompanying regulations, as modified by Chapter 1230a.

Summary of Changes:

- A citation was amended to reflect Chapter 1230a and temporary regulations was removed.

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Changes to Final § 1181a.33. Appeals
~~Chapter 5, Subchapter A~~ Sections 501-508 of 2 Pa. C.S. (relating to practice and procedure of Commonwealth agencies) and the accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure~~—temporary regulations~~), apply to all actions of the Department under this chapter constituting an adjudication as defined in 2 Pa. C.S. §101 (relating to definitions).

CHAPTER 1191a PATIENTS AND CAREGIVERS

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1191a.24. Medical marijuana cardholder responsibilities.
1191a.25. Application for, and issuance or denial of, identification cards.
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1191a.29. Renewing an identification card.
1191a.30. Revocation or suspension of identification card.
1191a.31. Obtaining medical marijuana products from a dispensary.
1191a.32. Medical marijuana patient authorization letters.
1191a.33. Appeals

This chapter, which tracks Chapters 3, 5 and 8 in the act, details patient and caregiver registration, cardholder responsibilities, application and fees for cardholders, background checks, renewing, revoking, or suspending identification cards, obtaining products and patient authorization letters. This chapter replaces temporary Chapter 1191 (relating to patients and caregivers—temporary regulations).

§ 1191a.22. Patient and caregiver registry

This section provides that the Department will maintain a registry of patients and caregivers and lists the information that must be included in the registry. This section also provides that the information

contained in that registry is confidential and not subject to disclosure. Further, this section provides that a caregiver may waive this confidentiality requirement and consent to providing the caregiver's name and contact information to the patient.

Summary of Changes:

- Subsection (b)(3) was amended to refer to this new chapter.

Changes to Final § 1191a.22. Patient and caregiver registry

…
(b)
…
(3) Criminal history record check information provided as part of an identification card application submitted by a caregiver under §1191a.27 (relating to criminal background checks).
…

§ 1191a.23. Patients and caregivers generally

This section provides that the qualifications to become a patient or caregiver are ongoing qualifications, and the Department may issue a certification card to those individuals who meet those qualifications. Further, this section provides that the Department may, with sufficient showing of suitability, allow a person under 21 years of age to serve as a caregiver. Finally, this section provides that a minor patient shall have a caregiver who meets the criteria specified in subsection (d).

Summary of Changes:

- Subsection (c) was deleted.
- Subsection (d) was relabeled as subsection (c),
- Original subsection (d)(3) was deleted.

Changes to Final § 1191a.23. Patients and caregivers generally

…
~~(c) The Department may issue an identification card to an individual who is under 21 years of age to serve as a caregiver when a sufficient showing is made to the Department that the individual should be permitted to serve as a caregiver, as determined by the Department.~~
(~~d~~c) A minor patient shall have a caregiver who is one of the following:
…

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~~(3) An appropriate individual approved by the Department upon a sufficient showing that a parent or legal guardian is not appropriate or available.~~

§ 1191a.24. Medical marijuana cardholder responsibilities

This section details cardholder responsibilities.

Summary of Changes:

- Subsection (a) amended to correct a typographical error and to change a citation to refer to a new chapter.
- The requirement that the cardholder must return the identification card upon receiving notification from the Department that the cardholder has been removed from the registry or the patient certification has been revoked was deleted was subsection (b), because the card will be deactivated.
- The provision regarding applying for a replacement identification card was relocated from § 1191.28(f) to subsection (b).

Changes to Final § 1191a.24. Medical marijuana cardholder responsibilities

(a)

…

(2) The withdrawal of a patient certification by a practitioner under §1181a.29 (relating to revocation of a patient certification).

…

(b) A medical marijuana cardholder shall ~~return the~~ apply ~~identification card~~ to the Department for a replacement identification card within 10 business days ~~following receipt of written notice from the Department of the occurrence of any of the following:~~ of discovering the loss or defacement of the identification card.

~~(1) The removal of the medical marijuana cardholder from the patient and caregiver registry under §1191.30 (relating to revocation or suspension of identification card).~~

~~(2) The Department has received notification from the practitioner who issued the patient certification to the patient of the occurrence of any of the circumstances described in §1181.29(b).~~

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§ 1191a.25. Application for, and issuance or denial of, identification cards

This section requires patient or caregiver identification card applicants to submit the proper application. It also details the procedure where an application designates a caregiver who is not authorized to serve as a caregiver. This section provides the grounds upon which an application may be denied and the potential for correction/resubmission.

Summary of Changes:

- Subsection (a) was amended to eliminate a duplication of language.
- "At a minimum" was deleted in subsections (b) and (d).
- Subsections (b)(5) and (6) were amended to change a citation to refer to a new chapter.
- "or other documentation acceptable to the Department" was deleted in subsection (d)(2).
- Subsections (d)(4), (5), and (7) were amended to change a citation to refer to a new chapter.
- "promptly" was deleted from subsection (f).
- Subsections (b)(9) and (d)(10) were deleted.
- The background check requirement for caregiver renewal applications was removed from subsection (d)(5).
- The five-patient caregiver cap was removed from subsection (d)(6).
- "a caregiver" was added to subsections (f) through (i) for clarification.

Changes to Final § 1191a.25. Application for, and issuance or denial of, identification cards

(a) An applicant shall submit an identification card application ~~on a form prescribed by the Department~~. The application will be made available on the Department's publicly-accessible web site and in hard copy upon request.

(b) An identification card application submitted by or on behalf of a patient must include~~, at a minimum,~~ the following information:

…

(5) The patient certification issued by the patient's practitioner, which shall be provided by the practitioner to the Department under §1181a.27(d)(2) (relating to issuing patient certifications).

(6) The appropriate fee or proof of financial hardship as provided for in §1191a.26 (relating to application fees).

…

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

….

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(d) An identification card application submitted by a caregiver must include~~, at a minimum,~~ the following information:

…

(2) The caregiver's Pennsylvania driver's license number~~;~~ or a Department of Transportation State-issued identification card, if applicable, ~~or other documentation acceptable to the Department~~ evidencing the caregiver's identification.

…

(4) The patient certification issued by the patient's practitioner, which will be provided by the practitioner to the Department under §1181a.27(d)(2).

(5) A copy of the criminal history record information required under §1191a.27 (relating to criminal background checks), except when not required pursuant to §1191a.29(c) (relating to renewing an identification card).

(6) The name, address, telephone number and e-mail address, if available, of ~~up to five patients~~ any patient for which the caregiver wishes to be approved by the Department as a caregiver.

(7) The appropriate fee or proof of financial hardship as provided for in §1191a.26.

…

~~(10) Any other information deemed necessary by the Department.~~

(e) The Department will review the criminal history record information obtained by a caregiver under §1191a.27 and the Prescription Drug Monitoring Program database before approving the issuance of an identification card to the caregiver. The Department will deny the issuance of an identification card to a caregiver if the caregiver has been convicted of a criminal offense relating to the sale or possession of drugs, narcotics or controlled substances that occurred within the 5 years immediately preceding the submission of the application. The Department may deny the issuance of an identification card to a caregiver if the caregiver has a history of drug abuse or of diverting controlled substances or illegal drugs.

(f) The Department will ~~promptly~~ notify ~~an~~ a caregiver applicant in writing if an identification card application is incomplete or factually inaccurate, and provide the applicant with an explanation as to what documents or information are necessary for the Department to consider the identification card application to be complete and accurate.

(g) ~~An~~ A caregiver applicant shall have 60 days from ~~receipt~~ mailing of a notification under subsection (f) to submit to the Department the documents or information requested. If ~~an~~ a caregiver applicant fails to submit the requested documents or information within 60 days, the Department may deny the identification card application.

(h) The Department will notify ~~an~~ a caregiver applicant in writing of the reasons for the denial of an identification card application.

(i) ~~An~~ A caregiver applicant whose identification card application is denied may submit a new identification card application. The Department may decline to consider a new application that does not correct the deficiencies in the initial application leading to a prior denial.

§ 1191a.26. Application fees

This section details application fees.

Summary of Changes:

- Subsection (b) was amended for clarification.
- Subsection (c) added clarifying language and eliminated the requirement for notice to be published in January, allowing it to be posted at any time.
- Unnecessary language was deleted from subsection (d), as was the requirement for notice to be published in January, allowing it to be posted at any time.

Changes to Final § 1191a.26. Application fees

…

(b) Notwithstanding subsection (a) the following apply:

…

(c) The Department may establish higher fees for issuance of a second identification card and subsequent replacement identification cards~~. Each January, the Department will post on its publicly-accessible web site the fees for issuance of a second and subsequent replacement identification cards, and will publish~~ by publishing notice of those fees in the *Pennsylvania Bulletin*.

(d) ~~Subject to §1191.32 (relating to medical marijuana patient authorization letters), the~~ Department may waive or reduce the fee for an identification card application or identification card renewal application for an applicant who demonstrates financial hardship. ~~Each January,~~ The Department will post on its publicly-accessible web site the qualifications for financial hardship that an applicant requesting a waiver or reduction of the application fee shall submit with an identification card application or identification card renewal application. The Department will publish notice of the qualifications for financial hardship in the *Pennsylvania Bulletin*.

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§ 1191a.27. Criminal background checks

This section requires an individual applying for an identification card as a caregiver to submit fingerprints to the Pennsylvania State Police for the purpose of obtaining a criminal background check. This section also provides that the Department reviews the individual's criminal history only to determine the caregiver's character, fitness, and suitability to serve in this capacity.

Summary of Changes:

- The requirement of a background check for caregivers renewing identification cards was eliminated from subsection (a).

Changes to Final § 1191a.27. Criminal background checks

(a) An individual applying for an identification card to serve as a caregiver, who has not previously been approved by the Department to serve as a caregiver, shall submit fingerprints to the Pennsylvania State Police, or an authorized agent, for the purpose of obtaining a criminal history record check. The Pennsylvania State Police, or an authorized agent, will submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the caregiver and obtaining a current record of any criminal arrests and convictions.

…

§ 1191a.28. Identification cards

This section provides that the Department will issue identification cards as soon as practicable and requires that the card must contain certain delineated information. Further, this section outlines the circumstances under which an identification card issued to a patient or caregiver will expire.

Summary of Changes:

- A minor language change was made to subsection (b)(7)
- Subsection (b)(8) was amended by deleting non-regulatory language.
- Subsection (f) was deleted and relocated to § 1191a.24(b).

