PART IXa. MEDICAL MARIJUANA

Ch.		Sec.
1141a.	GENERAL PROVISIONS	1141a.21
1151a.	GROWERS/PROCESSORS.	1151a.21
1161a.	DISPENSARIES	1161a.22
1171a.	LABORATORIES	1171a.22
1181a.	PHYSICIANS AND PRACTITIONERS	1181a.22
1191a.	PATIENTS AND CAREGIVERS	1191a.22
1211a.	CLINICAL REGISTRANTS AND ACADEMIC CLINICAL RESEARCH CENTERS.	1211a.22
1230a.	PRACTICE AND PROCEDURE	1230a.21

CHAPTER 1141a. GENERAL PROVISIONS

Sec.
1141a.21. Definitions.
1141a.22. Records subject to disclosure; confidentiality.
1141a.23. Limitation on number of permits.
1141a.24. Medical marijuana regions.
1141a.25. General requirements for permits.
1141a.26. Privilege and nontransferability.
1141a.27. General requirements for application.
1141a.28. Fees.
1141a.29. Initial permit application.
1141a.30. Capital requirements.
1141a.31. Background checks.
1141a.32. Diversity goals.
1141a.33. Review of initial permit applications.
1141a.34. Denial of a permit.
1141a.35. Notice of denial.
1141a.36. Permit renewal applications.
1141a.37. Denial of renewal of a permit.
1141a.38. Duty to report.
1141a.39. Change in ownership of a medical marijuana organization.
1141a.40. Application for approval of a change in location of an operational facility.
1141a.40.1 Request to change location of a non-operational facility.
1141a.41. Application for approval of alteration of a facility.
1141a.42. Failure to be operational.
1141a.43. Closure of a facility.
1141a.44. Insurance requirements.
1141a.45. Inspection and investigation.
1141a.46. Reports.
1141a.47. General penalties and sanctions.
1141a.48. Training.
1141a.49. Zoning.
1141a.50. Advertising by a medical marijuana organization.
1141a.51. Technical advisories.
Appendix A. Serious Medical Conditions

Authority

The provisions of this Chapter 1141a added under section 301(a)(3) and (b) of the Medical Marijuana Act (35 P.S. § 301(a)(3) and (b)), unless otherwise noted.

Source

The provisions of this Chapter 1141a added March 3, 2023, effective March 4, 2023, 53 Pa.B. 1275, unless otherwise noted.

Cross References

This chapter cited in 28 Pa. Code § 1211a.22 (relating to clinical registrants generally); 28 Pa. Code § 1211a.27 (relating to application for approval of a clinical registrant); 28 Pa. Code § 1211a.28 (relating to request for conversion of an existing permit); and 28 Pa. Code § 1211a.30 (relating to approval or denial of an application for approval of a clinical registrant).

§ 1141a.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.

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 any of the following:

(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.

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

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

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

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

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

CBD—Cannabidiol, 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 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, 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 ACRC under which the ACRC or its affiliate provides advice to the entity, regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances; and

(iii) Is approved by the Department.

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

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

Controlling interest—

(i) For a publicly traded 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 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).

Dispense—The activity of lawfully providing to a patient or caregiver medical marijuana products in a suitable container that is appropriately labeled for subsequent administration or use under a patient certification issued by a practitioner.

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, noteholder or other source of equity, capital or other assets other than a financial institution.

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

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

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

Grower/processor—

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

(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.

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.

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—An 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 the mature stalks of *Cannabis sativa* L., fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt or derivative, mixture or preparation of the mature stalks.

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

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.

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.

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) 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 be created by the General Assembly.

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

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

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

Office—The Department's Office of Medical Marijuana.

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

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

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

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

(i) Has a serious medical condition.

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

(iii) Is a resident of this Commonwealth.

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

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

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

Permit—An authorization issued by the Department to 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.

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. §§ 78a—78qq) 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. §§ 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. § 780(d)) by reason of having filed a registration statement which has become effective under the Securities Act of 1933 (15 U.S.C. §§ 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—The conditions listed in Appendix A (relating to serious medical condition).

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—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).

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 under court order:

(1) Information in the possession of the Department or any of its contractors regarding a 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) 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) 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) 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) 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.

Cross References

This section cited in 28 Pa. Code § 1141a.29 (relating to initial permit application); and 28 Pa. Code § 1141a.32 (relating to diversity goals).

§ 1141a.23. Limitation on number of permits.

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 growers/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 in the initial permit application or under § 1161a.40 (relating to additional dispensary locations).

§ 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.

(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*.

Cross References

This section cited in 28 Pa. Code § 1141a.33 (relating to review of initial permit applications).

