

RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CHS. 1141 AND 1151]

Medical Marijuana; General Provisions; Growers/ Processors; Amendments to Temporary Regula- tions

The Department of Health (Department) is publishing amendments to the temporary regulations in Chapters 1141 and 1151 (relating to general provisions; and growers/processors) to read as set forth in Annex A. The temporary regulations are published under the Medical Marijuana Act (act) (35 P.S. §§ 10231.101—10231.2110). Section 1107 of the act (35 P.S. § 10231.1107) specifically provides that, to facilitate the prompt implementation of the act, the Department may promulgate temporary regulations that are not subject to sections 201—205 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201—1205), known as the Commonwealth Documents Law, the Regulatory Review Act (71 P.S. §§ 745.1—745.14) and sections 204(b) and 301(10) of the Commonwealth Attorneys Act (71 P.S. §§ 732-204(b) and 732-301(10)).

To implement the Medical Marijuana Program (Program), the Department will be periodically publishing temporary regulations regarding various sections of the act. Chapter 1141 pertains to general provisions and Chapter 1151 pertains to growers/processors who will grow and process medical marijuana for use in the Program. The amendments to the temporary regulations and new § 1141.51 (relating to technical advisories) in Annex A will expire on January 14, 2019.

Interested persons are invited to submit written comments, suggestions or objections regarding the amendments to the temporary regulations to John J. Collins, Office of Medical Marijuana, Department of Health, Room 628, Health and Welfare Building, 625 Forster Street, Harrisburg, PA 17120, (717) 787-4366, RA-DHMed Marijuana@pa.gov. Persons with a disability who wish to submit comments, suggestions or objections regarding the amendments to the temporary regulations may do so by using the previous contact information. Speech and/or hearing impaired persons may use V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact John J. Collins so that necessary arrangements may be made.

KAREN M. MURPHY, PhD, RN,
Secretary

Fiscal Note: 10-199. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

CHAPTER 1141. GENERAL PROVISIONS

§ 1141.21. Definitions.

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

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

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, 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 or to purchase particular medical marijuana.

Applicant—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.

CBD—Cannabidiol.

Caregiver—An individual over 21 years of age, or if the patient is under 18 years of age, an individual under section 506(2) of the act (35 P.S. § 10231.506(2)), who is designated by a patient for certified medical use.

Certified medical use—The acquisition, possession, use or transportation of medical marijuana by a patient, or the acquisition, possession, delivery, transportation or administration of medical marijuana by a caregiver, for use as part of the treatment of the patient's serious medical condition, as authorized in a patient certification issued under the act, including enabling the patient to tolerate treatment for the serious medical condition.

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

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

Clinical registrant—An entity that:

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

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

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

Controlling interest—

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

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

Department—The Department of Health of the Commonwealth.

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.

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

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

Diverse participants—The term includes the following:

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

(ii) Women.

(iii) Veterans.

(iv) Individuals with disabilities.

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

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

(i) A grower/processor to log, verify and monitor the receipt, use and sale of seeds, immature medical marijuana plants or medical marijuana plants, the funds received by a grower/processor for the sale of medical marijuana to another medical marijuana organization, the disposal of medical marijuana waste and the recall of defective medical marijuana.

(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.

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

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

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

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

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

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

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

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

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

Grower/processor—

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

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

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

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

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

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

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

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

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

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

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

- (iii) Medical marijuana is packaged for sale or stored.
- (iv) Medical marijuana waste is processed, stored or destroyed.
- (v) Surveillance system devices are stored.

Marijuana—

(i) The plant, of genus *Cannabis sativa* L., within the family Cannabaceae, including any part of the plant genus *Cannabis*, within the family Cannabaceae and the immature plant or seeds of the plant genus *Cannabis*, within the family Cannabaceae.

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

Medical marijuana—Marijuana for certified medical use as set forth in the act.

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

Medical marijuana organization—

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

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

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.
 - (B) Any 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.

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 city, borough, incorporated town or township.

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.

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.

Patient—An individual who:

- (i) Has a serious medical condition.
- (ii) Has met the requirements for certification under the act.
- (iii) Is a resident of this Commonwealth.

Permit—An authorization issued by the Department to an applicant 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.

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

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.

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

- (i) Has a class or series of securities registered under the Securities Exchange Act of 1934 (15 U.S.C.A. §§ 78a—78pp) or on a foreign stock exchange determined by the Department to have similar listing and reporting requirements to exchanges that are regulated under the Securities Exchange Act of 1934.
- (ii) Is a registered management company under the Investment Company Act of 1940 (15 U.S.C.A. §§ 80a-1—80a-64).
- (iii) Is subject to the reporting obligations imposed by section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C.A. § 78o(d)) by reason of having filed a registration statement which has become effective under the Securities Act of 1933 (15 U.S.C.A. §§ 77a—77aa).

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

Serious medical condition—Any of the following conditions:

- (i) Cancer.
- (ii) Positive status for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome.
- (iii) Amyotrophic lateral sclerosis.
- (iv) Parkinson's disease.
- (v) Multiple sclerosis.
- (vi) Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity.
- (vii) Epilepsy.
- (viii) Inflammatory bowel disease.
- (ix) Neuropathies.
- (x) Huntington's disease.
- (xi) Crohn's disease.
- (xii) Post-traumatic stress disorder.
- (xiii) Intractable seizures.
- (xiv) Glaucoma.
- (xv) Sickle cell anemia.
- (xvi) Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or ineffective.
- (xvii) Autism.

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.

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

THC—Tetrahydrocannabinol.

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 medical marijuana between medical marijuana organizations or between medical marijuana organizations and a laboratory.

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

Vaporization or nebulization—The generation of medical marijuana in the form of vapor or fine spray 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).

§ 1141.22. Records subject to disclosure; confidentiality.

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

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

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

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

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

(1) Information in the possession of the Department or any of its contractors regarding 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) Any information on an identification card.

(6) Information provided by the Pennsylvania State Police regarding a caregiver, including criminal history record information, as set forth in § 1141.31 (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 and a dispensary.

(c) An applicant shall mark confidential proprietary information as confidential proprietary information prior to submission to the Department.

§ 1141.24. Medical marijuana regions.

(a) The Department will issue permits to applicants in each of six medical marijuana regions. The 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*.

§ 1141.27. 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 approval of a change in ownership of a medical marijuana organization authorized by a permit.
- (4) An application for approval of a change of location of a facility authorized by a permit.
- (5) An application for approval of alteration of a facility authorized by a permit.
- (6) An application for additional dispensary locations.

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

(c) An application is not complete and will be rejected by the Department unless:

- (1) The payment of the applicable application fee in § 1141.28 (relating to fees) is submitted with the application.

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

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

(d) An application that is rejected by the Department will be returned to the applicant without further consideration by the Department along with the refund of the initial permit fee.

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

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

§ 1141.28. Fees.

(a) An applicant for an initial grower/processor permit or renewal permit shall pay the following fees by certified 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 § 1141.29(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.

(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.

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

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

(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.

(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.

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

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

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

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

§ 1141.29. 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 redacted version 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 return of fees submitted by the applicant with the application.

(b) In addition to the requirements in § 1141.27 (relating to general requirements for application), the applicant shall provide the Department with the following information in the initial permit application:

(1) The legal name of the applicant.

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

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

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

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

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

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

(5) The following apply to the proposed facility:

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

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

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

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

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

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

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

(iii) A copy of a criminal history records check for each individual performed in accordance with § 1141.31 (relating to background checks). This subparagraph does not apply to an applicant who is an owner of securities in a publicly traded company if the Department determines that the owner of the securities is not substantially involved in the activities of the applicant.

(iv) An affidavit from each principal or operator 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 or a controlled substance.

(B) Whether the principal, operator or financial backer has been convicted of a criminal offense graded higher than a summary offense.

(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 § 1141.27.

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

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

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

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

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

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

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

- (i) Security.
- (ii) Employee qualifications and training.
- (iii) Transportation of medical marijuana.
- (iv) Storage of medical marijuana.
- (v) Labeling of medical marijuana.

