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OVERVIEW OF CHANGES TO FINAL MEDICAL MARIJUANA REGULATIONS
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§1181a.22 Practitioners generally.

(a) The qualifications that a physician shall meet to be registered with the Department and approved as a practitioner are continuing qualifications.

(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.~~

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§1181a.23. Medical professionals generally.

(a) The qualifications that a medical professional shall meet to be employed by a dispensary are continuing qualifications.

(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.

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

§1181a.24. ~~Physician~~ 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:

(1) The physician's full name, business address, professional e-mail address, telephone numbers and, if the physician owns or is affiliated with a medical practice, the name of the medical practice.

(2) The physician's credentials, education, specialty, training and experience, and supporting documentation when available.

(3) The physician's medical license number.

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

(i) That the physician's Pennsylvania license to practice medicine is active and in good standing.

(ii) Whether the physician has been subject to any type of professional disciplinary action that would prevent the physician from carrying out the responsibilities under the act and this part, together with, if applicable, an explanation of the professional disciplinary action.

(iii) That the physician does not hold a direct or economic interest in a medical marijuana organization.

(5) A statement that a false statement made by a physician in an application for registration is punishable under the applicable provisions of 18 Pa. C.S. Chapter 49 (relating to falsification and intimidation).

(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.

(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.~~

(b) The inclusion of a physician in the practitioner registry will be subject to annual review by the Department to determine if the physician's 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.

§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 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.

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(d) A physician who has been denied registration or whose practitioner registration has been revoked or suspended may not do any of the following:

(1) Have electronic access to a patient certification.

(2) Issue or modify a patient certification.

(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).

(e) The Department may revoke or suspend the registration of a practitioner for any of the following:

(1) A violation of the act or this part.

(2) A violation of an order issued under the act or this part.

(3) A violation of a regulation promulgated under the act.

(4) For conduct or activity that would have disqualified the practitioner from receiving a registration.

(5) Pending the outcome of a hearing in a case which the practitioner's registration could be suspended or revoked.

§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.

(2) The practitioner has determined the patient is likely to receive therapeutic or palliative medical benefit from the use of medical marijuana based upon the practitioner's professional opinion and review of the following:

(i) The patient's prior medical history as documented in the patient's health care records if the records are available for review.

(ii) The patient's controlled substance history if the records are available in the Prescription Drug Monitoring Program.

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

(1) A practitioner who is not board-eligible or board-certified in pediatrics or a pediatric specialty, neurology with special qualifications in child neurology, child and adolescent psychiatry, or adolescent

medicine (whether through pediatrics, internal medicine or family practice) may not issue a patient certification to a minor patient.

(2) Paragraph (1) will be effective upon the registration of a sufficient number of eligible practitioners to ensure adequate access for minor patients needing services under the act and this part based on location, serious medical condition and number of patients, specialty, and number and availability of practitioners. The Department will publish a notice in the *Pennsylvania Bulletin* 1 month before paragraph (1) becomes effective, stating that a sufficient number of eligible practitioners have registered to effectuate this subsection.

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

(1) The patient's name, home address, telephone number, date of birth and e-mail address, if available.

(2) The practitioner's name, business address, telephone numbers, professional e-mail address, medical license number, area of specialty, if any, and signature.

(3) The date of the patient consultation for which the patient certification is being issued.

(4) The patient's specific serious medical condition.

(5) A statement by the practitioner that the patient has a serious medical condition, and the patient is under the practitioner's continuing care for the condition.

(6) A statement as to the length of time, not to exceed 1 year, for which the practitioner believes the use of medical marijuana by the patient would be therapeutic or palliative.

(7) A statement by the practitioner that includes one of the following:

(i) The recommendations, requirements or limitations as to the form or dosage of medical marijuana product.

(ii) The recommendation that only a medical professional employed by the dispensary and working at the dispensary facility consult with the patient or the caregiver regarding the appropriate form and dosage of the medical marijuana product to be dispensed.

(8) A statement by the practitioner that the patient is terminally ill, if applicable.

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

(10) A statement that the patient is homebound or an inpatient during the time for which the patient certification is issued due to the patient's medical and physical condition and is unable to visit a dispensary to obtain medical marijuana products.

(11) A statement that the practitioner has explained the potential risks and benefits of the use of medical marijuana products to the patient and has documented in the patient's health care record that the explanation has been provided to the patient and informed consent has been obtained.

(12) A statement that a false statement made by the practitioner in the patient certification is punishable under the applicable provisions of 18 Pa. C.S. Chapter 49 (relating to falsification and intimidation).

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

(1) Provide a copy of the patient certification to the patient or the patient's caregiver, if the patient is a minor, and to an adult patient's caregiver if authorized by the patient.

(2) Provide the patient certification with the original signature to the Department, which may be submitted electronically.

(3) File a copy of the patient certification in the patient's health care record.

§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:

(1) Provide a copy of the patient certification to the patient or the patient's caregiver, if the patient is a minor, and to an adult patient's caregiver if authorized by the patient.

(2) Provide the patient certification with the original signature to the Department, which may be submitted electronically.

(3) File a copy of the patient certification in the patient's health care record.

§1181a.29. Revocation of a patient certification.

(a) A practitioner shall immediately notify the Department in writing if the practitioner knows or has reason to know that any of the following events are true with respect to a patient for whom the practitioner issued a patient certification:

(1) The patient no longer has the serious medical condition for which the patient certification was issued.

(2) The use of medical marijuana products by the patient would no longer be therapeutic or palliative.

(3) The patient has died.

(b) The Department will revoke a patient certification upon receiving notification of the occurrence of an event listed in subsection (a).

(c) Notwithstanding subsection (a), a practitioner may withdraw the issuance of a patient certification at any time by notifying, in writing, both the patient and the Department.

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(d) The Department will immediately notify a medical marijuana cardholder upon the revocation of a patient certification and the information shall be entered into the electronic tracking system.

§1181a.30. Prescription Drug Monitoring Program.

