RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CHS. 1141 AND 1151]

Medical Marijuana; General Provisions; Growers/Processors; Amended Temporary Regulations

The Department of Health (Department) is publishing amended temporary regulations in Chapters 1141 and 1151 (relating to general provisions—temporary regulations; and growers/processors—temporary regulations) to read as set forth in Annex A. These amended 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 periodically published temporary regulations regarding various sections of the act. Chapter 1141 sets forth the general requirements for the Medical Marijuana Program. Chapter 1151 sets forth the requirements for an entity to become permitted and operate as a grower/processor under the act.

The Department is amending the existing temporary regulations in Chapters 1141 and 1151 for the sake of consistency, and to take into account the need for changes that have arisen as each new set of temporary regulations has been implemented by the Department. Under section 1202 of the act (35 P.S. § 10231.1202), the Department is also amending the existing temporary regulations to effectuate the recommendations made by the Medical Marijuana Advisory Board (Board). After consideration of the Board's report, the Secretary of Health decided to implement the Board's recommendations through the promulgation of temporary regulations.

These amended temporary regulations in Chapters 1141 and 1151 will become effective May 17, 2018, and will expire on May 12, 2020.

Interested persons are invited to submit written comments, suggestions or objections regarding these amended 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) 547-3047, RA-DHMedMarijuana@pa.gov.

Persons with a disability who wish to submit comments, suggestions or objections regarding these amended temporary regulations or who require an alternative format of these amended temporary regulations (for example, large print, audiotape, Braille) may do so by using the previous contact information, or for speech and/or hearing impaired persons, call the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

RACHEL L. LEVINE, MD,
Secretary

(*Editor's Note*: Title 28 of the *Pennsylvania Code* is amended by adding temporary regulations in §§ 1141.52 and 1151.45 and amending the temporary regulations in §§ 1141.21—1141.51 and 1151.21—1151.44 to read as set forth in Annex A.)

Fiscal Note: 10-210. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

CHAPTER 1141. GENERAL PROVISIONS—TEMPORARY REGULATIONS

§ 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, medical marijuana products, funds or other property of a medical marijuana organization.

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

Applicant—

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

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

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

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

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

CBD—Cannabidiol.

Caregiver—One of the following:

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

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

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

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

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 products.

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

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

Diverse participants—The term includes the following:

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

(ii) Women.

(iii) Veterans.

(iv) Individuals with disabilities.

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

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

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

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

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

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

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

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

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

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

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

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

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

Grower/processor—

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

(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 a patient or caregiver to have access to medical marijuana products under the act.

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

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

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

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

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

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

(v) Surveillance system devices are stored or maintained.

Marijuana—

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

(ii) The term does not include industrial hemp.

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

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

(i) Pill.

(ii) Oil.

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

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

(v) Tincture.

(vi) Liquid.

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

Medical marijuana 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 product—The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary.

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

Medical marijuana 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.

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

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

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

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, including remission therapy.

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

(iii) Amyotrophic lateral sclerosis.

(iv) Parkinson's disease.

(v) Multiple sclerosis.

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

(vii) Epilepsy.

(viii) Inflammatory bowel disease.

(ix) Neuropathies.

(x) Huntington's disease.

(xi) Crohn's disease.

(xii) Post-traumatic stress disorder.

(xiii) Intractable seizures.

(xiv) Glaucoma.

(xv) Sickle cell anemia.

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

(xvii) Autism.

(xviii) Neurodegenerative diseases.

(ixx) Terminal illness.

(xx) Dyskinetic and spastic movement disorders.

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

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

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

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

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.

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

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

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

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

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

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

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

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

§ 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, an approved laboratory and a dispensary.

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

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

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

(d) An applicant's failure to redact confidential proprietary or trade secret information in its submitted permit application will result in disclosure to the public of the confidential proprietary or trade secret information in response to a Right-to-Know Law request.

(e) An applicant is responsible for defending its own redactions in any administrative or court proceeding, including any appeals. Any information not adequately defended by the applicant may result in full disclosure of the information in un-redacted form.

§ 1141.23. Limitation on number of permits.

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

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

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

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

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

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

(ii) A dispensary permit may be used to provide medical marijuana at no more than three separate locations as approved by the Department.

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

§ 1141.24. Medical marijuana regions.

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

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

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

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

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

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

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

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

(1) Regional population.

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

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

(4) Access to public transportation.

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

(6) Areas with recognized need for economic development.

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

§ 1141.25. General requirements for permits.

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

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

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

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

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

§ 1141.26. Privilege and nontransferability.

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

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

§ 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.

(7) An application for approval of a laboratory.

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

(c) An application 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.

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

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

(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.

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

(b) An applicant for an initial dispensary permit or renewal permit shall pay the following fees by certified 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.

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

(c) A medical marijuana organization shall pay a fee of $250 by certified 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 version that is redacted in accordance with the Right-to-Know Law (65 P.S. §§ 67.101—67.3104), as set out in § 1141.22 (relating to records subject to disclosure; confidentiality), by mail in an electronic format that is prescribed by the Department in the initial permit application instructions.

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

(b) In addition to the requirements in § 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, medical marijuana products 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

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

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

(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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products for potential contamination.

(ix) Recordkeeping.

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

(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 grower/processor permit applicant is able to continuously maintain effective security, surveillance and accounting control measures to prevent diversion, abuse and other illegal conduct regarding seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products. The dispensary permit applicant is able to continuously maintain effective security, surveillance and accounting control measures to prevent diversion, abuse and other illegal conduct regarding medical marijuana products.

(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 may notify the applicant in writing of the factors that require additional information and documentation. An applicant has 30 days from the mailing date of the notice to provide the requested information and documentation to the Department. An applicant's failure to provide the requested information to the Department by the deadline may be grounds for denial of the issuance of a permit. Nothing in this subsection requires the Department to request additional or supplemental information from an applicant.

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

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

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

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

§ 1141.30. Capital requirements.

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

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

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

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

§ 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 will submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the individuals whose fingerprints have been submitted and obtaining a current record of criminal arrests and convictions.

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

(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.

§ 1141.32. Diversity goals.

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

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

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

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

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

(c) Each medical marijuana organization shall include in its permit application a diversity plan that establishes a goal of equal opportunity and access in employment and contracting by the medical marijuana organization. The Department will determine whether the stated goals in

the diversity plan are reasonable and represent a good faith effort to meet the diversity goals of section 615(a) of the act.

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

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

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

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

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

(3) Employee retention efforts.

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

(g) A medical marijuana organization may request that any proprietary information submitted to the Department under this section be treated as confidential proprietary information and shall clearly mark this information as confidential proprietary information or trade secret under the Right-to-Know Law (65 P.S. §§ 67.101—67.3104) as set forth in § 1141.22 (relating to records subject to disclosure; confidentiality).

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

§ 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* before to the time the initial permit applications are made available for submission.

§ 1141.34. Denial of a permit.

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

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

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

(3) The results of the criminal history record check received by the Department under § 1141.31 (relating to background checks) for a principal, financial backer, operator or employee of the applicant indicates that the individual has been convicted of a criminal offense relating to the sale or possession of illegal drugs, narcotics or controlled substances and, following notification by the Department, the applicant fails or refuses to provide the Department with evidence satisfactory to the Department that the individual is no longer associated with the applicant in this capacity.

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

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

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

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

(8) The Department determines, in its sole discretion, that the applicant has not met the criteria under § 1141.33 (relating to review of initial permit applications).

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

§ 1141.35. Notice of denial.

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

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

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

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

§ 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products, plant matter 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 products to the grower/processor where the medical marijuana products originated.

(e) If a medical marijuana organization submits a permit renewal application and permit renewal fee to the Department as required under § 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 medical marijuana organization shall notify the Department:

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

(2) In writing of any proposed modification of its plan of operation 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 a facility operated by the medical marijuana organization or any vehicle transporting seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to or from a facility operated by the medical marijuana organization.

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

(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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products from the sites and locations by State or Federal authority.

§ 1141.39. Application for approval of a change in ownership of a medical marijuana organization.

(a) In the event of an impending change in ownership involving a change in control of a medical marijuana organization from the ownership listed in the initial permit application or a permit renewal application, the medical marijuana organization shall submit an application for approval of a change in ownership, on a form prescribed by the Department, to the Department together with the fee required under § 1141.28 (relating to fees).

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

(c) A medical marijuana organization's application for approval of a change in ownership will not be considered complete by the Department until all portions of the application are completed and the appropriate application fee under § 1141.28 is submitted. The Department may reject an incomplete application.

(d) For each individual that is part of the proposed change in ownership, the medical marijuana organization shall include all of the information required under § 1141.29 (relating to initial permit application) for the individuals listed in those capacities in the medical marijuana organization's initial permit application or any previously submitted permit renewal application.

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

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

§ 1141.40. Application for approval of a change in location of a facility.

(a) A medical marijuana organization wishing to change the location of a site or facility authorized under a permit issued to the medical marijuana organization shall submit an application for approval of a change in location to the Department together with the fee required under § 1141.28 (relating to fees).

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

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

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

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

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

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

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

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

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

§ 1141.41. Application for approval of alteration of a facility.

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

(b) A medical marijuana organization wishing to make any of the following alterations to the facility for which its permit was issued shall submit an application for approval of alteration of a facility, on a form prescribed by the Department, to the Department together with the fee required under § 1141.28 (relating to fees):

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

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

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

(i) Additional electric fixtures or lighting equipment.

(ii) The lowering of a ceiling.

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

§ 1141.42. Failure to be operational.

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

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

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

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

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

(1) The projected date of closure.

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

(3) How it intends to dispose of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products or other plant matter projected to still be in the facility at the time of the projected closure in accordance with § 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 and inspect the site and facility and the medical marijuana organization's vehicles following receipt of a medical marijuana organization's plan of closure to determine whether to approve the medical marijuana organization's closure plan.

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

§ 1141.44. Insurance requirements.

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

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

§ 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, financial backers, authorized agents of, and any other person or entity providing services to the medical marijuana organization.

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

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

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

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

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

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

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

(2) In the case of a dispensary:

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

(ii) The per-dose price of medical marijuana products 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 products 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.

§ 1141.47. General penalties and sanctions.

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

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

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

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

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

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

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

(i) The gravity of the violation.

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

(iii) The willfulness of the violation.

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

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

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

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

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

(i) An order may include a requirement that a medical marijuana organization cease or restrict some or all of its operations. In addition, the order may prohibit the use of some or all of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products grown, processed or to be sold by the medical marijuana organization.