(vi) Inventory management.

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

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

(ix) Recordkeeping.

(x) Preventing unlawful diversion of medical marijuana.

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

(xii) Establishment, implementation and monitoring of diversity goals under § 1141.32 (relating to diversity goals).

(13) The relevant financial information in § 1141.30 (relating to capital requirements).

(14) Statements that:

(i) The applicant and each principal, operator, financial backer and employee are of good moral character.

(ii) The applicant possesses the ability to obtain in an expeditious manner the right to use the proposed site and facility, including equipment, to properly perform the activity described in the initial permit application.

(iii) The applicant is able to continuously maintain effective security, surveillance and accounting control measures to prevent diversion, abuse and other illegal conduct regarding medical marijuana plants and medical marijuana.

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

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

(16) Other information required by the Department.

(c) If the Department determines that an initial permit application is complete but lacking sufficient information upon which to make a determination, the Department will 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.

(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.

ners, 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 medical marijuana to a facility or a laboratory.

§ 1141.31. Background checks.

(a) To provide the criminal history record check required under § 1141.29 (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 shall 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.

(c) This section does not apply to an owner of securities in a publicly traded company if the Department determines that the owner is not substantially involved in the activities of the medical marijuana organization.

(d) A financial backer, principal or employee may not hold a volunteer position, position for remuneration or otherwise be affiliated with a medical marijuana organization or a clinical registrant if the individual has been convicted of a criminal offense relating to the sale or possession of illegal drugs, narcotics or controlled substances.

§ 1141.33. 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 § 1141.24(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* prior to the time the initial permit applications are made available for submission.

§ 1141.36. 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 § 1141.28 (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) Any 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.

(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.

(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.

§ 1141.37. 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 § 1141.36 (relating to permit renewal applications) and remitted the required fees in accordance with § 1141.28 (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 § 1141.28, 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 medical marijuana, medical marijuana products, plant matter, seed or any growing equipment as set forth in § 1151.40 (relating to management and disposal of medical marijuana waste).

(3) In the case of a dispensary, return the medical marijuana or medical marijuana products to the grower/

processor where the medical marijuana and 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 § 1141.28, 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.

§ 1141.38. Duty to report.

(a) During the application process, or at any time during the permit period if a permit is issued, an applicant or permittee 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 at least 30 days prior to the proposed modification.

(3) Immediately upon becoming aware, and State and local law enforcement immediately upon becoming aware, of any adverse loss from the permittee's facility or any vehicle transporting medical marijuana to or from the permittee's facility.

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

(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 § 1141.43 (relating to closure of a facility):

- (1) Discontinuance of operations.
- (2) Removal of all medical marijuana from the sites and locations by State or Federal authority.

§ 1141.42. Failure to be operational.

(a) No more than 6 months from the date of issuance of a permit, a medical marijuana organization shall notify the Department, on a form prescribed by the Department, that it is operational.

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

(c) If the medical marijuana organization has not met the operational timetable in the initial permit application to the satisfaction of the Department at the time of the inspection conducted under subsection (b), the Department will notify the medical marijuana organization of the deficiencies. Within 30 days of receiving the 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 § 1141.47 (relating to general penalties and sanctions).

§ 1141.43. 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 its 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 closing the facility which 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 medical marijuana 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 § 1151.40 (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 § 1151.40.

(e) The Department may enter the site and facility and inspect 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 the 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.

§ 1141.45. 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 and financial backers of the medical marijuana organization.

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

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

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

(e) The Department and its authorized agents will have free access to any area within a site or facility that is being used to store medical marijuana for testing purposes and are permitted to collect test samples for testing at an approved laboratory.

§ 1141.46. 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 amount of medical marijuana sold by the grower/processor during the period for which the report is being submitted.

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

(2) In the case of a dispensary:

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

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

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

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

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

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

§ 1141.50. Advertising by a medical marijuana organization.

(a) In the advertising and marketing of medical marijuana, 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 items that the grower/processor is offering for sale to the dispensary.

§ 1141.51. 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, but will 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*.

CHAPTER 1151. GROWERS/PROCESSORS

§ 1151.21. Growers/processors generally.

(a) The qualifications that a grower/processor shall meet to receive a permit are continuing qualifications to maintain the permit.

(b) In addition to any other requirements in the act or this part, a grower/processor shall comply with the following:

(1) A grower/processor may not engage in the business of growing, processing, possessing, selling or offering to sell medical marijuana to another medical marijuana organization or to a clinical registrant within this Commonwealth without first being issued a permit by the Department and without first being determined operational by the Department as required under § 1141.42 (relating to failure to be operational).

(2) A grower/processor may not employ an individual at its facility who is under 18 years of age.

§ 1151.22. Plans of operation.

(a) At the time the Department determines a grower/processor to be operational, the grower/processor shall provide the Department with a full and complete plan of operation for review that includes the following:

(1) Employment policies and procedures.

(2) Security policies and protocols including:

(i) Staff identification measures.

(ii) Monitoring of attendance of staff and visitors.

(iii) Alarm systems.

(iv) Video surveillance.

(v) Monitoring and tracking inventory.

(vi) Personal security.

(3) A process for growing, receiving, processing, packaging, labeling, handling, tracking, transporting, storing, disposing and recalling of medical marijuana and a process for handling, tracking, transporting, storing and disposing of medical marijuana waste in accordance with applicable laws, rules and regulations.

(4) Workplace safety, including conducting necessary safety checks prior to starting the growing and processing of medical marijuana.

(5) Contamination protocols.

(6) Maintenance, cleaning and sanitation of equipment in the facility or on the site, or both.

(7) Maintenance and sanitation of the site or the facility, or both.

(8) Proper handling and storage of any solvent, gas or other chemical used in growing or processing medical marijuana in accordance with this part and other applicable laws, rules and regulations.

(9) Quality control, including regulation of the amount of THC in each process lot, proper labeling and minimization of medical marijuana contamination.

(10) Inventory maintenance and reporting procedures.

(11) The investigation of complaints and potential adverse events from other medical marijuana organizations, patients, caregivers or practitioners regarding the operation of the grower/processor.

(12) A recall plan meeting the requirements of § 1151.42(d) (relating to complaints about or recall of medical marijuana).

(b) A grower/processor shall make the full and complete plan of operation available to the Department upon request and during any inspection of the site and facility.

§ 1151.23. Grower/processor facilities.

(a) A grower/processor may only grow, store, harvest or process medical marijuana in an indoor, enclosed, secure facility as approved by the Department.

(b) The following areas of a facility must be clearly marked with proper signage:

(1) Medical marijuana growing and processing areas. These areas shall be easily observed by the Department and its authorized agents and by law enforcement.

(2) Nongrowing and nonprocessing areas.

(3) Limited access areas. All areas of ingress and egress to a limited access area must be clearly identified by the posting of a sign which must be not less than 12 inches wide and 12 inches long, composed of letters not less than 1/2 inch in height, which must state:

Do Not Enter—Limited Access Area—Access Limited to Authorized Personnel and Escorted Visitors.

(4) Areas that include business offices and reception rooms.

(c) A facility shall have an enclosed secure area out of public sight for the loading and unloading of medical marijuana into and from a transport vehicle.

§ 1151.25. Visitor access to grower/processor facilities.

(a) A grower/processor facility may not be open to the general public. A grower/processor shall require visitors, including vendors, contractors and other individuals requiring access to the facility for purposes regarding the growing, processing or testing of medical marijuana, to sign a visitor log and wear a visitor identification badge that is visible to others at all times while on the site and in the facility.

(b) A grower/processor shall require visitors to present government-issued identification that contains a photo to gain access to the site and facility.

(c) No one under 18 years of age is permitted to enter a grower/processor site and facility.

(d) A grower/processor shall post a sign in a conspicuous location at each entrance of the site and facility that states:

THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE. NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER.

(e) A grower/processor shall do the following when admitting a visitor to its site and facility:

(1) Require the visitor to sign a visitor log upon entering and leaving the facility.