§ 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.

(3) An application for change in ownership of a medical marijuana organization.

(4) An application for approval of a change of location of an operational facility.

(5) An application for approval of alteration of a facility.

(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 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) 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 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. Chapter 49 (relating to falsification and intimidation).

Cross References

This section cited in 28 Pa. Code § 1141a.29 (relating to initial permit application).

§ 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 provided in § 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 change in ownership of a medical marijuana organization.

(2) An application for approval of a change of location of an operational facility.

(3) An application for approval of alteration of a facility.

Cross References

This section cited in 28 Pa. Code § 1141a.27 (relating to general requirements for application); 28 Pa. Code § 1141a.36 (relating to permit renewal applications); 28 Pa. Code § 1141a.37 (relating to denial of renewal of a permit); 28 Pa. Code § 1141a.39 (relating to change in ownership of a medical marijuana organization); 28 Pa. Code § 1141a.40 (relating to application for approval of a change in location of an operational facility); and 28 Pa. Code § 1141a.41 (relating to application for approval of alteration of a facility).

§ 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.

(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 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 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) 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 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.

(iii) An affidavit from each principal, 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.

(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.

(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.

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

(x) Sanitation and safety.

(xi) Recordkeeping.

(xii) 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 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 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 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) 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.

Cross References

This section cited in 28 Pa. Code § 1141a.22 (relating to records subject to disclosure; confidentiality); 28 Pa. Code § 1141a.28 (relating to fees); 28 Pa. Code § 1141a.31 (relating to background checks); 28 Pa. Code § 1141a.39 (relating to change in ownership of a medical marijuana organization); 28 Pa. Code § 1141a.40 (relating to application for approval of a change in location of an operational facility); and 28 Pa. Code § 1161a.40 (relating to additional dispensary locations).

§ 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).

Cross References

This section cited in 28 Pa. Code § 1141a.29 (relating to initial permit application); and 28 Pa. Code § 1211a.24 (relating to capital requirements).

§ 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.

(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.

Cross References

This section cited in 28 Pa. Code § 1141a.22 (relating to records subject to disclosure; confidentiality); 28 Pa. Code § 1141a.29 (relating to initial permit application); and 28 Pa. Code § 1141a.34 (relating to denial of a permit).

§ 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 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 information regarding activities that 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.

Cross References

This section cited in 28 Pa. Code § 1141a.29 (relating to initial permit application).

§ 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.

Cross References

This section cited in 28 Pa. Code § 1141a.34 (relating to denial of a permit).

§ 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, 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.

§ 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 (relating to practice and procedure of Commonwealth agencies) and its accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure).

§ 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 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.

Cross References

This section cited in 28 Pa. Code § 1141a.37 (relating to denial of renewal of a permit); and 28 Pa. Code § 1211a.31 (relating to renewal of approval of a clinical registrant).

§ 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:

(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 no less than 30 days prior to the proposed modification.

(3) Immediately when they become aware or State and local law enforcement 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 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 authority.

§ 1141a.39. 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 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) 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) 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) 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.

Cross References

This section cited in 28 Pa. Code § 1141a.38 (relating to duty to report).

§ 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 an operational facility 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 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 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).

Cross References

This section cited in 28 Pa. Code § 1151a.21 (relating to growers/processors generally); and 28 Pa. Code § 1161a.22 (relating to dispensaries generally).

§ 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.

(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.

Cross References

This section cited in 28 Pa. Code § 1141a.38 (relating to duty to report).

§ 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 under 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 average price per unit of medical marijuana products sold by the grower/processor to a medical marijuana organization.

(iii) The number or amount of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products sold by the 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 average price per unit of medical marijuana products purchased by the dispensary.

(iii) The average price per unit of an amount of medical marijuana products dispensed to a patient or caregiver by the dispensary.

(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.

(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 an operational failure or evidence of diversion or contamination of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.

(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. §§ 501—508 (relating to practice and procedure of Commonwealth agencies) and its accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure).

Cross References

This section cited in 28 Pa. Code § 1141a.42 (relating to failure to be operational); and 28 Pa. Code § 1151a.42 (relating to complaints about or recall of medical marijuana products).

§ 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 shall complete a 2-hour training course developed by the Department. The following apply:

(1) Principals must successfully complete the course prior to starting initial operation of a facility.

(2) 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.

(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*.

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.
- Dyskinetic and spastic movement disorders.
- Tourette's Syndrome.
- 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.
- Chronic Hepatitis C.

Source

The provisions of this Appendix A amended March 17, 2023, effective March 18, 2023, 53 Pa.B. 1578.

[Next page is 1151a-1.]