

Grower/Processor Operational Checklist

Office of Medical Marijuana Grower/Processor Operational Checklist August 7, 2017

Grower/Processor	Primary Contact and Address	Municipality

Welcome to the Medical Marijuana Program managed by the Office of Medical Marijuana in the Department of Health.

This grower/processor implementation checklist is intended to assist the grower/processor permittee in becoming operational within the 6-month period required under the temporary regulations. It also contains information on areas that the Office of Medical Marijuana will continue to monitor solely for regulatory compliance as the grower/processor grows, harvests, tests, processes, produces and sells medical marijuana products to dispensaries in the commonwealth.

For additional information or questions concerning this checklist or the 6-month operational period, please contact:

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NOTE: This document establishes the general framework within which the Office of Medical Marijuana (Office) will make its determination as to the operational status of a grower/processor within the 6-month time period required for the grower/processor to be operational. The Office reserves the right to make additions or revisions to this document throughout the 6-month period to be operational. The Office also reserves the right to pursue any and all administrative actions to enforce the Medical Marijuana Act and its temporary regulations. This document does not provide or replace written approval by the Office regarding the grower/processor's specific conditions, conduct, and security features. The Office expressly reserves the discretion to deviate from this document to the extent allowed by law, and if circumstances warrant a deviation.

Grower/Processor Operational Checklist

Failure to be Operational.				
Generally: A grower/processor must be determined by the Department to be operational within 6-months from the date a permit is issued.				
Operational Requirement Regulations: 28 Pa. Code § 1141.42	Timeline	Grower/Processor Completed	Department Notified	Department Approval
No more than 6 months from the date of issuance of a permit, a grower/processor shall notify the Department, on a form prescribed by the Department, that it is operational.				
After the Department receives the notification, the Department will inspect the facility to determine if the grower/processor is operational to the satisfaction of the Department.				
If the grower/processor has not met the operational timetable in the initial permit application to the satisfaction of the Department at the time of the inspection, the Department will notify the grower/processor of the deficiencies. Within 30 days of receiving the Department's notice, the grower/processor shall submit to the Department for approval a plan of correction that sets forth the grower/processor's timeline and a date certain, which may not extend beyond 90 days following the date the Department approves the plan of correction, for correcting the deficiencies.				
If the grower/processor does not comply with its plan of correction as approved by the Department within 90 days following the Department's approval, the Department may revoke or suspend the grower/processor's permit under § 1141.47 (relating to general penalties and sanctions).				

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The Grower/Processor Permit.				
Generally: The qualifications that a grower/processor shall meet to receive a permit are continuing qualifications to maintain the permit.				
Operational Requirements Regulations: 28 Pa. Code § 1141.25; § 1141.26; § 1151.21	Timetable	Grower/Processor Completed	Department Notified	Department Approval
The issuance or renewal of a permit to a grower/processor is a revocable privilege.				
A grower/processor may not engage in the business of growing, processing, possessing, selling or offering to sell medical marijuana without first being issued a permit by the Department.				
A permit is valid only for the person named in the permit and only for the location specified in the permit.				
A permit is not transferable to any other person or any other location.				
A permit will specify that the permittee is authorized to begin the process necessary to become operational.				
A grower/processor may not engage in the business of growing, processing, possessing, selling or offering to sell medical marijuana without first being determined operational by the Department.				
The grower/processor shall conspicuously post its permit in a location within its facility that is visible to the Department or its authorized agents and law enforcement.				
A permit is valid for 1 year from the date of issuance.				

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Duty to Report.				
Generally: At any time during the permit period, a permittee shall notify the Department in writing of any change in facts or circumstances or any newly discovered or occurring fact or circumstance reflected in the initial permit application submitted to the Department.				
Operational Requirements Regulations: 28 Pa. Code § 1141.38	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall discuss with the Department any change in facts or circumstances or newly discovered or occurring facts or circumstances which would have been included in the application if known at the time the application was submitted.				
The grower/processor shall submit in writing any change in facts or circumstances or a newly discovered or occurring fact or circumstance of financial backers, principals, operators and employees listed in the initial application or added since the issuance of the permit.				
The grower/processor shall submit in writing any change in facts or circumstances or a newly discovered or occurring fact or circumstance contained in the operational timetable listed in the initial application or added since the issuance of the permit.				
The grower/processor shall submit in writing any change in facts or circumstances or a newly discovered or occurring fact or circumstance contained in the community impact statement provided in the initial application or added since the issuance of the permit.				
The grower/processor shall notify the Department in writing of any proposed modification of its plan of operation at least 30 days prior to the proposed modification.				