(2) Check the visitor's government-issued identification to verify that the name on the identification provided matches the name in the visitor log. A photocopy of the identification must be retained with the log.

(3) Issue a visitor identification badge with the visitor's name and company, if applicable, and a badge number.

(4) Escort the visitor while the visitor remains in the facility or on the site.

(5) Ensure that the visitor does not touch any medical marijuana plant or medical marijuana located in a limited access area.

(f) The following apply to the visitor log required under subsections (a) and (e):

(1) The grower/processor shall maintain the log for 4 years and make the log available to the Department, State or local law enforcement, and other State or local government officials upon request if necessary to perform the government officials' functions and duties.

(2) The log must include the full name of each visitor, the visitor identification badge number, the time of arrival, the time of departure and the purpose of the visit, including the areas of the site and the facility visited and the name of each employee visited.

(g) This section does not limit the right of the Department or its authorized agents, or other Federal, State or local government officials, from entering any area of a grower/processor site and facility if necessary to perform the governmental officials' functions and duties.

(h) A principal, financial backer, operator or an employee of a grower/processor may not receive any type of consideration or compensation for allowing a visitor to enter a limited access area.

§ 1151.26. Security and surveillance.

(a) A grower/processor shall have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse loss. The security and surveillance systems must include the following:

(1) A professionally-monitored security alarm system that includes the following:

(i) Coverage of all facility entrances and exits; rooms with exterior windows, exterior walls, roof hatches or skylights; storage rooms, including those that contain medical marijuana and safes; and the perimeter of the facility.

(ii) A silent security alarm system signal, known as a duress alarm, generated by the entry of a designated code into an arming station to signal that the alarm user is being forced to turn off the system.

(iii) An audible security alarm system signal, known as a panic alarm, generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring law enforcement response.

(iv) A silent alarm signal, known as a holdup alarm, generated by the manual activation of a device intended to signal a robbery in progress.

(v) An electrical, electronic, mechanical or other device capable of being programmed to send a prerecorded voice message requesting dispatch, when activated, over a telephone line, radio or other communication system to a law enforcement, public safety or emergency services agency.

(vi) A failure notification system that provides an audible, text or visual notification of any failure in the systems. The failure notification system must provide by telephone, e-mail or text message an alert to a designated security person within the facility within 5 minutes after the failure.

(vii) Smoke and fire alarms.

(viii) Auxiliary power sufficient to maintain operation of specified growing and processing areas identified in the grower/processor's plan of operation for at least 48 hours following a power outage.

(ix) The ability to ensure all access doors are not solely controlled by an electronic access panel to prevent locks from becoming released during a power outage.

(x) Motion detectors.

(2) A professionally-monitored security and surveillance system that is operational 24 hours a day, 7 days a week and records all activity in images capable of clearly revealing facial detail. The security and surveillance system must include the following:

(i) Fixed camera placement that allows for a clear image of all individuals and activities in and around the following:

(A) All limited access areas.

(B) A room or area containing a security and surveillance system storage device or equipment.

(C) Entrances to and exits from the facility. Entrances and exits must be recorded from both indoor and outdoor vantage points.

(D) Rooms with exterior windows, exterior walls, roof hatches, or skylights and storage rooms, including those that may contain medical marijuana and safes.

(E) Twenty feet from the exterior of the perimeter of the facility.

(ii) Auxiliary power sufficient to maintain operation for at least 48 hours following a power outage.

(iii) Ability to operate under the normal lighting conditions of each area under surveillance.

(iv) Ability to immediately produce a clear, color, still photograph in a digital format that meets the requirements of this subsection.

(3) Ability to clearly and accurately display the date and time. The date and time must be synchronized and set correctly and may not significantly obscure the picture.

(4) Ability to record all images captured by each surveillance camera for a minimum of 4 years in a format that may be easily accessed for investigative purposes. The recordings must be kept:

(i) At the facility:

(A) In a locked cabinet, closet or other secure place to protect it from tampering or theft.

(B) In a limited access area or other room to which access is limited to authorized individuals.

(ii) At a secure location other than the location of the facility if approved by the Department.

(5) A security alarm system separate from the facility's primary security system covering the limited access area or other room where the recordings under paragraph (4) are stored. The separate security alarm system must meet the same requirements as the facility's primary security alarm system.

(b) The following apply regarding the inspection, servicing or alteration of, and the upgrade to, the site's and facility's security and surveillance systems:

(1) The systems shall be inspected and all devices tested once every year by a qualified alarm system vendor and a qualified surveillance system vendor, as approved by the Department.

(2) The grower/processor shall conduct maintenance inspections once every month to ensure that any repairs, alterations or upgrades to the security and surveillance systems are made for the proper operation of the systems.

(3) The grower/processor shall retain at the facility, for at least 4 years, records of all inspections, servicing, alterations and upgrades performed on the systems and shall make the records available to the Department and its authorized agents within 2 business days following a request.

(4) In the event of a mechanical malfunction of the security or surveillance system that a grower/processor anticipates will exceed an 8-hour period, the grower/processor shall notify the Department immediately and, with Department approval, provide alternative security measures that may include closure of the facility.

(5) The grower/processor shall designate an employee to continuously monitor the security and surveillance systems at the facility.

(6) The following apply regarding records retention:

(i) Within 2 business days following a request, a grower/processor shall provide up to four screen captures of an unaltered copy of a video surveillance recording to the Department or its authorized agents, law enforcement or other Federal, State or local government officials if necessary to perform the governmental officials' functions and duties.

(ii) If a grower/processor has been notified in writing by the Department or its authorized agents, law enforcement or other Federal, State or local government officials of a pending criminal or administrative investigation for which a recording may contain relevant information, the grower/processor shall retain an unaltered copy of the recording for 4 years or until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the grower/processor that it is not necessary to retain the recording, whichever is longer.

(c) The grower/processor shall install commercial-grade, nonresidential doors and door locks on each external door of the facility. Keys or key codes for all doors shall remain in the possession of designated authorized individuals.

(d) During all nonworking hours, all entrances to and exits from the site and facility must be securely locked.

(e) The grower/processor shall have an electronic back-up system for all electronic records.

(f) The grower/processor shall install lighting to ensure proper surveillance inside and outside of the facility.

(g) A grower/processor shall limit access to a room containing security and surveillance monitoring equipment to persons who are essential to maintaining security and surveillance operations; Federal, State and local law enforcement; security and surveillance system service employees; the Department or its authorized agents; and other persons with the prior written approval of the Department. The following apply:

(1) A grower/processor shall make available to the Department or the Department's authorized agents, upon request, a current list of authorized employees and service employees or contractors who have access to any security and surveillance areas.

(2) A grower/processor shall keep security and surveillance rooms locked at all times and may not use these rooms for any other purpose or function.

§ 1151.27. Requirements for growing and processing medical marijuana.

(a) A grower/processor shall use only pesticides, fungicides or herbicides that are approved by the Department of Agriculture for use on medical marijuana plants and listed in Appendix A (relating to acceptable pesticide active ingredients for use). The Department will periodically publish a notice in the *Pennsylvania Bulletin* updating the list of pesticides, fungicides or herbicides.

(b) A grower/processor shall use the pesticides, fungicides or herbicides listed in Appendix A in a manner that is approved by the Department of Agriculture on the basis of Federal law and regulations.

(c) A grower/processor shall maintain a log of all actions taken to detect pests or pathogens, and the measures taken for control.

(d) A grower/processor shall:

- (1) Use appropriate nutrient practices.
- (2) Use a fertilizer or hydroponic solution of a type, formulation and at a rate to support healthy growth of plants.

(3) Maintain records of the type and amounts of fertilizer and any growth additives used.

(e) A grower/processor shall perform visual inspections of growing plants and harvested plant material to ensure there is no visible mold, mildew, pests, rot, or grey or black plant material that is greater than an acceptable level as determined by the Department.