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Changes to Final § 1191a.28. Identification cards

…
(b)
…
(7) A~~ny~~ requirement or limitation on the patient certification concerning the recommended form of medical marijuana products or limitation on the duration of use, if applicable.
~~(8) Any other information deemed necessary by the Department.~~
…
~~(f) A medical marijuana cardholder shall apply to the Department for a replacement identification card within 10 business days of discovering the loss or defacement of the identification card.~~

§ 1191a.29. Renewing an identification card

This section provides that a cardholder shall submit an application for card renewal no later than 30 days prior to the expiration of the current card, and that a cardholder shall obtain a new or updated certification. Further, this section provides that the identification card will not be valid beyond the stated expiration date, and the Department may remove the individual from the patient and caregiver registry if the Department denies a renewal application or if the cardholder fails to submit a renewal application.

Summary of Changes:

- Subsection (a) was amended to require a medical marijuana cardholder to obtain a new patient certification at the time the cardholder applies for a new identification card only if the certification is expired and to change the citation to refer to a new chapter.
- Subsection (c) was added to effectuate the statutory change in Act 44 of 2021, eliminating the background check requirement for an applicant who was previously approved by the Department to serve as a caregiver. (See 35 P.S. § 10231.502(b))

Changes to Final § 1191a.29. Renewing an identification card

(a) A medical marijuana cardholder shall submit an identification card renewal application to the Department no later than 30 days prior to the expiration date on the card. The form of the renewal application will be prescribed by the Department and will be made available on the Department's publicly-accessible web site and in hard copy upon request. If a medical marijuana cardholder's patient certification is expired, the cardholder shall obtain ~~include with the~~

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~~identification card renewal application~~ a new or updated patient certification issued by the patient's practitioner, which will be provided by the practitioner to the Department under §1181a.27(d)(2) (relating to issuing patient certifications).

…

(c) Section 1191a.27 (relating to criminal background checks) shall not apply to an applicant who has been previously approved by the Department to serve as a caregiver.

§ 1191a.30. Revocation or suspension of identification card

This section provides the instances in which the Department may suspend or revoke a cardholder's identification card. Further, this section provides that if a patient's practitioner's registration has been revoked or suspended, or if a patient's practitioner withdraws the patient's patient certification, the cardholder is required to obtain a new patient certification within 90 days of receiving notice from the Department or prior to the expiration of the identification card, whichever is sooner.

Summary of Changes:

- Citations were amended to refer to a new chapter in subsections (a)(1) and (c).
- Subsection (a)(3) was amended to remove non-regulatory language and include the regulations.
- Language was added to subsection (a)(5) to address deactivation of a card when a patient desires to withdraw from participation in the program.
- Subsection (a)(5) was amended to eliminate the word "promptly" by inserting a period after "invalid" and deleting the remainder of the sentence as unnecessary.
- "promptly" was deleted from subsection (b).
- Subsection (c) was amended to require a new patient certification rather applying for a new identification card.

Changes to Final § 1191a.30. Revocation or suspension of identification card

(a)

(1) The Department receives written notice from a practitioner under §1181a.29(a) (relating to revocation of a patient certification).

…

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(3) The patient or caregiver has intentionally, knowingly or recklessly violated the act or this part. ~~regulations as determined by the Department~~. The suspension or revocation will be in addition to any criminal or other penalty that may apply.

…

(5) A patient notifies the Department in writing that the patient has elected to withdraw from participation in the Medical Marijuana Program or that the patient has removed or changed a current caregiver. If the caregiver is not serving as a caregiver for any other patient, the Department will issue a notification to the caregiver that the caregiver's identification card is invalid ~~and shall be promptly returned to the Department~~.

(b) The Department will ~~promptly~~ notify a medical marijuana cardholder in writing of any action taken by the Department regarding the medical marijuana cardholder as a result of information received under subsection (a).

(c) If a patient's practitioner's registration has been revoked or suspended under §1181a.26 (relating to denial, revocation or suspension of a practitioner registration) or if a patient's practitioner withdraws the patient's patient certification under §1181a.29(c), a medical marijuana cardholder shall ~~submit a new application for an identification card~~ obtain a new patient certification within 90 days of receiving written notice from the Department or prior to the expiration date on the identification card, whichever is sooner.

§ 1191a.31. Obtaining medical marijuana products from a dispensary

This section provides that a medical marijuana cardholder may only obtain medical marijuana products from a dispensary, and that the cardholder may only obtain medical marijuana products from a dispensary based on the recommendation provided in a valid patient certification that the dispensary may access through the electronic tracking system.

Summary of Changes:

- Subsections (a) and (b) were amended to change a citation to refer to a new chapter.

Changes to Final § 1191a.31. Obtaining medical marijuana products from a dispensary

(a) A medical marijuana cardholder may only obtain medical marijuana products from a dispensary in accordance with §1161a.24 (relating to limitations on dispensing).

(b) A medical marijuana cardholder may only obtain medical marijuana products from a dispensary based upon the recommendation in a patient certification that has not been revoked under §1181a.29 (relating to revocation of a patient certification) and that may be accessed by a dispensary through the electronic tracking system.

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§ 1191a.32. Medical marijuana patient authorization letters

This section provides that the Department will issue a medical marijuana patient authorization letter to a minor patient and may issue a patient authorization letter to an adult patient, instead of issuing an identification card. Further, this section provides that when the minor patient who has been issued a patient authorization letter turns 18 years of age, the patient is entitled to apply for an identification card. This section also provides that a medical marijuana patient authorization letter confers the same rights and obligations, and is subject to the same terms and conditions, as apply to a medical marijuana cardholder, except that an identification card will be required for entry into a dispensary. Finally, this section provides that a patient who has been issued a medical marijuana patient authorization letter will not be required to pay an identification card application fee or an identification card renewal application fee.

Summary of Changes:

- Subsection(a) was amended to change a citation to refer to a new chapter.
- Language was added to subsection (b) to clarify that a patient authorization letter may be issued to an adult patient only when the patient's illness or infirmity permanently prevents the patient from visiting a dispensary.

Changes to Final § 1191a.32. Medical marijuana patient authorization letters

(a) The Department will issue a medical marijuana patient authorization letter to a minor patient instead of issuing an identification card to the minor patient. Upon reaching 18 years of age, a minor patient who has been issued a medical marijuana patient authorization letter will be entitled to receive an identification card upon application under §1191a.25 (relating to application for, and issuance or denial of, identification cards).

(b) The Department may issue a medical marijuana patient authorization letter to an adult patient only when the patient's illness or infirmity permanently prevents the patient from visiting a dispensary.

…

§ 1191a.33. Appeals

This section provides that all actions of the Department under this chapter are governed by 2 Pa. C.S. §§ 501—508, as modified by Chapter 1230a.

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Summary of Changes:

- A citation was amended to reflect Chapter 1230a and temporary regulations was removed.

Changes to Final § 1191a.33. Appeals
~~Chapter 5, Subchapter A~~ Section 501-508 of 2 Pa. C.S. (relating to practice and procedure of Commonwealth agencies) and the accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure~~—temporary regulations~~), apply to all actions of the Department under this chapter constituting an adjudication as defined in 2 Pa. C.S. §101 (relating to definitions).

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This chapter in this final-form rulemaking contains general provisions that apply to all permittees such as: definitions; public and confidential records; permitting regions; requirements and fees for permit applications, including renewal applications; changes in ownership and facility location; alteration of facilities; facility and training requirements; and penalties and sanctions for noncompliance. The provisions of this chapter are promulgated in accordance with Chapters 1, 3, 6 and 13 of the act. This chapter is substantially similar to temporary Chapter 1141 (relating to general provisions—temporary regulations).

§ 1141a.21. Definitions

This section includes all terms that were contained in temporary § 1141.21, as well as additional terms. This section also consolidates all definitions for Part IXa into this section instead of defining the terms separately in each chapter as was done in the temporary rulemakings. Because of the request for clarity and to make it easier for the regulated community to understand the changes that were made special formatting is used here.

Summary of Changes:

- The following terms were deleted:
  - ✓ Approved clinical registrant
  - ✓ Certified ACRC
  - ✓ Immediate family
  - ✓ Industrial hemp

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  - ✓ Laboratory applicant
- The following terms were added:
  - ✓ ACRC
  - ✓ Added substance
  - ✓ CAS number
  - ✓ CBC
  - ✓ CBDA
  - ✓ CBDV
  - ✓ CBG
  - ✓ CBN
  - ✓ Cannabinoids
  - ✓ D8
  - ✓ De-identified data
  - ✓ Harvested hemp
  - ✓ Medical marijuana extract
  - ✓ Postharvest plant material
  - ✓ Research initiative
  - ✓ Species
  - ✓ Synchronous interaction
  - ✓ THCA
  - ✓ THCV
  - ✓ Terpenes
- The definitions of the following terms were amended:
  - ✓ Applicant
  - ✓ CBD
  - ✓ Caregiver
  - ✓ Clinical registrant
  - ✓ Controlling interest
  - ✓ Marijuana
  - ✓ Medical marijuana organization
  - ✓ Medical marijuana waste
  - ✓ Municipality
  - ✓ Patient
  - ✓ Publicly traded company
  - ✓ Serious medical condition
  - ✓ THC

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Changes to Final § 1141a.21. Definitions

Due to the numerous definition additions, deletions, and changes, all definition changes are included at the end of this document.

§ 1141a.22. Records subject to disclosure; confidentiality

This section addresses which records are subject to disclosure and which records must remain confidential.

Summary of Changes:

- Language was removed from subsection (b)(11) to eliminate any ambiguity relating to the confidentiality of individuals who review permit applications to protect the identities of, and any other information pertaining to, those individuals.
- Subsection (d) was amended to clarify when redactions are required.
- Subsection (e) was amended to reflect the holding of the Pennsylvania Supreme Court in *McKelvey v. DOH*, 255 A.3d 385 (Pa. 2021) that the Department is obligated to make its own determination as to whether records marked as confidential, proprietary or trade secret should be released.
- Subsection (f) was added allowing the Department to release de-identified data for research purposes that are subject to approval and oversight by the Department and an institutional review board.
- Subsection (g) was added permitting the Department to collaborate with other Commonwealth agencies for purposes of investigating and enforcing violations of the act and regulations.