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Background Checks.

Generally: A grower/processor shall submit fingerprints of its principals, financial backers, operators and employees to the Pennsylvania State Police. The Pennsylvania State Police or its authorized agent shall submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the individuals whose fingerprints have been submitted and obtaining a current record of criminal arrests and convictions.

Operational Requirements Regulation: 28 Pa. Code § 1141.31	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor has discussed with the Department the use of criminal history background check information to determine the character, fitness and suitability to serve in the designated capacity of the financial backer, principal, operator and employee.				
The grower/processor has discussed with the Department that a financial backer, principal or employee may not hold a volunteer position, position for remuneration or otherwise be affiliated with a grower/processor or a clinical registrant if the individual has been convicted of a criminal offense relating to the sale or possession of illegal drugs, narcotics or controlled substances.				
The grower/processor has identified any financial backers, principals or operators that are owners of securities in a publicly traded company, and the Department has determined that the identified individual is not substantially involved in the activities of the grower/processor.				

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Electronic Tracking System.

Generally - A grower/processor shall use the electronic tracking system prescribed by the Department as published in the *Pennsylvania Bulletin*.

Operational Requirements Regulations: 28 Pa. Code § 1151.39	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor has begun training with MJ Freeway at least 60 days prior to the implementation date of the system.				
The grower/processor has completed staff identification measures with MJ Freeway.				
The grower/processor has fully implemented the required electronic tracking system.				

Administrative and Agency Compliance.

Generally - The grower/processor will contact other commonwealth agencies to discuss additional approvals, authorizations, or permits that are required.

Operational Requirements Regulations: 28 Pa. Code § 1141.27; § 1141.44§ 1151.40; § 1151.43	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall contact the Department of Revenue to discuss tax clearance and remittance issues.				
The grower/processor shall contact the Department of Labor and Industry to discuss workers' compensation issues.				
The grower/processor shall contact the Department of Environmental Protection to discuss management and disposal of medical marijuana waste.				
The grower/processor shall contact the Department of Transportation to discuss transportation issues.				
The grower/processor shall contact the Department of Agriculture to discuss pesticide issues.				

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The Grower/Processor Facility.				
Generally: A grower/processor may only grow, store, harvest or process medical marijuana in an indoor, enclosed, secure facility as approved by the Department.				
Operational Requirements Regulations: 28 Pa. Code § 1141.25; § 1151.23	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall post its permit in a location where it can be seen by visitors permitted to be in the facility.				
All signage shall be easily observed by the Department and its authorized agents and by law enforcement.				
The grower/processor shall clearly mark with proper signage all medical marijuana growing and processing areas.				
The grower/processor shall clearly mark with proper signage all non-growing and non-processing areas.				
The grower/processor shall clearly mark with proper signage all areas that include business offices and reception rooms.				
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.”				
The grower/processor shall have an enclosed secure area out of public sight for the loading and unloading of medical marijuana into and from a transport vehicle.				

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The Grower/Processor Facility (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.25; § 1151.33	Timeline	Grower/Processor Completed	Department Notified	Department Approval
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.				
The 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.				

Inspection and Investigation.				
Generally: The Department may conduct announced or unannounced inspections or investigations to determine the grower/processor's compliance with its permit, the Medical Marijuana Act or the temporary regulations.				
Operational Requirements Regulations: 28 Pa. Code § 1141.45	Timeline	Grower/Processor Completed	Department Notified	Department Approval
An investigation or inspection may include inspection of a grower/processor's site, facility, vehicles, books, records, papers, documents, data, and other physical or electronic information.				
An investigation or inspection may include inspection of a grower/processor facility's equipment, instruments, tools and machinery that are used to grow, process and package medical marijuana, including containers and labels.				
The grower/processor acknowledges that an investigation or inspection may include questioning of employees, principals, operators and financial backers.				

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Advertising by a Grower/Processor.				
Generally: A Grower/Processor shall be consistent with the Federal regulations governing prescription drug advertising and marketing in 21 CFR 202.1 (relating to prescription-drug advertisements).				
Operational Requirements Regulations: 28 Pa. Code § 1141.50	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor has submitted promotional, advertising and marketing materials to the Department for approval and prior to their use.				
The grower/processor understands that this part does not apply to information provided by a grower/processor to a dispensary listing various medical marijuana items that the grower/processor is offering for sale to the dispensary.				