(f) A grower/processor may not add any additional active ingredients or materials to medical marijuana that alters the color, appearance, smell, taste, effect or weight of the medical marijuana unless the grower/processor has first obtained the prior written approval of the Department. Excipients must be pharmaceutical grade, unless otherwise approved by the Department.

(g) A grower/processor shall have a separate and secure area for temporary storage of medical marijuana that is awaiting disposal by the grower/processor.

(h) A grower/processor shall only process the parts of the medical marijuana plant that:

- (1) Are free of seeds and stems.

(2) Are free of dirt, sand, debris or other foreign matter.

(3) Contain a level of mold, rot or other fungus or bacterial diseases acceptable to the Department.

(i) A grower/processor shall process the medical marijuana plants in a safe and sanitary manner. The following apply:

(1) Medical marijuana, raw material and other product used in the processing of medical marijuana shall be handled on food-grade stainless steel benches or tables.

(2) Proper sanitation shall be maintained.

(3) Proper rodent, bird and pest exclusion practices shall be employed.

(j) A grower/processor shall install a system to monitor, record and regulate:

- (1) Temperature.
- (2) Humidity.
- (3) Ventilation.
- (4) Lighting.
- (5) Water supply.

§ 1151.29. Limit on medical marijuana processing.

(a) In the form intended to be sold to another medical marijuana organization, medical marijuana must have a specific concentration of total THC and total CBD and must have a consistent cannabinoid profile. The concentration of the following cannabinoids, at a minimum, shall be reported to the Department by an approved laboratory and include the following on the label:

- (1) Tetrahydrocannabinol (THC).
- (2) Tetrahydrocannabinol acid (THCA).
- (3) Tetrahydrocannabivarin (THCV).
- (4) Cannabidiol (CBD).
- (5) Cannabinadiolic acid (CBDA).
- (6) Cannabidivarin (CBDV).
- (7) Cannabinol (CBN).
- (8) Cannabigerol (CBG).
- (9) Cannabichromene (CBC).
- (10) Any other cannabinoid component at > 0.1%.

(b) Within the first 6 months after the Department determines the grower/processor to be operational, the grower/processor shall provide the Department with a forecast of the amount of medical marijuana it projects it will produce and in what form. The grower/processor shall notify the Department in writing immediately upon becoming aware of a potential increase or decrease in the forecasted amount occurring within any subsequent 6-month period.

§ 1151.30. Inventory data.

(a) A grower/processor shall maintain the following inventory data in its electronic tracking system which must include an accounting of and an identifying tracking number for:

- (1) The number, weight and type of seeds.
- (2) The number of immature medical marijuana plants.
- (3) The number of medical marijuana plants.
- (4) The number of medical marijuana products ready for sale.

(5) The number of damaged, defective, expired or contaminated seeds, immature medical marijuana plants, medical marijuana plants and medical marijuana products awaiting disposal.

(b) A grower/processor shall establish inventory controls and procedures to conduct inventory reviews and comprehensive inventories at its facility. The following apply:

(1) Inventory reviews of medical marijuana plants in the process of growing and medical marijuana and medical marijuana products that are being stored for future sale shall be conducted monthly.

(2) Comprehensive inventories of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products shall be conducted at least annually.

(c) A written or electronic record shall be created and maintained of each inventory conducted under subsection (b) that includes the date of the inventory, a summary of the inventory findings, and the employee identification numbers and titles or positions of the individuals who conducted the inventory.

§ 1151.31. Storage requirements.

(a) A grower/processor shall have separate locked limited access areas for storage of seeds, immature medical marijuana plants, medical marijuana plants and medical marijuana that are expired, damaged, deteriorated, mislabeled, contaminated, recalled or whose containers or packaging have been opened or breached until the seeds, immature medical marijuana plants, medical marijuana plants and medical marijuana are destroyed or otherwise disposed of as required under § 1151.40 (relating to management and disposal of medical marijuana waste).

(b) A grower/processor shall maintain all storage areas in a clean and orderly condition and free from infestation by insects, rodents, birds and pests.

§ 1151.33. Sanitation and safety in a facility.

(a) A grower/processor shall maintain its facility in a sanitary condition to limit the potential for contamination or adulteration of the medical marijuana grown and processed in the facility. The following apply:

(1) Equipment and surfaces, including floors, counters, walls and ceilings, shall be cleaned and sanitized as frequently as necessary to protect against contamination, using a sanitizing agent registered by the United States Environmental Protection Agency, in accordance with the instructions printed on the label. Equipment and utensils shall be so designed and of such material and workmanship as to be capable of being adequately cleaned.

(2) Trash shall be properly removed.

(3) Floors, walls and ceilings shall be kept in good repair.

(4) Equipment, counters and surfaces for processing must be food grade quality and may not react adversely with any solvent being used.

(5) Adequate protection against pests shall be provided through the use of integrated pest management practices and techniques that identify and manage plant pathogens and pest problems, and the regular disposal of trash to prevent infestation.

(6) Toxic cleaning compounds, sanitizing agents, solvents used in the growing and processing of medical marijuana, and pesticide chemicals must be labeled and stored in a manner that prevents contamination of seeds,

immature medical marijuana plants, medical marijuana plants and medical marijuana, and in a manner that otherwise complies with other applicable laws and regulations.

(b) An employee working in direct contact with medical marijuana is subject to the restrictions on food handlers in § 27.153 (relating to restrictions on food handlers). An employee shall otherwise conform to sanitary practices while on duty, including the following:

(1) Maintaining adequate personal hygiene.

(2) Wearing proper clothing, including gloves.

(3) Washing hands thoroughly in an adequate hand-washing area before starting work and at any other time when hands may have become soiled or contaminated.

(c) A grower/processor shall provide its employees and visitors with adequate and convenient hand-washing facilities furnished with running water at a temperature suitable for sanitizing hands. The following apply:

(1) Hand-washing facilities must be located in processing areas and where good sanitary practices require employees to wash and sanitize their hands.

(2) Effective nontoxic sanitizing cleansers and sanitary towel service or suitable drying devices shall be provided.

(d) A grower/processor shall provide its employees and visitors with adequate, readily accessible lavatories that are maintained in a sanitary condition and in good repair.

(e) A grower/processor shall ensure that its facility is provided with a water supply sufficient for its operations, which shall be derived from a source that is a public water system, or a nonpublic system that is capable of providing a safe, potable and adequate supply of water to meet the operational needs of the facility.

(f) A grower/processor shall comply with all other applicable State and local building code requirements.

§ 1151.34. Packaging and labeling of medical marijuana.

(a) A grower/processor shall package and label at its facility each form of medical marijuana prepared for sale. The original seal of a package may not be broken, except for quality control testing at an approved laboratory, for adverse loss investigations conducted by the Department or by a dispensary that purchased the medical marijuana.

(b) A grower/processor shall package the medical marijuana in a package that minimizes exposure to oxygen and that is:

(1) Child-resistant.

(2) Tamper-proof or tamper-evident.

(3) Light-resistant and opaque.

(4) Resealable.

(c) A grower/processor shall identify each process lot of medical marijuana with a unique identifier.

(d) A grower/processor shall obtain the prior written approval of the Department of the content of any label to be affixed to a medical marijuana package. Each label must:

(1) Be easily readable.

(2) Made of weather-resistant and tamper-resistant materials.

(3) Be conspicuously placed on the package.

(4) Include the name, address and permit number of the grower/processor.

(5) List the form, quantity and weight of medical marijuana included in the package.

(6) List the amount of individual doses contained within the package and the species and percentage of THC and CBD.

(7) Contain an identifier that is unique to a particular harvest batch of medical marijuana, including the number assigned to each harvest lot or process lot in the harvest batch.

(8) Include the date the medical marijuana was packaged.

(9) State the employee identification number of the employee preparing the package and packaging the medical marijuana.

(10) State the employee identification number of the employee shipping the package, if different than the employee described in paragraph (9).

(11) Contain the name and address of the dispensary to which the package is to be sold.

(12) List the date of expiration of the medical marijuana.

(13) Include instructions for proper storage of the medical marijuana in the package.