(a) A practitioner shall review the Prescription Drug Monitoring Program prior to issuing or modifying a patient certification to determine the controlled substance history of the patient to determine whether the controlled substance history of the patient would impact the patient's use of medical marijuana products.

(b) A practitioner may access the Prescription Drug Monitoring Program to do any of the following:

(1) Determine whether a patient may be under treatment with a controlled substance by another physician or other person.

(2) Allow the practitioner to review the patient's controlled substance history as deemed necessary by the practitioner.

(3) Provide to the patient, or caregiver if authorized by the patient, a copy of the patient's controlled substance history.

§1181a.31. Practitioner prohibitions.

(a) A practitioner may not accept, solicit or offer any form of remuneration from or to any individual, prospective patient, patient, prospective caregiver, caregiver or medical marijuana organization, including an employee, financial backer or principal, to certify a patient, other than accepting a fee for service with respect to a patient consultation of the prospective patient to determine if the prospective patient should be issued a patient certification to use medical marijuana products.

(b) A practitioner may not hold a direct or economic interest in a medical marijuana organization.

(c) A practitioner may not advertise the practitioner's services as a practitioner who can certify a patient to receive medical marijuana products.

(d) A practitioner may not issue a patient certification for the practitioner's own use or for the use of a family or household member.

(e) A practitioner may not be a designated caregiver for a patient that has been issued a patient certification by that practitioner.

(f) A practitioner may not receive or provide medical marijuana product samples.

(g) A practitioner may not excessively charge a patient for any expense related to the certification and follow-up process.

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§1181a.32. Training.

(a) Within the time specified, the following individuals shall complete a 4-hour training course approved by the Department:

(1) A physician prior to being included in the practitioner registry under §1181a.24 (relating to ~~physician~~ practitioner registration).

(2) A medical professional prior to assuming any duties at a dispensary under §1161a.25 (relating to licensed medical professionals at facility).

(b) The requirements of the training course required under subsection (a) must include~~, at a minimum,~~ all of the following:

(1) The provisions of the act and this part relevant to the responsibilities of a practitioner or medical professional.

(2) General information about medical marijuana under Federal and State law.

(3) The latest scientific research on the endocannabinoid system and medical marijuana, including the risks and benefits of medical marijuana.

(4) Recommendations for medical marijuana as it relates to the continuing care of a patient in the following areas:

(i) Pain management, including opioid use in conjunction with medical marijuana.

(ii) Risk management, including drug interactions, side effects and potential addiction from medical marijuana use.

(iii) Palliative care.

(iv) The misuse of opioids and medical marijuana.

(v) Recommendations for use of medical marijuana and obtaining informed consent from a patient.

(vi) Any other area determined by the Department.

(5) Use of the Prescription Drug Monitoring Program.

(6) Best practices for recommending the form and dosage of medical marijuana products based on the patient's serious medical condition and the practitioner's or medical professional's medical specialty and training.

(c) Successful completion of the course required under subsection (a) shall be approved as continuing education credits as determined by:

(1) The State Board of Medicine and the State Board of Osteopathic Medicine.

(2) The State Board of Pharmacy.

(3) The State Board of Nursing.

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(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).

(e) The Department will maintain on its publicly-accessible web site a list of approved training providers that offer the 4-hour training course.

(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.

~~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).

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§1191a.22. Patient and caregiver registry.

(a) The Department will maintain a patient and caregiver registry.

(b) Patient and caregiver information maintained by the Department is confidential and not subject to public disclosure, including disclosure under the Right-to-Know Law (65 P.S. § §67.101—67.3104). Patient and caregiver information must include the following:

(1) Information provided in an identification card application.

(2) Information in a patient certification issued by a practitioner.

(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).

(4) Information encoded in the 2D barcode of an identification card.

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

(c) A caregiver who is listed in the patient and caregiver registry may waive in writing the caregiver's right to confidentiality and consent to the caregiver's name and contact information being provided to a patient who has obtained a patient certification from a practitioner.

§1191a.23. Patients and caregivers generally.

(a) The qualifications that a patient or caregiver shall meet to be included in the patient and caregiver registry and to obtain an identification card or a medical marijuana patient authorization letter are continuing qualifications.

(b) Except with respect to a minor patient as provided in §1191a.32 (relating to medical marijuana patient authorization letters), the Department may issue an identification card to an applicant who meets the qualifications in the act and this part.

~~(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:

(1) A parent or legal guardian.

(2) An individual designated by a parent or legal guardian.

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

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§1191a.24. Medical marijuana cardholder responsibilities.

(a) A medical marijuana cardholder shall immediately contact the Department upon the occurrence of any of the following:

(1) A change of the medical marijuana cardholder's name or address.

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

(3) A decision by a patient or the patient's legal guardian to discontinue the services of a caregiver.

(4) A decision by a caregiver to no longer serve as a caregiver for a patient.

(5) A decision by a patient, the patient's legal guardian or a parent on behalf of a patient to discontinue obtaining medical treatment from the practitioner who issued the 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).~~

§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:

(1) The name, address, telephone number, e-mail address, if available, and date of birth of the patient.

(2) The patient's Pennsylvania driver's license number, a Department of Transportation State-issued identification card, if applicable, or other documentation acceptable to the Department evidencing the patient's identification and residency in this Commonwealth.

(3) The name, address and telephone number of the practitioner who issued the patient certification.

(4) The name, birth date, address, telephone number and e-mail address, if applicable, of up to two individuals designated by the applicant to serve as caregivers, if applicable.

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(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).

(7) The signature of the applicant and the date signed.

(8) A statement that a false statement made in the application is punishable under the applicable provisions of 18 Pa. C.S. Chapter 49 (relating to falsification and intimidation).

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

(c) For an application submitted under this section that designates an individual as a caregiver who is not authorized under the act or this part to serve as a caregiver, the following apply:

(1) The Department may deny that portion of the application and approve the balance of the application. In that case, an identification card may be issued to the patient but the designated caregiver will not be authorized to serve in that capacity.