(ii) An order may be issued by an authorized agent of the Department immediately upon completion of an inspection or investigation if the agent observes or suspects an operational failure or determines that the conditions will likely create a diversion or contamination of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products, or a risk to patients or the public.

(iii) An order may include:

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

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

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

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

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

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

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

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

(d) The Department's actions under subsections (a) and (b) are subject to 2 Pa.C.S. Chapter 5, Subchapter A (relating to practice and procedure of Commonwealth agencies) and its accompanying regulations, as modified by Chapter 1230 (relating to practice and procedure—temporary regulations).

§ 1141.48. Training.

(a) As required under the act, the following individuals shall complete a 2-hour training course developed by the Department within the times specified:

(1) Each principal of a medical marijuana organization, prior to starting initial operation of a facility.

(2) Each employee of a medical marijuana organization who has direct contact with patients or caregivers or who physically handles seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, within 90 days after starting employment at the facility.

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

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

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

(3) Proper recordkeeping.

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

(5) Best practice security procedures.

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

(i) A medical emergency.

(ii) A fire.

(iii) A chemical spill.

(iv) A threatening event including:

(A) An armed robbery.

(B) A burglary.

(C) A criminal incident.

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

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

§ 1141.49. Zoning.

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

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

§ 1141.50. Advertising by a medical marijuana organization.

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

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

(c) This part does not apply to information provided by a grower/processor to a dispensary listing various medical marijuana products, instruments and devices that the grower/processor is offering for sale to the dispensary.

§ 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. Technical advisories provide guidance on the Department's interpretation of, and how a permittee may maintain compliance with, the act and this part. Notice of the availability of a technical advisory will be published in the *Pennsylvania Bulletin*.

§ 1141.52. Effective date and applicability.

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

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

CHAPTER 1151. GROWERS/PROCESSORS—TEMPORARY REGULATIONS

§ 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to another medical marijuana organization 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.

(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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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 contamination of medical marijuana or medical marijuana products.

(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 products).

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

§ 1151.23. Grower/processor facilities.

(a) A grower/processor may only grow, store, harvest or process seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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) 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 must have an enclosed secure area out of public sight for the loading and unloading of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products into and from a transport vehicle.

§ 1151.24. Start-up inventory.

(a) A grower/processor may obtain seeds or immature medical marijuana plants from outside of this Commonwealth for the purpose of securing its start-up inventory. Seeds or immature medical marijuana plants obtained from outside of this Commonwealth shall be obtained within 30 days from the date that the Department determines that the grower/processor is operational.

(b) A grower/processor may not obtain medical marijuana plants from outside of this Commonwealth at any time.

(c) Within 24 hours of receipt, a grower/processor shall, record in the electronic tracking system each seed and immature medical marijuana plant that enters the site during the 30-day period under subsection (a).

(d) After the 30-day period in subsection (a), a grower/processor shall only grow medical marijuana plants from seeds or immature medical marijuana plants located physically in its facility, or purchase seeds, immature medical marijuana plants or medical marijuana plants from another grower/processor.

§ 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, 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 or facility.

(d) A grower/processor shall post a sign in a conspicuous location at each entrance of a site and a 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 a site or 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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 or 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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 per day, 7 days per 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 a 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, 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) The ability to operate under the normal lighting conditions of each area under surveillance.

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

(3) The 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) The ability to record and store all images captured by each surveillance camera for a minimum of 2 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 in writing 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 requirements regarding the inspection, servicing or alteration of, and the upgrade to, the site's and facility's security and surveillance systems apply:

(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 the Department's request or the request of the Department's authorized agents.

(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 steel doors and door locks on each room where seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are stored, and 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 a site and a 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 a facility.

(g) A grower/processor shall limit access to a room in a facility 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 requirements 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 facility 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 a pesticide, fungicide or herbicide that is 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 approved pesticides, fungicides and herbicides.

(b) A grower/processor shall use a pesticide, fungicide or herbicide 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 dosage level, 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products that are 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 requirements apply:

(1) Medical marijuana plants, 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.

§ 1151.28. Forms of medical marijuana.

(a) A grower/processor may only process medical marijuana for dispensing to a patient or caregiver in the following forms:

(1) Pill.

(2) Oil.

(3) Topical forms, including gel, creams or ointments.

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

(5) Tincture.

(6) Liquid.

(b) A grower/processor may not manufacture, produce or assemble any medical marijuana product, instrument or device without the prior written approval of the Department.

§ 1151.29. Limit on medical marijuana processing.

(a) In the form intended to be sold to another medical marijuana organization, medical marijuana or a medical marijuana product 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) Cannabidivarine (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 products 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, medical marijuana 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 requirements 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 ensure that a facility has separate and locked limited access areas for storage of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products 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, medical marijuana and medical marijuana products are destroyed or otherwise disposed of as required under § 1151.40 (relating to management and disposal of medical marijuana waste).

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

§ 1151.32. Equipment, operation and maintenance.

(a) A grower/processor shall ensure that a facility has a written process in place to maintain the sanitation and operation of equipment that comes into contact with seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to prevent contamination. The grower/processor shall provide a copy of the written process to the Department upon request.

(b) As part of the written process required under subsection (a), a grower/processor shall:

(1) Routinely calibrate, check and inspect the following to ensure accuracy:

(i) Automatic, mechanical or electronic equipment.

(ii) Scales, balances or other measurement devices used in the grower/processor's operations.

(2) Maintain an accurate log recording the following:

(i) Maintenance of equipment.

(ii) Cleaning of equipment.

(iii) Calibration of equipment.

§ 1151.33. Sanitation and safety in a facility.

(a) A grower/processor shall maintain a facility in a sanitary condition to limit the potential for contamination or adulteration of the seeds, immature medical marijuana

plants, medical marijuana plants, medical marijuana or medical marijuana products grown and processed in the facility and any medical marijuana product produced at a facility. The following requirements 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, and pesticide chemicals must be labeled and stored in a manner that prevents contamination and 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 requirements apply:

(1) A grower/processor shall locate hand-washing facilities in processing areas and where good sanitary practices require employees to wash and sanitize their hands.

(2) A grower/processor shall provide its employees and visitors with effective nontoxic sanitizing cleansers and sanitary towel service or suitable drying devices.

(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 provide a facility with a water supply sufficient for the facility's 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 products.

(a) A grower/processor shall package and label at its facility each form of medical marijuana products 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 products.

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

(1) Child-resistant.

(2) Tamper-proof or tamper-evident.

(3) Light-resistant or opaque, or both.

(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 product package. Each label must meet the following requirements:

(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 number 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 product was packaged.

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

(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 product.

(13) Include instructions for proper storage of the medical marijuana product 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 product 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 product 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to a medical marijuana organization or an approved laboratory in this Commonwealth in accordance with this section. The following requirements apply:

(1) Unless otherwise approved by the Department, a grower/processor may deliver seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to any location outside of this Commonwealth.

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

(b) Vehicles permitted to transport seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(3) Be capable of being temperature-controlled for perishable seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products, 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(d) Seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products 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 a grower/processor facility, where the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are loaded, directly to a medical marijuana organization facility or approved laboratory, where the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple medical marijuana organization facilities or approved laboratories, as appropriate, to deliver seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(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 facility or approved laboratory receiving the delivery and the name of and contact information for a representative of the medical marijuana organization facility or approved laboratory.

(3) The quantity, by weight or unit, of each seed, immature medical marijuana plant, medical marijuana plant, medical marijuana harvest batch, harvest lot or process lot, medical marijuana and medical marijuana product 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to multiple medical marijuana organizations or approved laboratories, the transport manifest must correctly reflect the specific seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products in transit. Each recipient shall provide the grower/processor with a printed receipt for the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products received.

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

(d) A grower/processor shall provide a copy of the transport manifest to the recipient receiving the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products 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 §§ 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 seeds, immature medical marijuana plants, medical marijuana plants, 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 seeds, immature medical marijuana plants, medical marijuana plants, 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 requirements apply:

(i) The grower/processor shall submit a written preliminary report of the investigation to the Department within 7 days of discovering the discrepancy.

(ii) The grower/processor shall submit a final written report of the investigation 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 before 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 facility within 15 days of initiating the composting activity.

§ 1151.42. Complaints about or recall of medical marijuana products.

(a) A dispensary shall notify the Department and the grower/processor from which it obtained the medical marijuana product in question 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 products purchased by the dispensary from the grower/processor. A grower/processor shall investigate the report. The following requirements apply:

(1) A grower/processor shall investigate a complaint to determine if a voluntary or mandatory recall of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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 requirements apply to voluntary recalls:

(1) A grower/processor may voluntarily recall seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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 requirements apply to mandatory recalls:

(1) If a grower/processor discovers that a condition relating to the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products that may have been affected by the condition and remains in its possession. The grower/processor may not dispose of affected seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.

(2) Procedures for identifying and isolating the affected seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.

(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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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 affected medical marijuana products were 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products and minimizes risks to public health and safety.

(f) A grower/processor shall coordinate the disposal of recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products with the Department. The Department or its authorized agents may oversee the disposal to ensure that the recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products are 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, including types, forms, harvest batches, harvest lots and process lots, if applicable.

(2) The amount of recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products 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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products were received.

(6) The means of transport of the recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.

(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 seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, including:

(i) The name of the individual overseeing the disposal of the recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.

(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 seeds, immature medical marijuana plants, medical marijuana plants or 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 seeds, immature medical marijuana plants, medical marijuana plants or 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 requirements 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.

§ 1151.45. Effective date and applicability.

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

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

Appendix A. Acceptable Pesticide Active Ingredients for Use

The following pesticides can be used legally in the growing and processing of seeds, immature medical marijuana plants, medical marijuana plants or medical marijuana and in accordance with the Pennsylvania Pesticide Control Act of 1973 (3 P.S. §§ 111.21—112). Products containing the following active ingredients must also be labeled for use in greenhouses on food crops to qualify.

