CHAPTER 1151a. GROWERS/PROCESSORS

a		
	ec	
J		

- 1151a.21. Growers/processors generally.
- 1151a.22. Plans of operation.
- 1151a.23. Grower/processor facilities.
- 1151a.24. Growing and processing inventory.
- 1151a.25. Access to grower/processor facilities.
- 1151a.26. Security and surveillance.
- 1151a.27. Requirements for growing and processing medical marijuana.
- 1151a.28. Forms of medical marijuana.
- 1151a.29. Limit on medical marijuana processing.
- 1151a.30. Inventory data.
- 1151a.31. Storage requirements.
- 1151a.32. Equipment, operation and maintenance.
- 1151a.33. Sanitation and safety in a facility.
- 1151a.34. Packaging and labeling of medical marijuana products.
- 1151a.35. Transportation of medical marijuana.
- 1151a.36. Transport manifest.
- 1151a.37. Transportation of seeds, immature medical marijuana plants, medical marijuana plants and postharvest plant material.
- 1151a.38. Evidence of adverse loss during transport.
- 1151a.39. Electronic tracking system.
- 1151a.40. Management and disposal of medical marijuana waste.
- 1151a.42. Complaints about or recall of medical marijuana products.
- 1151a.43. Pesticides.
- 1151a.44. Treatment and quarantine orders.

Authority

The provisions of this Chapter 1151a added under section 301(a)(3) and (b) of the Medical Marijuana Act (35 P.S. § 301(a)(3) and (b)), unless otherwise noted.

Source

The provisions of this Chapter 1151a added March 3, 2023, effective March 4, 2023, 53 Pa.B. 1275, unless otherwise noted.

Cross References

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

§ 1151a.21. Growers/processors generally.

- (a) The qualifications that a grower/processor shall meet to receive a permit are continuing qualifications to maintain the permit.
- (b) In addition to any other requirements in the act or this part, a grower/processor shall comply with the following:
 - (1) A grower/processor may not engage in the business of growing, processing, possessing, selling or offering to sell seeds, immature medical mari-

juana plants, medical marijuana plants, medical marijuana or medical marijuana products to another medical marijuana organization without first being issued a permit by the Department and without first being determined operational by the Department as required under § 1141a.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.

§ 1151a.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 individuals requiring access to the facility.
 - (iii) Alarm systems.
 - (iv) Video surveillance.
 - (v) Monitoring and tracking inventory.
 - (vi) Personal security.
 - (3) A process for growing, receiving, processing, packaging, labeling, handling, tracking, transporting, storing, disposing and recalling of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, and a process for handling, tracking, transporting, storing and disposing of medical marijuana waste in accordance with applicable laws, rules and regulations.
 - (4) Workplace safety, including conducting necessary safety checks prior to starting the growing and processing of seeds, immature medical marijuana plants, medical marijuana products.
 - (5) Contamination protocols.
 - (6) Maintenance, cleaning and sanitation of equipment in the facility or on-site, or both.
 - (7) Maintenance and sanitation of the site or the facility, or both.
 - (8) Proper handling and storage of any solvent, gas or other chemical used in growing or processing seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products in accordance with this part and other applicable laws, rules and regulations.
 - (9) Quality control, including regulation of the amount of THC in each process lot, proper labeling and minimization of contamination of medical marijuana or medical marijuana products.
 - (10) Inventory maintenance and reporting procedures.

- (11) The investigation of complaints and potential adverse events from other medical marijuana organizations, patients, caregivers or practitioners regarding the operation of the grower/processor.
- (12) A recall plan meeting the requirements of § 1151a.42(d) (relating to complaints about or recall of medical marijuana products).
- (b) A grower/processor shall make the full and complete plan of operation available to the Department upon request and during any inspection of a site or a facility, or both.
 - (c) A grower/processor shall comply with its plan of operation.

§ 1151a.23. Grower/processor facilities.

- (a) A grower/processor may only grow, store, harvest or process seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products in an indoor, enclosed, secure facility that has been inspected and deemed operational.
- (b) The following areas of a facility must be clearly marked with proper signage:
 - (1) Growing and processing areas. These areas shall be easily observed by the Department and its authorized agents and by law enforcement.
 - (2) Nongrowing and nonprocessing areas.
 - (3) Limited access areas. 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 Individuals.
 - (4) Areas that include business offices and reception rooms.
- (c) A facility must have an enclosed secure area out of public sight for the loading and unloading of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products into and from a transport vehicle.

Cross References

This section cited in 28 Pa. Code § 1141a.40 (relating to application for approval of a change in location of an operational facility).

§ 1151a.24. Growing and processing inventory.