Insurance Requirements.				
Generally: A grower/processor shall obtain and maintain an appropriate amount of insurance coverage that insures the site and facility and equipment used in the operation of the facility.				
Operational Requirements Regulations: 28 Pa. Code § 1141.44	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall maintain an adequate amount of comprehensive liability insurance covering the grower/processor's activities authorized by the permit that shall begin on the date the initial permit is issued by the Department and continuing for as long as the grower/processor is operating under the permit.				
The grower/processor shall obtain and maintain workers' compensation insurance coverage for employees at the time the grower/processor is determined to be operational by the Department.				
The grower/processor shall obtain and maintain workers' compensation insurance coverage for employees at the time the medical marijuana organization is determined to be operational by the Department.				

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Plans of Operation.				
Generally – The grower/processor shall maintain a standard plan of operation that describes the 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.				
Operational Requirements Regulations: 28 Pa. Code § 1151.22	Timeline	Grower/Processor Completed	Department Notified	Department Approval
At the time the Department determines the grower/processor to be operational, the grower/processor shall provide the Department with a full and complete plan of operation for review.				
A grower/processor shall make the full and complete plan of operation available to the Department upon request and during any inspection.				

Employment Policies and Procedures.				
Generally – The grower/processor will include age limitations as part of its hiring procedures and standard operating procedures.				
Operational Requirements Regulations: § 1141.32; § 1151.21; § 1151.33	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor as part of its hiring practices agrees not to employ an individual at its facility who is under 18 years of age.				
An employee working in direct contact with medical marijuana is subject to the restrictions on food handlers in 28 Pa. Code § 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.				

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Workplace Safety, Personal Security and Training				
Generally - Certain individuals employed by the grower/processor shall complete a 2-hour training course developed by the Department within the specified times. The 2-hour training course will be available at no cost on the Department's website.				
Operational Requirements Regulations: 28 Pa. Code § 1141.48; § 1151.22	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall develop and implement workplace safety protocols, including conducting necessary safety checks, prior to starting the growing and processing of medical marijuana.				
Each principal shall complete the 2-hour training course prior to starting initial operation of a facility.				
Each employee who has direct contact with patients or caregivers or who physically handles medical marijuana shall complete the 2-hour training course within 90 days after starting work at the facility.				

Equipment, Operation and Maintenance.				
Generally: A grower/processor 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.				
Operational Requirements Regulations: 28 Pa. Code § 1151.22; § 1151.32	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall provide a copy of the written process under this section to the Department upon request.				
The written process shall have a schedule for the routine inspection and calibration for automatic, mechanical or electronic equipment.				
The written process shall follow the schedule for the routine inspection and calibration for scales, balances or other measurement devices provided by MJ Freeway in the grower/processor's operations.				
The grower/processor shall maintain an accurate log recording the maintenance, cleaning and calibration of equipment.				

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Security and Surveillance.				
Generally - 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.				
Operational Requirements Regulations: 28 Pa. Code § 1151.26	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The security and surveillance systems must be a professionally-monitored security alarm system that includes the following:				
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.				
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.				
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.				
A silent alarm signal, known as a holdup alarm, generated by the manual activation of a device intended to signal a robbery in progress.				
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.				
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.				

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Security and Surveillance (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.26	Timeline	Grower/Processor Completed	Department Notified	Department Approval
Smoke and fire alarms.				
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.				
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.				
Motion detectors.				
The grower/processor must have 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 a fixed camera placement that allows for a clear image of all individuals and activities in and around the following locations:				
All limited access areas.				
A room or area containing a security and surveillance system storage device or equipment.				
Entrances to and exits from the facility. Entrances and exits must be recorded from both indoor and outdoor vantage points.				
Rooms with exterior windows, exterior walls, roof hatches, or skylights and storage rooms, including those that may contain medical marijuana and safes.				
Twenty feet from the exterior of the perimeter of the facility.				

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Security and Surveillance (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.26	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The security and surveillance system must include auxiliary power sufficient to maintain operation for at least 48 hours following a power outage.				
The security and surveillance system must have the ability to operate under the normal lighting conditions of each area under surveillance.				
The security and surveillance system must have the ability to immediately produce a clear, color, still photograph in a digital format that meets the requirements of this section.				
The security and surveillance system must have 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.				
The security and surveillance system must have the 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 at the facility in a locked cabinet, closet or other secure place to protect it from tampering or theft within a limited access area or other room to which access is limited to authorized individuals.				
The grower/processor may request approval from the Department to maintain the recordings at a secure location other than the location of the facility.				