EPA Status	*Pesticide Type*	*Comments*	*Active Ingredient*
25(b)	Insecticide		Castor Oil
25(b)	Insecticide		Cedar Oil
25(b)	Insecticide		Cinnamon
25(b)	Fungicide, Insecticide		Cinnamon Oil
25(b)	Fungicide, Insecticide		Citric Acid
25(b)	Bactericide, Fungicide		Clove
25(b)	Insecticide		Clove Oil
25(b)	Fungicide		Corn Oil
25(b)	Insecticide		Cottonseed Oil
25(b)	Insecticide		Garlic
25(b)	Insect Repellent		Garlic Oil
25(b)	Fungicide		Geraniol
25(b)	Insecticide		Geranium Oil
25(b)	Fungicide, Insecticide		Lemon Grass Oil
25(b)	Insecticide		Peppermint Oil
25(b)	Insecticide		Peroxyacetic Acid
25(b)	Fungicide		Potassium Sorbate
25(b)	Insecticide		Rosemary
25(b)	Insecticide		Rosemary Oil
25(b)	Fungicide, Insecticide, Miticide		Sesame Oil
25(b)	Fungicide, Insecticide		Sodium Lauryl Sulfate
25(b)	Insecticide		Soybean Oil
25(b)	Fungicide		Thyme
25(b)	Fungicide, Insecticide, Miticide		Thyme Oil
25(b)	Insecticide		White Pepper
Sec 3 Products	Insecticide		Azadirachtin
Sec 3 Products	Fungicide		Bacillus Amyloliquefaciens Strain D747
Sec 3 Products	Fungicide	For use in protected growing environments only (for example, greenhouses).	Bacillus Pumilus Strain GHA 180
Sec 3 Products	Fungicide		Bacillus Subtilis QST713 Strain
Sec 3 Products	Insecticide		Bacillus Thuringiensis SSP. Aizawai
Sec 3 Products	Insecticide		Canola Oil
Sec 3 Products	Insect Repellent		Capsicum Oleoresin Extract
Sec 3 Products	Insecticide	Ground application only to nonblooming plants.	Chromobacterium Sub Strain PRAA4-1 Cells
Sec 3 Products	Fungicide, Insecticide		Clarified Hydrophobic Extract of Neem Oil
Sec 3 Products	Fungicide		Copper Octanoate
Sec 3 Products	PGR		Cytokinin (Kinetin)
Sec 3 Products	Insecticide		Diatomaceous Earth
Sec 3 Products	PGR		Gibberellins (Gibberellic Acid)
Sec 3 Products	PGR		Harpin Alpha Beta
Sec 3 Products	Antimicrobial, Fungicide	No foliar applications allowed.	Hydrogen Peroxide

EPA Status	*Pesticide Type*	*Comments*	*Active Ingredient*
Sec 3 Products	PGR	Applications allowed in furrow at planting or in hydroponics only.	IBA (Indole-3-Butyric Acid)
Sec 3 Products	Insecticide, PGR		Kaolin
Sec 3 Products	Insecticide		Mineral Oil
Sec 3 Products	Fungicide	Use only allowed prior to final transplant, unless grown in recirculating hydroponics systems.	Mono-Potassium and Di-Potassium Salts of Phosphorous Acid
Sec 3 Products	Insecticide		Monopotassium Phosphate
Sec 3 Products	Nematicide		Myrothecium Verrucaria
Sec 3 Products	Fungicide, Insecticide		Neem Oil, Cold Pressed
Sec 3 Products	Insecticide	Use allowed prior to final transplant.	Potassium Laurate
Sec 3 Products	Fungicide, Insecticide		Potassium Salts of Fatty Acids
Sec 3 Products	Insecticide		Pyrethrins
Sec 3 Products	Insecticide		Pyrethrins
Sec 3 Products	Molluscicide		Sodium Ferric EDTA
Sec 3 Products	Fungicide		Trichoderma Asperellum Strain ICC 012

[Pa.B. Doc. No. 18-726. Filed for public inspection May 11, 2018, 9:00 a.m.]

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 1161]

Medical Marijuana; Dispensaries; Amended Temporary Regulations

The Department of Health (Department) is publishing amended temporary regulations in Chapter 1161 (relating to dispensaries—temporary regulations) to read as set forth in Annex A. These amended 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 periodically published temporary regulations regarding various sections of the act. Chapter 1161 sets forth the requirements for an entity to become permitted and operate as a dispensary under the act.

The Department is amending the existing temporary regulations in Chapter 1161 for the sake of consistency, and to take into account the need for changes that have arisen as each new set of temporary regulations has been implemented by the Department. Under section 1202 of the act (35 P.S. § 10231.1202), the Department is also amending the existing temporary regulations to effectuate the recommendations made by the Medical Marijuana Advisory Board (Board). After consideration of the Board's Report, the Secretary of Health decided to implement the Board's recommendations through the promulgation of temporary regulations.

These amended temporary regulations in Chapter 1161 will become effective May 17, 2018, and will expire on May 12, 2020.

Interested persons are invited to submit written comments, suggestions or objections regarding these amended 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) 547-3047, RA-DHMedMarijuana@pa.gov.

Persons with a disability who wish to submit comments, suggestions or objections regarding these amended temporary regulations or who require an alternative format of these amended temporary regulations (for example, large print, audiotape, Braille) may do so by using the previous contact information, or for speech and/or hearing impaired persons, call the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

RACHEL L. LEVINE, MD,
Secretary

(*Editor's Note*: Title 28 of the *Pennsylvania Code* is amended by adding a temporary regulation in § 1161.41 and amending the temporary regulations in §§ 1161.21—1161.40 to read as set forth in Annex A.)

Fiscal Note: 10-212. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

CHAPTER 1161. DISPENSARIES—TEMPORARY REGULATIONS

§ 1161.21. Definitions.

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

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

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

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

Medical marijuana product—The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary.

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

Physician—The term as defined in section 2 of the Medical Practice Act of 1985 (63 P.S. § 422.2) and section 2 of the Osteopathic Medical Practice Act (63 P.S. § 271.2).

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

§ 1161.22. Dispensaries generally.

(a) The qualifications that a dispensary 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 dispensary shall comply with the following:

(1) A dispensary may not engage in the business of possessing, dispensing, selling or offering to dispense or sell medical marijuana products to a patient or caregiver in 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 dispensary may not employ an individual at a facility who is under 18 years of age.

(3) A dispensary may not permit a patient to self-administer medical marijuana products at the facility unless the patient is also an employee of the dispensary, and the dispensary permits self-administration of medical marijuana products at the facility by the employees.

§ 1161.23. Dispensing medical marijuana products.

(a) A dispensary may only dispense medical marijuana products to a patient or caregiver who presents a valid identification card to an employee at the facility who is authorized to dispense medical marijuana products at the facility.

(b) Prior to dispensing medical marijuana products to a patient or caregiver, the dispensary shall:

(1) Verify the validity of the patient or caregiver identification card using the electronic tracking system.

(2) Review the information on the patient's most recent certification by using the electronic tracking system to access the Department's database. The following requirements apply:

(i) If a practitioner sets forth recommendations, requirements or limitations as to the form or dosage of a medical marijuana product on the patient certification, the medical marijuana product dispensed to a patient or a caregiver by a dispensary must conform to those recommendations, requirements or limitations.

(ii) If a practitioner does not set forth recommendations, requirements or limitations as to the form or dosage of a medical marijuana product on the patient certification, the physician, pharmacist, physician assistant or certified registered nurse practitioner employed by the dispensary and working at the facility shall consult with the patient or the caregiver regarding the appropriate form and dosage of the medical marijuana product to be dispensed.

(iii) The dispensary shall update the patient certification in the electronic tracking system by entering any recommendation as to the form or dosage of medical marijuana product that is dispensed to the patient.

(c) Prior to the completion of the transaction, the employee conducting the transaction at the dispensary shall prepare a receipt of the transaction, and file the receipt information with the Department utilizing the electronic tracking system. A dispensary shall provide a copy of the receipt to the patient or the caregiver, unless the patient or the caregiver declines the receipt. The receipt must include all of the following information:

(1) The name, address and any permit number assigned to the dispensary by the Department.

(2) The name and address of the patient and, if applicable, the patient's caregiver.

(3) The date the medical marijuana product was dispensed.

(4) Any requirement or limitation noted by the practitioner on the patient's certification as to the form of medical marijuana product that the patient should use.

(5) The form and the quantity of medical marijuana product dispensed.

(d) Except as provided in sections 2001—2003 of the act (35 P.S. §§ 10231.2001—10231.2003) and this part, a dispensary shall destroy any paper copy of the patient certification or delete any electronically recorded patient certification stored on the dispensary's network, server or computer system as the result of a transaction after the receipt relating to that transaction has been filed under subsection (c).

§ 1161.24. Limitations on dispensing.

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

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

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

(3) A form of medical marijuana products 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 product 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 products 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.

§ 1161.26. Dispensary facilities.

(a) A dispensary may only dispense medical marijuana products to a patient or caregiver in an indoor, enclosed, secure facility as approved by the Department.

(b) A dispensary may not be located:

(1) Within 1,000 feet of the property line of a public, private or parochial school, or a day-care center.

(2) At the same site used for growing and processing medical marijuana.

(3) In the same office space as a practitioner or other physician.

(c) The Department may waive or amend the prohibition under subsection (b)(1) if it is shown by clear and convincing evidence that the waiver or amendment is necessary to provide patients with adequate access to medical marijuana. A waiver or amendment by the Department under this subsection may require additional security measures, changes to the physical plant of a facility or other conditions necessary to protect individuals under 18 years of age and to prevent unauthorized access to medical marijuana.

(d) No one under 18 years of age is permitted to enter a dispensary unless the individual is a patient or accompanied by a parent, guardian or caregiver. If a dispensary facility is located adjacent to a commercial operation, the facility shall provide additional means of security satisfactory to the Department to prevent individuals under 18 years of age from entering the facility from the commercial operation unless the individual is accompanied by an adult.

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

(1) 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 shall 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.

(2) Areas that are open to patients and caregivers.

(f) A dispensary shall ensure that a facility has an enclosed, secure area out of public sight for the loading and unloading of medical marijuana products into and from a transport vehicle.

§ 1161.27. Items and services provided at a dispensary.

(a) A dispensary shall dispense the form of medical marijuana products under § 1161.23(b)(2) (relating to dispensing medical marijuana products).

(b) A dispensary shall purchase medical marijuana products only from a grower/processor.

(c) A dispensary may sell, offer for sale or provide at a facility, with the prior written approval of the Department, instruments, devices and services related to the use of medical marijuana products.

(d) A dispensary may dispense a medical marijuana product with a THC concentration of 0.3% or less so long as the dispensary purchases it from a grower/processor and the grower/processor obtained Department approval under § 1151.28(b) (relating to forms of medical marijuana).

(e) A dispensary may not:

(1) Advertise medical marijuana products:

(i) As a promotional item.

(ii) As part of a giveaway.

(iii) As part of a coupon program.

(2) Provide medical marijuana products at no cost or free, unless the patient is approved for financial assistance by the Department.