Changes to Final § 1141a.22. Records subject to disclosure; confidentiality

…

(b)

(11) ~~The names and any other information relating to~~ Information that would identify persons reviewing permit applications, including a reviewer's name, individual permit application reviews and notes.

…

(d) An applicant's failure to redact confidential proprietary or trade secret information in accordance with § 1141a.29(a)(2) (relating to initial permit application) ~~its submitted permit application~~ will result in disclosure to the public of the confidential proprietary or trade secret information in response to a Right-to-Know Law request.

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(e) ~~An applicant is responsible for defending its own redactions in any administrative or court proceeding, including any appeals. Any information not adequately defended by the applicant may result in full disclosure of the information in un-redacted form.~~ In accordance with section 707(b) of the Right-to-Know Law (65 P.S. § 67.707(b)), the Department will make an independent determination as to whether to release the information marked as confidential proprietary or trade secret.

(f) Nothing in this section shall preclude the Department from releasing de-identified data for research purposes, subject to approval and oversight by the Department and an IRB to ensure that the use of the data is limited to the specified research purposes.

(g) Notwithstanding subsection (b), in accordance with section 301(a)(11) of the act (35 P.S. § 10231.301(a)(11)), the Department may collaborate with other Commonwealth agencies as necessary to carry out the provisions of the act and this part. Collaboration shall include the sharing of information, including information deemed confidential under the act and this part, with any other agency, when needed to investigate a potential violation of the act or this part. Information shared under this section shall remain confidential and may not be disclosed except for investigatory or enforcement purposes.

§ 1141a.23. Limitation on number of permits

This section sets the limits on the amount of grower/processor and dispensary permits the Department may issue and the limit of permits that may be received by one person.

Summary of Changes:

- "Notwithstanding" was changed to Except as provided in" in the introduction.
- Subsection (2)(ii) was amended by replacing "as approved by the Department" with "as approved in the initial permit application or under § 1161a.40".
- Subsection (3) was deleted to comport with deletion of this requirement in Act 44 of 2021.

Changes to Final § 1141a.23. Limitation on number of permits

~~Notwithstanding~~ Except as provided in section 2002 of the act (35 P.S. § 10231.2002), the following limitations apply regarding the number of permits to be issued under this part:

…

(2)

…

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(ii) A dispensary permit may be used to provide medical marijuana at no more than three separate locations as approved ~~by the Department.~~ in the initial permit application or under § 1161a.40 (relating to additional dispensary locations).

~~(3) In accordance with section 1202(j)(5)(iv) of the act (35 P.S. § 10231.1202(j)(5)(iv)), the Department may issue permits in addition to those in paragraphs (1) and (2) if necessary as the Medical Marijuana Program expands, including to comply with an order of court. No more than 20% of the total number of growers/processors may also be issued permits as dispensaries.~~

§ 1141a.24. Medical marijuana regions

This section outlines the geographic areas contained in each of the six medical marijuana regions in this Commonwealth. Further, this section provides factors the Department will consider when issuing a permit and allows the Department to change the number or boundaries of the regions every 2 years.

Summary of Changes:

- No changes were made to this section.

§ 1141a.25. General requirements for permits

This section outlines the general guidelines and prohibitions with respect to permits.

Summary of Changes:

- No changes were made to this section.

§ 1141a.26. Privilege and nontransferability

This section provides that the issuance or renewal of a permit is a revocable privilege, and that permits are nontransferable.

Summary of Changes:

- No changes were made to this section.

§ 1141a.27. General requirements for application

This section outlines the general requirements for an application.

Summary of Changes:

- Subsections (a)(3) thought (5) were amended by deleting unnecessary language.
- Subsection (a)(4) was amended for clarification.

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- Renewal was added to subsection (a)(7).
- Non-regulatory language was removed from subsection (b).
- A citation was changed in subsection (c) to refer to the new chapter and language was added for clarification.
- Subsection (d) was amended by relocating language regarding refunds to § 1141a.28(a)(2) and (b)(2) and by adding clarifying language.

Changes to Final § 1141a.27. General requirements for application

(a)

…

(3) An application for ~~approval of a~~ change in ownership of a medical marijuana organization ~~authorized by a permit~~.

(4) An application for approval of a change of location of ~~a~~ an operational facility ~~authorized by a permit~~.

(5) An application for approval of alteration of a facility ~~authorized by a permit~~.

…

(7) An application for approval or renewal of a laboratory.

(b) By submitting an application to the Department, an applicant consents to any investigation~~, to the extent deemed appropriate by the Department,~~ of the applicant's ability to meet the requirements under the act applicable to the application.

(c) An application for an initial permit or for a renewal permit is not complete and will be rejected by the Department unless:

(1) The payment of the applicable application fee in § 1141a.28 (relating to fees) is submitted with the application.

…

(3) ~~All r~~Required information for each section of the application, including attachments and any supplemental information required by the Department, is submitted to the Department.

…

(d) An application ~~that is rejected by the Department as incomplete will be returned to the applicant without further consideration by the Department and the initial permit fee will be refunded.~~ for an initial permit that is incomplete will be rejected by the Department.

…

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§ 1141a.28. Fees

This section pertains to permit and application fees.

Summary of Changes:

- Subsection (a) was amended to add another payment method; a citation was changed in subsection (a)(1) to reflect the new chapter.
- Clarification language was added to subsection (a)(2).
- Subsection (b) was amended to add another payment method; a citation was changed in subsection (b)(1) to reflect the new chapter.
- Clarification language was added to subsection (b)(2).
- Subsection (c) was amended to add another payment method.
- Unnecessary language was removed from subsections (c)(2) and (3).
- Subsection (c)(2) was amended to be consistent with § 1141a.27(a)(4) (relating to general requirements for application).

Changes to Final § 1141a.28. Fees

(a) An applicant for an initial grower/processor permit or renewal permit shall pay the following fees by certified or cashier's check or money order to the Department:

(1) Initial permit application fee—$10,000. The initial permit application fee shall be submitted with the initial permit application and is nonrefundable, except as provided in § 1141a.29(a)(3) (relating to initial permit application).

(2) Initial permit fee—$200,000. The initial permit fee shall be submitted with the initial permit application and will be refunded if the initial permit is not granted or the application is rejected.

…

(b) An applicant for an initial dispensary permit or renewal permit shall pay the following fees by certified or cashier's check or money order to the Department:

(1) Initial permit application fee—$5,000. The initial permit application fee shall be submitted with the initial permit application and is nonrefundable, except as otherwise provided in ~~this part.~~ § 1141a.29(a)(3).

(2) Initial permit fee—$30,000 for each dispensary location. The initial permit fee shall be submitted with the initial permit application and will be refunded if the initial permit is not granted or the application is rejected

…

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(c) A medical marijuana organization shall pay a fee of $250 by certified or cashier's check or money order to the Department with the submission of the following:

(1) An application for ~~approval of a~~ change in ownership of a medical marijuana organization.

(2) An application for approval of a change of location of ~~a~~ an operational facility ~~authorized by a permit~~.

(3) An application for approval of alteration of a facility ~~authorized by a permit~~.

§ 1141a.29. Initial permit application

This section details permit application requirements.

Summary of Changes:

- Changes to citations were made to reflect this new chapter in subsections (a)(2), (b), (b)(6)(iii), (b)(9)(iv), (b)(12)(xii), and (b)(13).
- Non-regulatory language was deleted from subsections (b)(3)(ii) and (iii) and (12).
- Subsection (b)(6)(ii) was deleted to comport with elimination of this requirement in Act 44 of 2021. Also, subsection (b)(6)(iii) and (iv) is renumbered due to the deletion of subsection (ii) and amended to effectuate statutory changes made by Act 44 of 2021.
- Former subsection (b)(6)(iii), now subsection (b)(6)(ii), was amended to effectuate statutory changes made by Act 44 of 2021.
- Former subsection (b)(6)(iv), now subsection (b)(6)(iii), was amended by adding language for consistency.
- Subsection (b)(6)(iii)(B) was amended by adding language to reflect changes made by Act 44 of 2021.
- Subsection (b)(6)(iii) added subsections (C) and (D), which were relocated from subsection (b)(9)(vi) and (vii).
- Subsection (b)(9)(v) was deleted due to being duplicative.
- Subsection (b)(12) was amended to specifically detail other requirements to be included in the plan of operation.
- Subsection (b)(14)(i) was amended to comport with the requirements of Act 44 of 2021.
- Subsection (b)(16) was to list the specific requirement for inclusion of a diversity plan in an application.
- Subsection (b)(17) was added to require inclusion of a community impact statement in an application.

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Changes to Final § 1141a.29. Initial permit application

(a)

…

(2) An applicant shall submit an initial permit application using the form posted on the Department's web site together with a version that is redacted in accordance with the Right-to-Know Law (65 P.S. § § 67.101—67.3104), as set out in § 1141a.22 (relating to records subject to disclosure; confidentiality), by mail in an electronic format that is prescribed by the Department in the initial permit application instructions.

…

(b) In addition to the requirements in § 1141a.27 (relating to general requirements for application), the applicant shall provide the Department with the following information in the initial permit application:

…

(3)

…

(iii) Other evidence satisfactory to the Department that shows the applicant has the authority to use the proposed site and facility as a site and facility for~~, at a minimum,~~ the term of the permit.

…

(6)

…

~~(ii) Evidence of good moral character and reputation of each principal, operator, financial backer or employee.~~

~~(iii)~~ (ii) A copy of a criminal history records check for each individual performed in accordance with § 1141a.31 (relating to background checks). This subparagraph does not apply to an applicant who is an owner of securities in a publicly traded company or an owner of 5% or less in a privately held business entity and who does not have voting rights to elect or appoint one or more members of the board of directors or other governing board. ~~if the Department determines that the owner of the securities is not substantially involved in the activities of the applicant.~~

~~(iv)~~ (iii) An affidavit from each principal, ~~or~~ operator, or financial backer of the applicant setting forth the following:

…

(B) Whether the principal, operator or financial backer has been convicted of a felony criminal offense related to the manufacture, delivery or possession with intent to manufacture or deliver a controlled substance in violation of The Controlled Substance, Drug, Device and

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Cosmetic Act (35 P.S. §§ 780-101—780-144), or similar law in any other jurisdiction and, if yes, whether 10 or more years have passed since entry of a final disposition on the conviction or 1 or more years have passed since the individual's release from incarceration for the conviction, whichever is later. ~~a criminal offense graded higher than a summary offense.~~

(C) Whether the principal, operator or financial backer has been a party in any civil or administrative action under the laws of the Commonwealth or any other state, the United States or a military, territorial or tribal authority relating to the principal, operator or financial backer's profession, occupation or fraudulent practices, including fraudulent billing practices.