(2) If the application is submitted on behalf of a minor patient but does not include the designation of another individual as a caregiver who is authorized under the act or this part to serve as a caregiver, the Department will deny the entire application unless and until the applicant designates an individual who is authorized to serve.

(3) An individual designated as a caregiver may not serve as a caregiver unless and until the individual submits an application under subsection (d) and the individual is issued an identification card by the Department.

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

(1) The name, address, telephone number, e-mail address, if available, and date of birth of the caregiver.

(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.

(3) The name, address and telephone number of the practitioner who issued the patient certification.

(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.

(8) The signature of the applicant and the date signed.

(9) A statement that a false statement made in the application is punishable under the applicable provisions of 18 Pa. C.S. Chapter 49.

~~(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.

(a) An applicant shall pay no more than one fee of $50 in a 12-month period for an identification card with an identification card application.

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

(1) An applicant shall submit a fee of $25 if the Department issues a replacement identification card as a result of a lost, stolen, destroyed, defaced or illegible identification card.

(2) An applicant shall pay a second fee of $50 in the same 12-month period with an identification card renewal application.

(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*.

§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.

(b) The Department may only review the criminal history record information received under subsection (a) to determine the caregiver's character, fitness and suitability to serve as a caregiver under the act and this part.

§1191a.28. Identification cards.

(a) The Department will issue an identification card to a patient or caregiver as soon as reasonably practicable after approving an identification card application.

(b) An identification card will contain all of the following information:

(1) The full name of the medical marijuana cardholder.

(2) The address of the medical marijuana cardholder.

(3) A designation of the medical marijuana cardholder as a patient or a caregiver.

(4) The date of issuance and the date of expiration of the identification card.

(5) A unique identification number for the medical marijuana cardholder.

(6) A photograph of the medical marijuana cardholder unless the patient or caregiver provides the Department with a statement in accordance with subsection (c).

(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.~~

(c) Notwithstanding subsection (b)(6), the Department may not require a photograph on an identification card if a statement is provided to the Department in an identification card application that a photograph cannot be provided due to religious beliefs.

(d) An identification card issued to a patient will expire on the earlier to occur of the following:

(1) The date occurring 1 year from the date of issuance.

(2) The date, if any, contained in the patient certification issued to the patient beyond which the practitioner does not believe the use of medical marijuana by the patient would be therapeutic or palliative.

(3) The date the patient dies.

(e) An identification card issued to a caregiver will expire on the earlier to occur of the following:

(1) The date that occurs 1 year from the date of issuance.

(2) Any of the events listed under subsection (d)(2) or (3).

(3) The date the caregiver dies.

~~(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.

(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 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).

(b) If the Department denies an identification card renewal application or if the Department does not receive a complete identification card renewal application by the expiration date on the identification card, the identification card will no longer be valid beyond the expiration date and the Department may remove a medical marijuana cardholder from the patient and caregiver registry.

(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.

(a) The Department may revoke or suspend a medical marijuana cardholder's identification card upon the occurrence of any of the following:

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

(2) A caregiver notifies the Department in writing that the caregiver is no longer acting as a caregiver.

(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.

(4) Except for good cause shown, a medical marijuana cardholder does not visit a dispensary within 60 days from the issuance date on an identification card.

(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.

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§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.

§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.

(c) A patient who has been issued a medical marijuana patient authorization letter by the Department under this section shall have all of the rights and obligations of a medical marijuana cardholder under this chapter, except that an identification card shall be required for entry into a dispensary.

(d) A medical marijuana patient authorization letter is subject to the same terms and conditions, including expiration, revocation and suspension requirements, as an identification card under this chapter.

(e) A patient who has been issued a medical marijuana patient authorization letter by the Department under this section will not be required to pay an identification card application fee or an identification card renewal application fee.

§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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Appendix A. Serious Medical Conditions

§ 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.

(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.

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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.

~~(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.

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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.

(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.

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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.

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).

Dispensary—

(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).

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Grower/processor—

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

(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.~~

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

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.

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(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)).

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).

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.

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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.

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

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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:

(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.~~

~~(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.~~

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~~(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.

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).

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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).

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

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

(1) An application submitted under the act, except to the extent that the application contains any of the information listed in subsection (b).

(2) The name, business address and medical credentials of a practitioner.

(3) Information regarding penalties or other disciplinary actions taken against a permittee by the Department for a violation of the act.

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

(1) Information in the possession of the Department or any of its contractors regarding practitioner's registration information that is not listed as a public record under subsection (a).

(2) The name or other personal identifying information of a patient or caregiver who applies for or is issued an identification card.

(3) Individual identifying information concerning a patient or caregiver, or both.

(4) A patient certification issued by a practitioner.

(5) Any information on an identification card.

(6) Information provided by the Pennsylvania State Police regarding a caregiver, including criminal history record information, as set forth in § 1141a.31 (relating to background checks).

(7) Information regarding a patient's serious medical condition.

(8) Other information regarding a patient, caregiver, practitioner or medical marijuana organization not listed in subsection (a) that falls within an exception to the Right-to-Know Law, or is otherwise considered to be confidential proprietary information by other law.

(9) Information regarding the physical features of, and security measures installed in, a facility.

(10) Information maintained in the electronic tracking system of a grower/processor, an approved laboratory and a dispensary.

(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.

(12) Information relating to an applicant's diversity plan that is marked confidential proprietary or trade secret.

(c) An applicant shall mark confidential proprietary information as confidential proprietary or trade secret information, as defined in section 102 of the Right-to-Know Law (65 P.S. § 67.102), prior to submission of a permit application to the Department.

(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.

(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.

~~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:

(1) The Department will not initially issue permits to more than 25 applicants for grower/processor permits. The following apply:

(i) The Department will not issue more than one individual grower/processor permit to one person.

(ii) The Department will not issue an individual dispensary permit to more than five individual grower/processors.