(3) Make the dispensing of medical marijuana products to a patient or caregiver conditional upon:

(i) The purchase of a medical device, instrument or service provided at a dispensary facility.

(ii) The purchase of a medical device, instrument or service provided at a location other than a dispensary facility.

(4) The offer for the delivery of or to deliver medical marijuana products to a patient or caregiver at the patient's or caregiver's home or any other location.

§ 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 products 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 number of individual doses contained within the package and the species and percentage of THC and CBD.

(7) Contains a warning that the medical marijuana product 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) Includes the identification number of the sales clerk dispensing the medical marijuana products to the patient or caregiver and the patient identification number.

(11) Lists a use by or expiration date.

(12) Lists the packaging date.

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

(14) 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 products 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 products.

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

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

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

(5) How to prevent or deter the misuse of medical marijuana products 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.

§ 1161.29. Plans of operation.

(a) At the time the Department determines a dispensary to be operational, the dispensary 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) Personnel security.

(3) A process for receiving, packaging, labeling, handling, tracking, transporting, storing, disposing, returning and recalling medical marijuana products in accordance with all applicable laws, rules and regulations.

(4) Workplace safety.

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

(6) Inventory maintenance and reporting procedures.

(7) The investigation of complaints and potential adverse events from other medical marijuana organizations, patients, caregivers or practitioners.

(8) The use of the electronic tracking system prescribed by the Department.

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

§ 1161.30. Visitor access to dispensary facilities.

(a) A dispensary shall post a sign in a conspicuous location at each entrance of the facility that reads:

THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE.

NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER UNLESS THE INDIVIDUAL IS A PATIENT OR ACCOMPANIED BY A PARENT, GUARDIAN OR CAREGIVER.

(b) Except as provided in subsection (c), only authorized employees of a dispensary may enter a limited access area.

(c) A dispensary shall require visitors to a facility, including vendors and contractors requiring access to a limited access area in the dispensary facility, to present government-issued identification, sign a visitor log for

that specific facility and wear a visitor identification badge that is visible to others at all times while in a limited access area.

(d) When admitting a visitor under subsection (c) to a limited access area, a dispensary shall:

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

(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 a limited access area.

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

(e) The following requirements apply regarding the visitor log required under subsections (c) and (d):

(1) The dispensary 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 visited and the name of each employee visited.

(f) 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 dispensary if necessary to perform the government officials' functions and duties.

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

§ 1161.31. Security and surveillance.

(a) A dispensary 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 all of 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 in order 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 security and surveillance systems 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 per day, 7 days per week and records all activity in images capable of clearly revealing facial detail. The security and surveillance system must include all of the following:

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

(A) Any area of a facility where medical marijuana products are loaded or unloaded into or from transport vehicles.

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

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

(D) Five feet from the exterior of the perimeter of a facility.

(E) All limited access areas.

(ii) Auxiliary power sufficient to maintain security and surveillance systems for at least 48 hours following a power outage.

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

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

(3) The 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) The ability to record and store all images captured by each surveillance camera for a minimum of 2 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 dispensary 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 dispensary 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 dispensary 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 the dispensary anticipates will exceed a 4-hour period, the dispensary shall notify the Department immediately and, with Department approval, provide alternative security measures that may include closure of the facility.

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

(6) The following requirements apply regarding records retention:

(i) Within 2 business days following a request, a dispensary 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 government officials' functions and duties.

(ii) If a dispensary 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 dispensary 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 dispensary that it is not necessary to retain the recording, whichever is longer.

(c) A dispensary shall install commercial-grade, nonresidential steel doors and door locks on each room where medical marijuana products are stored and 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 facility must be securely locked.

(e) A dispensary shall have an electronic back-up system for all electronic records.

(f) A dispensary shall install lighting to ensure proper surveillance inside and outside of the facility.

(g) A dispensary shall limit access to a room in a facility 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 requirements apply:

(1) A dispensary 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 dispensary facility shall keep security and surveillance rooms locked at all times and may not use these rooms for any other purpose or function.

§ 1161.32. Inventory data.

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

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

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

(3) Damaged, defective, expired or contaminated medical marijuana products 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 products 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 and locked limited access areas for storage of medical marijuana products that are expired, damaged, deteriorated, mislabeled, contaminated, recalled, or whose containers or packaging have been opened or breached until the medical marijuana products are 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.

§ 1161.34. Sanitation and safety in a facility.

(a) A dispensary shall maintain a facility in a sanitary condition to limit the potential for contamination or adulteration of the medical marijuana products stored in or dispensed at the facility. The following requirements apply:

(1) Trash shall be properly removed.

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

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

(4) Toxic cleaning compounds, sanitizing agents, solvents and pesticide chemicals must be labeled and stored in a manner that prevents contamination of medical marijuana products and in a manner that otherwise complies with other applicable laws and regulations.

(b) An employee working in direct contact with medical marijuana products 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) Washing hands thoroughly in an adequate handwashing area before starting work and at any other time when hands may have become soiled or contaminated and at all times before dispensing medical marijuana products to a patient or caregiver.

(c) A dispensary 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 requirements apply:

(1) A dispensary shall locate hand-washing facilities where good sanitary practices require employees to wash and sanitize their hands.

(2) A dispensary shall provide its employees and visitors with effective nontoxic sanitizing cleansers and sanitary towel service or suitable hand drying devices.

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

(e) A dispensary shall comply with all other applicable State and local building code requirements.

§ 1161.35. Transportation of medical marijuana products.

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

(1) Unless otherwise approved by the Department, a dispensary may deliver medical marijuana products to a medical marijuana organization only between 7 a.m. and 9 p.m. for the purposes of transporting medical marijuana products among the permittee's dispensary locations and returning medical marijuana products 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 products 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 products to a medical marijuana organization.

(b) Vehicles permitted to transport medical marijuana products 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 products.

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

(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 products.

(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 products.

(d) Medical marijuana products 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 facility, where the medical marijuana products are loaded, directly to the medical marijuana organization facility, where the medical marijuana products are unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple facilities, as appropriate, to deliver medical marijuana products.

(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 products.

(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 products to multiple facilities, the transport manifest must correctly reflect the specific medical marijuana products in transit. Each recipient shall provide the dispensary with a printed receipt for the medical marijuana products received.

(c) All medical marijuana products 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 products; and labels and safety inserts).

(d) A dispensary shall provide a copy of the transport manifest to the recipient receiving the medical marijuana products 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 products 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 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 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 requirements apply:

(i) The dispensary shall submit a written preliminary report of the investigation to the Department within 7 days of discovering the discrepancy.

(ii) The dispensary shall submit a final written report of the investigation to the Department within 30 days of discovering the discrepancy.

§ 1161.38. Complaints about or recall of medical marijuana products.

(a) A dispensary shall notify the Department and the grower/processor from which it received the medical marijuana product in question 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 products dispensed by the dispensary.

(b) Upon notification by the grower/processor under § 1151.42 (relating to complaints about or recall of medical marijuana products), the dispensary shall cease dispensing the affected medical marijuana products immediately.

(c) A dispensary shall coordinate the return of the recalled medical marijuana products with the grower/processor.

§ 1161.39. Electronic tracking system.

A dispensary 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 that shall be utilized by a dispensary in the *Pennsylvania Bulletin* 60 days prior to the implementation date of the system.

§ 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 permit 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.

§ 1161.41. Effective date and applicability.

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

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

[Pa.B. Doc. No. 18-727. Filed for public inspection May 11, 2018, 9:00 a.m.]

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 1171]

Medical Marijuana; Laboratories; Amended Temporary Regulations

The Department of Health (Department) is publishing amended temporary regulations in Chapter 1171 (relating to laboratories—temporary regulations) to read as set forth in Annex A. These amended 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 periodically published temporary regulations regarding various sections of the act. Chapter 1171 sets forth the requirements for a laboratory to become approved by the Department to test medical marijuana under the act.

The Department is amending the existing temporary regulations in Chapter 1171 for the sake of consistency, and to take into account the need for changes that have arisen as each new set of temporary regulations has been implemented by the Department. Under section 1202 of the act (35 P.S. § 10231.1202), the Department is also amending the existing temporary regulations to effectuate the recommendations made by the Medical Marijuana Advisory Board (Board). After consideration of the Board's Report, the Secretary of Health decided to implement the Board's recommendations through the promulgation of temporary regulations.

These amended temporary regulations in Chapter 1171 will become effective May 17, 2018, and will expire on May 12, 2020.

Interested persons are invited to submit written comments, suggestions or objections regarding these amended 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) 547-3047, RA-DHMedMarijuana@pa.gov.

Persons with a disability who wish to submit comments, suggestions or objections regarding these amended temporary regulations or who require an alternative format of these amended temporary regulations (for example, large print, audiotape, Braille) may do so by using the previous contact information, or for speech and/or hearing impaired persons, call the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

RACHEL L. LEVINE, MD,
Secretary

(*Editor's Note*: Title 28 of the *Pennsylvania Code* is amended by adding temporary regulations in §§ 1171.38 and 1171.39 and amending the temporary regulations in §§ 1171.21—1171.37 to read as set forth in Annex A.)

Fiscal Note: 10-213. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

CHAPTER 1171. LABORATORIES—TEMPORARY REGULATIONS

§ 1171.21. Definitions.

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

Accreditation body—An organization which:

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

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

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

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

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

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

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

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

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

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

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

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

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

Medical marijuana product—The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary.

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

Physician—The term as defined in section 2 of the Medical Practice Act of 1985 (63 P.S. § 422.2) and section 2 of the Osteopathic Medical Practice Act (63 P.S. § 271.2).

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

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

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

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

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

§ 1171.22. Laboratories generally.

(a) A laboratory may not identify, collect, handle or conduct tests on samples from a grower/processor or conduct tests on test samples for the Department unless the laboratory has been approved by the Department under § 1171.23 (relating to approval of laboratories) and has entered into a written contract with the grower/processor under § 1171.29 (relating to testing requirements).

(b) The Department will post on its web site a current list of approved laboratories.

(c) An approved laboratory shall employ at least one director to oversee and be responsible for the identification, collection, handling and testing operations of the approved laboratory. A director shall have earned, from a college or university accredited by a National or regional accrediting authority, at least one of the following:

(1) A doctorate of science or an equivalent degree in chemistry, biology, or a subdiscipline of chemistry or biology.

(2) A master's level degree in a chemical or biological science and a minimum of 2 years post-degree laboratory experience related to testing of medicinal or pharmaceutical products or other experience as approved by the Department.