(a) A grower/processor may obtain and transport 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; between December 1 and December 30 annually; or within any 30-day window established by the Department under the following process:

- (1) A grower/processor may make a written request to the Department to open an additional 30-day window for the importation of seeds and immature medical marijuana plants.
- (2) The written request must provide a justification for the importation of additional seeds or immature medical marijuana plants including, but not limited to, the need to refresh or improve genetics, patient demand, and the need to ensure ample supply of product.
- (3) The written request must state the starting and ending date being requested.
- (4) The request must be submitted at least 60 days in advance of the proposed start date.
- (5) The Department will provide written notice to the grower/processor, no later than 30 days prior to the proposed start date, approving or denying the request based on sufficiency of the justification presented.
- (b) A grower/processor may not obtain medical marijuana plants from outside of this Commonwealth at any time.
- (c) Within 24 hours of receipt, a grower/processor shall, record in the electronic tracking system each seed or immature medical marijuana plant that enters the site during a 30-day period under subsection (a).
- (d) Outside a 30-day period permitted under 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.
- (e) A grower/processor may obtain and transport bulk postharvest medical marijuana plant material from another grower/processor within this Commonwealth to process medical marijuana.
- (f) A grower/processor may obtain harvested hemp from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp under the 3 Pa.C.S. Chapter 15 (relating to controlled plants and noxious weeds) if the hemp received by a grower/processor is subject to the laboratory testing requirements of section 704 of the act (35 P.S. § 10231.704).
- (g) A grower/processor may add hemp or hemp-derived additives obtained or cultivated in accordance with subsection (f).

§ 1151a.25. Access to grower/processor facilities.

(a) A grower/processor facility may not be open to the general public. When an individual who is not approved to enter the facility requires access to the facility for purposes regarding the growing, processing or testing of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, or for potential investment or employment, a grower/processor shall require the individual to sign a log, detailing the need for

entry, and to wear a temporary identification badge that is visible to others at all times while onsite and in the facility.

- (b) A grower/processor shall require an individual to present government-issued identification that contains a photo to gain access to the site and facility.
- (c) No one under 18 years of age is permitted to enter a grower/processor site or facility.
- (d) A grower/processor shall post a sign in a conspicuous location at each entrance of a site and a facility that states:

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

- (e) A grower/processor shall do the following when admitting an individual to a site or facility:
 - (1) Require the individual to sign a log and detail the need for entry upon entering and to sign the log when leaving the facility.
 - (2) Check the individual's government-issued identification to verify that the name on the identification provided matches the name in the log. A photocopy of the identification must be retained with the log.
 - (3) Issue a temporary identification badge with the individual's name and company, if applicable, and a badge number.
 - (4) Escort the individual while the individual remains in the facility or onsite.
 - (5) Ensure that the individual does not touch seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products located in a limited access area.
 - (f) The following apply to the log required under subsections (a) and (e):
 - (1) The grower/processor shall maintain the log for 180 days, unless otherwise required for investigative or litigation purposes, either in paper or electronic form, 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 individual granted access to the facility, the temporary identification badge number, the date and time of arrival, the date and 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, State or local law enforcement or other Federal, State or local government officials, from entering any area of a grower/processor site or facility if necessary to perform the governmental officials' functions and duties that pertain to the act or this part.
- (h) A principal, financial backer, operator or employee of a grower/processor may not receive any type of consideration or compensation for allowing an individual to enter a limited access area.