(14) Contain the following warning stating:

This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children.

(15) Contain a warning that the medical marijuana must be kept in the original container in which it was dispensed.

(16) Contain a warning that unauthorized use is unlawful and will subject the purchaser to criminal penalties.

(e) Labeling by a grower/processor of any medical marijuana may not bear:

(1) Any resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available food or beverage product.

(2) Any statement, artwork or design that could reasonably lead an individual to believe that the package contains anything other than medical marijuana.

(3) Any seal, flag, crest, coat of arms or other insignia that could reasonably mislead an individual to believe that the product has been endorsed, manufactured or approved for use by any state, county or municipality or any agency thereof.

(4) Any cartoon, color scheme, image, graphic or feature that might make the package attractive to children.

§ 1151.35. Transportation of medical marijuana.

(a) A grower/processor may transport and deliver medical marijuana to a medical marijuana organization or an approved laboratory in this Commonwealth in accordance with this section. The following apply:

(1) A grower/processor may deliver medical marijuana to a medical marijuana organization or an approved laboratory only between 7 a.m. and 9 p.m.

(2) A grower/processor may contract with a third-party contractor for delivery so long as the contractor complies with this section.

(3) A grower/processor may not transport medical marijuana to any location outside of this Commonwealth.

(4) A grower/processor shall use a global positioning system to ensure safe, efficient delivery of the medical marijuana to a medical marijuana organization or an approved laboratory.

(b) Vehicles permitted to transport medical marijuana must:

(1) Be equipped with a secure lockbox or locking cargo area.

(2) Have no markings that would either identify or indicate that the vehicle is being used to transport medical marijuana.

(3) Be capable of being temperature-controlled for perishable medical marijuana, as appropriate.

(4) Display current State inspection stickers and maintain a current State vehicle registration.

(5) Be insured in an amount that is commercially reasonable and appropriate.

(c) A transport vehicle must be staffed with a delivery team consisting of at least two individuals and comply with the following:

(1) At least one delivery team member shall remain with the vehicle at all times that the vehicle contains medical marijuana.

(2) Each delivery team member shall have access to a secure form of communication with the grower/processor, such as a cellular telephone, at all times that the vehicle contains medical marijuana.

(3) Each delivery team member shall carry an identification badge or card at all times and shall, upon demand, produce it to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

(4) Each delivery team member shall have a valid driver's license.

(5) While on duty, a delivery team member may not wear any clothing or symbols that may indicate ownership or possession of medical marijuana.

(d) Medical marijuana stored inside the transport vehicle may not be visible from the outside of the transport vehicle.

(e) Except as provided in subsection (h), a delivery team shall proceed in a transport vehicle from the facility, where the medical marijuana is loaded, directly to the medical marijuana organization or approved laboratory, where the medical marijuana is unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple facilities or approved laboratories, as appropriate, to deliver medical marijuana.

(f) A grower/processor shall immediately report to the Department, either through a designated phone line established by the Department or by electronic communication with the Department in a manner prescribed by

the Department, vehicle accidents, diversions, losses or other reportable events that occur during transport of medical marijuana.

(g) A grower/processor shall notify the Department daily of its delivery schedule, including routes and delivery times, either through a designated phone line established by the Department or by electronic communication with the Department in a manner prescribed by the Department.

(h) A transport vehicle is subject to inspection by the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties. A transport vehicle may be stopped and inspected along its delivery route or at any medical marijuana organization or approved laboratory.

§ 1151.36. Transport manifest.

(a) A grower/processor shall generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information:

(1) The name, address and permit number of the grower/processor and the name of and contact information for a representative of the grower/processor who has direct knowledge of the transport.

(2) The name, address and permit number of the medical marijuana organization or approved laboratory receiving the delivery and the name of and contact information for a representative of the medical marijuana organization or approved laboratory.

(3) The quantity, by weight or unit, of each medical marijuana harvest batch, harvest lot or process lot contained in the transport, along with the identification number for each batch or lot.

(4) The date and approximate time of departure.

(5) The date and approximate time of arrival.

(6) The transport vehicle's make and model and license plate number.

(7) The identification number of each member of the delivery team accompanying the transport.

(b) When a delivery team delivers medical marijuana to multiple medical marijuana organizations or approved laboratories, the transport manifest must correctly reflect the specific medical marijuana in transit. Each recipient shall provide the grower/processor with a printed receipt for the medical marijuana received.

(c) All medical marijuana being transported shall be packaged in shipping containers and labeled in accordance with § 1151.34 (relating to packaging and labeling of medical marijuana).

(d) A grower/processor shall provide a copy of the transport manifest to the recipient receiving the medical marijuana described in the transport manifest. To maintain confidentiality, a grower/processor may prepare separate manifests for each recipient.

(e) A grower/processor shall, if requested, provide a copy of the printed transport manifest, and any printed receipts for medical marijuana being transported, to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

§ 1151.37. Transportation of seeds, immature medical marijuana plants and medical marijuana plants.

(a) A grower/processor may transport seeds, immature medical marijuana plants and medical marijuana plants within this Commonwealth for the growing and processing of medical marijuana.

(b) A grower/processor may not transport seeds, immature medical marijuana plants or medical marijuana plants to a location outside of this Commonwealth.

(c) A grower/processor's authorization to transport seeds, immature medical marijuana plants or medical marijuana plants shall be subject to the requirements of §§ 1151.35, 1151.36 and 1151.38 (relating to transportation of medical marijuana; transport manifest; and evidence of adverse loss during transport).

§ 1151.38. Evidence of adverse loss during transport.

(a) If a grower/processor receiving a delivery of medical marijuana or medical marijuana products from a medical marijuana organization discovers a discrepancy in the transport manifest upon delivery, the grower/processor shall refuse acceptance of the delivery and immediately report the discrepancy to the Department either through a designated phone line established by the Department or by electronic communication with the Department in a manner prescribed by the Department, and to the appropriate law enforcement authorities.

(b) If a grower/processor discovers evidence of, or reasonably suspects, a theft or diversion of medical marijuana or medical marijuana products during transport, the grower/processor shall immediately report its findings or suspicions to the Department either through a designated phone line established by the Department or by electronic communication with the Department in a manner prescribed by the Department and to law enforcement.

(c) If a grower/processor discovers a discrepancy in the transport manifest, the grower/processor shall:

(1) Conduct an investigation.

(2) Amend the grower/processor's standard plan of operation, if necessary, to prevent future discrepancies between the quantity or description of inventory listed in the transport manifest and the quantity or description of inventory delivered.

(3) Submit a report of the investigation to the Department. The following apply:

(i) A written preliminary report of the investigation shall be submitted to the Department within 7 days of discovering the discrepancy.

(ii) A final written report of the investigation shall be submitted to the Department within 30 days of discovering the discrepancy.

§ 1151.39. Electronic tracking system.

A grower/processor shall use the electronic tracking system prescribed by the Department containing the requirements in section 701 of the act (35 P.S. § 10231.701). The Department will publish notice of the electronic tracking system to be utilized by a grower/processor in the *Pennsylvania Bulletin* 60 days prior to the implementation date of the system.

§ 1151.40. Management and disposal of medical marijuana waste.

(a) Medical marijuana waste generated by a grower/processor or an approved laboratory shall be stored, collected and transported in accordance with 25 Pa. Code Chapter 285 (relating to storage, collection and transportation of municipal waste), provided the medical marijuana waste is not hazardous.

(b) The following types of medical marijuana waste shall be rendered unusable and unrecognizable prior to being transported from a grower/processor or an approved laboratory:

(1) Unused, surplus, returned, recalled, contaminated or expired medical marijuana.

(2) Any 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) Medical marijuana waste is unusable and unrecognizable if all components of the waste are indistinguishable and incapable of being ingested, inhaled, injected, swallowed or otherwise used for certified medical use. Acceptable methods of rendering the waste unusable and unrecognizable include thermal treatment or melting; shredding, grinding or tearing; and incorporating the medical marijuana waste with other municipal waste.