(2) The Department will not initially issue permits to more than 50 applicants for dispensary permits. The following apply:

(i) The Department will not issue more than five individual dispensary permits to one person.

(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.

(a) The Department will issue permits to applicants in each of six medical marijuana regions. The six medical marijuana regions are as follows:

(1) *Region 1*—The geographical region comprised of the counties of the Department's Southeast District, which includes Berks, Bucks, Chester, Delaware, Lancaster, Montgomery, Philadelphia and Schuylkill.

(2) *Region 2*—The geographical region comprised of the counties of the Department's Northeast District, which includes Carbon, Lackawanna, Lehigh, Luzerne, Monroe, Northampton, Pike, Susquehanna, Wayne and Wyoming.

(3) *Region 3*—The geographical region comprised of the counties of the Department's Southcentral District, which includes Adams, Bedford, Blair, Cumberland, Dauphin, Franklin, Fulton, Huntingdon, Juniata, Lebanon, Mifflin, Perry and York.

(4) *Region 4*—The geographical region comprised of the counties of the Department's Northcentral District, which includes Bradford, Centre, Clinton, Columbia, Lycoming, Montour, Northumberland, Potter, Snyder, Sullivan, Tioga and Union.

(5) *Region 5*—The geographical region comprised of the counties of the Department's Southwest District, which includes Allegheny, Armstrong, Beaver, Butler, Cambria, Fayette, Greene, Indiana, Somerset, Washington and Westmoreland.

(6) *Region 6*—The geographical region comprised of the counties of the Department's Northwest District, which includes Cameron, Clarion, Clearfield, Crawford, Elk, Erie, Forest, Jefferson, Lawrence, McKean, Mercer, Venango and Warren.

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(b) The Department will consider the following factors about each region in its determination to grant or deny an initial permit to an applicant:

(1) Regional population.

(2) The number of patients suffering from a serious medical condition.

(3) The types of serious medical conditions in the region.

(4) Access to public transportation.

(5) The health care needs of rural and urban areas.

(6) Areas with recognized need for economic development.

(c) The publication of this section in the *Pennsylvania Bulletin* is deemed to be the notice of the establishment of the regions required under section 604 of the act (35 P.S. § 10231.604). The Department may change the number or boundaries of the regions every 2 years upon publication of notice of the adjustment in the *Pennsylvania Bulletin*.

§ 1141a.25. General requirements for permits.

(a) The Department may issue a permit to an applicant only for the specific location identified in the applicant's application, by name and address. A permit will specify that the applicant is authorized to begin the process necessary to become operational. A permit is only valid for the person named in the permit and only for the location specified in the permit.

(b) The medical marijuana organization shall conspicuously post its permit in a location within its facility that is visible to the Department or its authorized agents and law enforcement.

(c) A permit will not be issued to a medical marijuana organization for use in a personal residence or any other location where the Department or its authorized agents or law enforcement would have limited access.

(d) A permit will not be issued to a medical marijuana organization for a site or facility located on lands owned by the United States or the Commonwealth.

(e) A permit is valid for 1 year from the date of issuance.

§ 1141a.26. Privilege and nontransferability.

(a) The issuance or renewal of a permit to a medical marijuana organization is a revocable privilege.

(b) A permit issued under this part is not transferable to any person or any location.

§ 1141a.27. General requirements for application.

(a) The types of applications to be submitted to the Department under this part include:

(1) An initial permit application.

(2) A permit renewal application.

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(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~~.

(6) An application for additional dispensary locations.

(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.

(2) The applicant and its principals and other persons affiliated with the applicant identified by the Department are current in all tax obligations due and owing to the Commonwealth. An applicant, as part of the application, shall provide tax clearance certificates issued by the Department of Revenue and the Department of Labor and Industry for the applicant and its principals and other persons affiliated with the applicant identified by the Department verifying that the applicant does not have outstanding tax obligations to the Commonwealth. The Department may consider the application to be complete if the applicant states on a form prescribed by the Department of Revenue or the Department of Labor and Industry that tax clearance certificates have been requested at the time the application was submitted to the Department.

(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.

(4) Nothing in this subsection requires the Department to request additional or supplemental information from an applicant.

(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.

(e) An application submitted under this part must contain the following statement signed by the applicant:

A false statement made in this application is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).

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§ 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.

(3) Permit renewal fee—$10,000. The permit renewal fee shall be submitted with a renewal application and will be refunded if the renewal permit is not granted.

(4) An initial permit fee refund will be issued to the business named by the applicant in the permit application, in care of the primary contact provided by the applicant, and mailed to the primary contact's mailing address provided by the applicant.

(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.

(3) Permit renewal fee—$5,000. The permit renewal fee shall be submitted with a renewal application and will be refunded if the renewal permit is not granted.

(4) An initial permit fee refund will be issued to the business named by the applicant in the permit application, in care of the primary contact provided by the applicant, and mailed to the primary contact's mailing address provided by the applicant.

(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.

(a) The Department will publish in the *Pennsylvania Bulletin* notice of initial permit application availability and the time frame during which initial permit applications will be accepted.

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(1) An applicant shall only use the initial permit application form prescribed by the Department on its web site.

(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.

(3) An initial permit application received from an applicant after the time frame during which the Department is accepting applications will be rejected by the Department and returned to the applicant without further consideration along with the initial permit application fee and initial permit fee submitted by the applicant with the permit application.

(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:

(1) The legal name of the applicant.

(2) Certified copies of the applicant's organizational documents, if applicable, and, if the applicant was not organized in this Commonwealth, evidence that it is authorized to conduct business in this Commonwealth.

(3) The physical address of the applicant's proposed site and facility, including the following, as applicable:

(i) Evidence of the applicant's clear legal title to or option to purchase the proposed site and the facility.

(ii) A fully-executed copy of the applicant's unexpired lease for the proposed site and facility that includes the consent by the property owner to the use by the applicant of that site and facility on the proposed site for, at a minimum, the term of the initial permit.