§ 1151a.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 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 seeds, immature medical marijuana plants, medical marijuana products and safes; and the perimeter of the facility.
 - (ii) A silent security alarm system signal, known as a duress alarm, generated by the entry of a designated code into an arming station to signal that the alarm user is being forced to turn off the system.
 - (iii) An audible security alarm system signal, known as a panic alarm, generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring law enforcement response.
 - (iv) A silent alarm signal, known as a holdup alarm, generated by the manual activation of a device intended to signal a robbery in progress.
 - (v) An electrical, electronic, mechanical or other device capable of being programmed to send a prerecorded voice message requesting dispatch, when activated, over a telephone line, radio or other communication system to a law enforcement, public safety or emergency services agency.
 - (vi) A failure notification system that provides an audible, text or visual notification of any failure in the systems. The failure notification system must provide by telephone, e-mail or text message an alert to a designated security person within the facility within 5 minutes after the failure.
 - (vii) Smoke and fire alarms.
 - (viii) Auxiliary power sufficient to maintain operation of specified growing and processing areas identified in the grower/processor's plan of operation for no less than 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 continuously 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) All limited access areas.
- (B) A room or area containing a security and surveillance system storage device or equipment.
- (C) Entrances to and exits from a facility. Entrances and exits must be recorded from both indoor and outdoor vantage points.
- (D) Rooms with exterior windows, exterior walls, roof hatches, or skylights and storage rooms, including those that may contain seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, and safes.
 - (E) Twenty feet from the exterior of the perimeter of the facility.
- (ii) Auxiliary power sufficient to maintain operation for no less than 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 180 days, unless otherwise required for investigative or litigation purposes, in a format that may be easily accessed for investigative purposes. The recordings must be kept:
 - (i) At the facility:
 - (A) In a locked cabinet, closet or other secure place to protect it from tampering or theft.
 - (B) In a limited access area or other room to which access is limited to authorized individuals.
 - (ii) At a secure location other than the location of the facility if approved in writing by the Department.
- (5) A security alarm system separate from the facility's primary security system covering the limited access area or other room where the recordings under paragraph (4) are stored. The separate security alarm system must meet the same requirements as the facility's primary security alarm system.
- (b) The following requirements regarding the inspection, servicing or alteration of, and the upgrade to, the site's and facility's security and surveillance systems apply:
 - (1) The systems shall be inspected and all devices tested once every year by a qualified alarm system vendor and a qualified surveillance system vendor.
 - (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 4 years, in paper or electronic form, records of all inspections, servicing, alterations and upgrades performed on the systems and shall make the records available to the Department and its authorized agents within 2 business days following the Department's request or the request of the Department's authorized agents.
- (4) In the event of a mechanical malfunction of the security or surveillance system that a grower/processor anticipates will exceed an 8-hour period, the grower/processor shall notify the Department immediately and, with Department approval, provide alternative security measures that may include closure of the facility.
- (5) The grower/processor shall designate employees to continuously monitor the security and surveillance systems at the facility.
 - (6) The following apply regarding records retention:
 - (i) Within 2 business days following a request, a grower/processor shall provide up to four screen captures of an unaltered copy of a video surveillance recording to the Department or its authorized agents, law enforcement or other Federal, State or local government officials if necessary to perform the governmental officials' functions and duties.
 - (ii) If a grower/processor has been notified in writing by the Department or its authorized agents, law enforcement or other Federal, State or local government officials of a pending criminal or administrative investigation for which a recording may contain relevant information, the grower/processor shall retain an unaltered copy of the recording for 4 years or until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the grower/processor that it is not necessary to retain the recording, whichever is longer.
- (c) The grower/processor shall install commercial-grade, nonresidential steel doors and door locks on each room where seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are stored, and on each external door of the facility. Keys or key codes for all doors shall remain in the possession of designated authorized individuals.
- (d) At all times, all entrances to and exits from a site and a facility must be securely locked.
- (e) The grower/processor shall have an electronic back-up system for all electronic records.
- (f) The grower/processor shall install lighting to ensure proper surveillance inside and outside of a facility.
- (g) A grower/processor shall limit access to a room in a facility containing security and surveillance monitoring equipment to persons who are essential to maintaining security and surveillance operations; Federal, State and local law enforcement; security and surveillance system service employees; the Department or its authorized agents; and other persons with the prior written approval of the Department. The following requirements apply:

- (1) A grower/processor shall make available to the Department or the Department's authorized agents, upon request, a current list of authorized employees and service employees or contractors who have access to any security and surveillance areas.
- (2) A grower/processor facility shall keep security and surveillance rooms locked at all times and may not use these rooms for any other purpose or function.

This section cited in 28 Pa. Code § 1141a.40 (relating to application for approval of a change in location of an operational facility).

§ 1151a.27. Requirements for growing and processing medical marijuana.

- (a) A grower/processor may use a pesticide that is registered by the Department of Agriculture under the Pennsylvania Pesticide Control Act of 1973 (3 P.S. §§ 111.21—112), and designated by the Secretary of Agriculture in consultation with the secretary for use by a grower/processor. The following apply:
 - (1) The Secretary of Agriculture will publish the list of approved pesticides by notice in the *Pennsylvania Bulletin*.
 - (2) The list shall be posted on the Department's publicly accessible Internet web site and shall be reviewed and updated by the Secretary of Agriculture, in consultation with the secretary, at least once annually and transmitted to the Legislative Reference Bureau for publication in the *Pennsylvania Bulletin*.
- (b) A grower/processor shall use an approved pesticide 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.
- (f) A grower/processor may not use any added substance that alters the dosage level, color, appearance, smell, taste, effect or weight of the medical marijuana unless the grower/processor has first obtained the prior written approval of the Department. Excipients must be pharmaceutical grade, unless otherwise approved by the Department. In determining whether to approve an added substance, the Department will consider:

- (i) Whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under Federal guidelines.
- (ii) Whether the added substance constitutes a known hazard such as, but not limited to, diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6.
- (iii) Whether the added substance is permitted by the United States Food and Drug Administration for the applicable route of administration and dosage.
 - (iv) Whether the added substance has known drug interactions.
- (g) A grower/processor shall have a separate and secure area for temporary storage of seeds, immature medical marijuana plants, medical marijuana and medical marijuana products that are awaiting disposal by the grower/processor.
- (h) A grower/processor may 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) Do not contain a level of mold, rot or other fungus or bacterial diseases higher than the minimum levels contained in the standards for testing under § 1171a.30 (relating to standards for testing).
- (i) A grower/processor shall process the medical marijuana plants in a safe and sanitary manner. The following requirements apply:
 - (1) Medical marijuana plants, raw material and other product used in the processing of medical marijuana shall be handled on food-grade stainless steel benches or tables.
 - (2) Proper sanitation shall be maintained.
 - (3) Proper rodent, bird and pest exclusion practices shall be employed.
 - (i) A grower/processor shall install a system to monitor, record and regulate:
 - (1) Temperature.
 - (2) Humidity.
 - (3) Ventilation.
 - (4) Lighting.
 - (5) Water supply.