(d) Unusable and unrecognizable medical marijuana waste identified in subsection (b) and other solid or semi-solid medical marijuana waste that is not hazardous shall be disposed of at a permitted municipal waste landfill or processed at a permitted resource recovery facility or incinerator.

(e) Wastewater or spent hydroponic nutrient solution generated or produced from the growing, harvesting or processing of immature medical marijuana plants or medical marijuana plants shall be managed in accordance with one of the following:

(1) Discharged into a permitted sewage treatment system in accordance with local, Federal and State requirements, including The Clean Streams Law (35 P.S. §§ 691.1—691.1001) and 25 Pa. Code Chapter 92a (relating to National Pollutant Discharge Elimination System permitting, monitoring and compliance).

(2) Treated and discharged into waters of the Commonwealth under a National Pollutant Discharge Elimination System permit or water quality management permit in accordance with the requirements of The Clean Streams Law, including 25 Pa. Code Chapter 91 (relating to general provisions) and 25 Pa. Code Chapter 92a.

(3) Disposed in a municipal waste landfill if placed in a container that is less than 1 gallon in size.

(f) Hazardous waste shall be managed in accordance with Federal and State law, rules and regulations related to hazardous waste, including sections 3001—3024 of the Resource Conservation and Recovery Act of 1976 (42 U.S.C.A. §§ 6921—6939g), the Solid Waste Management Act (35 P.S. §§ 6018.101—6018.1003) and regulations promulgated thereunder.

(g) The type of medical marijuana waste identified in subsection (b)(2) may be composted and beneficially used at the grower/processor facility through a permit-by-rule provided the requirements of 25 Pa. Code § 271.103(d)(1)—(3) and (5) (relating to permit-by-rule for

municipal waste processing facilities other than for regulated medical or chemotherapeutic waste; qualifying facilities; general requirements) are satisfied, and the compost is beneficially used at the grower/processor facility as a soil substitute, soil conditioner, soil amendment, fertilizer or mulch. The notice required under 25 Pa. Code § 271.103(d)(5) shall be submitted to the Solid Waste Manager of the Department of Environmental Protection's regional office having jurisdiction over the grower/processor's facility within 15 days of initiating the composting activity.

§ 1151.42. Complaints about or recall of medical marijuana.

(a) A dispensary shall notify the Department and the grower/processor immediately upon becoming aware of any complaint made to the dispensary by a patient, caregiver or practitioner who reports an adverse event from using medical marijuana purchased by the dispensary from the grower/processor. A grower/processor shall investigate the report. The following apply:

(1) A grower/processor shall investigate a complaint to determine if a voluntary or mandatory recall of medical marijuana is necessary or if any further action is required.

(2) If a grower/processor determines that further action is not required, the grower/processor shall notify the Department of its decision and, within 24 hours, submit a written report to the Department stating its rationale for not taking further action.

(b) The following apply to voluntary recalls:

(1) A grower/processor may voluntarily recall medical marijuana from the market at its discretion for reasons that do not pose a risk to public health and safety.

(2) If a grower/processor initiates a recall for a reason that does not pose a risk to public health and safety, the grower/processor shall notify the Department at the time the grower/processor begins the recall.

(c) The following apply to mandatory recalls:

(1) If a grower/processor discovers that a condition relating to the medical marijuana grown or processed at its facility poses a risk to public health and safety, the grower/processor shall:

(i) Immediately notify the Department by phone.

(ii) Secure, isolate and prevent the distribution of the medical marijuana that may have been affected by the condition and remains in its possession. The grower/processor may not dispose of affected medical marijuana prior to notifying the Department and coordinating the disposal with the Department.

(2) If a grower/processor fails to cooperate with the Department in a recall, or fails to immediately notify the Department of a need for a recall under paragraph (1), the Department may seek a cease and desist order under § 1141.47 (relating to general penalties and sanctions) and the grower/processor may be subject to any other penalties or sanctions provided for in the act or this part.

(d) A grower/processor's recall plan must include the following:

(1) Designation of one or more employees to serve as the recall coordinators. A recall coordinator shall be responsible for, among other duties, accepting the recalled medical marijuana.

(2) Procedures for identifying and isolating the affected medical marijuana to prevent or minimize its distribution

to patients, caregivers and other medical marijuana organizations and approved laboratories.

(3) Procedures to retrieve and dispose of the affected medical marijuana.

(4) A communications plan to notify those affected by the recall, including:

(i) The manner in which the grower/processor will notify other medical marijuana organizations or approved laboratories in possession of medical marijuana subject to the recall.

(ii) The use of press releases and other appropriate notifications to ensure that patients and caregivers are notified of the recall if the affected medical marijuana was dispensed to patients and caregivers.

(5) Procedures for notifying the Department.

(6) Procedures for entering information relating to the recall into the grower/processor's electronic tracking system.

(e) A grower/processor shall follow the procedures outlined in its recall plan, unless the grower/processor obtains the prior written approval of the Department. The grower/processor shall conduct recall procedures in a manner that maximizes the recall of affected medical marijuana and minimizes risks to public health and safety.

(f) A grower/processor shall coordinate the disposal of recalled medical marijuana with the Department. The Department or its authorized agents may oversee the disposal to ensure that the recalled medical marijuana is disposed of in a manner that will not pose a risk to public health and safety.

(g) The grower/processor shall enter information relevant to the recall into the electronic tracking system as part of the daily inventory, including:

(1) The total amount of recalled medical marijuana, including types, forms, harvest batches, harvest lots and process lots, if applicable.

(2) The amount of recalled medical marijuana received by the grower/processor, including types, forms, harvest batches, harvest lots and process lots, if applicable, by date and time.

(3) The total amount of recalled medical marijuana returned to the grower/processor, including types, forms, harvest batches, harvest lots and process lots, if applicable.

(4) The names of the recall coordinators.

(5) From whom the recalled medical marijuana was received.

(6) The means of transport of the recalled medical marijuana.

(7) The reason for the recall.

(8) The number of recalled samples or test samples, types, forms, harvest batches, harvest lots and process lots, if applicable, sent to approved laboratories, the names and addresses of the approved laboratories, the dates of testing and the results by sample or test sample.

(9) The manner of disposal of the recalled medical marijuana, including:

(i) The name of the individual overseeing the disposal of the recalled medical marijuana.

(ii) The name of the disposal company, if applicable.

(iii) The method of disposal.

(iv) The date of disposal.

(v) The amount disposed of by types, forms, harvest batches, harvest lots and process lots, if applicable.

(10) Any other information required by the Department.

§ 1151.43. Pesticides.

(a) The use of a pesticide by a grower/processor in the growing or processing of medical marijuana shall be in accordance with the Pennsylvania Pesticide Control Act of 1973 (Pesticide Control Act) (3 P.S. §§ 111.21—112) and this part.

(b) The Department and the Department of Agriculture will cooperate to inspect for and enforce the requirements of this section.

(c) The following apply regarding recordkeeping requirements for pesticide applications:

(1) The grower/processor shall maintain a record of each application of a pesticide. The record must include the following information:

(i) The date of application. For a pesticide requiring a re-entry time, the date of application must include the hour completed.

(ii) The place of application, including the specific block, section, or immature medical marijuana plants or medical marijuana plants treated.

(iii) The size of the area treated.

(iv) The product name of every pesticide used.

(v) The United States Environmental Protection Agency product registration number. This requirement is unnecessary for products exempted under section 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.A. § 136w).

(vi) The total amount of every pesticide used in pounds, ounces, gallons or liters applied to a treated area.

(vii) The dosage or rate of application of every pesticide used.

(viii) If applicable, the employee identification numbers of the individuals involved in making the pesticide and the permit or certification numbers of the individuals making or supervising the application.

(ix) Copies of pesticide labels and Safety Data Sheets for the pesticides used at the facility.

(2) A record required to be kept under this section shall be completed within 24 hours of the completion of the application and maintained for at least 4 years. A record shall be made immediately available to the Department or its authorized agents and medical personnel or first responders in an emergency. A record shall be made available to the Department of Agriculture upon request.