(3) A bachelor's degree in a biological science and a minimum of 4 years post-degree laboratory experience related to testing of medicinal or pharmaceutical products or other experience as approved by the Department.

(d) A principal or employee of a medical marijuana organization may not also own, be employed by or affiliated with an approved laboratory that has a contract with that medical marijuana organization.

(e) An approval issued by the Department to a laboratory under this part is valid for 2 years from the date of issuance and is valid only for the laboratory named and the location specified in the approval.

(f) An approval issued by the Department to a laboratory under this part is not transferable to any other person or any other location unless the laboratory obtains the prior written consent of the Department.

§ 1171.23. Approval of laboratories.

(a) A laboratory wishing to identify, collect, handle and conduct tests on samples and test samples and other items used by a grower/processor in the growing and processing of medical marijuana and medical marijuana products as required under the act and this part shall submit an application for approval to the Department on a form and in a manner prescribed by the Department.

(b) An application submitted under this section must include the following information:

(1) The name and address of the laboratory applicant or its authorized agent.

(2) The name and address of the owner of the laboratory applicant, and, if applicable, the medical or pharmacy licensure information regarding the owner.

(3) The name of the laboratory applicant's proposed director and technical personnel who are or will be employed by the laboratory at the location to be approved.

(4) A copy of the laboratory applicant's most recent certificate of accreditation.

(5) Copies of the standard operating procedures and sampling procedures adopted by the laboratory applicant and approved by the accreditation body that issued the certificate of accreditation to the laboratory applicant.

(6) A list of the specialized laboratory equipment utilized or to be utilized by the laboratory applicant in its testing operations, including the manufacturer's name

and the serial and model number of the equipment, and other specifications as may be required by the Department.

(7) A description of the tests which are capable of being conducted by the laboratory applicant at the location to be approved.

(8) A description of the laboratory applicant's quality assurance program, which must be in compliance with § 1171.32 (relating to quality assurance program).

(9) The procedures to be followed to establish chain of custody when collecting samples or test samples.

(10) A copy of the evaluation process that the laboratory applicant uses or will use to monitor, evaluate and document the competency of employees when testing samples and test samples and overseeing quality assurance controls.

(11) Other information required by the Department.

(c) By submitting an application for approval to the Department, a laboratory applicant consents to an investigation of any person, information or physical location the Department or its authorized agents deem appropriate for the Department to make a determination of the laboratory applicant's ability to meet the requirements under the act and this part.

(d) An application for approval submitted under this chapter must include a statement that a false statement made in the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

(e) The Department may issue an approval under this chapter if the Department determines that the laboratory applicant is financially and professionally suitable to conduct the testing required under the act and this part.

§ 1171.24. Suspension or revocation of an approval issued to a laboratory.

(a) An approval issued by the Department under this chapter may be suspended or revoked if the Department determines that the approved laboratory has engaged in unethical practices or has failed to do any of the following:

(1) Maintain proper standards of accuracy.

(2) Comply with the requirements of the act or this part applicable to the approved laboratory.

(b) An approval issued by the Department under this chapter may be revoked if the Department determines that the approved laboratory has engaged in any of the following conduct:

(1) Dishonest reporting.

(2) Repeated errors in conducting the required testing.

(3) Allowing unauthorized individuals to perform testing or to sign reports.

(4) Inclusion of false statements in the application for approval or renewal.

(5) Advertising of medical marijuana testing services to the general public.

(6) Knowingly accepting a sample from an individual other than a grower/processor or a test sample from an individual other than the Department or an authorized agent of the Department.

(7) Failure to maintain standard operating procedures approved by the accreditation body that issued the certificate of accreditation to the approved laboratory.

(8) Failure to properly enter test results into the electronic tracking system.

(9) Loss by the approved laboratory of its certificate of accreditation.

§ 1171.25. Renewal of an approval issued to a laboratory.

An approved laboratory wishing to renew its approval under this chapter shall, not more than 6 months nor less than 4 months prior to the expiration of the approval, submit an application under § 1171.23 (relating to approval of laboratories) and update the information required to be submitted with the application as necessary.

§ 1171.26. Stability testing and retention of samples.

(a) A grower/processor shall request that a sample be identified and collected by an approved laboratory from each harvest batch sufficient to perform stability testing at 6-month intervals for a 1-year period.

(b) The stability test shall be performed to ensure product potency and purity and provide support for expiration dating.

(c) An approved laboratory shall retain a sample from each harvest batch sufficient to provide for stability testing and properly store the sample for 1 year.

§ 1171.27. Sampling procedures for testing.

(a) An approved laboratory shall ensure that its employees prepare all samples in accordance with policies and procedures that include appropriate information necessary for identifying, collecting and transporting samples in a manner that does not endanger the integrity of the samples for any testing required by this part.

(b) The sampling policies must, at a minimum, meet the following requirements:

(1) Be appropriate to the matrix being sampled.

(2) Be in accordance with guidance provided by the Department.

(c) The sampling procedures must include the following procedures:

(1) Surveying the conditions in which the sample is being stored.

(2) Using appropriate sampling equipment and consistent procedures.

(3) Selecting and removing equal portions for each sample.

(4) Random or systematic taking of samples throughout the harvest batch or harvest lot.

(5) Obtaining a minimum number of samples based on harvest batch or harvest lot size.

(6) Checking all parts of the harvest batch when harvest lots are created from that harvest batch.

(7) Recording on a form prescribed by the Department all observations and procedures used when collecting the sample.

(8) Creating a unique sample identification number that will be linked to the harvest batch or harvest lot number assigned by the grower/processor in the electronic tracking system.

(9) Entering all required information into the electronic tracking system.

§ 1171.28. Selection protocols for samples.

(a) An employee of an approved laboratory may only enter a grower/processor facility for the purpose of identifying and collecting samples and shall have access to limited access areas in the facility for these purposes.

(b) An employee identifying and collecting samples under subsection (a) shall follow the chain of custody procedures included in the approved laboratory's application and approved by the Department.

(c) While at a grower/processor facility, an employee of an approved laboratory shall identify and collect the following for testing:

(1) Samples at the time of harvest.

(2) Samples of medical marijuana product before being sold or provided to a dispensary.

(3) Test samples at other times when requested by the Department.

§ 1171.29. Testing requirements.

(a) Prior to conducting any testing of a sample at the request of a grower/processor, an approved laboratory shall enter into a written contract with the grower/processor for testing services. The approved laboratory shall provide a copy of the contract to the Department within 2 days following the Department's request.

(b) A grower/processor shall submit through the electronic tracking system a request to the approved laboratory with which it has a written contract under subsection (a) for each test to be conducted.

(c) At a minimum, an approved laboratory shall perform tests as prescribed by the Department on the following items:

(1) Samples from a harvest batch or harvest lot prior to being used to produce a medical marijuana product.

(2) Samples from each process lot before the medical marijuana is sold or offered for sale to another medical marijuana organization.

(d) The samples identified in subsection (c) shall be tested, at a minimum, for the following:

(1) Pesticides.

(2) Solvents.

(3) Water activity and moisture content.

(4) THC and CBD concentration.

(5) Microbiological contaminants.

(6) Terpenes.

(e) Sampling and testing under this chapter shall be conducted with a statistically significant number and size of samples and with methodologies acceptable to the Department to ensure that all harvest batches, harvest lots and medical marijuana products are adequately tested for contaminants and that the cannabinoid profile is consistent throughout the harvest batch, harvest lot or medical marijuana products.

(f) An approved laboratory may not test any samples when there is evidence of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection of the sample and testing, or any other factor sufficient to render the findings of questionable validity.

(g) An approved laboratory shall enter test results into the electronic tracking system and, under § 1151.40 (relating to management and disposal of medical marijuana waste), properly dispose of all tested and untested samples and test samples.

§ 1171.30. Standards for testing.

An approved laboratory shall follow the methodologies, ranges and parameters acceptable to the Department that are contained in the scope of the certificate of accreditation issued to the laboratory.

§ 1171.31. Test results and reporting.

(a) Only the results of the following tests are in compliance with the testing requirements of this chapter:

(1) Tests conducted on harvest batch samples or harvest lot samples requested by a grower/processor under § 1171.29 (relating to testing requirements) and identified and collected by an employee of an approved laboratory.

(2) Tests conducted on process lot samples requested by a grower/processor under § 1171.29 and identified and collected by either an employee of a grower/processor or an employee of an approved laboratory.

(b) The test results for each sample shall be entered into the electronic tracking system and shall only be accessible to the grower/processor submitting the sample and to the Department.

(c) If a sample fails any test required under § 1171.29, the following apply to the sample:

(1) The approved laboratory that performed the initial test may re-test the sample upon a request from the grower/processor in accordance with subsection (d).

(2) If the sample passes the re-test, another approved laboratory shall sample the same harvest batch, harvest lot or process lot to confirm the passing test result.

(3) If the Department does not agree to accept the results from the approved laboratory, the sample shall be disposed of by the approved laboratory under § 1151.40 (relating to management and disposal of medical marijuana waste).

(d) A grower/processor shall notify the Department and the approved laboratory through the electronic tracking system of its intent to re-test the sample or test another sample from the same harvest batch, harvest lot or process lot that failed a test.

(e) An approved laboratory shall issue to a grower/processor a certificate of analysis, including the supporting data, for each harvest batch, harvest lot or process lot sample that was tested at the request of the grower/processor. The certificate of analysis must include the following information:

(1) Whether the chemical profile of the harvest batch, harvest lot or process lot conforms to the chemical profile of the strain as determined by the Department for the following compounds:

(i) THC.

(ii) Tetrahydrocannabinolic acid.

(iii) CBD.

(iv) Cannabidiolic acid.

(v) Cannabigerol.

(vi) Cannabinol.

(2) That the presence of the following contaminants within the harvest batch, harvest lot or process lot does not exceed the levels as determined by the Department for the following:

(i) Heavy metals, mercury, lead, cadmium or arsenic.

(ii) Foreign material such as hair, insects, or any similar or related adulterant.

(iii) Any microbiological impurity, including:

(A) Total aerobic microbial count.

(B) Total yeast mold count.

(C) *P. aeruginosa.*

(D) *Aspergillus* spp.

(E) *S. aureus.*

(F) Aflatoxin B1, B2, G1 and G2.

(G) Ochratoxin A.

(H) Pesticide residue.

(iv) Whether the harvest batch, harvest lot or process lot is within the specification for the strain for the characteristics of:

(A) Odor.

(B) Appearance.

(C) Fineness.

(D) Moisture content.

§ 1171.32. Quality assurance program.