This section cited in 28 Pa. Code § 1151a.43 (relating to pesticides).

§ 1151a.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.

1151a-10

- (3) Topical forms, including gel, creams or ointments.
- (4) A form medically appropriate for administration by vaporization or nebulization, including dry leaf or plant form for administration by vaporization
 - (5) Tincture.
- (6) Liquid.
- (b) A grower/processor may not manufacture, produce or assemble any medical marijuana product, instrument or device without the prior written approval of the Department.

§ 1151a.29. Limit on medical marijuana processing.

- (a) In the form intended to be sold to another medical marijuana organization, medical marijuana or a medical marijuana product must have a specific concentration of total THC and total CBD and must have a consistent cannabinoid profile. The concentration of the following cannabinoids shall be reported to the Department by an approved laboratory and include the following on the label (CAS numbers need not be displayed on the label):
 - (1) THC.
 - (2) THCA, if greater than 0.0%.
 - (3) THCV, if greater than 0.0%.
 - (4) CBD.
 - (5) CBDA, if greater than 0.0%.
 - (6) CBDV, if greater than 0.0%.
 - (7) CBN, if greater than 0.0%.
 - (8) CBG, if greater than 0.0%.
 - (9) CBC, if greater than 0.0%.
 - (10) D8, if greater than 0.0%.
 - (11) Any other cannabinoid component at 0.1%.
- (b) Within the first 6 months after the Department determines the grower/processor to be operational, the grower/processor shall provide the Department with a forecast of the amount of medical marijuana products it projects it will produce and in what form. The grower/processor shall notify the Department in writing within 48 hours upon becoming aware of a potential increase or decrease in the forecasted amount occurring within any subsequent 6-month period.

Cross References

This section cited in 28 Pa. Code § 1151a.34 (relating to packaging and labeling of medical marijuana products); and 28 Pa. Code § 1161a.28 (relating to labels and safety inserts).

§ 1151a.30. Inventory data.

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

- (1) The number, weight and type of seeds.
- (2) The number of immature medical marijuana plants.
- (3) The number of medical marijuana plants.
- (4) The number of medical marijuana products ready for sale.
- (5) The number of damaged, defective, expired or contaminated seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana products awaiting disposal.
- (b) A grower/processor shall establish inventory controls and procedures to conduct inventory reviews and comprehensive inventories at its facility. The following requirements apply:
 - (1) Inventory reviews of medical marijuana plants in the process of growing, and medical marijuana and medical marijuana products that are being stored for future sale shall be conducted monthly.
 - (2) Comprehensive inventories of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products shall be conducted 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.

§ 1151a.31. Storage requirements.

- (a) A grower/processor shall ensure that a facility has separate and locked limited access areas for storage of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products that are expired, damaged, deteriorated, mislabeled, contaminated, recalled or whose containers or packaging have been opened or breached until the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are destroyed or otherwise disposed of as required under § 1151a.40 (relating to management and disposal of medical marijuana waste).
- (b) A grower/processor facility shall maintain all storage areas in a clean and orderly condition and free from infestation by insects, rodents, birds and pests.

§ 1151a.32. Equipment, operation and maintenance.

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

- (1) Annually, or more frequently if recommended by the manufacturer, 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.

§ 1151a.33. Sanitation and safety in a facility.

- (a) A grower/processor shall maintain a facility in a sanitary condition to limit the potential for contamination or adulteration of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products grown and processed in the facility and any medical marijuana product produced at a facility. The following requirements apply:
 - (1) Equipment and surfaces, including floors, counters, walls and ceilings, shall be cleaned and sanitized as frequently as necessary to protect against contamination, using a sanitizing agent registered by the United States Environmental Protection Agency, in accordance with the instructions printed on the label. Equipment and utensils shall be so designed and of such material and workmanship as to be capable of being adequately cleaned.
 - (2) Trash shall be properly removed.
 - (3) Floors, walls and ceilings shall be kept in good repair.
 - (4) Equipment, counters and surfaces for processing must be food grade quality and may not react adversely with any solvent being used.
 - (5) Adequate protection against pests shall be provided through the use of integrated pest management practices and techniques that identify and manage plant pathogens and pest problems, and the regular disposal of trash to prevent infestation.
 - (6) Toxic cleaning compounds, sanitizing agents, solvents used in the growing and processing of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, and pesticide chemicals must be labeled and stored in a manner that prevents contamination and that otherwise complies with other applicable laws and regulations.
- (b) An employee working in direct contact with medical marijuana is subject to the restrictions on food handlers in § 27.153 (relating to restrictions on food handlers). An employee shall otherwise conform to sanitary practices while on duty, including the following:
 - (1) Maintaining adequate personal hygiene.
 - (2) Wearing proper clothing, including gloves.