(D) Whether the principal, operator or financial backer has attempted to obtain a registration, license, permit or other authorization to operate a medical marijuana organization in any jurisdiction by fraud, misrepresentation or the submission of false information.

(9)

…

(iv) Evidence that the applicant and its principals and other persons affiliated with the applicant identified by the Department is in compliance with all the laws of the Commonwealth regarding the payment of State taxes as shown on the tax clearance certificates issued by the Department of Revenue and the Department of Labor and Industry under § 1141a.27.

~~(v) Evidence of any criminal action under the laws of the Commonwealth or any other state, the United States or a military, territorial or tribal authority, graded higher than a summary offense, against a principal, operator, financial backer or employee, or which involved the possession, transportation or sale of illegal drugs, or which related to the provision of marijuana for medical purposes, including any action against an organization providing marijuana for medical purposes in which those individuals either owned shares of stock or served as executives, and which resulted in a conviction, guilty plea or plea of nolo contendere, or an admission of sufficient facts.~~

~~(vi) Evidence of any civil or administrative action under the laws of the Commonwealth or any other state, the United States or a military, territorial or tribal authority relating to a principal, operator, financial backer or employee of the applicant's profession, or occupation or fraudulent practices, including fraudulent billing practices.~~

~~(vii) Evidence of any attempt by the applicant to obtain a registration, license, permit or other authorization to operate a medical marijuana organization in any jurisdiction by fraud, misrepresentation or the submission of false information.~~

~~(viii)~~ (v) A statement that the applicant shall provide evidence of workers' compensation insurance if the applicant is issued a permit and the facility is determined to be operational by

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the Department.

…

(12) A summary of the intended plan of operation that describes~~, at a minimum,~~ how the applicant's proposed business operations will comply with the act and this part relating to:

…

(v) With respect to an application for a grower/processor permit, packaging and labeling of medical marijuana products.

…

(vii) With respect to a grower/processor's facility, nutrient and additive practice.

…

(ix) ~~Recordkeeping.~~ With respect to a grower/processor's facility, processing and extraction.

(x) ~~Preventing unlawful diversion of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.~~ Sanitation and safety.

(xi) ~~With respect to a grower/processor's facility, growing of medical marijuana, including a detailed summary of policies and procedures for its growth.~~ Recordkeeping.

(xii) ~~Establishment, implementation and monitoring of diversity goals under § 1141.32 relating to diversity goals).~~ Preventing unlawful diversion of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(xiii) With respect to a grower/processor's facility, growing of medical marijuana, including a detailed summary of policies and procedures for its growth.

(xiv) Establishment, implementation and monitoring of diversity goals under § 1141a.32 (relating to diversity goals).

(13) The relevant financial information in § 1141a.30 (relating to capital requirements).

(14) Statements that:

(i) The applicant ~~and each principal, operator, financial backer and employee are of good moral character.~~ possesses the ability to obtain in an expeditious manner the right to use the proposed site and facility, including equipment, to properly perform the activity described in the initial permit application.

(ii) ~~The applicant possesses the ability to obtain in an expeditious manner the right to use the proposed site and facility, including equipment, to properly perform the activity described in the initial permit application.~~ The grower/processor permit applicant is able to continuously maintain effective security, surveillance and accounting control measures to prevent diversion, abuse and other illegal conduct regarding seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products. The dispensary permit applicant is able to continuously maintain effective security, surveillance and accounting control measures to prevent diversion, abuse and other illegal conduct regarding medical marijuana products.

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(iii) ~~The grower/processor permit applicant is able to continuously maintain effective security, surveillance and accounting control measures to prevent diversion, abuse and other illegal conduct regarding seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products. The dispensary permit applicant is able to continuously maintain effective security, surveillance and accounting control measures to prevent diversion, abuse and other illegal conduct regarding medical marijuana products.~~ The applicant is able to continuously comply with all applicable laws of the Commonwealth, the act, this part, and the terms and conditions of the initial permit.

(iv) ~~The applicant is able to continuously comply with all applicable laws of the Commonwealth, the act, this part, and the terms and conditions of the initial permit.~~

…

(16) ~~Other information required by the Department~~. A diversity plan demonstrating ability to meet the diversity goals outlined in section 615 of the act (35 P.S. § 10231.615).

(17) A statement summarizing how the applicant intends to positively impact the community where operations are proposed to be located.

§ 1141a.30. Capital requirements

This section provides that a medical marijuana organization applicant must provide an affidavit, confirming that the applicant has the necessary amount of funds on deposit with one or more financial institutions.

Summary of Changes:

- No changes were made to this section.

§ 1141a.31. Background checks

This section details background check requirements.

Summary of Changes:

- A citation was changed in subsection (a) to refer to the new chapter.
- Subsection (b)(1) was added to comport with new language in Act 44 of 2021.
- Subsection (c) was amended by adding language and also under Act 44 of 2021.
- Subsection (d) was amended to reflect changes made by Act 44 of 2021.

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Changes to Final § 1141a.31. Background checks

(a) To provide the criminal history record check required under § 1141a.29 (relating to initial permit application), an applicant shall submit fingerprints of its principals, financial backers, operators and employees to the Pennsylvania State Police. The Pennsylvania State Police or its authorized agent will submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the individuals whose fingerprints have been submitted and obtaining a current record of criminal arrests and convictions.

(b.1) After submitting proof to the Department that fingerprints have been obtained, an individual may begin employment at a medical marijuana organization in a supervised capacity until the Department approves the individual to affiliate with the medical marijuana organization. If the Department does not approve the individual to affiliate with the medical marijuana organization, the individual shall be immediately terminated from the medical marijuana organization.

(c) This section does not apply to an owner of securities in a publicly traded corporation or an owner of 5% or less in a privately held business entity and who does not have voting rights to elect or appoint one or more members of the board of directors or other governing board. ~~company if the Department determines that the owner is not substantially involved in the activities of the medical marijuana organization.~~

(d) A financial backer, principal or employee may not hold a volunteer position, position for remuneration or otherwise be affiliated with a medical marijuana organization or a clinical registrant if the individual has been convicted of a felony criminal offense relating to the manufacture, delivery or possession with intent to manufacture or deliver a controlled substance in violation of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144), or similar law in any other jurisdiction unless: 10 or more years have passed since the entry of a final disposition of the felony conviction, or 1 year has passed since the individual's release from imprisonment for the felony conviction, whichever is later. ~~criminal offense relating to the sale or possession of illegal drugs, narcotics or controlled substances.~~

§ 1141a.32. Diversity goals

This section outlines the Department's intent that medical marijuana organizations establish practices and procedures for promoting and ensuring diversity.

Summary of Changes:

- Non-regulatory language was removed from subsection (c).

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- Grammatical changes were made in subsection (h).

Changes to Final § 1141a.32. Diversity goals

…

(c) Each medical marijuana organization shall include in its permit application a diversity plan that establishes a goal of equal opportunity and access in employment and contracting by the medical marijuana organization. The Department will determine whether the stated goals in the diversity plan ~~are reasonable and represent a good faith effort to~~ meet the diversity goals of section 615(a) of the act.

…

(h) The Department will review the diversity plan and provide the medical marijuana organization with ~~advice~~ information regarding activities that ~~should~~ may be undertaken by the medical marijuana organization to improve its efforts to encourage and promote participation by diverse participants and diverse groups to comply with the diversity goals of the act. The Department may consult with the Department of General Services, Bureau of Diversity, Inclusion and Small Business Opportunities in the review of diversity plans and the reports submitted by medical marijuana organizations under this section.

§ 1141a.33. Review of initial permit applications

This section provides that the Department will review initial permit applications in accordance with section 603(a.1) of the act and the factors in § 1141a.24(b) (relating to medical marijuana regions). Further, the Department will publish the number of permits to be issued and the locations thereof in the *Pennsylvania Bulletin* before the initial permit applications are made available for submission.

Summary of Changes:

- An amendment of the citation in subsection (a) was made to refer to the new chapter.

Change to Final § 1141a.33. Review of initial permit applications

(a) The Department will review initial permit applications submitted by applicants according to the criteria in section 603(a.1) of the act (35 P.S. § 10231.603(a.1)) and the factors in § 1141a.24(b) (relating to medical marijuana regions).

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§ 1141a.34. Denial of permit

This section delineates the grounds upon which the Department will deny the issuance of a permit to an applicant.

Summary of Changes:

- Amendments were made to the citations in paragraphs (3) and (8) to refer to the new chapter.
- Language was changed in paragraph (3) to address statutory changes made in Act 44 of 2021.

Changes to Final § 1141a.34. Denial of permit

…

(3) The results of the criminal history record check received by the Department under § 1141a.31 (relating to background checks) for a principal, financial backer, operator or employee of the applicant indicates that the individual has been convicted of a prohibitive criminal offense as detailed under § 1141a.31(d) and, ~~a criminal offense relating to the sale or possession of illegal drugs, narcotics or controlled substances and,~~ following notification by the Department, the applicant fails or refuses to provide the Department with evidence satisfactory to the Department that the individual is no longer associated with the applicant in this capacity.

…

(8) The Department determines, in its sole discretion, that the applicant has not met the criteria under § 1141a.33 (relating to review of initial permit applications).

§ 1141a.35. Notice of denial

Under this section, the Department will provide written notice of denial to an applicant and the applicant may then appeal a notice of denial.

Summary of Changes:

- A citation was changed in subsection (b) to refer to a new chapter.

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Changes to Final § 1141a.35. Notice of denial

…

(b) The applicant may appeal a notice of denial under 2 Pa. C.S. §§ 501—508 ~~Chapter 5, Subchapter A~~ (relating to practice and procedure of Commonwealth agencies) and its accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure—~~temporary regulations~~).

§ 1141a.36. Permit renewal applications

This section provides the procedure for medical marijuana organizations applying for a permit renewal, in addition to specifying the information that must be included in the application.

Summary of Changes:

- An amendment of the citation in subsection (b) was made to refer to the new chapter.
- Subsection (c)(3) is amended for clarification.