(d) For purposes of enforcement, the Pesticide Control Act and 7 Pa. Code Chapter 128 (relating to pesticides) are incorporated by reference and adopted as standards for use by the Department in enforcing this section.

(e) A grower/processor shall only use the pesticide active ingredients in Appendix A in the growing and processing of medical marijuana.

(f) The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:

Defoliant—A substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

Desiccant—A substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

Pesticide—A substance or mixture of substances intended for preventing, destroying, repelling or mitigating a pest, and a substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant.

Plant regulator—

(i) A substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but may not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants and soil amendments.

(ii) The term does not include any of the nutrient mixtures or soil amendments commonly known as vitamin-hormone horticultural products, which are intended for improvement, maintenance, survival, health and propagation of plants, and are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

§ 1151.44. Treatment and quarantine orders.

(a) If a grower/processor fails or refuses to eradicate a plant pest that is found at its facility, the Department, in cooperation with the Department of Agriculture, may issue and enforce a treatment order against the grower/processor, including an order to eradicate, for any immature medical marijuana plants or medical marijuana plants that may carry or harbor the plant pest. The order will be issued in writing and set forth the necessary treatment, control or eradication measures required. If the grower/processor fails or refuses to comply with the order, the Department, acting in cooperation with the Department of Agriculture, may carry out the control measures established in the treatment order with all expenses associated with the measures accruing to the grower/processor.

(b) The Department of Agriculture, acting with the cooperation of the Department, may establish a quarantine to prevent the dissemination of plant pests within this Commonwealth or to prevent or delay the introduction of a plant pest into this Commonwealth from any country, state or territory. The following apply:

(1) Upon finding a plant pest in a facility that has the potential to cause serious damage to other grower/processors or to agriculture in general, the geographic area in which the plant pest was found and any adjacent areas as the Department of Agriculture deems necessary may be quarantined.

(2) The quarantine order will establish conditions and restrictions determined by the Department of Agriculture to be necessary to prevent or reduce the movement of the plant pest from the quarantined area. Vehicles or any means of conveyance suspected of carrying the plant pest

may also be subject to quarantine and a treatment order under subsection (a) may be issued as necessary to eradicate the plant pest.

(3) The quarantine order may regulate the planting, growing or harvesting of any immature medical marijuana plants or medical marijuana plants that serve as a host or reservoir for the plant pest within the quarantined area and may include prohibiting the processing of a specific harvest batch or harvest lot of medical marijuana within a specific geographic area or during a specified time period. An immature medical marijuana plant or medical marijuana plant suspected of harboring the plant pest may be ordered to be treated or destroyed.

[Pa.B. Doc. No. 17-60. Filed for public inspection January 13, 2017, 9:00 a.m.]

**DEPARTMENT OF HEALTH
[28 PA. CODE CH. 1161]**

Medical Marijuana; Dispensaries; Amendments to Temporary Regulations

The Department of Health (Department) is publishing amendments to the temporary regulations in Chapter 1161 (relating to dispensaries) to read as set forth in Annex A. The temporary regulations are published under the Medical Marijuana Act (act) (35 P.S. §§ 10231.101—10231.2110). Section 1107 of the act (35 P.S. § 10231.1107) specifically provides that, to facilitate the prompt implementation of the act, the Department may promulgate temporary regulations that are not subject to sections 201—205 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201—1205), known as the Commonwealth Documents Law, the Regulatory Review Act (71 P.S. §§ 745.1—745.14) and sections 204(b) and 301(10) of the Commonwealth Attorneys Act (71 P.S. §§ 732-204(b) and 732-301(10)).

To implement the Medical Marijuana Program, the Department will be periodically publishing temporary regulations regarding various sections of the act. Chapter 1161 pertains to dispensaries that will dispense medical marijuana to patients and caregivers in accordance with the act. The amendments to the temporary regulations in Annex A will expire on January 14, 2019.

Interested persons are invited to submit written comments, suggestions or objections regarding the amendments to the temporary regulations to John J. Collins, Office of Medical Marijuana, Department of Health, Room 628, Health and Welfare Building, 625 Forster Street, Harrisburg, PA 17120, (717) 787-4366, RA-DHMed Marijuana@pa.gov. Persons with a disability who wish to submit comments, suggestions or objections regarding the temporary regulations may do so by using the previous contact information. Speech and/or hearing impaired persons may use V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact John J. Collins so that necessary arrangements may be made.

KAREN M. MURPHY, PhD, RN,
Secretary

Fiscal Note: 10-201. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

CHAPTER 1161. DISPENSARIES

§ 1161.24. Limitations on dispensing.

(a) A dispensary may not dispense to a patient or caregiver:

(1) A quantity of medical marijuana that is greater than the amount indicated on the patient's certification, if any.

(2) A form or dosage of medical marijuana that is listed as a restriction or limitation on the patient certification.

(3) A form of medical marijuana not permitted by the act or this part, unless otherwise provided in regulations adopted by the Department under section 1202 of the act (35 P.S. § 10231.1202).

(b) A dispensary may not dispense an amount of medical marijuana greater than a 30-day supply to a patient or caregiver until the patient has exhausted all but a 7-day supply provided pursuant to the patient certification currently on file with the Department.

§ 1161.25. Licensed medical professionals at facility.

(a) Except as provided in subsection (b), a dispensary shall ensure that a physician or a pharmacist is present at the facility at all times during the hours the facility is open to dispense or to offer to dispense medical marijuana to patients and caregivers.

(b) If a dispensary is authorized to operate more than one facility under its permit, a physician assistant or a certified registered nurse practitioner may be present onsite at each of the other locations instead of a physician or pharmacist.

(c) As required under the act, a physician, a pharmacist, a physician assistant or a certified registered nurse practitioner shall, prior to assuming any duties at a facility, successfully complete a 4-hour training course developed by the Department. The course must provide instruction in the latest scientific research on medical marijuana, including the risks and benefits of medical marijuana, and other information deemed necessary by the Department.

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

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

(2) The State Board of Pharmacy.

(3) The State Board of Nursing.

(e) A practitioner or a physician, while at the facility, may not issue a patient certification to a patient.

§ 1161.28. Labels and safety inserts.

(a) Medical marijuana products dispensed by a dispensary must only be identified by the name of the grower/processor, the name of the dispensary, the form and species of medical marijuana, the percentage of THC and CBD contained in the medical marijuana product, and any other labeling required by the Department.

(b) A dispensary shall dispense medical marijuana to a patient or caregiver in a sealed and properly labeled package.

(c) The dispensary shall inspect the label to ensure that the label:

(1) Is easily readable.

(2) Is conspicuously placed on the package.

(3) Includes the name, address and permit number of the grower/processor.

(4) Lists the form and quantity of medical marijuana.

(5) Contains the following warning stating:

This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children.

(6) Lists the amount of individual doses contained within the package and the species and percentage of THC and CBD.

(7) Contains a warning that the medical marijuana must be kept in the original container in which it was dispensed.

(8) Contains a warning that unauthorized use is unlawful and will subject the purchaser or user to criminal penalties.

(9) Includes the name and address of the dispensary.

(10) Lists a use by or expiration date.

(11) Lists the packaging date.

(12) Includes instructions for proper storage of the medical marijuana in the package.

(13) Contains any other information required by the Department.

(d) The dispensary shall inspect the label to ensure that the label does not bear:

(1) Any resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available food or beverage product.

(2) Any statement, artwork or design that could reasonably lead an individual to believe that the package contains anything other than medical marijuana.

(3) Any seal, flag, crest, coat of arms or other insignia that could reasonably mislead an individual to believe that the product has been endorsed, manufactured or approved for use by any state, county or municipality or any agency thereof.

(4) Any cartoon, color scheme, image, graphic or feature that might make the package attractive to children.

(e) When a dispensary dispenses medical marijuana to a patient or caregiver, the dispensary shall also provide the patient or caregiver with a safety insert developed and approved by the Department that includes the following information:

(1) The method or methods for administering individual doses of medical marijuana.