- (3) Washing hands thoroughly in an adequate hand-washing area before starting work and at any other time when hands may have become soiled or contaminated.
- (c) A grower/processor shall provide adequate and convenient hand-washing facilities furnished with running water at a temperature suitable for sanitizing hands. The following requirements apply:
 - (1) A grower/processor shall locate hand-washing facilities in processing areas and where good sanitary practices require employees to wash and sanitize their hands.
 - (2) A grower/processor shall provide effective nontoxic sanitizing cleansers and sanitary towel service or suitable drying devices.
- (d) A grower/processor shall provide adequate, readily accessible lavatories that are maintained in a sanitary condition and in good repair.
- (e) A grower/processor shall provide a facility with a water supply sufficient for the facility's operations, which shall be derived from a source that is a public water system, or a nonpublic system that is capable of providing a safe, potable and adequate supply of water to meet the operational needs of the facility.
- (f) A grower/processor shall comply with all other applicable State and local building code requirements.

This section cited in 28 Pa. Code § 1141a.40 (relating to application for approval of a change in location of an operational facility).

§ 1151a.34. Packaging and labeling of medical marijuana products.

- (a) A grower/processor shall package and label at its facility each form of medical marijuana products prepared for sale. The original seal of a package may not be broken, except for quality control testing at an approved laboratory, for adverse loss investigations conducted by the Department or by a dispensary that purchased the medical marijuana products.
- (b) A grower/processor shall package the medical marijuana products in a package that minimizes exposure to oxygen and that:
 - (1) Is child-resistant.
 - (2) Is tamper-proof or tamper-evident.
 - (3) Is opaque. This requirement does not apply to packages containing dry leaf.
 - (4) Is resealable.
 - (5) Clearly distinguishes the contents of the package from the contents of any other package of similar appearance.
 - (6) Lists all product ingredients and includes a warning for known allergens, such as tree nuts.
- (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 all packaging and the content of any label to be affixed to a medical marijuana product package. Each label must meet all of the following requirements:
 - (1) Be easily readable.
 - (2) Be made of weather-resistant and tamper-resistant materials.
 - (3) Be conspicuously placed on the package.
 - (4) Include the name, address and permit number of the grower/processor.
 - (5) List the form, quantity and weight of medical marijuana included in the package.
 - (6) List the number of individual doses contained within the package, the species and percentage of THC and CBD and other cannabinoids as enumerated in § 1151a.29 (relating to limit on medical marijuana processing), and the individual terpenes and corresponding percentages, if greater than 0.0%. CAS numbers need not be displayed on the label.
 - (7) Contain an identifier that is unique to a particular harvest batch of medical marijuana, including the number assigned to each harvest lot or process lot in the harvest batch.
 - (8) Include the date the medical marijuana product was packaged.
 - (9) State the employee identification number of the employee preparing the package and packaging the medical marijuana product.
 - (10) State the employee identification number of the employee shipping the package, if different than the employee described in paragraph (9).
 - (11) Contain the name and address of the dispensary to which the package is to be sold, except where a clinical registrant sells medical marijuana products to another grower processor and the intended dispensary is not known. In this case, the grower processor selling to a dispensary is required to affix a label bearing the dispensary name and address to the outer packaging, notwith-standing paragraph (17).
 - (12) List the date of expiration of the medical marijuana product.
 - (13) Include instructions for proper storage of the medical marijuana product in the package.
 - (14) Contain the following warning stating: This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician. This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children.
 - (15) Contain a warning that the medical marijuana product must be kept in the original container in which it was dispensed.
 - (16) Contain a warning that unauthorized use is unlawful and will subject the purchaser to criminal penalties.

- (17) Be firmly affixed to the container directly holding medical marijuana product, except when the product is being used for a blinded research program, and be firmly affixed to outer packaging if used.
- (18) List THC as the first number when THC and CBD are listed on a label as a ratio.
- (e) Labeling by a grower/processor of any medical marijuana product may not bear:
 - (1) A resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available food or beverage product.
 - (2) A statement, artwork or design that could reasonably lead an individual to believe that the package contains anything other than medical marijuana.
 - (3) A 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) A cartoon, color scheme, image, graphic or feature that might make the package attractive to children.

This section cited in 28 Pa. Code § 1151a.36 (relating to transport manifest); and 28 Pa. Code § 1161a.36 (relating to transport manifest).

§ 1151a.35. Transportation of medical marijuana.

