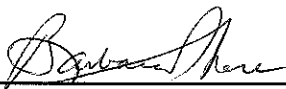
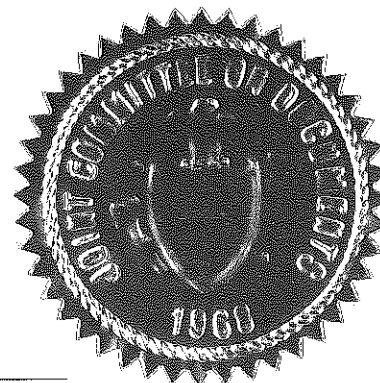

CERTIFICATION
Legislative Reference Bureau
Documents Law Section

I, Barbara Lane, Assistant Director of the Legislative Reference Bureau, hereby certify that 28 Pa. Code Chapter 1151 as follows has been certified as official through March 31, 2017.

Amendments to 28 Pa. Code Chapter 1151 published at 47 Pa.B. 199 (January 14, 2017) will be codified in the April 2017 *Pennsylvania Code Reporter* (Master Transmittal Sheet No. 509). Further, a search of the *Pennsylvania Bulletin* has not disclosed amendments to 28 Pa. Code Chapter 1151 through January 26, 2017.



Barbara Lane
Assistant Director
Legislative Reference Bureau
January 26, 2017



CHAPTER 1151. GROWERS/PROCESSORS

§ 1151.21. Growers/processors generally.

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

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

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

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

§ 1151.22. Plans of operation.

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

(1) Employment policies and procedures.

(2) Security policies and protocols including:

(i) Staff identification measures.

(ii) Monitoring of attendance of staff and visitors.

(iii) Alarm systems.

(iv) Video surveillance.

(v) Monitoring and tracking inventory.

(vi) Personal security.

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

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

(5) Contamination protocols.

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

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

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

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

(10) Inventory maintenance and reporting procedures.

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

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

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

§ 1151.23. Grower/processor facilities.

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

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

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

(2) Nongrowing and nonprocessing areas.

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

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

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

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

§ 1151.24. 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) A grower/processor shall, within 24 hours of receipt, 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 medical marijuana, to sign a visitor log and wear a visitor identification badge that is visible to others at all times while on the site and in the facility.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 1151.26. Security and surveillance.

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

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

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

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

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

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

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

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

(vii) Smoke and fire alarms.

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

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

(x) Motion detectors.

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

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

(A) All limited access areas.

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

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

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

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

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

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

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

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

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

(i) At the facility:

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

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

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

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

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

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

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

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

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

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

(6) The following apply regarding records retention:

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

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

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

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

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

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

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

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

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

§ 1151.27. Requirements for growing and processing medical marijuana.

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

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

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

(d) A grower/processor shall:

(1) Use appropriate nutrient practices.

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

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

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

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

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

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

(1) Are free of seeds and stems.

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

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

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

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

(2) Proper sanitation shall be maintained.

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

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

(1) Temperature.

(2) Humidity.

(3) Ventilation.

(4) Lighting.

(5) Water supply.

§ 1151.28. 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.
- (5) Tincture.
- (6) Liquid.

(b) A grower/processor may not process medical marijuana to dispense in dry leaf or plant form.

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

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

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

§ 1151.30. Inventory data.

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

- (1) The number, weight and type of seeds.
- (2) The number of immature medical marijuana plants.
- (3) The number of medical marijuana plants.
- (4) The number of medical marijuana products ready for sale.
- (5) The number of damaged, defective, expired or contaminated seeds, immature medical marijuana plants, medical marijuana plants and medical marijuana products awaiting disposal.

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

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

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

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

§ 1151.31. Storage requirements.

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

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

§ 1151.32. Equipment, operation and maintenance.

(a) A grower/processor facility shall have a written process in place to maintain the sanitation and operation of equipment that comes into contact with medical marijuana 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 its facility in a sanitary condition to limit the potential for contamination or adulteration of the medical marijuana grown and processed in the facility. The following apply:

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

(2) Trash shall be properly removed.

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

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

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

(6) Toxic cleaning compounds, sanitizing agents, solvents used in the growing and processing of medical marijuana, and pesticide chemicals must be labeled and stored in a manner that prevents contamination of seeds, immature medical marijuana plants, medical marijuana plants and medical marijuana, and in a manner that otherwise complies with other applicable laws and regulations.

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

(1) Maintaining adequate personal hygiene.

(2) Wearing proper clothing, including gloves.

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

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

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

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

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

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

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

§ 1151.34. Packaging and labeling of medical marijuana.

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

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

(1) Child-resistant.

(2) Tamper-proof or tamper-evident.

(3) Light-resistant and opaque.

(4) Resealable.

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

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

(1) Be easily readable.

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

(3) Be conspicuously placed on the package.

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

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

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

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

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

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

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

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

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

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

(14) Contain the following warning stating:

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

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

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

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

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

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

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

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

§ 1151.35. Transportation of medical marijuana.

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

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

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

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

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

(b) Vehicles permitted to transport medical marijuana must:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 1151.36. Transport manifest.

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

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

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

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

(4) The date and approximate time of departure.

(5) The date and approximate time of arrival.

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

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

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

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

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

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

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

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

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

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

§ 1151.38. Evidence of adverse loss during transport.

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

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

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

(1) Conduct an investigation.

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

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

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

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

§ 1151.39. Electronic tracking system.

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

§ 1151.40. Management and disposal of medical marijuana waste.

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

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

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

(2) Any medical marijuana plant material that is not used in the growing, harvesting or processing of medical marijuana, including flowers, stems, trim, leaves, seeds, dead medical marijuana plants, dead immature medical marijuana plants, unused medical marijuana plant parts, unused immature medical marijuana plant parts or roots.

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

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

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

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

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

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

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

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

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

§ 1151.42. Complaints about or recall of medical marijuana.

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

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

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

(b) The following apply to voluntary recalls:

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

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

(c) The following apply to mandatory recalls:

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

(i) Immediately notify the Department by phone.

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

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

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

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

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

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

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

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

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

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

(5) Procedures for notifying the Department.

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

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

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

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

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

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

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

(4) The names of the recall coordinators.

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

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

(7) The reason for the recall.

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

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

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

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

(iii) The method of disposal.

(iv) The date of disposal.

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

(10) Any other information required by the Department.

§ 1151.43. Pesticides.

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

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

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

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

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

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

(iii) The size of the area treated.

(iv) The product name of every pesticide used.

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

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

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

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

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

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

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

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

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

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

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

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

Plant regulator—

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

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

§ 1151.44. Treatment and quarantine orders.

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

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

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

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

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

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

Appendix A. Acceptable Pesticide Active Ingredients for Use

The following pesticides can be used legally in the growing and processing of 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.

<i>EPA Status</i>	<i>Pesticide Type</i>	<i>Comments</i>	<i>Active Ingredient</i>
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

<i>EPA Status</i>	<i>Pesticide Type</i>	<i>Comments</i>	<i>Active Ingredient</i>
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

<i>EPA Status</i>	<i>Pesticide Type</i>	<i>Comments</i>	<i>Active Ingredient</i>
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
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

<i>EPA Status</i>	<i>Pesticide Type</i>	<i>Comments</i>	<i>Active Ingredient</i>
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