(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.

(4) Evidence that the applicant is or will be in compliance with the municipality's zoning requirements.

(5) The following apply to the proposed facility:

(i) If the facility is in existence at the time the initial permit application is submitted to the Department, the applicant shall submit plans and specifications drawn to scale for the interior of the facility.

(ii) If the facility is in existence at the time the initial permit application is submitted to the Department, and the applicant intends to make alterations to the facility, the applicant shall submit renovation plans and specifications for the interior and exterior of the facility to be altered.

(iii) If the facility is not in existence at the time the initial permit application is submitted to the Department, the applicant shall submit a plot plan that shows the proposed location of the facility and

an architect's drawing of the facility, including a detailed drawing, to scale, of the interior of the facility.

(6) The name, residential address, date of birth, title and short version of a curriculum vitae of each principal, operator, financial backer and employee of the applicant, or of any person holding an interest in the applicant's proposed site or facility, including:

(i) A verification of identity that is satisfactory to the Department.

~~(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:

(A) Any position of management or ownership held during the 10 years preceding the filing date of the initial permit application of a controlling interest in any other business in this Commonwealth or any other jurisdiction involving the manufacturing or distribution of medical marijuana, medical marijuana products or a controlled substance.

(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 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.

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(7) If a principal, operator or financial backer is a corporation or limited liability company:

(i) The names, residential addresses, titles and short version of a curricula vitae of each principal of the corporation or limited liability company.

(ii) A certified copy of the filed articles of incorporation of the corporation or filed certificate of organization of the limited liability company.

(iii) Unless the corporation or limited liability company is a publicly traded company, the names and mailing addresses of all persons owning securities in the corporation or membership interests in the limited liability company.

(8) If a principal, operator or financial backer is a general partnership, limited partnership, limited liability partnership or limited liability limited partnership:

(i) The names, residential addresses, titles and short version of a curricula vitae of each partner and general partner of a general partnership, limited partnership, limited liability partnership or limited liability limited partnership, and if any of the partners is a corporation or a limited liability company, the names, residential addresses, titles and short version of a curricula vitae of each principal of that corporation or limited liability company.

(ii) A certified copy of its filed certificate of limited partnership or other formation document, if applicable.

(iii) A certified copy of its partnership agreement.

(iv) Unless the entity is a publicly traded company, the names and mailing addresses of each of its partners.

(9) Evidence that the applicant is responsible and capable of successfully establishing and operating a facility, including the following:

(i) Demonstrated experience, if any, running a for-profit or nonprofit organization or other business within this Commonwealth or any other jurisdiction and the nature of the business conducted by the organization.

(ii) History relating to a similar license, permit or other authorization in other jurisdictions, including provisional licenses, suspensions, revocations or disciplinary actions, including civil monetary penalties or warnings.

(iii) History of response to sanctions, disciplinary actions or civil monetary penalties imposed relating to any similar license, permit or other authorization in another jurisdiction, and the plans of correction or other responses made to those actions.

(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.

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~~(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 the Department.

(10) A description of the duties, responsibilities and roles of each principal, operator, financial backer and employee.

(11) A timetable outlining the steps the applicant will take to become operational.

(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:

(i) Security.

(ii) Employee qualifications and training.

(iii) Transportation of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(iv) Storage of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

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

(vi) Inventory management.

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

(viii) With respect to a grower/processor's facility, quality control and testing of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products for potential contamination.

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

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(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.

(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.~~

(15) The applicant shall provide the Department with releases sufficient to obtain information from a governmental agency, financial institutions, an employer or any other person. Failure to provide these releases will result in the rejection of the initial permit application.

(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.

(c) If the Department determines that an initial permit application is complete but lacking sufficient information upon which to make a determination, the Department may notify the applicant in writing of the factors that require additional information and documentation. An applicant has 30 days from the mailing date of the notice to provide the requested information and documentation to the Department. An applicant's failure to provide the requested information to the Department by the deadline may be grounds for denial of the issuance of a permit. Nothing in this subsection requires the Department to request additional or supplemental information from an applicant.

(d) At the discretion of the Department, the Department may extend the deadline in subsection (c) for up to an additional 15 days.

(e) The Department may conduct an inspection to determine the appropriateness of a proposed site and facility, the applicant's operational status, the applicant's compliance with the laws and regulations of the Commonwealth, the municipality's zoning requirements relating to the applicant's proposed site and facility, if applicable, and its use as outlined in the permit application. The Department may do the following:

(1) Interview principals, operators, financial backers and employees, including physicians, pharmacists, physician assistants and certified registered nurse practitioners, engaged and to be engaged in the applicant's operations for the purpose of verifying the information contained in the initial permit application.

(2) Inspect transport vehicles that are or will be utilized in the transportation of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to a facility or an approved laboratory.

§ 1141a.30. Capital requirements.

(a) An applicant for a grower/processor permit shall provide an affidavit that the applicant has at least $2 million in capital, $500,000 of which is on deposit with one or more financial institutions.

(b) An applicant for a dispensary permit shall provide an affidavit that the applicant has at least $150,000 on deposit with one or more financial institutions.

(c) The affidavit will be in a form prescribed by the Department.

(d) An applicant shall submit with the initial permit application a signed release allowing the Department to contact each financial institution listed in the application to verify the requirements of subsection (a) or (b).

§ 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) The Department may only use criminal history background check information obtained under this section to determine the character, fitness and suitability to serve in the designated capacity of the principal, financial backer, operator and employee.

(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.

(a) In accordance with section 615 of the act (35 P.S. § 10231.615), this section establishes the procedures for promoting and ensuring the involvement of diverse participants and diverse groups in the activities permitted by the act and this part.

(b) In furtherance of the policy in section 615 of the act, the Department will:

(1) Allocate appropriate staff of the Department to assist medical marijuana organizations in fostering the involvement of diverse participants and diverse groups in their operations.