- (a) A grower/processor may transport and deliver seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, and medical marijuana products to a medical marijuana organization or an approved laboratory in this Commonwealth in accordance with this section. All of the following requirements apply:
 - (1) Unless otherwise approved by the Department, a grower/processor may deliver seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, and medical marijuana products to a grower/processor, dispensary, or an approved laboratory only between 7 a.m. and 9 p.m.
 - (2) A grower/processor may contract with a third-party contractor for delivery so long as the contractor complies with this section.
 - (3) A grower/processor may not transport seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, postharvest plant material or medical marijuana products to any location outside of this Commonwealth.
 - (4) A grower/processor shall use a global positioning system to ensure safe, efficient delivery of the seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, and medical marijuana products to a medical marijuana organization or an approved laboratory.

- (5) A grower/processor shall obtain and transport postharvest plant material only from another grower/processor within this Commonwealth to process medical marijuana.
- (b) Vehicles permitted to transport seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products must:
 - (1) Be equipped with a secure lockbox or locking cargo area.
 - (2) Have no markings that would either identify or indicate that the vehicle is being used to transport seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products.
 - (3) Be capable of being temperature-controlled for perishable seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, and medical marijuana products, as appropriate.
 - (4) Maintain current State inspection and vehicle registrations.
 - (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 two or more individuals and comply with all of the following:
 - (1) One delivery team member shall remain with the vehicle at all times that the vehicle contains seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products.
 - (2) Each delivery team member shall have access to a secure form of communication with the grower/processor, such as a cellular telephone, at all times that the vehicle contains seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products.
 - (3) Each delivery team member shall carry an identification badge or card at all times and shall, upon demand, produce it to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.
 - (4) Each delivery team member shall have a valid driver's license.
 - (5) While on duty, a delivery team member may not wear any clothing or symbols that may indicate ownership or possession of seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products.
- (d) Seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, and medical marijuana products stored inside the transport vehicle must be placed inside a secure lockbox or locking cargo area and may not be visible from the outside of the transport vehicle.
- (e) Except as provided in subsection (h), a delivery team shall proceed in a transport vehicle from a grower/processor facility, where the seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products are loaded, directly to a medical marijuana organization facility or approved laboratory, where the seeds, immature medical mari-

juana plants, medical marijuana plants, postharvest plant material and medical marijuana products are unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple medical marijuana organization facilities or approved laboratories, as appropriate, to deliver seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products.

- (f) A grower/processor shall immediately report to the Department, either through a designated phone line established by the Department or by electronic communication with the Department, vehicle accidents, diversions, losses or other reportable events that occur during transport of seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products.
- (g) A grower/processor shall notify the Department daily of its delivery schedule, including routes and delivery times, either through a designated phone line established by the Department or by electronic communication with the Department.
- (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.

Cross References

This section cited in 28 Pa. Code § 1151a.37 (relating to transportation of seeds, immature medical marijuana plants, medical marijuana plants and postharvest plant material); and 28 Pa. Code § 1171a.33 (relating to transporting samples).

§ 1151a.36. Transport manifest.

- (a) A grower/processor shall generate a printed or electronic transport manifest that accompanies every transport vehicle and contains all of the following information:
 - (1) The name, address and permit number of the grower/processor and the name of and contact information for a representative of the grower/processor who has direct knowledge of the transport.
 - (2) The name, address and permit number of the medical marijuana organization facility or approved laboratory receiving the delivery and the name of and contact information for a representative of the medical marijuana organization facility or approved laboratory.
 - (3) The quantity, by weight or unit, of each seed, immature medical marijuana plant, medical marijuana plant, medical marijuana harvest batch, harvest lot or process lot, postharvest plant material and medical marijuana product contained in the transport, along with the identification number for each batch or lot.

- (4) The date and approximate time of departure.
- (5) The date and approximate time of arrival.
- (6) The transport vehicle's make and model and license plate number.
- (7) The identification number of each member of the delivery team accompanying the transport.
- (b) When a delivery team delivers seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products to multiple medical marijuana organizations or approved laboratories, the transport manifest must correctly reflect the specific seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products in transit. Each recipient shall provide the grower/ processor with a printed receipt for the seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products received.
- (c) All seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products being transported shall be packaged in shipping containers and labeled in accordance with § 1151a.34 (relating to packaging and labeling of medical marijuana products).
- (d) A grower/processor shall provide a copy of the transport manifest to the recipient receiving the seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products described in the transport manifest. To maintain confidentiality, a grower/processor may prepare separate manifests for each recipient.
- (e) A grower/processor shall, if requested, provide a copy of the printed transport manifest, and any printed receipts for seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material and medical marijuana products being transported, to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

This section cited in 28 Pa. Code § 1151a.37 (relating to transportation of seeds, immature medical marijuana plants, medical marijuana plants and postharvest plant material); and 28 Pa. Code § 1171a.33 (relating to transporting samples).

