

• RULES AND REGULATIONS

- Title 28–HEALTH AND SAFETY
- DEPARTMENT OF HEALTH
- [28 PA.CODE CH. 1161]
- Medical Marijuana; Dispensaries; Amended Temporary Regulations
- [48 Pa.B. 2793]
- [Saturday, May 12, 2018]

The Department of Health (Department) is publishing amended temporary regulations in Chapter 1161 (relating to dispensariestemporary regulations) to read as set forth in Annex A. These amended temporary regulations are published under the Medical Marijuana Act (act) (35 P.S. 10231.10110231.2110). 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 201205 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. 12011205), known as the Commonwealth Documents Law, the Regulatory Review Act (71 P.S. 745.1745.14) 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 1161.211161.40 to read as set forth in Annex A.)

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

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

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 20012003 of the act (35 P.S. 10231.200110231.2003) 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 EnterLimited Access AreaAccess 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 hand-washing 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.