(2) Provide enhanced publicity of permitting opportunities and information to assist diverse participants and diverse groups in learning how to apply for permits to be issued under the act and this part.

(3) Compile, maintain and make available to medical marijuana organizations lists of diverse participants and diverse groups for the purpose of encouraging medical marijuana organizations to provide employment and contracting opportunities consistent with the act.

(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.

(d) A medical marijuana organization may demonstrate achievement of its diversity goals by employing diverse participants and transacting business with diverse groups.

(e) The list of diverse groups that are verified by the Department of General Services, Bureau of Diversity, Inclusion and Small Business Opportunities may be used by a medical marijuana organization to establish the eligibility of a diverse group for purposes of this section.

(f) As part of each application to renew a permit submitted to the Department, a medical marijuana organization shall include information of its efforts to meet the diversity goals of the act and the effectiveness of its diversity plan. The report must include information regarding the following, as applicable:

(1) Representation of diverse participants in the medical marijuana organization's workforce.

(2) Efforts to reach out to and recruit diverse participants for employment, including for executive and managerial positions.

(3) Employee retention efforts.

(4) A list of all contracts entered into or transactions conducted by the medical marijuana organization for goods or services with diverse groups.

(g) A medical marijuana organization may request that any proprietary information submitted to the Department under this section be treated as confidential proprietary information and shall clearly mark this information as confidential proprietary information or trade secret under the Right-to-Know Law (65 P.S. § § 67.101—67.3104) as set forth in § 1141a.22 (relating to records subject to disclosure; confidentiality).

(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.

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§ 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).

(b) The Department will publish the number of permits to be issued and the location of each permit in the *Pennsylvania Bulletin* before the initial permit applications are made available for submission.

§ 1141a.34. Denial of a permit.

The Department may deny the issuance of a permit for any of the following reasons:

(1) Failure or refusal to submit information or documentation requested by the Department during the review process. Nothing in this paragraph requires the Department to request additional or supplemental information from an applicant.

(2) Misrepresentation by an applicant of fact, or failure to disclose a material fact to the Department during the review process.

(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.

(4) Failure to meet the capital funding requirements identified in an affidavit by the applicant or a determination by the Department that the capital funding identified by the applicant is unverifiable.

(5) The applicant denies the Department or its authorized agents access to any place where a permitted activity is proposed to take place or fails to produce any book, paper, record, document, data or other information when requested by the Department.

(6) The applicant's medical marijuana license, permit or other authorization in another state or jurisdiction was, is or has been suspended or revoked or the applicant was otherwise disciplined.

(7) The applicant's plan of operation does not demonstrate, to the satisfaction of the Department, that the applicant is qualified for a permit.

(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).

(9) The Department determines, in its sole discretion, that the issuance of the permit will not be in the best interest of the welfare, health or safety of the citizens of this Commonwealth.

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§ 1141a.35. Notice of denial.

(a) The Department will provide written notice of denial to an applicant.

(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.

(a) A medical marijuana organization wishing to renew its permit shall submit to the Department a permit renewal application not more than 6 months, nor less than 4 months, prior to the current permit's expiration.

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

(c) A medical marijuana organization shall include the following in the permit renewal application:

(1) Information regarding any charge, or any initiated, pending or concluded investigation, during the period of the initial permit or prior renewal period, by any governmental or administrative agency with respect to:

(i) An~~y~~ incident involving the theft, loss or possible diversion of medical marijuana by the medical marijuana organization or from the medical marijuana organization's facility.

(ii) Compliance by the medical marijuana organization with the laws of the Commonwealth with respect to any substance in section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).

(2) Information concerning the medical marijuana organization's ability to carry on the activity for which the permit was issued, including medical marijuana product shortages or wait lists occurring during the 12 months prior to the date the renewal permit application was submitted.

(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.

(d) If the Department determines that a permit renewal application is complete but 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 the permit renewal application. Nothing in this subsection requires the Department to request additional or supplemental information from an applicant.

(e) The Department may conduct an onsite inspection of the medical marijuana organization's site and facility to determine an applicant's continuing compliance with the act and this part.

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

(a) The Department will deny the renewal of a permit if the Department determines:

(1) The medical marijuana organization has not or is unlikely to be able to continuously maintain effective control against diversion of medical marijuana at its facility.

(2) The medical marijuana organization falsified any part of the permit renewal application or any other application submitted to the Department under this part.

(3) The medical marijuana organization is unlikely to comply with all Commonwealth and local laws applicable to the activities in which it may engage under the permit, if renewed.

(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).

(c) Except as provided in subsection (e), a medical marijuana organization may not operate if its permit is not renewed prior to expiration.

(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:

(1) Cease all operations authorized by the permit.

(2) In the case of a grower/processor, dispose of any remaining seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products, plant matter or any growing equipment as set forth in § 1151a.40 (relating to management and disposal of medical marijuana waste).

(3) In the case of a dispensary, return the medical marijuana products to the grower/processor where the medical marijuana products originated.

(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.

(a) During the application process, or at any time during the permit period if a permit is issued, an applicant or medical marijuana organization shall notify the Department:

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(1) In writing of any change in facts or circumstances reflected in the initial permit application or any permit renewal application submitted to the Department, or any newly discovered or occurring fact or circumstance which would have been included in the application if known at the time the application was submitted.

(2) In writing of any proposed modification of its plan of operation at least 30 days prior to the proposed modification.

(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):

(1) Discontinuance of operations.

(2) Removal of all seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products from the sites and locations by Federal or State ~~or Federal~~ authority.

§ 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.~~

(f) ~~A change in ownership of a medical marijuana organization that occurs without the Department's prior written approval of the change as provided in this section is a violation of the act and this part.~~

§ 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.

(c) The medical marijuana organization shall submit an application for approval of a change in location on a form prescribed by the Department.

(d) An application for approval of a change in location must include the reason for requesting the change and other information about the new location as the Department may require.

(e) The Department will issue a new permit to the medical marijuana organization for the new location if the request is approved.