§ 1151a.37. Transportation of seeds, immature medical marijuana plants, medical marijuana plants and postharvest plant material.

- (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 shall obtain and transport postharvest plant material only from another grower/processor within this Commonwealth to process medical marijuana.

- (c) A grower/processor may not transport seeds, immature medical marijuana plants, medical marijuana plants or postharvest plant material to a location outside of this Commonwealth.
- (d) A grower/processor's authorization to transport seeds, immature medical marijuana plants, medical marijuana plants or postharvest plant material shall be subject to §§ 1151a.35, 1151a.36 and 1151a.38 (relating to transportation of medical marijuana; transport manifest; and evidence of adverse loss during transport).

§ 1151a.38. Evidence of adverse loss during transport.

- (a) If a grower/processor receiving a delivery of seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material or medical marijuana products from a medical marijuana organization discovers a discrepancy in the transport manifest that remains unresolved 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, and to the appropriate law enforcement authorities.
- (b) If a grower/processor discovers evidence of, or reasonably suspects, a theft or diversion of seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material 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, 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. All of the following requirements apply:
 - (i) The grower/processor shall submit a written preliminary report of the investigation to the Department within 7 days of discovering the discrepancy.
 - (ii) The grower/processor shall submit a final written report of the investigation to the Department within 30 days of discovering the discrepancy.

This section cited in 28 Pa. Code § 1151a.37 (relating to transportation of seeds, immature medical marijuana plants, medical marijuana plants and postharvest plant material).

§ 1151a.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 electronic tracking system prescribed by the Department shall allow for two-way communication, automation and secure application-programming interface with a medical marijuana organization's enterprise resource planning, inventory, accounting and point-of-sale software. The electronic tracking system prescribed by the Department shall include a secure application program interface capable of accessing all data required to be transmitted to the Department to ensure compliance with the operational reporting requirements of the act and these regulations.

§ 1151a.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) 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. §§ 6921—6939g), the Solid Waste Management Act (35 P.S. §§ 6018.101—6018.1003) and regulations promulgated thereunder.
- (g) The type of medical marijuana waste identified in subsection (b)(2) may be composted and beneficially used at the grower/processor facility through a permit-by-rule provided the requirements of 25 Pa. Code § 271.103(d)(1)—(3) and (5) (relating to permit-by-rule for municipal waste processing facilities other than for regulated medical or chemotherapeutic waste; qualifying facilities; general requirements) are satisfied, and the compost is beneficially used at the grower/processor facility as a soil substitute, soil conditioner, soil amendment, fertilizer or mulch. The notice required under 25 Pa. Code § 271.103(d)(5) shall be submitted to the Solid Waste Manager of the Department of Environmental Protection's regional office having jurisdiction over the grower/processor facility within 15 days of initiating the composting activity.

This section cited in 28 Pa. Code § 1141a.37 (relating to denial of renewal of a permit); 28 Pa. Code § 1141a.43 (relating to closure of a facility); 28 Pa. Code § 1151a.31 (relating to storage requirements); 28 Pa. Code § 1161a.33 (relating to storage requirements); 28 Pa. Code § 1171a.29 (relating to testing requirements); and 28 Pa. Code § 1171a.31 (relating to test results and reporting).

§ 1151a.42. Complaints about or recall of medical marijuana products.

(a) A dispensary shall notify the Department and the grower/processor from which it obtained the medical marijuana product in question immediately upon becoming aware of any complaint made to the dispensary by a patient, caregiver or practitioner who reports an adverse event from using medical marijuana prod-

ucts purchased by the dispensary from the grower/processor. A grower/processor shall investigate the report. The following requirements apply:

- (1) A grower/processor shall immediately investigate a complaint to determine if a voluntary or mandatory recall of seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products is necessary or if any further action is required.
- (2) If a grower/processor determines that further action is not required, the grower/processor shall notify the Department of its decision and, within 24 hours, submit a written report to the Department stating its rationale for not taking further action.
- (b) The following requirements apply to voluntary recalls:
- (1) A grower/processor may voluntarily recall seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products from the market at its discretion for reasons that do not pose a risk to public health and safety.
- (2) If a grower/processor initiates a recall for a reason that does not pose a risk to public health and safety, the grower/processor shall notify the Department at the time the grower/processor begins the recall.
- (c) The following requirements apply to mandatory recalls:
- (1) If a grower/processor discovers that a condition relating to the seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products grown or processed at its facility poses a risk to public health and safety, the grower/processor shall:
 - (i) Immediately notify the Department by phone.
 - (ii) Secure, isolate and prevent the distribution of the seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products that may have been affected by the condition and remains in its possession. The grower/processor may not dispose of affected seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products prior to notifying the Department and coordinating the disposal with the Department.
- (2) If a grower/processor fails to cooperate with the Department in a recall, or fails to immediately notify the Department of a need for a recall under paragraph (1), the Department may seek a cease and desist order under § 1141a.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, accept-

ing the recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products.