Changes to Final § 1141a.36. Permit renewal applications

…

(b) A medical marijuana organization shall submit the applicable fee in § 1141a.28 (relating to fees) with the permit renewal application.

(c)

…

(3) The medical marijuana organization's history of compliance with the act and this part including a summary of any noncompliance and corrective action taken or a statement indicating that the medical marijuana organization has not violated the act or regulations as of the date the renewal application is submitted.

§ 1141a.37. Denial of renewal of a permit

This section provides the grounds upon which the Department will deny the renewal of a medical marijuana organization's permit and outlines the obligations of a medical marijuana organization should it fail to file a permit renewal application or should the Department deny its application for a renewal permit.

Summary of Changes:

- Citations in subsections (b), (d) and (e) were changed to refer to the new chapter.

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Changes to Final § 1141a.37. Denial of renewal of a permit

…

(b) An existing permit is immediately invalid upon expiration if the medical marijuana organization has not filed a permit renewal application in accordance with § 1141a.36 (relating to permit renewal applications) and remitted the required fees in accordance with § 1141a.28 (relating to fees).

…

(d) If the Department denies renewal of the permit or if the medical marijuana organization fails to submit a permit renewal application and permit renewal fee as required under § 1141a.28, the medical marijuana organization shall do the following upon the expiration of the permit:

(e) If a medical marijuana organization submits a permit renewal application and permit renewal fee to the Department as required under § 1141a.28, the Department may administratively extend the existing permit from the date the existing permit expires until the Department can complete its permit renewal application review.

§ 1141a.38. Duty to report

This section outlines the circumstances under which an applicant must report changes of information during the application process, as well as during the permit period, to the Department.

Summary of Changes:

- Non-regulatory language was removed from subsection (a)(2).
- Subsection (a)(3) includes a non-substantive edit for clarification.

Changes to Final § 1141a.38. Duty to report

(a)

…

(3) Immediately ~~upon becoming~~ when they become aware, ~~and~~ or State and local law enforcement ~~immediately upon becoming~~ make them aware, of any adverse loss from a facility operated by the medical marijuana organization or any vehicle transporting seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to or from a facility operated by the medical marijuana organization.

(b) If the change in information involves a change in control of the medical marijuana organization, the medical marijuana organization shall surrender its existing permit to the Department, unless the medical marijuana organization ~~submits an application for approval of a change in ownership of a medical marijuana organization in accordance with § 1141.39 (relating~~

~~to application for approval of a change in ownership of a medical marijuana organization)~~ notifies the Department of the change in ownership of a medical marijuana organization in accordance with § 1141a.39 (relating to change in ownership of a medical marijuana organization).

(c) If the change in information involves a change in any of the activities on the medical marijuana organization site, including any of the following, the medical marijuana organization shall surrender its existing permit to the Department and take action as required under § 1141a.43 (relating to closure of a facility):

§ 1141a.39. Change in ownership of a medical marijuana organization

This section replaces temporary § 1141.39 (relating to application for approval of a change in ownership of a medical marijuana organization).

Summary of Changes:

- The title of the section was changed for consistency.
- Subsection (a) was amended for clarification.
- Subsection (b) was amended to reflect actual practice, for consistency, and for clarification.
- Subsection (c) was amended for consistency.
- Subsection (d) was amended for consistency and to reflect actual practice.
- Subsection (e) was deleted to eliminate a process that is not utilized.

Changes to Final § 1141a.39. Change in ownership of a medical marijuana organization

§ 1141a.39. ~~Application for approval of a change in ownership of a medical marijuana organization.~~ Change in ownership of a medical marijuana organization.

(a) In the event of an impending change in ownership involving a change in control of a medical marijuana organization from the ownership listed in the initial permit application or a permit renewal application, the medical marijuana organization shall submit ~~an application for approval of a change in ownership, on a form prescribed by the Department, to the Department together with the fee required under § 1141.28 (relating to fees).~~ to the Department the name of each individual affiliating, and each individual no longer affiliating, with the medical marijuana organization, together with the fee required under § 1141a.28 (relating to fees).

(b) ~~The Department, in its sole discretion, may permit the medical marijuana organization to incorporate by reference all of the information in the medical marijuana organization's initial permit application, and any previously submitted permit renewal application, into the application for approval of a change in ownership.~~ A medical marijuana organization's change in ownership

will not be considered complete by the Department until the names of all incoming and outgoing affiliates have been submitted to the Department and the appropriate application fee under § 1141a.28 is submitted.

(c) ~~A medical marijuana organization's application for approval of a change in ownership will not be considered complete by the Department until all portions of the application are completed and the appropriate application fee under § 1141.28 is submitted. The Department may reject an incomplete application.~~ For each individual that is part of the proposed change in ownership, the medical marijuana organization shall include all of the information required under § 1141a.29 (relating to initial permit application) for the individuals listed in those capacities in the medical marijuana organization's initial permit application or any previously submitted permit renewal application.

(d) ~~For each individual that is part of the proposed change in ownership, the medical marijuana organization shall include all of the information required under § 1141.29 (relating to initial permit application) for the individuals listed in those capacities in the medical marijuana organization's initial permit application or any previously submitted permit renewal application.~~ A change in ownership of a medical marijuana organization that occurs without the Department's knowledge of all individuals affiliating with the medical marijuana organization is a violation of the act and this part.

(e) ~~If the Department determines that an application for approval of a change in ownership is lacking sufficient information upon which to make a determination, the Department will notify the medical marijuana organization in writing of the factors that require additional information and documentation. The medical marijuana organization shall have 30 days from the mailing date of the notice to provide the requested information and documentation to the Department. A medical marijuana organization's failure to provide the requested information to the Department by the deadline may be grounds for denial of approval for the requested change in ownership. Nothing in this subsection requires the Department to request additional or supplemental information from a medical marijuana organization.~~

§ 1141a.40. Application for approval of a change in location of an operational facility

This section provides the procedure in which an operational facility may apply to relocate and the applicant's responsibilities with respect to the content of the application, duties after receiving approval and grounds for denial of an application.

Summary of Changes:

- The title of the section was changed for consistency.

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- A citation was changed in subsection (a) to reflect the new chapter.
- Subsections (a) and (b) were amended for consistency and non-regulatory language was removed from both subsections.
- Subsection (h) was added for clarification.

Changes to Final § 1141a.40. Application for approval of a change in location of an operational facility

§ 1141a.40. Application for approval of a change in location of an operational facility.

(a) A medical marijuana organization wishing to change the location of ~~a site or~~ an operational facility ~~authorized under a permit issued to the medical marijuana organization~~ shall submit an application for approval of a change in location to the Department together with the fee required under § 1141a.28 (relating to fees).

(b) A change in location of an operational facility ~~authorized under a permit~~ may not occur until the Department approves the change, in writing, under this section.

…

(h) The Department will approve a change in location if the permittee submits an application containing complete information that the Department deems compliant with §§ 1141a.29, 1151a.23, 1151a.26, 1151a.33, 1161a.26, 1161a.31 and 1161a.34 regarding the following:

(1) Application name, address and contact information.
(2) Facility information.
(3) Principals, financial backers, operators and employees.
(4) Operational timetable.
(5) Security and surveillance.
(6) Sanitation and safety.
(7) Community impact.
(8) Property title, lease or option to acquire property location.
(9) Site and facility plan.

§ 1141a.40.1. Request to change location of a non-operational facility

This new section is added in response to public comments and provides that the Department will review a request to change the location of a non-operational facility based upon individual circumstances and in consideration of the following factors: (1) inability to operationalize the location due to circumstances beyond the permittee's control and the permittee knew, or should have known, of the circumstances prior to selecting the site location; (2) viability of the permittee or

the ability to sustain the permitted location, or both, is at risk; and (3) impact on patient access to medical marijuana or resulting acquisition costs of medical marijuana in this market, or both, may be excessive. This section further provides that the Department will not approve a change of location that is outside the boundaries of the region for which the initial permit was issued and may require relocation within the same municipality or county as the originally designated location.

Summary of Changes:

- This entire section is new.

New – Final § 1141a.40.1. Request to change location of a non-operational facility

(a) The Department will review a request to change the location of a non-operational facility based upon individual circumstances and in consideration of the following factors:

(1) Inability to operationalize the location due to circumstances beyond the permittee's control unless the permittee knew, or should have known, of the circumstances prior to selecting the site location.

(2) Viability of the permittee, the ability to sustain the permitted location, or both, is at risk.

(3) Impact on patient access to medical marijuana, resulting acquisition costs of medical marijuana in this market, or both, may be excessive.

(b) The Department will not approve a change of location that is outside the boundaries of the region for which the initial permit was issued and may require relocation within the same municipality or county as the originally designated location.

§ 1141a.41. Application for approval of alteration of a facility

This section provides that, generally, a medical marijuana organization may not alter its facility after the issuance of a permit. This section further provides that a medical marijuana organization wishing to make this type of alteration must submit an application to do so.

Summary of Changes:

- The citation in subsection (b) was amended to refer to this new chapter.

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Changes to Final § 1141a.41. Application for approval of alteration of a facility

…

(b) A medical marijuana organization wishing to make any of the following alterations to the facility for which its permit was issued shall submit an application for approval of alteration of a facility, on a form prescribed by the Department, to the Department together with the fee required under § 1141a.28 (relating to fees):

§ 1141a.42. Failure to be operational

This section requires a medical marijuana organization to notify the Department that it is operational within 6 months from the date the Department issues the permit.

Summary of Changes:

- Subsection (c) was amended for clarification.
- Subsection (d) was amended to refer to the new chapter.

Changes to Final § 1141a.42. Failure to be operational

…

(c) If the medical marijuana organization has not met the operational timetable in the initial permit application to the satisfaction of the Department at the time of the inspection conducted under subsection (b), the Department will notify the medical marijuana organization of the deficiencies. Within 30 days of ~~receiving~~ the mailing date on the Department's notice, the medical marijuana organization shall submit to the Department for approval a plan of correction that sets forth the medical marijuana organization's timeline and a date certain, which may not extend beyond 90 days following the date the Department approves the plan of correction, for correcting the deficiencies.

(d) If the medical marijuana organization does not comply with its plan of correction as approved by the Department within 90 days following the Department's approval, the Department may revoke or suspend the medical marijuana organization's permit under § 1141a.47 (relating to general penalties and sanctions).