(f) Within 180 days of the issuance by the Department of a new permit under subsection (e), the medical marijuana organization shall change the location of its operation to the new location designated in the new permit. Simultaneously with the completion of the move, the medical marijuana organization shall cease to operate at the former location and surrender its existing permit to the Department. The following apply:

(1) At no time may a medical marijuana organization operate or exercise any of the privileges granted under the permit in both locations.

(2) At the discretion of the Department, the Department may extend the 180-day deadline for relocation for up to an additional 90 days.

(3) Once the new facility is determined to be operational by the Department, the medical marijuana organization may resume operations under the new permit at the new location.

(g) The Department will not approve a change of location that is outside the boundaries of the region for which the initial permit was issued.

(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.

(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.

(a) Except as provided in subsection (b), after the issuance of a permit, a medical marijuana organization may not make a physical change, alteration or modification to the facility that materially or substantially alters the facility or its usage as listed in the plot plans originally approved by the Department.

(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):

(1) An increase or decrease in the total square footage of the facility.

(2) The sealing off, creation of or relocation of a common entryway, doorway, passage or other means of public ingress or egress when the common entryway, doorway or passage alters or changes limited access areas.

(3) Any of the following made to enhance activities authorized under the permit:

(i) Additional electric fixtures or lighting equipment.

(ii) The lowering of a ceiling.

(iii) Electrical modifications that require inspection by the local municipality.

§ 1141a.42. Failure to be operational.

(a) Within 6 months from the date of issuance of a permit, a medical marijuana organization shall notify the Department, on a form prescribed by the Department, that it is operational.

(b) After the Department receives the notification in subsection (a), the Department will inspect the facility to determine if the medical marijuana organization is operational to the satisfaction of the Department.

(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.

(a) A medical marijuana organization shall notify the Department in writing immediately, but in no event less than 60 days prior to the projected date of closure, upon making a determination that it intends to close a facility.

(b) A medical marijuana organization may not accept or purchase seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, other plant matter, medical marijuana products, equipment, or medical devices or instruments as of the date of notice.

(c) The notice must be accompanied by the medical marijuana organization's written plan for the facility being closed that must include the following information:

(1) The projected date of closure.

(2) How it intends to notify in writing, prior to the projected date for closure, any person to which the medical marijuana organization provides seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products or medical marijuana services prior to closure.

(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).

(4) How it intends to dispose of equipment or medical devices or instruments used by the medical marijuana organization in its operations at the facility.

(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.

(e) The Department may enter and inspect the site and facility and the medical marijuana organization's vehicles following receipt of a medical marijuana organization's plan of closure to determine whether to approve the medical marijuana organization's closure plan.

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(f) If the Department approves the medical marijuana organization's plan to close a facility submitted under this section, the medical marijuana organization shall surrender its permit to the Department on or before the date for closure provided in the plan.

§ 1141a.44. Insurance requirements.

(a) A medical marijuana organization shall obtain and maintain an appropriate amount of insurance coverage that insures the site and facility and equipment used in the operation of the facility. An adequate amount of comprehensive liability insurance covering the medical marijuana organization's activities authorized by the permit shall begin on the date the initial permit is issued by the Department and continuing for as long as the medical marijuana organization is operating under the permit.

(b) A medical marijuana organization shall obtain and maintain workers' compensation insurance coverage for employees at the time the medical marijuana organization is determined to be operational by the Department.

§ 1141a.45. Inspection and investigation.

(a) The Department may conduct announced or unannounced inspections or investigations to determine the medical marijuana organization's compliance with its permit, the act or this part.

(b) An investigation or inspection may include:

(1) Inspection of a medical marijuana organization's site, facility, vehicles, books, records, papers, documents, data, and other physical or electronic information.

(2) Questioning of employees, principals, operators, financial backers, authorized agents of, and any other person or entity providing services to the medical marijuana organization.

(3) Inspection of a grower/processor facility's equipment, instruments, tools and machinery that are used to grow, process and package medical marijuana, including containers and labels.

(c) The Department and its authorized agents will have free access to review and, if necessary, make copies of books, records, papers, documents, data, or other physical or electronic information that relates to the business of the medical marijuana organization, including financial data, sales data, shipping data, pricing data and employee data.

(d) Failure of a medical marijuana organization to provide the Department and its authorized agents immediate access to any part of a medical marijuana organization's site or facility, requested material, physical or electronic information, or individual as part of an inspection or investigation may result in the imposition of a civil monetary penalty, suspension or revocation of its permit, or an immediate cessation of operations pursuant to a cease and desist order issued by the Department.

(e) The Department and its authorized agents will have free access to any area within a site or facility that is being used to store seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana

or medical marijuana products for testing purposes and are permitted to collect test samples for testing at an approved laboratory.

§ 1141a.46. Reports.

(a) A medical marijuana organization shall submit the following reports to the Department, on forms prescribed by the Department, at the end of the first 12-month period following the issuance of a permit, and as of the end of each 3-month period thereafter:

(1) In the case of a grower/processor:

(i) The number of medical marijuana products sold by the grower/processor to dispensaries during the period for which the report is being submitted.

(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~~.

(iii) The number or amount of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products sold by a grower/processer to other growers/processors during the period for which the report is being submitted.

(2) In the case of a dispensary:

(i) The number of medical marijuana products purchased by the dispensary during the period for which the report is being submitted.

(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~~.

(b) The Department will aggregate the information in the reports submitted by medical marijuana organizations under subsection (a) and post the information on the Department's web site.

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

(d) The Department may require any reports necessary to carry out its responsibilities under the act and this part.

§ 1141a.47. General penalties and sanctions.

(a) In addition to any other penalty imposed by law for violations of the act or this part, the Department may take one or more of the following actions:

(1) Suspend or revoke a permit if any of the following occur:

(i) The medical marijuana organization fails to maintain effective control against diversion of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products from a facility operated by it or under its control.

(ii) The medical marijuana organization violates a provision of the act or this part, or an order issued under the act or this part.