(a) An approved laboratory shall establish and implement a quality assurance program to ensure that measurements are accurate, errors are controlled, and devices used for testing are routinely and properly calibrated.

(b) The quality assurance program required under subsection (a) must include the following components:

(1) An organizational chart that includes the testing responsibilities of each employee of the approved laboratory named in the chart.

(2) A description of sampling procedures to be utilized.

(3) Appropriate chain of custody protocols.

(4) Analytical procedures.

(5) Data reduction and validation procedures.

(6) A plan for implementing corrective action, when necessary.

(7) A requirement for the provision of quality assurance reports to management.

(8) A description of the internal and external quality control systems.

§ 1171.33. Transporting samples.

(a) An employee of an approved laboratory, grower/processor or third-party contractor shall follow the transportation requirements under §§ 1151.35 and 1151.36 (relating to transportation of medical marijuana; and transport manifest) when transporting a sample or test sample under this part.

(b) An employee of an approved laboratory, grower/processor or third-party contractor who transports process lot samples from a grower/processor to an approved laboratory shall:

(1) Protect the physical integrity of the sample.

(2) Keep the composition of the sample intact.

(3) Protect the sample against factors that interfere with the validity of testing results, including the factors of time, temperature and other environmental factors that may work to jeopardize the integrity of the sample.

§ 1171.34. Department request for testing.

(a) The Department, in its sole discretion, may identify and collect a test sample from a grower/processor at any time and request an approved laboratory to conduct proficiency testing, conduct quality assurance measures and perform tests under this chapter.

(b) The approved laboratory shall provide the Department with a written report of the test results from a test sample tested under subsection (a) within 7 days of the collection of the test sample, or sooner if requested by the Department.

§ 1171.35. Laboratory reporting.

(a) An approved laboratory shall enter into the electronic tracking system the following information for each sample collected and each test conducted:

(1) The unique sample identification number the approved laboratory assigns to the sample.

(2) The name of the grower/processor that supplied the sample.

(3) The employee identification number of the employee of the approved laboratory who identified and collected the sample at the request of the grower/processor.

(4) The date and time the sample was collected from the grower/processor.

(5) The date and time the sample was received by the approved laboratory.

(6) The date the test was completed.

(7) The condition of the sample when it was received by the approved laboratory.

(8) A description of each test performed.

(9) The results from the certificate of analysis issued under § 1171.31 (relating to test results and reporting).

(10) The date the testing results were provided to the grower/processor under § 1171.31 or the Department under § 1171.34 (relating to Department request for testing).

(b) An approved laboratory shall keep for 4 years a paper or electronic copy of the certificate of analysis performed on samples submitted by a grower/processor or test samples submitted by the Department. The approved laboratory shall provide a copy of a certificate of analysis to the Department within 2 days of a request made by the Department.

§ 1171.36. Advertising.

(a) An approved laboratory may not advertise, market or otherwise promote its medical marijuana testing services to the general public.

(b) An approved laboratory may only promote its medical marijuana testing services to a grower/processor. An approved laboratory may use advertising, marketing and promotional materials directed at a grower/processor to promote its medical marijuana testing services. The advertising, marketing and promotional materials proposed to be used by an approved laboratory under this section shall be reviewed and approved by the Department prior to circulation or other use.

(c) Personal solicitation by an employee, representative or agent of an approved laboratory to a grower/processor is considered advertising, marketing or otherwise promoting its medical marijuana testing services for the purposes of this section.

(d) An approved laboratory may only advertise, market or otherwise promote its medical marijuana testing services that are performed onsite at the location designated in the laboratory's application.

(e) A sign installed at the location of an approved laboratory that is designed to identify the laboratory or access to the laboratory is permissible as long as the sign meets local zoning requirements and does not violate the provisions of this section.

§ 1171.37. Ownership prohibition.

The following individuals may not have a management, a direct or indirect financial, or other ownership interest in an approved laboratory:

(1) A principal, owner, financial backer or employee of a medical marijuana organization.

(2) A practitioner.

(3) A physician, pharmacist, physician assistant or certified registered nurse practitioner who is currently employed by a medical marijuana organization.

(4) Any other person, other than a patient, who may receive a direct or indirect financial benefit from the growing, processing, transporting, dispensing or selling of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.

§ 1171.38. Appeals.

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

§ 1171.39. Effective date and applicability.

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

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

[Pa.B. Doc. No. 18-728. Filed for public inspection May 11, 2018, 9:00 a.m.]

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 1181]

Medical Marijuana; Physicians and Practitioners; Amended Temporary Regulations

The Department of Health (Department) is publishing amended temporary regulations in Chapter 1181 (relating to physicians and practitioners—temporary regulations) to read as set forth in Annex A. These amended 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 periodically published temporary regulations regarding various sections of the act. Chapter 1181 sets forth the requirements for a physician to become a practitioner who may issue patient certifications under the act.

The Department is amending the existing temporary regulations in Chapter 1181 for the sake of consistency, and to take into account the need for changes that have arisen as each new set of temporary regulations has been implemented by the Department. Under section 1202 of the act (35 P.S. § 10231.1202), the Department is also amending the existing temporary regulations to effectuate the recommendations made by the Medical Marijuana Advisory Board (Board). After consideration of the Board's Report, the Secretary of Health decided to implement the Board's recommendations through the promulgation of temporary regulations.

These amended temporary regulations in Chapter 1181 will become effective May 17, 2018, and will expire on May 12, 2020.

Interested persons are invited to submit written comments, suggestions or objections regarding these amended 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) 547-3047, RA-DHMedMarijuana@pa.gov.

Persons with a disability who wish to submit comments, suggestions or objections regarding these amended temporary regulations or who require an alternative format of these amended temporary regulations (for example, large print, audiotape, Braille) may do so by using the previous contact information, or for speech and/or hearing impaired persons, call the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

RACHEL L. LEVINE, MD,
Secretary

(*Editor's Note*: Title 28 of the *Pennsylvania Code* is amended by adding temporary regulations in §§ 1181.33 and 1181.34 and amending the temporary regulations in §§ 1181.21—1181.32 to read as set forth in Annex A.)

Fiscal Note: 10-214. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

CHAPTER 1181. PHYSICIANS AND PRACTITIONERS—TEMPORARY REGULATIONS

§ 1181.21. Definitions.

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

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

Medical Board—Either of the following:

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

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

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

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

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

Patient certification—The document issued by a practitioner under § 1181.27 (relating to issuing patient certifications) certifying that a patient has one or more serious medical conditions.

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

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

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

Professional disciplinary action—A disciplinary proceeding taken by the applicable Medical Board against a physician that results in a corrective action or measure.

§ 1181.22. Practitioners generally.

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

(b) A physician may not issue a patient certification without being registered by the Department as a practitioner in accordance with § 1181.24 (relating to physician registration).

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

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

§ 1181.23. Medical professionals generally.

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

(b) A medical professional may not assume any duties at a dispensary until the training required under § 1181.32 (relating to training) and any other requirements for medical professionals under the act and this part are completed.

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

§ 1181.24. Physician registration.

(a) A physician may file an application for registration with the Department as a practitioner on a form prescribed by the Department if the physician meets both of the following qualifications:

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

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

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

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

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

(3) The physician's medical license number.

(4) A certification by the physician that states:

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

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

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

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

(c) The Department may list a physician on the practitioner registry only after the physician has successfully completed the training course required under § 1181.32 (relating to training) and any other requirements for registration under the act and this part.

§ 1181.25. Practitioner registry.

(a) The Department will maintain a practitioner registry for use by a patient or caregiver registered by the Department.

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

(c) The inclusion of a physician in the practitioner registry will be subject to annual review by the Department to determine if the physician's license is inactive, expired, suspended, revoked, limited or otherwise restricted by the applicable Medical Board, or if the physician has been subject to professional disciplinary action.

§ 1181.26. Denial, revocation or suspension of a practitioner registration.

(a) A practitioner registration will be denied, revoked or suspended if the practitioner's medical license is inactive, expired, suspended, revoked, limited or otherwise restricted by the applicable Medical Board, or if the

physician has been subject to professional disciplinary action, including an immediate temporary action.

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

(c) A physician who has been denied registration or whose practitioner registration has been revoked or suspended may reapply to the Department for inclusion in the practitioner registry in accordance with § 1181.24 (relating to physician registration) if the event that led to the physician's denial, revocation or suspension has been resolved and the physician's medical license is designated as active without limitation by the applicable Medical Board. The physician's application for registration under this subsection must include evidence of the resolution.

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

(1) Have electronic access to a patient certification.

(2) Issue or modify a patient certification.

(3) Provide a copy of an existing patient certification to any person, including a patient or a caregiver, except in accordance with applicable law.

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

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

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

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

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

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

§ 1181.27. Issuing patient certifications.

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

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

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

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

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

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

(1) A practitioner who is not board-eligible or board-certified in pediatrics or a pediatric specialty, neurology with special qualifications in child neurology, child and adolescent psychiatry, or adolescent medicine (whether through pediatrics, internal medicine or family practice) may not issue a patient certification to a minor patient.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) Upon completion of a patient certification, a practitioner shall:

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

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

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

§ 1181.28. Modifying a patient certification.

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

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

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

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

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

§ 1181.29. Revocation of a patient certification.

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

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

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

(3) The patient has died.

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

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

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

§ 1181.30. Prescription Drug Monitoring Program.

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

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

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

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

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

§ 1181.31. Practitioner prohibitions.

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

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

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

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

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

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

§ 1181.32. Training.

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

(1) A physician prior to being included in the practitioner registry under § 1181.24 (relating to physician registration).

(2) A medical professional prior to assuming any duties at a dispensary under § 1161.25 (relating to licensed medical professionals at facility).

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

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

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

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

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

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

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

(iii) Palliative care.

(iv) The misuse of opioids and medical marijuana.

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

(vi) Any other area determined by the Department.

(5) Use of the Prescription Drug Monitoring Program.

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

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

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

(2) The State Board of Pharmacy.

(3) The State Board of Nursing.

(d) The individuals listed in subsection (a) shall submit documentation of the completion of the 4-hour training course to the Department.

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

§ 1181.33. Appeals.

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

§ 1181.34. Effective date and applicability.

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

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

[Pa.B. Doc. No. 18-729. Filed for public inspection May 11, 2018, 9:00 a.m.]