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Security and Surveillance (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.26	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor must maintain a security alarm system separate from the facility's primary security system covering the limited access area or other room where the recordings are stored. The separate security alarm system must meet the same requirements as the facility's primary security alarm system.				
A security and surveillance system 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.				
The grower/processor shall conduct monthly maintenance inspections to ensure that any repairs, alterations or upgrades to the security and surveillance systems are made for the proper operation of the systems.				
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.				
The grower/processor shall immediately notify the Department in the event of a mechanical malfunction of the security or surveillance system that is anticipated to exceed an 8-hour period in order to seek approval to implement alternative security measures that may include closure of the facility.				
The grower/processor shall designate an employee to continuously monitor the security and surveillance systems at the facility.				

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Security and Surveillance (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.26	Timeline	Grower/Processor Completed	Department Notified	Department Approval
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.				
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.				
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.				
During all nonworking hours, all entrances to and exits from the site and facility must be securely locked.				
The grower/processor shall have an electronic back-up system for all electronic records.				
The grower/processor shall install lighting to ensure proper surveillance inside and outside of the facility.				

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Security and Surveillance (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.26	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The 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 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.				
The grower/processor shall keep security and surveillance rooms locked at all times and may not use these rooms for any other purpose or function.				

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Storage Requirements.				
Generally: A grower/processor shall have procedures for the proper storage of medical marijuana in each designated area of the facility				
Operational requirement Regulations: 28 Pa. Code § 1151.31	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall develop a process to check and maintain storage containers in a condition that prevents contamination.				
A grower/processor shall maintain all storage areas in a clean and orderly condition and free from infestation by insects, rodents, birds and pests.				
The 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).				

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Sanitation and Safety in a Facility.				
Generally: 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.				
Operational Requirements Regulations: 28 Pa. Code § 1151.33	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall clean and sanitize equipment and surfaces, including floors, counters, walls and ceilings, 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.				
Trash shall be properly removed from the site to prevent infestation.				
All floors, walls and ceilings in the facility shall be kept in good repair.				
Equipment, counters and surfaces for processing must be food grade quality and may not react adversely with any solvent being used.				
The grower/processor shall provide adequate protection against pests through the use of integrated pest management practices and techniques that identify and manage plant pathogens and pest problems.				

Grower/Processor Operational Checklist

Sanitation and Safety in a Facility (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.33	Timeline	Grower/Processor Completed	Department Notified	Department Approval
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.				
The 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.				
Hand-washing facilities must be located in processing areas and where good sanitary practices require employees to wash and sanitize their hands.				
Hand-washing facilities must provide effective nontoxic sanitizing cleansers and sanitary towel service or suitable drying devices.				
The grower/processor shall provide its employees and visitors with adequate, readily accessible lavatories that are maintained in a sanitary condition and in good repair.				
The grower/processor shall comply with all other applicable State and local building code requirements when dealing with sanitation.				
The 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.				

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Visitor Access.				
Generally: A grower/processor facility may not be open to the general public.				
Operational Requirements Regulations: 28 Pa. Code § 1151.22; § 1151.25	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall require the following when admitting a visitor to its site and facility:				
Request from the visitor a government-issued identification that contains a photo.				
Require the visitor to sign a visitor log upon entering and leaving the facility.				
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.				
Issue a visitor identification badge with the visitor's name and company, if applicable, and a badge number.				
Escort the visitor while the visitor remains in the facility or on the site.				

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Visitor Access (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.22; § 1151.25	Timeline	Grower/Processor Completed	Department Notified	Department Approval
Ensure that the visitor does not touch any medical marijuana plant or medical marijuana located in a limited access area.				
The visitor 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.				
The grower/processor shall maintain the visitor 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.				
The grower/processor shall not allow a principal, financial backer, operator or an employee to receive any type of consideration or compensation for allowing a visitor to enter a limited access area.				

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Requirements for Growing and Processing.				
Generally: A grower/processor shall maintain an up-to-date growing and processing plan that will be available to the Department upon request.				
Operational Requirements Regulations: 28 Pa. Code § 1151.27	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The 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 <i>Pennsylvania Bulletin</i> updating the list of pesticides, fungicides or herbicides.				
The 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.				
The grower/processor shall maintain a log of all actions taken to detect pests or pathogens, and the measures taken for control.				
The grower/processor shall use appropriate nutrient practices.				
The grower/processor shall use a fertilizer or hydroponic solution of a type, formulation and at a rate to support healthy growth of plants.				
The grower/processor shall maintain records of the type and amounts of fertilizer and any growth additives used.				