- (2) Procedures for identifying and isolating the affected seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products to prevent or minimize its distribution to patients, caregivers and other medical marijuana organizations and approved laboratories.
- (3) Procedures to retrieve and dispose of the affected seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products.
 - (4) A communications plan to notify those affected by the recall, including:
 - (i) The manner in which the grower/processor will notify other medical marijuana organizations or approved laboratories in possession of seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products subject to the recall.
 - (ii) The use of press releases and other appropriate notifications to ensure that patients and caregivers are notified of the recall if affected medical marijuana products were dispensed to patients and caregivers.
 - (5) Procedures for notifying the Department.
- (6) Procedures for entering information relating to the recall into the grower/processor's electronic tracking system.
- (e) A grower/processor shall follow the procedures outlined in its recall plan, unless the grower/processor obtains the prior written approval of the Department. The grower/processor shall conduct recall procedures in a manner that maximizes the recall of affected seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products and minimizes risks to public health and safety.
- (f) A grower/processor shall coordinate the disposal of recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products with the Department. The Department or its authorized agents may oversee the disposal to ensure that the recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products are disposed of in a manner that will not pose a risk to public health and safety.
- (g) The grower/processor shall enter information relevant to the recall into the electronic tracking system as part of the daily inventory, including all of the following:
 - (1) The total amount of recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products, including types, forms, harvest batches, harvest lots and process lots, if applicable.

- (2) The amount of recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products received by the grower/processor, including types, forms, harvest batches, harvest lots and process lots, if applicable, by date and time.
- (3) The total amount of recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products returned to the grower/processor, including types, forms, harvest batches, harvest lots and process lots, if applicable.
 - (4) The names of the recall coordinators.
- (5) From whom the recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products were received.
- (6) The means of transport of the recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products.
 - (7) The reason for the recall.
- (8) The number of recalled samples or test samples, types, forms, harvest batches, harvest lots and process lots, if applicable, sent to approved laboratories, the names and addresses of the approved laboratories, the dates of testing and the results by sample or test sample.
- (9) The manner of disposal of the recalled seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products, including all of the following:
 - (i) The name of the individual overseeing the disposal of the recalled seeds, immature medical marijuana plants, medical marijuana plants, post-harvest plant material, medical marijuana or medical marijuana products.
 - (ii) The name of the disposal company, if applicable.
 - (iii) The method of disposal.
 - (iv) The date of disposal.
 - (v) The amount disposed of by types, forms, harvest batches, harvest lots and process lots, if applicable.
- (h) The Department may initiate a mandatory recall upon receipt of information that a condition relating to the seeds, immature medical marijuana plants, medical marijuana plants, postharvest plant material, medical marijuana or medical marijuana products grown, processed or dispensed by a medical marijuana organization poses a risk to public health and safety.

This section cited in 28 Pa. Code § 1151a.22 (relating to plans of operation).

§ 1151a.43. Pesticides.

- (a) The use of a pesticide by a grower/processor in the growing or processing of seeds, immature medical marijuana plants, postharvest plant material, medical marijuana plants or medical marijuana shall be in accordance with the Pennsylvania Pesticide Control Act of 1973 (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. § 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 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 of Agriculture, in coordination with the Department, in enforcing this section.
- (e) A grower/processor shall only use the pesticide active ingredients approved under § 1151a.27 (relating to requirements for growing and processing

medical marijuana) in the growing and processing of seeds, immature medical marijuana plants, postharvest plant material, medical marijuana plants or medical marijuana.

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

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

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

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

Plant regulator—

- (i) A substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but may not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants and soil amendments.
- (ii) The term does not include any of the nutrient mixtures or soil amendments commonly known as vitamin-hormone horticultural products, which are intended for improvement, maintenance, survival, health and propagation of plants, and are not for pest destruction and are nontoxic, non-poisonous in the undiluted packaged concentration.

§ 1151a.44. Treatment and quarantine orders.

- (a) If a grower/processor fails or refuses to eradicate a plant pest that is found at its facility, the Department, in cooperation with the Department of Agriculture, may issue and enforce a treatment order against the grower/processor, including an order to eradicate, for any immature medical marijuana plants or medical marijuana plants that may carry or harbor the plant pest. The order will be issued in writing and set forth the necessary treatment, control or eradication measures required. If the grower/processor fails or refuses to comply with the order, the Department, acting in cooperation with the Department of Agriculture, may carry out the control measures established in the treatment order with all expenses associated with the measures accruing to the grower/processor.
- (b) The Department of Agriculture, acting with the cooperation of the Department, may establish a quarantine to prevent the dissemination of plant pests within this Commonwealth or to prevent or delay the introduction of a plant pest into this Commonwealth from any country, state or territory. The following requirements apply:
 - (1) Upon finding a plant pest in a facility that has the potential to cause serious damage to other growers/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.