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 1191]

Medical Marijuana; Patients and Caregivers; Amended Temporary Regulations

The Department of Health (Department) is publishing amended temporary regulations in Chapter 1191 (relating to patients and caregivers—temporary regulations) to read as set forth in Annex A. These amended 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 periodically published temporary regulations regarding various sections of the act. Chapter 1191 sets forth the requirements for a patient and caregiver to become registered with the Department to participate in the Medical Marijuana Program under the act.

The Department is amending the existing temporary regulations in Chapter 1191 for the sake of consistency, and to take into account the need for changes that have arisen as each new set of temporary regulations has been implemented by the Department. Under section 1202 of the act (35 P.S. § 10231.1202), the Department is also amending the existing temporary regulations to effectuate the recommendations made by the Medical Marijuana Advisory Board (Board). After consideration of the Board's Report, the Secretary of Health decided to implement the Board's recommendations through the promulgation of temporary regulations.

These amended temporary regulations in Chapter 1191 will become effective May 17, 2018, and will expire on May 12, 2020.

Interested persons are invited to submit written comments, suggestions or objections regarding these amended 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) 547-3047, RA-DHMedMarijuana@pa.gov.

Persons with a disability who wish to submit comments, suggestions or objections regarding these amended temporary regulations or who require an alternative format of these amended temporary regulations (for example, large print, audiotape, Braille) may do so by using the previous contact information, or for speech and/or hearing impaired persons, call the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

RACHEL L. LEVINE, MD,
Secretary

(*Editor's Note*: Title 28 of the *Pennsylvania Code* is amended by adding a temporary regulation in § 1191.34 and amending the temporary regulations in §§ 1191.21—1191.33 to read as set forth in Annex A.)

Fiscal Note: 10-215. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

CHAPTER 1191. PATIENTS AND CAREGIVERS—TEMPORARY REGULATIONS

§ 1191.21. Definitions.

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

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

Applicant—

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

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

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

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

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

Caregiver—One of the following:

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

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

Legal guardian—

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

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

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

Medical marijuana patient authorization letter—A document issued by the Department under § 1191.32 (relating to medical marijuana patient authorization letters).

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

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

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

Patient certification—The document issued by a practitioner under § 1181.27 (relating to issuing patient certifications) certifying that a patient has one or more serious medical conditions.

§ 1191.22. Patient and caregiver registry.

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

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

(1) Information provided in an identification card application.

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

(3) Criminal history record check information provided as part of an identification card application submitted by a caregiver under § 1191.27 (relating to criminal background checks).

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

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

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

§ 1191.23. Patients and caregivers generally.

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

(b) Except with respect to a minor patient as provided in § 1191.32 (relating to medical marijuana patient authorization letters), the Department may issue an identification card to an applicant who meets the qualifications in the act and this part.

(c) The Department may issue an identification card to an individual who is under 21 years of age to serve as a caregiver when a sufficient showing is made to the Department that the individual should be permitted to serve as a caregiver, as determined by the Department.

(d) A minor patient shall have a caregiver who is one of the following:

(1) A parent or legal guardian.

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

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

§ 1191.24. Medical marijuana cardholder responsibilities.

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

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

(2) The withdraw of a patient certification by a practitioner under § 1181.29 (relating to revocation of a patient certification).

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

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

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

(b) A medical marijuana cardholder shall return the identification card to the Department within 10 business days following receipt of written notice from the Department of the occurrence of any of the following:

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

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

§ 1191.25. Application for, and issuance or denial of, identification cards.

(a) An applicant shall submit an identification card application on a form prescribed by the Department. The

application will be made available on the Department's publicly-accessible web site and in hard copy upon request.

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

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

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

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

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

(5) The patient certification issued by the patient's practitioner, which shall be provided by the practitioner to the Department under § 1181.27(d)(2) (relating to issuing patient certifications).

(6) The appropriate fee or proof of financial hardship as provided for in § 1191.26 (relating to application fees).

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

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

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

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

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

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

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

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

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

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

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

(4) The patient certification issued by the patient's practitioner, which will be provided by the practitioner to the Department under § 1181.27(d)(2).

(5) A copy of the criminal history record information required under § 1191.27 (relating to criminal background checks).

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

(7) The appropriate fee or proof of financial hardship as provided for in § 1191.26.

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

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

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

(e) The Department will review the criminal history record information obtained by a caregiver under § 1191.27 and the Prescription Drug Monitoring Program database before approving the issuance of an identification card to the caregiver. The Department will deny the issuance of an identification card to a caregiver if the caregiver has been convicted of a criminal offense relating to the sale or possession of drugs, narcotics or controlled substances that occurred within the 5 years immediately preceding the submission of the application. The Department may deny the issuance of an identification card to a caregiver if the caregiver has a history of drug abuse or of diverting controlled substances or illegal drugs.

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

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

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

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

§ 1191.26. Application fees.

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

(b) Notwithstanding subsection (a):

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

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

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

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

§ 1191.27. Criminal background checks.

(a) An individual applying for an identification card to serve as a caregiver shall submit fingerprints to the Pennsylvania State Police, or an authorized agent, for the purpose of obtaining a criminal history record check. The Pennsylvania State Police, or an authorized agent, will submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the caregiver and obtaining a current record of any criminal arrests and convictions.

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

§ 1191.28. Identification cards.

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

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

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

(2) The address of the medical marijuana cardholder.

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

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

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

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

(7) Any requirement or limitation on the patient certification concerning the recommended form of medical marijuana products or limitation on the duration of use, if applicable.

(8) Any other information deemed necessary by the Department.

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

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

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

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

(3) The date the patient dies.

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

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

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

(3) The date the caregiver dies.

(f) A medical marijuana cardholder shall apply to the Department for a replacement identification card within 10 business days of discovering the loss or defacement of the identification card.

§ 1191.29. Renewing an identification card.

(a) A medical marijuana cardholder shall submit an identification card renewal application to the Department no later than 30 days prior to the expiration date on the card. The form of the renewal application will be prescribed by the Department and will be made available on the Department's publicly-accessible web site and in hard copy upon request. A medical marijuana cardholder shall include with the identification card renewal application a new or updated patient certification issued by the patient's practitioner, which will be provided by the practitioner to the Department under § 1181.27(d)(2) (relating to issuing patient certifications).

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

§ 1191.30. Revocation or suspension of identification card.

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

(1) The Department receives written notice from a practitioner under § 1181.29(a) (relating to revocation of a patient certification).

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

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

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

(5) A patient notifies the Department in writing that the patient has removed or changed a current caregiver. If the caregiver is not serving as a caregiver for any other

patient, the Department will issue a notification to the caregiver that the caregiver's identification card is invalid and shall be promptly returned to the Department.

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

(c) If a patient's practitioner's registration has been revoked or suspended under § 1181.26 (relating to denial, revocation or suspension of a practitioner registration) or if a patient's practitioner withdraws the patient's patient certification under § 1181.29(c), a medical marijuana cardholder shall submit a new application for an identification card within 90 days of receiving written notice from the Department or prior to the expiration date on the identification card, whichever is sooner.

§ 1191.31. Obtaining medical marijuana products from a dispensary.

(a) A medical marijuana cardholder may only obtain medical marijuana products from a dispensary in accordance with § 1161.24 (relating to limitations on dispensing).

(b) A medical marijuana cardholder may only obtain medical marijuana products from a dispensary based upon the recommendation in a patient certification that has not been revoked under § 1181.29 (relating to revocation of a patient certification) and that may be accessed by a dispensary through the electronic tracking system.

§ 1191.32. Medical marijuana patient authorization letters.

(a) The Department will issue a medical marijuana patient authorization letter to a minor patient instead of issuing an identification card to the minor patient. Upon reaching 18 years of age, a minor patient who has been issued a medical marijuana patient authorization letter will be entitled to receive an identification card upon application under § 1191.25 (relating to application for, and issuance or denial of, identification cards).

(b) The Department may issue a medical marijuana patient authorization letter to an adult patient.

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

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

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

§ 1191.33. Appeals.

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

§ 1191.34. Effective date and applicability.

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

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

[Pa.B. Doc. No. 18-730. Filed for public inspection May 11, 2018, 9:00 a.m.]

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 1230]

Medical Marijuana; Practice and Procedure; Temporary Regulations

The Department of Health (Department) is publishing temporary regulations in Chapter 1230 (relating to practice and procedure—temporary regulations) to read as set forth in Annex A. These 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 periodically published temporary regulations regarding various sections of the act. The temporary regulations for practice and procedure will expire on May 12, 2020.

Chapter 1230 pertains to growers/processors, dispensaries, laboratories, disappointed medical marijuana organization permit applicants and any other person choosing to challenge an action taken by the Office of Medical Marijuana under the act.

Interested persons are invited to submit written comments, suggestions or objections regarding these 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) 547-3047, RA-DHMedMarijuana@pa.gov.

Persons with a disability who wish to submit comments, suggestions or objections regarding these temporary regulations or who require an alternative format of these temporary regulations (for example, large print, audiotape, Braille) may do so by using the previous contact information, or for speech and/or hearing impaired persons, call the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

RACHEL L. LEVINE, MD,
Secretary

(*Editor's Note*: Title 28 of the *Pennsylvania Code* is amended by adding temporary regulations in §§ 1230.21—1230.24, 1230.25, 1230.26, 1230.38, 1230.39 and 1230.43—1230.46 to read as set forth in Annex A.)

Fiscal Note: 10-207. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

CHAPTER 1230. PRACTICE AND PROCEDURE—TEMPORARY REGULATIONS

Subchap.
A. PRELIMINARY PROVISIONS
B. FORMAL PROCEEDINGS

Subchapter A. PRELIMINARY PROVISIONS

GENERAL

Sec.
1230.21. Scope.
1230.22. Definitions.
1230.23. Docket.
1230.24. Filing generally.

TIME

1230.25. Effective date of adjudication, actions or order.
1230.26. Representation.

GENERAL

§ 1230.21. Scope.

(a) This chapter governs practice and procedure before the Department in medical marijuana appeals and in any action taken by the Office under the act.

(b) This chapter is not applicable to a proceeding to the extent that the applicable statute governing or authorizing the proceeding sets forth inconsistent practice or procedure.

(c) Except when inconsistent with this chapter, 1 Pa. Code Part II (relating to General Rules of Administrative Practice and Procedure) is applicable insofar as it relates to adjudicatory proceedings.

(d) Subsections (a)—(c) supplement 1 Pa. Code § 31.1 (relating to scope of part).

§ 1230.22. Definitions.

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

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

Clerk—The Department's Docket Clerk in the Office of Legal Counsel.

Department—The Department of Health.

Office—The Department's Office of Medical Marijuana.