§ 1141a.43. Closure of a facility

This section outlines the procedure for a medical marijuana facility to close a facility. This section also lists activities in which a medical marijuana organization is prohibited from engaging after providing notice of its intention to close a facility.

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Summary of Changes:

- Citations in subsections (c)(3) and (d) were changed to refer to the new chapter.

Changes to Final § 1141a.43. Closure of a facility

…
(c)
…
(3) How it intends to dispose of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products or other plant matter projected to still be in the facility at the time of the projected closure in accordance with § 1151a.40 (relating to management and disposal of medical marijuana waste).
…
(d) A medical marijuana organization may not remove or destroy any seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, other plant matter, medical marijuana products, equipment, or medical devices or instruments until the Department has approved its plan for closure submitted under subsection (c) and shall comply with all requirements regarding disposal of medical marijuana in § 1151a.40.
…

§ 1141a.44. Insurance requirements

This section requires a medical marijuana organization to obtain and maintain an adequate amount of insurance coverage for its activities, facilities, and equipment. This section further provides that a medical marijuana organization must obtain and maintain adequate workers' compensation insurance coverage.

Summary of Changes:

- No changes were made to this section.

§ 1141a.45. Inspection and investigation

This section provides that the Department may conduct announced or unannounced inspections to ensure a medical marijuana organization's compliance with its permit, the act and this part, and specifies the elements of the inspections. This section further provides the extent to which the Department and its authorized agents may inspect a facility. The section also outlines the penalty for a medical marijuana organization's failure to provide immediate access to its facility.

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Summary of Changes:

- No changes were made to this section.

§ 1141a.46. Reports

This section details reports required to be submitted by medical marijuana organizations.

Summary of Changes:

- Subsection (a)(1)(ii) and (2) were amended by changing the reporting data.
- Non-regulatory language was removed from subsection (a)(2)(iii) and subsection (c).

Changes to Final § 1141a.46. Reports

(a)

(1)

…

(ii) The ~~per-dose price of an amount~~ average price per unit of medical marijuana products sold by the grower/processor to a medical marijuana organization ~~in a unit of measurement as determined by the Department~~.

(2)

…

(ii) The ~~per-dose price~~ average price per unit of medical marijuana products purchased by ~~a~~ the dispensary ~~in a unit of measurement as determined by the Department~~.

(iii) The ~~per-dose price~~ average price per unit of an amount of medical marijuana products dispensed to a patient or caregiver by ~~a~~ the dispensary ~~and in a unit of measurement as determined by the Department~~.

…

(c) The Department may require ongoing reporting of operational and financial information ~~in a form and manner prescribed by the Department~~.

…

§ 1141a.47. General penalties and sanctions

This section outlines the penalties and sanctions the Department may impose for violations of the act and this part. This section further provides that individuals who assist in the violation of the act or this part are subject to civil penalties.

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Summary of Changes:

- Subsection (a)(v) was added to underscore the Department's expectation that applicants be truthful in all submissions.
- Non-regulatory language was deleted from subsection (a)(5)(ii).
- Subsection (d) was amended to refer to the new chapter.

Changes to Final § 1141a.47. General penalties and sanctions

(a)
(1)
…
(v) The medical marijuana organization submitted falsified information on any application submitted to the Department including, but not limited to:
(A) Failure to comply with an executed labor peace agreement submitted with the permit application.
(B) Failure to follow through on commitments made in the Community Impact section of the permit application.
…
(5)
…
(ii) An order may be issued by an authorized agent of the Department immediately upon completion of an inspection or investigation if the agent observes ~~or suspects~~ an operational failure or ~~determines that the conditions will likely create~~ evidence of ~~a~~ diversion or contamination of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products~~, or a risk to patients or the public~~.
...
(d) The Department's actions under subsections (a) and (b) are subject to 2 Pa. C.S. ~~Chapter 5, Subchapter A~~ §§ 501—508 (relating to practice and procedure of Commonwealth agencies) and its accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure—~~temporary regulations~~).

§ 1141a.48. Training

This section outlines who must undergo a 2-hour training course developed by the Department, in addition to the information that must be included in the training. This section further provides that the Department will make its training course available at no cost to medical marijuana organizations,

and medical marijuana organizations must retain the attendance records for the training and make them available to the Department upon request.

Summary of Changes:

- Subsection (a) was reorganized for clarification.

Changes to Final § 1141a.48. Training

(a) As required under the act, the principals and employees of a medical marijuana organization who either have direct contact with patients or caregivers or physically handle seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products ~~the following individuals~~ shall complete a 2-hour training course developed by the Department. ~~within the times specified:~~ The following apply:

(1) ~~Each principal of a medical marijuana organization,~~ Principals must successfully complete the course prior to starting initial operation of a facility.

(2) ~~Each employee of a medical marijuana organization who has direct contact with patients or caregivers or who physically handles seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, within~~ Employees must successfully complete the course no later than 90 days after starting employment at the facility.

§ 1141a.49. Zoning

This section provides that medical marijuana organizations must meet the same municipal zoning and land use requirements as other similar facilities located in the same zoning district.

Summary of Changes:

- No changes were made to this section.

§ 1141a.50. Advertising by a medical marijuana organization

This section provides that medical marijuana organizations must be consistent with applicable Federal regulations when advertising or marketing medical marijuana products, and before use, these materials must first be approved by the Department. This section further provides that it does not apply to information provided by a grower/processor to a dispensary listing various medical marijuana products, instruments, and devices that the grower/processor is offering for sale to the dispensary. As proposed, this section mirrored temporary § 1141.50 (relating to advertising by a medical marijuana organization).

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Summary of Changes:

- No changes were made to this section.

§ 1141a.51. Technical advisories

This section provides that the Department may publish technical advisories in the *Pennsylvania Bulletin* to provide guidance with respect to the Department's interpretation of the act and this part, but that the advisories would not have the force of law or regulation.

Summary of Changes:

- No changes were made to this section.

Appendix A. Serious Medical Conditions

This appendix lists the medical conditions approved as a "serious medical condition" under the law. The serious medical conditions were previously listed in § 1181.21 of the temporary regulations. They were relocated from the definitions in Chapter 1141a. to this appendix.

Summary of Changes:

- Other than being relocated to Appendix A, no changes were made to this list of serious medical conditions.

New – Final Appendix A. Serious Medical Conditions

The following list is comprised of all medical conditions approved as a "serious medical condition" under the law:

- Cancer, including remission therapy.
- Positive status for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome.
- Amyotrophic lateral sclerosis.
- Parkinson's disease.
- Multiple sclerosis.
- Damage to the nervous tissue of the central nervous system (brain-spinal cord) with objective neurological indication of intractable spasticity, and other associated neuropathies.
- Epilepsy.
- Inflammatory bowel disease.
- Neuropathies.

- Huntington's disease.
- Crohn's disease.
- Post-traumatic stress disorder.
- Intractable seizures.
- Glaucoma.
- Sickle cell anemia.
- Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.
- Autism.
- Neurodegenerative diseases.
- Terminal illness.
- Dyskinetic and spastic movement disorders.
- Opioid use disorder for which conventional therapeutic interventions are contraindicated or ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions.
- Anxiety disorders.
- Tourette's Syndrome.

§ 1141.21. Definitions.

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

ACRC—Academic clinical research center—An accredited medical school in this Commonwealth that operates or partners with an acute care hospital licensed and operating in this Commonwealth that has been approved and certified by the Department to enter into a contract with a clinical registrant.

Accreditation body—An organization which:

(i) Certifies the competency, expertise and integrity of a laboratory and operates in conformance with the current version of International Organization Standard ISO/IEC 17011.

(ii) Determines a laboratory's compliance with and conformance to the relevant standards established by the International Organization for Standardization, including ISO/IEC 17025.

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(iii) Is a signatory to the International Accreditation Cooperation Mutual Recognition Arrangement for Testing.

(iv) Is not affiliated with a laboratory applicant for which it has or will issue a certificate of accreditation.

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.

Act—The Medical Marijuana Act (35 P.S. § § 10231.101—10231.2110).

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.

Added substance—An additional ingredient added to medical marijuana during or after processing that is present in the final product or any substance used to change the viscosity or consistency of a cannabinoid product.

Adult patient—A patient who is 18 years of age or older.

Adverse event—An injury resulting from the use of medical marijuana dispensed at a dispensary. An injury includes physical harm, mental harm or loss of function.

Adverse loss—A loss, discrepancy in inventory, diversion or theft of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products, funds or other property of a medical marijuana organization.

Advertising—The publication, dissemination, solicitation or circulation, for a fee, that is visual, oral, written or electronic to induce directly or indirectly an individual to patronize a particular dispensary, laboratory or practitioner, or to purchase particular medical marijuana products.

Applicant— Depending on the context the term may mean either of the following:

~~(i) Depending on the context the term may mean either of the following:~~

~~(A)~~ (i) A person who wishes to submit or submits an application to the Department for a permit to operate as a grower/processor or dispensary, or both, under the act and this part.

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~~(B)~~ (ii) A patient or a caregiver who submits an identification card application to the Department.

~~(ii)~~ (A) The term includes a legal guardian or a parent who submits an application on behalf of a patient.

~~(iii)~~ (B) The term does not include an individual under 21 years of age unless the Department has determined under section 507(a) of the act (35 P.S. § 10231.507(a)) that the individual should be permitted to serve as a caregiver.

(iii) A person who submits an application to the Department to become an approved laboratory, an ACRC or a 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/1 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 laboratory—A laboratory that has applied for, and received, the approval of the Department to identify, collect, handle and conduct tests on samples from a grower/processor and test samples from the Department used in the growing and processing of medical marijuana or dispensing of medical marijuana products as required by the act and this part.

CAS number—The unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service, a division of the American Chemical Society.

CBC—Cannabichromene, CAS number 20675-51-8.

CBD—~~Cannabidiol.~~ Cannabidiol, CAS number 13956-29-1.

CBDA—Cannabidiolic acid, CAS number 1244-58-2.

CBDV—Cannabidivarin, CAS number 24274-48-4

CBG—Cannabigerol, CAS number 25654-31-3.

CBN—Cannabinol, CAS number 521-35-7.

Cannabinoids—The chemical compounds that are the active constituents of marijuana.

Caregiver—One of the following:

(i) An individual designated by a patient to obtain on behalf of a patient, and provide to a patient, a medical marijuana product.