(2) Any potential dangers stemming from the use of medical marijuana.

(3) How to recognize what may be problematic usage of medical marijuana and how to obtain appropriate services or treatment for problematic usage.

(4) The side effects and contraindications associated with medical marijuana, if any, which may cause harm to the patient.

(5) How to prevent or deter the misuse of medical marijuana by an individual under 18 years of age or others.

(6) Any other information determined by the Department to be relevant to enhance patient safety.

§ 1161.32. Inventory data.

(a) A dispensary shall maintain the following inventory data in its electronic tracking system:

(1) Medical marijuana received from a grower/processor.

(2) Medical marijuana dispensed to a patient or caregiver.

(3) Damaged, defective, expired or contaminated medical marijuana awaiting return to a grower/processor or awaiting disposal.

(b) A dispensary shall establish inventory controls and procedures to conduct monthly inventory reviews and annual comprehensive inventories of medical marijuana at its facility.

(c) A written or electronic record shall be created and maintained of each inventory which includes the date of the inventory, a summary of the inventory findings, and the employee identification numbers and titles or positions of the individuals who conducted the inventory.

§ 1161.33. Storage requirements.

(a) A dispensary shall have separate locked limited access areas for storage of medical marijuana that is expired, damaged, deteriorated, mislabeled, contaminated, recalled, or whose containers or packaging have been opened or breached until the medical marijuana is returned to a grower/processor, destroyed or otherwise disposed of as required under § 1151.40 (relating to management and disposal of medical marijuana waste).

(b) A dispensary shall maintain all storage areas in a clean and orderly condition and free from infestation by insects, rodents, birds and pests.

§ 1161.35. Transportation of medical marijuana.

(a) A dispensary may transport and deliver medical marijuana to a medical marijuana organization in this Commonwealth in accordance with this section. The following apply:

(1) A dispensary may deliver medical marijuana to a medical marijuana organization only between 7 a.m. and 9 p.m. for the purposes of transferring medical marijuana among the permittee's dispensary locations and returning medical marijuana to a grower/processor.

(2) A dispensary may contract with a third-party contractor for delivery so long as the contractor complies with this section.

(3) A dispensary may not transport medical marijuana to any location outside of this Commonwealth.

(4) A dispensary shall use a global positioning system to ensure safe, efficient delivery of the medical marijuana to a medical marijuana organization.

(b) Vehicles permitted to transport medical marijuana must:

(1) Be equipped with a secure lockbox or locking cargo area.

(2) Have no markings that would either identify or indicate that the vehicle is being used to transport medical marijuana.

(3) Be capable of being temperature-controlled for perishable medical marijuana, as appropriate.

(4) Display current State inspection stickers and maintain a current State vehicle registration.

(5) Be insured in an amount that is commercially reasonable and appropriate.

(c) A transport vehicle shall be staffed with a delivery team consisting of at least two individuals and comply with the following:

(1) At least one delivery team member shall remain with the vehicle at all times that the vehicle contains medical marijuana.

(2) Each delivery team member shall have access to a secure form of communication with the dispensary, such as a cellular telephone, at all times that the vehicle contains medical marijuana.

(3) Each delivery team member shall carry an identification badge or card at all times and shall, upon demand, produce it to the Department or its authorized agents, law enforcement or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

(4) Each delivery team member shall have a valid driver's license.

(5) While on duty, a delivery team member may not wear any clothing or symbols that may indicate ownership or possession of medical marijuana.

(d) Medical marijuana stored inside the transport vehicle may not be visible from the outside of the transport vehicle.

(e) Except as provided in subsection (h), a delivery team shall proceed in a transport vehicle from the dispensary, where the medical marijuana is loaded, directly to the medical marijuana organization, where the medical marijuana is unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple facilities, as appropriate, to deliver medical marijuana.

(f) A dispensary shall immediately report to the Department, either through a designated phone line established by the Department or by electronic communication with the Department in a manner prescribed by the Department, any vehicle accidents, diversions, losses or other reportable events that occur during transport of medical marijuana.

(g) A dispensary shall notify the Department daily of its delivery schedule, including routes and delivery times, either through a designated phone line established by the Department or by electronic communication with the Department in a manner prescribed by the Department.

(h) A transport vehicle is subject to inspection by the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions

and duties. A transport vehicle may be stopped and inspected along its delivery route or at any medical marijuana organization.

§ 1161.36. Transport manifest.

(a) A dispensary shall generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information:

(1) The name, address and permit number of the dispensary, and the name of and contact information for a representative of the dispensary who has direct knowledge of the transport.

(2) The name, address and permit number of the medical marijuana organization receiving the delivery, and the name of and contact information for a representative of the medical marijuana organization.

(3) The quantity, by weight or unit, of each medical marijuana harvest batch, harvest lot or process lot contained in the transport, along with the identification number for each harvest batch, harvest lot or process lot.

(4) The date and approximate time of departure.

(5) The date and approximate time of arrival.

(6) The transport vehicle's make and model and license plate number.

(7) The identification number of each member of the delivery team accompanying the transport.

(b) When a delivery team delivers medical marijuana to multiple medical marijuana organizations, the transport manifest must correctly reflect the specific medical marijuana in transit. Each recipient shall provide the dispensary with a printed receipt for the medical marijuana received.

(c) All medical marijuana being transported shall be packaged in shipping containers and labeled in accordance with §§ 1151.34 and 1161.28 (relating to packaging and labeling of medical marijuana; and labels and safety inserts).

(d) A dispensary shall provide a copy of the transport manifest to the recipient receiving the medical marijuana described in the transport manifest. To maintain confidentiality, a dispensary may prepare separate manifests for each recipient.

(e) A dispensary shall, if requested, provide a copy of the printed transport manifest, and any printed receipts for medical marijuana being transported, to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

§ 1161.37. Evidence of adverse loss during transport.

(a) If a dispensary receiving a delivery of medical marijuana or medical marijuana products from a medical marijuana organization discovers a discrepancy in the transport manifest upon delivery, the dispensary shall refuse acceptance of the delivery and immediately report the discrepancy to the Department either through a designated phone line established by the Department or by electronic communication with the Department in a manner prescribed by the Department, and to the appropriate law enforcement authorities.

(b) If a dispensary discovers evidence of, or reasonably suspects, a theft or diversion of medical marijuana or medical marijuana products during transport, the dispensary shall immediately report its findings or suspicions to the Department either through a designated phone line established by the Department or by electronic communication with the Department in a manner prescribed by the Department, and to law enforcement.

(c) If a dispensary discovers a discrepancy in the transport manifest, the dispensary shall:

(1) Conduct an investigation.

(2) Amend the dispensary's standard plan of operation, if necessary, to prevent future discrepancies between the quantity or description of inventory listed in the transport manifest and the quantity or description of inventory delivered.

(3) Submit a report of the investigation to the Department. The following apply:

(i) A written preliminary report of the investigation shall be submitted to the Department within 7 days of discovering the discrepancy.

(ii) A final written report of the investigation shall be submitted to the Department within 30 days of discovering the discrepancy.

§ 1161.40. Application for additional dispensary locations.

(a) An applicant for a dispensary permit shall include a primary dispensary facility location, and may include up to two additional dispensary facility locations, in its initial permit application. A permittee may file an application under this section for additional dispensary facility locations at a later date.

(b) A dispensary shall submit an application for additional dispensary locations on a form prescribed by the Department.

(c) A dispensary submitting an application for additional dispensary locations shall include with the application the following fees:

(1) An application fee of \$5,000, which is nonrefundable.

(2) A permit fee of \$30,000 for each dispensary location being proposed. The permit fee shall be submitted with the application for additional dispensary locations and will be refunded if the application is not granted.

(d) A dispensary may not begin operations at an additional location until the Department approves the application for additional dispensary locations, in writing, under this section.

(e) A dispensary submitting an application for additional dispensary locations shall follow the requirements in § 1141.29 (relating to initial permit application) and this part.

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