(iii) The medical marijuana organization violates a provision of other State or local laws regarding the operation of its facility.

(iv) The medical marijuana organization engages in conduct, or an event occurs, that would have disqualified the medical marijuana organization from being issued a permit or having its permit renewed.

(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.

(2) Impose a civil penalty of not more than $10,000 for each violation and an additional penalty of not more than $1,000 for each day of a continuing violation. In determining the amount of each penalty, the Department will take the following into consideration:

(i) The gravity of the violation.

(ii) The potential harm resulting from the violation to patients, caregivers or the general public.

(iii) The willfulness of the violation.

(iv) Previous violations, if any, by the medical marijuana organization being assessed.

(v) The economic benefit to the medical marijuana organization being assessed resulting from the violation.

(3) Suspend or revoke a permit pending the outcome of a hearing if the Department determines that the health, safety or welfare of the public, a patient or a caregiver is at risk.

(4) Order the restitution of funds or property unlawfully obtained or retained by a medical marijuana organization.

(5) Issue a cease and desist order to immediately restrict the operations of a medical marijuana organization conducted under the permit to protect the public's health, safety and welfare. The following requirements apply:

(i) An order may include a requirement that a medical marijuana organization cease or restrict some or all of its operations. In addition, the order may prohibit the use of some or all of the seeds,

immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products grown, processed or to be sold by the medical marijuana organization.

(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~~.

(iii) An order may include:

(A) An immediate evacuation of the site and facility and the sealing of the entrances to the facility.

(B) A quarantine of some or all of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products found at the facility.

(C) The suspension of the sale or shipment of some or all of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products found at the facility.

(6) Issue a written warning if the Department determines that either:

(i) The public interest will be adequately served under the circumstances by the issuance of the warning.

(ii) The violation does not threaten the safety or health of a patient, caregiver or the general public, and the medical marijuana organization took immediate action to remedy the violation.

(b) A person who aids, abets, counsels, induces, procures or causes another person to violate the act or this part, or an order issued under the act or this part, shall also be subject to the civil penalties provided under this section.

(c) For violations of the act or this part, the Department may require a medical marijuana organization to develop and adhere to a plan of correction approved by the Department. The Department will monitor compliance with the plan of correction. Failure to comply with the plan of correction may result in the Department's taking action under applicable provisions of this section as it deems appropriate.

(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.

(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.

(b) The training course required under subsection (a) must provide the following information:

(1) The provisions of the act and this part relevant to the responsibilities of principals and employees of medical marijuana organizations.

(2) Proper handling of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(3) Proper recordkeeping.

(4) How to prevent and detect the diversion of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(5) Best practice security procedures.

(6) Best practice safety procedures, including responding to the following:

(i) A medical emergency.

(ii) A fire.

(iii) A chemical spill.

(iv) A threatening event including:

(A) An armed robbery.

(B) A burglary.

(C) A criminal incident.

(c) A medical marijuana organization shall retain the attendance records of its principals and employees and make them available for inspection by the Department and its authorized agents upon request.

(d) The Department will make the 2-hour training course available at no cost to the medical marijuana organization, its principals or employees.

§ 1141a.49. Zoning.

(a) A grower/processor shall meet the identical municipal zoning and land use requirements as other manufacturing, processing and production facilities that are located in the same zoning district.

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(b) A dispensary shall meet the identical municipal zoning and land use requirements as other commercial facilities that are located in the same zoning district.

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

(a) In the advertising and marketing of medical marijuana and medical marijuana products, a medical marijuana organization shall be consistent with the Federal regulations governing prescription drug advertising and marketing in 21 CFR 202.1 (relating to prescription-drug advertisements).

(b) Promotional, advertising and marketing materials shall be approved by the Department prior to their use.

(c) This part 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.

§ 1141a.51. Technical advisories.

The Department may issue technical advisories to assist permittees in complying with the act and this part. Technical advisories do not have the force of law or regulation. Technical advisories provide guidance on the Department's interpretation of, and how a permittee may maintain compliance with, the act and this part. Notice of the availability of a technical advisory will be published in the *Pennsylvania Bulletin*.

~~**§ 1141.52. Effective date and applicability.**~~

~~(a) The amended temporary regulations in this chapter take effect on May 17, 2018.~~

~~(b) The amended temporary regulations in this chapter do not apply to the evaluation or scoring of a Medical Marijuana Organization Permit Application submitted to the Department from April 5, 2018, through May 17, 2018, as part of the implementation of Phase II of the Medical Marijuana Program.~~

APPENDIX A. SERIOUS MEDICAL CONDITIONS

The act of June 30, 2021 (P.L. 210, No. 44) (Act 44 of 2021) amended the statutory definition of "serious medical condition" under the Medical Marijuana Act (act) (35 P.S. §§ 10231.101—10231.2110), to include "other conditions that are recommended by the Advisory Board (Board) and approved by the Secretary under section 1202." Section 1201(j)(5)(ii) of the act charges the Board with the responsibility to issue written reports, which include the Board's recommendation on "whether to change, add or reduce the types of medical conditions which qualify as serious medical conditions. . . ." See 35 P.S. § 10231.1201(j)(5)(ii). This amendment was given retroactive effect to May 18, 2016, codifying conditions added by the Board between the act's commencement and Act 44 of 2021's passage.

At a public meeting on April 9, 2018, the Board adopted a final report recommending that a process be established for a subcommittee of the Board to review and approve additional serious medical conditions on a

continuous basis. See 35 P.S. § 1201(j)(6). The Secretary approved this recommendation which is published at 48 Pa. B 2898 (May 12, 2018). The Department attaches this Appendix A to reflect all approved serious medical conditions. The Department will periodically, no less than annually if additional serious medical conditions have been recommended by the Board and approved by the Secretary, publish notice in the *Pennsylvania Bulletin* updating the list of serious medical conditions. The list will also be posted on the Department's publicly accessible Internet web site.

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.

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- 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.