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(ii) For a minor patient, an individual who meets the requirements in section 506(2) of the act (35 P.S. § 10231.506(2)).

(iii) Individuals designated in writing by an organization that provides hospice, palliative or home care services and who:

(A) Are employed by an organization licensed under the Health Care Facilities Act;

(B) Have significant responsibility for managing the health care and well-being of a patient; and

(C) Were designated by the organization to provide care to a patient who authorized the designation.

(iv) Individuals designated in writing by a residential facility, including a long-term care nursing facility, a skilled nursing facility, an assisted living facility, a personal care home, an independent long-term care facility or an intermediate care facility for individuals with intellectual disabilities who:

(A) Are licensed by the Department or the Department of Human Services;

(B) Have significant responsibility for managing the health care and well-being of the patient; and

(C) Were designated by the residential facility to provide care to a patient who authorized the designation.

Certificate of accreditation—A document issued by an accreditation body evidencing that a laboratory is in compliance with International Organization for Standardization Standard ISO/IEC 17025 or other standards relevant to the operation of laboratories conducting tests on medical marijuana, medical marijuana products and other items used in the growing and processing of medical marijuana or dispensing of medical marijuana products.

Certificate of analysis—A document that confirms that the test performed by an approved laboratory on a harvest batch, harvest lot, process lot, or sample for stability meets the testing requirements set forth by 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.~~

Certified medical use—The acquisition, possession, use or transportation of medical marijuana products by a patient, or the acquisition, possession, delivery, transportation or administration of medical marijuana products by a caregiver, for use as part of the treatment of the patient's serious medical

condition, as authorized in a patient certification issued under the act, including enabling the patient to tolerate treatment for the serious medical condition.

Certified registered nurse practitioner—The term as defined in section 2 of The Professional Nursing Law (63 P.S. § 212).

Chain of custody—The written procedures used by employees of an approved laboratory to record the possession and transfer of samples and test samples and the real-time documentation of actions taken from the time the samples and test samples are collected until the test of the sample or test sample is completed.

Change in control—The acquisition by a person or group of persons acting in concert of a controlling interest in an applicant or permittee either all at one time or over the span of a 12-consecutive-month period.

Change in ownership—The addition or removal of a principal, operator or financial backer or a change in control of a medical marijuana organization after the Department approves an initial permit application or a permit renewal application.

Clinical registrant—An entity that:

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

(ii) Has a contractual relationship with an ~~academic clinical research center~~ ACRC under which the ~~academic clinical research center~~ 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~~.~~; and

(iii) Is approved by the Department.

Continuing care—Treating a patient, in the course of which the practitioner has completed a full assessment of the patient's medical history and current medical condition, including a consultation with the patient.

Controlled substance—A drug, substance or immediate precursor included in Schedules I—V as listed in section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).

Controlling interest—

(i) For a publicly traded ~~company~~ entity, voting rights that entitle a person to elect or appoint one or more of the members of the board of directors or other governing board or the ownership or beneficial holding of 5% or more of the securities of the publicly traded ~~company~~ entity.

(ii) For a privately held entity, the ownership of any security in the entity.

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D8—Delta 8 tetrahydrocannabinol, CAS number 5957-75-5.

De-identified data—A record retrieved from the electronic tracking system transmitted to an ACRC for medical marijuana research purposes after removal of all personal information that could identify a patient.

Department—The Department of Health of the Commonwealth.

Device—An object used, intended for use or designed for use in preparing, storing, ingesting, inhaling or otherwise introducing medical marijuana into the human body.

Disadvantaged business—The term as defined in 74 Pa. C.S. § 303(b) (relating to diverse business participation).

D*ispensary*—

(i) A person who holds a permit issued by the Department to dispense medical marijuana products.

(ii) The term does not include a health care medical marijuana organization as defined under sections 1901—1908 of the act (35 P.S. § § 10231.1901—10231.1908).

Diverse group—A disadvantaged business, minority-owned business, women-owned business, service-disabled veteran-owned small business or veteran-owned small business that has been certified by a third-party certifying organization.

Diverse participants—The term includes the following:

(i) Individuals from diverse racial, ethnic and cultural backgrounds and communities.

(ii) Women.

(iii) Veterans.

(iv) Individuals with disabilities.

Diversity plan—A strategy that promotes or ensures participation by diverse groups in the management and operation of a medical marijuana organization through contracting and employment opportunities.

Electronic tracking system—An electronic seed-to-sale system approved by the Department that is utilized by:

(i) A grower/processor to log, verify and monitor the receipt, use and sale of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products, the funds received by a grower/processor for the sale of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical

marijuana products to another medical marijuana organization, the disposal of medical marijuana waste and the recall of defective seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(ii) A dispensary to log, verify and monitor the receipt of medical marijuana product from a grower/processor, the verification of the validity of an identification card presented by a patient or caregiver, the dispensing of medical marijuana product to a patient or caregiver, the disposal of medical marijuana waste and the recall of defective medical marijuana products.

(iii) An approved laboratory to log, verify and monitor the receipt of samples and test samples for testing, the results of tests performed by the approved laboratory, and the disposal of tested and untested samples and test samples.

Employee—An individual who is hired for a wage, salary, fee or payment to perform work for an applicant or permittee.

Excipients—Solvents, chemicals or materials reported by a medical marijuana organization and approved by the Department for use in the processing of medical marijuana.

Facility—A structure and other appurtenances or improvements where a medical marijuana organization grows and processes or dispenses medical marijuana.

Family or household member—The term as defined in 23 Pa. C.S. § 6102 (relating to definitions).

Financial backer—An investor, mortgagee, bondholder, note holder, or other source of equity, capital or other assets other than a financial institution.

Financial institution—A bank, a National banking association, a bank and trust company, a trust company, a savings and loan association, a building and loan association, a mutual savings bank, a credit union or a savings bank.

Form of medical marijuana—The characteristics of the medical marijuana recommended or limited for a particular patient, including the method of consumption and any particular dosage, strain, variety and quantity or percentage of medical marijuana or particular active ingredient.

Fund—The Medical Marijuana Program Fund established in section 902 of the act (35 P.S. § 10231.902).

Grower/processor—

(i) A person who holds a permit from the Department under the act to grow and process medical marijuana.

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(ii) The term does not include a health care medical marijuana organization as defined under sections 1901—1908 of the act.

Harvest batch—A specifically identified quantity of medical marijuana plant that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time and at the same location, and cured under uniform conditions.

Harvest lot—A specifically identified quantity of medical marijuana plant taken from a harvest batch.

Harvested hemp—Plant material, certified as hemp by a Department of Agriculture approved laboratory, obtained directly from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp under the 3 Pa. C.S. Chapter 15 (relating to controlled plants and noxious weeds) by a grower/processor holding a permit under the act.

Health care medical marijuana organization—A vertically integrated health system approved by the Department to dispense medical marijuana or grow and process medical marijuana, or both, in accordance with a research study under sections 1901—1908 of the act.

Hydroponic nutrient solution—A mixture of water, minerals and essential nutrients without soil used to grow medical marijuana plants.

IRB—Institutional review board—A board, committee, RAC or group designated by an 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).

Identification card—A document issued under section 501 of the act (35 P.S. § 10231.501) that authorizes a patient or caregiver to have access to medical marijuana products under the act.

Immature medical marijuana plant—A rootless, nonflowering part of a medical marijuana plant that is no longer than 12 inches and no wider than 12 inches produced from a cutting, clipping or seedling and that is in a growing container that is no larger than 2 inches wide and 2 inches tall that is sealed on the sides and bottom.

~~*Immediate family*—The term as defined in 4 Pa.C.S. § 1512(b) (relating to financial and employment interests).~~

~~*Industrial hemp*—The plant *Cannabis sativa* L., and any part of the plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3% on a dry-weight basis.~~

Initial permit application—The document submitted to the Department by an applicant that, if approved, grants a permit to an applicant.

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

Laboratory—A place, establishment or institution within this Commonwealth that has been issued a certificate of accreditation.

~~*Laboratory Applicant*—A laboratory that submits an application to the Department for approval to identify, collect, handle and test medical marijuana, medical marijuana products and other items used by a medical marijuana organization in the growing and processing of medical marijuana or dispensing of medical marijuana products as required under the act and this part for the Department or a grower/processor.~~

Legal guardian—

(i) An individual appointed as a guardian of a patient under the laws of the Commonwealth.

(ii) The term does not include an individual who has been appointed a guardian only of a patient's property.

Limited access area—Any area on a site or within a facility where:

(i) Immature medical marijuana plants or medical marijuana plants are growing or being processed into medical marijuana.

(ii) Immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products are being loaded into or out of transport vehicles.

(iii) Seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products are packaged for sale or stored.

(iv) Medical marijuana waste is processed, stored or destroyed.

(v) Surveillance system devices are stored or maintained.

Marijuana—

(i) All parts of the plant *Cannabis sativa* L., whether growing or not, the seeds of that plant and resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin.

~~(ii) The term does not include industrial hemp.~~

~~(iii)~~(ii) The term does not include the mature stalks of *Cannabis sativa* L., fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt or derivative, mixture or preparation of the mature stalks.

(iii) The term does not include synthetic cannabinoids as defined in section 4(1)(vii) of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104(1)(vii)).

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Medical board—Either of the following:

(i) The State Board of Medicine as defined in section 2 of the Medical Practice Act of 1985 (63 P.S. § 422.2).

(ii) The State Board of Osteopathic Medicine as defined in section 2 of the Osteopathic Medical Practice Act (63 P.S. § 271.2).

Medical marijuana—Marijuana for certified medical use, limited to the following forms:

(i) Pill.

(ii) Oil.

(iii) Topical forms, including gels, creams or ointments.

(iv) A form medically appropriate for administration by vaporization or nebulization, including dry leaf or plant form for administration by vaporization.

(v) Tincture.

(vi) Liquid.

Medical marijuana cardholder—An adult patient or caregiver who possesses a valid identification card.

Medical marijuana container—A sealed, traceable, food compliant, tamper resistant, tamper evident container used for the purpose of containment of packaged medical marijuana products being transported from a grower/processor to a medical marijuana organization or an approved laboratory.

Medical marijuana extract—A substance obtained by separating cannabinoids from a medical marijuana plant by a mechanical, chemical or other process.

Medical marijuana organization—

(i) A dispensary or a grower/processor.