Person—An individual, partnership, association, corporation, political subdivision, municipal authority or other entity.

(b) Subsection (a) supplements 1 Pa. Code § 31.3 (relating to definitions).

§ 1230.23. Docket.

(a) The Clerk has the following duties:

(1) Provide information as to practice and procedure before the Department, under this chapter.

(2) Receive and docket pleadings and other documents required by the Department to be filed with the Clerk.

(b) A filing shall be directed to the Clerk at the following address, by first class mail, postage prepaid:

Department of Health
Office of Legal Counsel
ATTN: Docket Clerk
Room 825, Health and Welfare Building
625 Forster Street
Harrisburg, Pennsylvania 17120-0701

(c) Pleadings, submittals or other documents required or permitted to be filed under this chapter, the regulations of the Department or any other provision of law shall be received for filing by the Clerk within the time limits, if any, for the filing. The date of receipt by the Clerk and not the date of deposit in the mail is determinative. Electronic submissions will not be accepted by the Clerk for filing, unless the electronic filing is specifically permitted by the Department.

(d) The Clerk shall maintain a docket of proceedings. Each proceeding as initiated will be assigned a docket number.

(e) The docket will be available for inspection and copying by the public, at the requestor's expense, during the office hours of the Department insofar as consistent with the proper discharge of the duties of the Department.

(f) Subsections (a)—(e) supersede 1 Pa. Code §§ 33.11 and 33.51 (relating to execution; and docket).

§ 1230.24. Filing generally.

(a) Pleadings and other documents filed with the Clerk must clearly designate the docket number, if one has been assigned, the application or permit number, if one has been assigned, and a short title identifying the pleading or other document. The identity of the individual or person filing the pleading or other document, including the name, mailing address and status (for example, party or attorney for a party) must appear on the pleading or other document being filed.

(b) If a pleading or other document tendered for filing does not comply with this chapter, does not sufficiently set forth required material or is otherwise deficient, the Department may decline to accept the pleading or other document for filing and may return it without filing, or the Department may accept the pleading or other document for filing and advise the individual or person tendering it of the deficiency and require that the deficiency be corrected within a reasonable period of time.

(c) The Department may require redundant, immaterial, obscene or otherwise inappropriate comments stricken from a pleading or other document before accepting it for filing.

TIME

§ 1230.25. Effective date of adjudication, actions or order.

(a) An adjudication, action or order will be effective as of the date of mailing unless otherwise specifically provided.

(b) Subsection (a) supersedes 1 Pa. Code § 31.14 (relating to effective dates of agency orders).

§ 1230.26. Representation.

(a) A party, except an individual appearing on his own behalf, shall be represented by an attorney at all stages of the proceedings subsequent to the filing of the Notice of Appeal or Order to Show Cause.

(b) A corporation shall be represented by an attorney of record admitted to practice before the Supreme Court of Pennsylvania. A corporation may also be represented by an attorney in good standing and admitted to practice before the highest court of another state on a motion pro hac vice filed by the Pennsylvania attorney of record.

(c) A group of individuals acting in concert, whether formally or informally, shall be represented by an attorney admitted to practice law before the Supreme Court of Pennsylvania or by an attorney in good standing admitted to practice before the highest court of another state who has made a motion to appear pro hoc vice and has agreed in that motion to abide by the rules and regulations of the Department and the Pennsylvania Rules of Professional Conduct.

(d) An individual may appear in person on his own behalf. The individual is encouraged to appear through counsel. If the Department determines that the individual is acting in concert with or as a representative of a group of individuals, the individual may be required to appear through counsel under subsection (c).

(e) Subsections (a)—(d) supersede 1 Pa. Code §§ 31.21—31.23 (relating to appearance in person; appearance by attorney; and other representation prohibited at hearings).

Subchapter B. FORMAL PROCEEDINGS

APPEALS

SPECIAL ACTIONS

APPEALS

§ 1230.38. Commencement, form and content of Notice of Appeal.

(a) An appeal from an action of the Office shall start with the filing of a Notice of Appeal with the Department.

(b) The caption of a Notice of Appeal must be in the following form:

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH

Name of Appellant
Address of Appellant
Telephone Number of Appellant,
Appellant/Petitioner,
v.
The Pennsylvania Department of Health,
Office of Medical Marijuana,
Appellee/Respondent.

Docket No.: _____

NOTICE OF APPEAL

(c) The Notice of Appeal must set forth the name, mailing address, e-mail address, permit number or application number, if one has been assigned, and telephone number of the appellant. If the appellant is represented by an attorney, the Notice of Appeal shall be signed by at least one attorney of record in the attorney's individual name.

(d) If the appellant has received written notification of an action of the Office, a copy of the action must be attached to the Notice of Appeal.

(e) The Notice of Appeal must set forth in separate numbered paragraphs the specific objections to the action of the Office. The objections may be factual or legal.

(f) The Notice of Appeal must be typewritten on letter-size paper (approximately 8 to 8 1/2 inches by 10 1/2 to 11 inches) and pages after the first must be numbered. Photocopies will be accepted as typewritten, provided that the copies are legible. Failure to comply with these requirements will not result in rejection or dismissal of the Notice of Appeal. The Department may request that the appellant file an amended version of the Notice of Appeal in proper form.

(g) The appellant shall, concurrent with or prior to the filing of a Notice of Appeal, serve two copies on the Department's Office of Legal Counsel in the same manner in which the Notice of Appeal is filed with the Department.

(h) Subsections (a)—(g) supersede 1 Pa. Code §§ 35.5—35.7 and 35.20 (relating to informal complaints; and appeals from actions of the staff).

§ 1230.39. Timeliness of Notice of Appeal.

(a) Jurisdiction of the Department will not attach to an appeal from an action of the Office unless the Notice of Appeal is in writing and is timely filed with the Department within 30 days after the individual or person to whom the action of the Office is directed or issued has received written notice of the action, unless a different time is provided by statute.

(b) Failure to file a timely Notice of Appeal may be deemed an admission or may be dismissed with prejudice by the Department.

(c) The Office may file an answer and new matter to the Notice of Appeal within 30 days of its service on the Office, but is not required to do so.

(d) Subsection (a) supersedes 1 Pa. Code §§ 35.5—35.7, 35.20 and 35.35 (relating to informal complaints; appeals from actions of the staff; and answers to complaints and petitions).

SPECIAL ACTIONS

§ 1230.43. Orders to Show Cause, orders or petitions filed by the Office.

(a) The Office may start an action by filing an Order to Show Cause, order or other petition filed by the Office and a notice of a right to respond or defend. The action is

begun when the Order to Show Cause, order or other petition of the Office is filed with the Clerk.

(b) Service of the Order to Show Cause, order or other petition filed by the Office shall be by personal service or by United States first class mail, postage prepaid. In the instance of mail, service will be deemed complete 3 days after the date of mailing by the Office.

(c) An Order to Show Cause must set forth the authority under which the Department is authorized to act and must set forth in separate numbered paragraphs the specific facts and circumstances upon which the request for action is based.

(d) The notice of a right to respond or defend shall conform substantially to the following:

[Case Caption]

NOTICE

If you wish to defend against the claims set forth in the following pages, you must take action within thirty (30) days after this Order to Show Cause and notice are served by entering a written appearance personally or by attorney and filing in writing with the Clerk in accordance with § 1230.23 your answers, defenses or objections to the claims set forth against you. You are warned that if you fail to do so, the case may proceed without you, and a judgment may be entered against you by the Department without further notice for any claim or relief requested by the Office. You should take this paper to your lawyer at once.

(e) Subsections (a)—(d) supersede 1 Pa. Code § 35.14 (relating to orders to show cause).

§ 1230.44. Answers to Orders to Show Cause, orders or other petitions filed by the Office.

(a) Answers to Orders to Show Cause, orders or other petitions filed by the Office shall be filed with the Clerk within 30 days after the date of service of the Order to Show Cause, order or other petition filed by the Office, unless, for cause, the Department, with or without motion, prescribes a different time.

(b) Answers to Orders to Show Cause, orders or other petitions filed by the Office must set forth legal objections and any denial of facts in a single pleading.

(c) Answers must be in writing and drafted as to fully and completely advise the parties and the Department as to the nature of the defense, including affirmative defenses. Answers must admit or deny specifically and in detail each material allegation of the Order to Show Cause, order or petition filed by the Office, and state clearly and concisely the facts and matters of law relied upon.

(d) A Respondent failing to file an answer within the prescribed time will be deemed in default and, upon motion made as set forth in § 1230.46 (relating to entry of default judgment), all relevant facts in the Order to Show Cause, order or other petition filed by the Office may be deemed admitted, and default judgment may be entered.

(e) New matter or preliminary objections may not be filed. To the extent that new matter or preliminary objections are filed, new matter or preliminary objections will be deemed stricken.

(f) Subsections (a)—(e) supersede 1 Pa. Code § 35.37 (relating to answers to orders to show cause).

§ 1230.45. Verifications and affidavits.

(a) Pleadings or other documents containing an averment of fact not appearing of record in the action or containing a denial of fact shall be personally verified by a party thereto or by an authorized officer of the party if a corporation or other business entity. Verification means a signed written statement of fact supported by oath or affirmation or made subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities). If verification is required, notarization is not necessary.

(b) The verification form must comply substantially with the following:

VERIFICATION

I, _____ , hereby state that the facts above set forth are true and correct (or are true and correct to the best of my knowledge, information and belief). I understand that the statements herein are made subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities).

_____

Date

_____

Signature

_____

Printed Name

(c) When an affidavit is used, the form should comply substantially with the following:

AFFIDAVIT

I, _____ (Affiant), being duly sworn (affirmed) according to law, depose and say that (I am authorized to make this affidavit on behalf of _____ corporation/business entity, being the holder of the office of _____ with that corporation/business entity,) and that the facts above set forth are true and correct (or are true and correct to the best of my knowledge, information and belief).

_____

(Signature of affiant)

Sworn and subscribed before me this _____ day of _____ , 20____ .

_____

(Signature of official administering oath)

§ 1230.46. Entry of default judgment.

(a) The Department, on motion of the Office, may enter default judgment against the Respondent for failure to file within the required time an answer to an Order to Show Cause, order or other petition allowed for under these regulations that contains a notice of a right to respond or defend.

(b) The Respondent may answer the motion for default judgment and request a hearing. If a request for a hearing on the default judgment is made, the Department may not grant default judgment prior to a hearing and the filing of an answer.

[Pa.B. Doc. No. 18-731. Filed for public inspection May 11, 2018, 9:00 a.m.]