(ii) The term does not include a health care medical marijuana organization under sections 1901—1908 of the act ~~or a clinical registrant under sections 2001—2003 of the act (35 P.S. § § 10231.2001—10231.2003)~~.

Medical marijuana patient authorization letter—A document issued by the Department under § 1191a.32 (relating to medical marijuana patient authorization letters).

Medical marijuana plant—A plant which is greater than 12 vertical inches in height from where the base of the stalk emerges from the growth medium to the tallest point of the plant, or greater than 12 horizontal inches in width from the end of one branch to the end of another branch.

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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.

Medical Marijuana Program—The program authorized under the act and implemented by the Department.

Medical marijuana unit—An amount of medical marijuana equivalent to 3.5 grams of dry leaf, 1 gram of concentrate or 100 milligrams of THC infused into a pill, capsule, oil, liquid, tincture or topical form.

Medical marijuana waste—

(i) Solid, liquid, semi-solid or contained gaseous materials that are generated by a grower/processor or an approved laboratory.

(ii) The term includes:

(A) Unused, surplus, returned, recalled, contaminated or expired medical marijuana, except as described in subsection (iii).

(B) ~~Any m~~Medical marijuana plant material that is not used in the growing, harvesting or processing of medical marijuana, including flowers, stems, trim, leaves, seeds, dead medical marijuana plants, dead immature medical marijuana plants, unused medical marijuana plant parts, unused immature medical marijuana plant parts or roots.

(C) Spent hydroponic nutrient solution.

(D) Unused containers for growing immature medical marijuana plants or medical marijuana plants or for use in the growing and processing of medical marijuana.

(E) Unused fertilizers and pesticides.

(F) Unused excipients.

(G) Wastewater.

(iii) The term does not include medical marijuana products erroneously delivered to a dispensary other than the dispensary intended for sale, provided that the packaging remains unopened, with tamper-evident seals intact, and the medical marijuana products are immediately delivered to the correct dispensary.

Medical professional—A physician, pharmacist, physician assistant or certified registered nurse practitioner employed by a dispensary.

Minor patient—A patient who is under 18 years of age.

Minority-owned business—The term as defined in 74 Pa. C.S. § 303(b).

Municipal waste—The term as defined in section 103 of the Solid Waste Management Act (35 P.S. § 6018.103).

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Municipality—A county, city, borough, incorporated town or township, or any similar general-purpose unit of government which shall hereafter by created by the General Assembly.

Nebulization—The generation of medical marijuana products in the form of fine spray for medicinal inhalation.

Nutrient—The essential elements and compounds necessary for the growth, metabolism and development of medical marijuana plants.

Nutrient practice—The use by a grower/processor of essential elements and compounds necessary for the growth, metabolism and development of seeds, immature medical marijuana plants or medical marijuana plants.

Office—The Department's Office of Medical Marijuana.

Operational—The time at which the Department determines that a medical marijuana organization is ready, willing and able to properly carry on the activity for which a permit has been issued under this part, including the implementation of an electronic tracking system.

Operator—An individual who directly oversees or manages the day-to-day business functions for an applicant or permittee and has the ability to direct employee activities onsite and offsite or within a facility for which a permit is sought or has been issued under this part.

Parent—The biological, natural or adoptive mother or father of a patient.

Patient—An individual who meets all of the following qualifications:

(i) Has a serious medical condition.

(ii) Has met the requirements for certification under the act.

(iii) Is a resident of this Commonwealth.

Patient and caregiver registry—A list of patients and caregivers established and maintained by the Department.

Patient certification—The document issued by a practitioner under § 1181a.27 (relating to issuing patient certifications) certifying that a patient has one or more serious medical conditions.

Patient consultation—A complete examination of a patient and the patient's health care records at the time a patient certification is issued by a practitioner.

Permit—An authorization issued by the Department to ~~an applicant~~ a medical marijuana organization to conduct activities authorized under the act.

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Permittee—A person who has been issued an authorization to operate as a medical marijuana organization under the act and this part.

Person—A natural person, corporation, foundation, organization, business trust, estate, limited liability company, licensed corporation, trust, partnership, limited liability partnership, association or other form of legal business entity.

Pharmacist—The term as defined in section 2 of the Pharmacy Act (63 P.S. § 390-2).

Physician—The term as defined in section 2 of the Medical Practice Act of 1985 or section 2 of the Osteopathic Medical Practice Act.

Physician assistant—The term as defined in section 2 of the Medical Practice Act of 1985 or section 2 of the Osteopathic Medical Practice Act.

Postharvest plant material—Unfinished plant and plant-derived material, whether fresh, dried, partially dried, frozen or partially frozen, oil, concentrate or similar byproducts derived or processed from medical marijuana or medical marijuana plants.

Practitioner—A physician who is registered with the Department under section 401 of the act (35 P.S. § 10231.401).

Practitioner registry—A list of practitioners established and maintained by the Department.

Prescription Drug Monitoring Program—The Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act (35 P.S. §§ 872.1—872.40).

Principal—An officer, director or person who directly or beneficially owns securities of an applicant or permittee, or a person who has a controlling interest in an applicant or permittee or who has the ability to elect the majority of the board of directors of an applicant or permittee or otherwise control an applicant or permittee, other than a financial institution.

Process lot—Any amount of a medical marijuana product of the same type and processed using the same medical marijuana extract, standard operating procedures and the same or combination of different harvest lots.

Processing—The compounding or conversion of medical marijuana extract by a grower/processor into a medical marijuana product.

Professional disciplinary action—A disciplinary proceeding taken by the applicable medical board against a practitioner that results in a corrective action or measure.

Publicly traded company—A person other than an individual who:

(i) Has a class or series of securities registered under the Securities Exchange Act of 1934 (15 U.S.C.~~A~~. § § 78a—78~~pp~~qq) or on a foreign stock exchange determined by the Department to have similar listing and reporting requirements to exchanges that are regulated under the Securities Exchange Act of 1934.

(ii) Is a registered management company under the Investment Company Act of 1940 (15 U.S.C.~~A.~~ § § 80a-1—80a-64).

(iii) Is subject to the reporting obligations imposed by section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C.~~A.~~ § § 780~~o~~(d)) by reason of having filed a registration statement which has become effective under the Securities Act of 1933 (15 U.S.C.~~A.~~ § § 77a—77aa).

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

Research—A 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 an 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 ACRC intend to conduct under this chapter and under which the 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 initiative—A nonpatient investigation not subject to Institutional Review Board or Research Approval Committee approval requirements of a patient-based research program, project or study, conducted by an ACRC and its contracted clinical registrant.

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*—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, project or study that includes all of the following information:

(i) With respect to the investigator:

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(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, project or study:

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

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

Sample—Medical marijuana or medical marijuana products collected by an employee of an approved laboratory from a grower/processor facility for testing by the laboratory.

Security—The term as defined in section 102(t) of the Pennsylvania Securities Act of 1972 (70 P.S. § 1-102(t)).

Serious medical condition—~~Any of the following conditions~~: The conditions listed in Appendix A (relating to serious medical condition).

~~(i) Cancer, including remission therapy.~~

~~(ii) Positive status for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome.~~

~~(iii) Amyotrophic lateral sclerosis.~~

~~(iv) Parkinson's disease.~~

~~(v) Multiple sclerosis.~~

~~(vi) Damage to the nervous tissue of the central nervous system (brain-spinal cord) with objective neurological indication of intractable spasticity, and other associated neuropathies.~~

~~(vii) Epilepsy.~~

~~(viii) Inflammatory bowel disease.~~

~~(ix) Neuropathies.~~

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~~(x) Huntington's disease.~~

~~(xi) Crohn's disease.~~

~~(xii) Post-traumatic stress disorder.~~

~~(xiii) Intractable seizures.~~

~~(xiv) Glaucoma.~~

~~(xv) Sickle cell anemia.~~

~~(xvi) Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.~~

~~(xvii) Autism.~~

~~(xviii) Neurodegenerative diseases.~~

~~(ixx) Terminal illness.~~

~~(xx) Dyskinetic and spastic movement disorders.~~

~~(xxi) Opioid use disorder for which conventional therapeutic interventions are contraindicated or ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions.~~

Service-disabled—The term as defined in 51 Pa. C.S. § 9601 (relating to definitions).

Service-disabled veteran-owned small business—The term as defined in 51 Pa. C.S. § 9601.

Site—The total area contained within the property line boundaries in which a facility is operated by a medical marijuana organization.

Species—*Cannabis sativa*, *Cannabis indica* or a hybrid of the two.

Spent hydroponic nutrient solution—Hydroponic nutrient solution that has been used and can no longer serve the purpose for which it was produced.

Synchronous interaction—A two-way or multiple-way exchange of information between a patient and a health care provider that occurs in real time by means of audio or video conferencing.

THC—~~Tetrahydrocannabinol~~ Delta-9 tetrahydrocannabinol, CAS number 1972-08-3.

THCA—Tetrahrydrocannabinolic acid, CAS number 23978-85-0.

THCV—Tetrahydrocannabivarin, CAS number 31262-37-0.

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Terminal illness—A condition or disease for which the medical prognosis of life expectancy is approximately 1 year or less if the condition or disease runs its normal course.

Terpenes—Naturally occurring hydrocarbons found in essential oil secreted from the marijuana plant.

Test sample—An amount of medical marijuana, medical marijuana products or an amount of soil, growing medium, water or solvents used to grow or process medical marijuana, dust or other particles obtained from the swab of a counter or equipment used in the growing or processing of medical marijuana, or other item used in the growing or processing of medical marijuana in a grower/processor facility taken by an employee of an approved laboratory or an agent of the Department at the request of the Department from a grower/processor facility and provided to an approved laboratory for testing.

Third-party certifying organization—The term as defined in 74 Pa. C.S. § 303(b).

Transport vehicle—A vehicle that meets the requirements of the act and is used to transport seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products between medical marijuana organizations or between medical marijuana organizations and an approved laboratory.

Unit—The weight or volume of total usable medical marijuana products, calculated in metric units.

Vaporization—The generation of medical marijuana products in the form of vapor for medicinal inhalation.

Veteran—The term as defined in 51 Pa. C.S. § 9601.

Veteran-owned small business—The term as defined in 51 Pa. C.S. § 9601.

Women-owned business—The term as defined in 74 Pa. C.S. § 303(b).