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Requirements for Growing and Processing (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.27	Timeline	Grower/Processor completed	Department Notified	Department Approval
The 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.				
The 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.				
The grower/processor shall have a separate and secure area for temporary storage of medical marijuana that is awaiting disposal by the grower/processor.				
The grower/processor shall only process the parts of the medical marijuana plant that are free of seeds and stems, dirt, sand, debris and other foreign matter.				
The grower/processor shall only process the parts of the medical marijuana plant that do not contain a level of mold, rot or other fungus or bacterial diseases acceptable to the Department.				
A grower/processor shall process the medical marijuana plants in a safe and sanitary manner.				
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.				
The grower/processor shall maintain proper sanitation while processing medical marijuana and shall maintain practices that exclude rodents, birds and pests from the processing area.				
A grower/processor shall install a system to monitor, record and regulate temperature, humidity, ventilation, lighting and water supply.				

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Forms of Medical Marijuana.				
Generally: A grower/processor may only process medical marijuana in specific forms.				
Operational Requirements Regulations: 28 Pa. Code § 1151.28	Timeline	Grower/Processor Completed	Department Notified	Department Approval
(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.				
The grower/processor may not process medical marijuana to dispense in dry leaf or plant form.				
The grower/processor may not manufacture, produce or assemble any medical marijuana product, instrument or device without the prior written approval of the Department.				

Grower/Processor Operational Checklist

Limit on Medical Marijuana Processing.				
Generally: A grower/processor shall only process medical marijuana to have a specific concentration of total THC and total CBD and must have a consistent cannabinoid profile.				
Operational Requirements Regulations: 28 Pa. Code § 1151.29	Timeline	Grower/Processor Completed	Department Notified	Department Approval
<p>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:</p> <ul style="list-style-type: none"> (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%. 				
<p>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.</p>				

Grower/Processor Operational Checklist

Complaints About or Recall of Medical Marijuana.				
Generally: 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.				
Operational Requirements Regulations: 28 Pa. Code § 1151.42	Timeline	Grower/Processor	Department Notified	Department approval
The grower/processor shall investigate a report or complaint from a dispensary concerning an adverse event involving a patient using medical marijuana purchased by the dispensary from the grower/processor.				
If the 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.				
Voluntary Recalls.				
The 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.				
If the 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.				
Mandatory Recalls.				
The grower/processor shall contact the Department immediately by phone if it 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 then 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.				

Grower/Processor Operational Checklist

Recall Plans.				
Operational Requirements Regulations: 28 Pa. Code § 1151.42	Timeline	Grower/Processor Completed	Department Notified	Department approval
A grower/processor's recall plan must include at a minimum the following items:				
A 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.				
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.				
Procedures to retrieve and dispose of the affected medical marijuana.				
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.				
Procedures for notifying the Department and entering information relating to the recall into the grower/processor's electronic tracking system.				

Grower/Processor Operational Checklist

Electronic Tracking System for Recalls.				
Operational Requirements Regulations: 28 Pa. Code § 1151.42	Timeline	Grower/Processor Completed	Department Notified	Department approval
The grower/processor shall enter the following information relevant to the recall into the electronic tracking system as part of the daily report:				
The total amount of recalled medical marijuana, including types, forms, harvest batches, harvest lots and process lots, if applicable.				
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.				
The total amount of recalled medical marijuana returned to the grower/processor, including types, forms, harvest batches, harvest lots and process lots, if applicable.				
The name(s) of the recall coordinator(s).				
The name of the dispensary or approved laboratory from whom the recalled medical marijuana was received.				
The means of transport of the recalled medical marijuana.				
The reason for the recall.				
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.				

Grower/Processor Operational Checklist

Electronic Tracking System for Recalls (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.42	Timeline	Grower/Processor Completed	Department Notified	Department approval
The manner of disposal of the recalled medical marijuana, including: <ul style="list-style-type: none"> (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. 				
If the grower/processor fails to cooperate with the Department in a mandatory recall, or fails to immediately notify the Department of a need for a mandatory recall, 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 Medical Marijuana Act or the temporary regulations.				

Grower/Processor Operational Checklist

Management and Disposal of Medical Marijuana Waste.				
Generally: 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.				
Operation Requirements Regulations: 28 Pa. Code § 1151.40	Timeline	Grower/Processor Completed	Department Notified	Department Approval
Unused, surplus, returned, recalled, contaminated or expired medical marijuana shall be rendered unusable and unrecognizable prior to being transported from a grower/processor or an approved laboratory.				
Unusable and unrecognizable medical marijuana waste 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.				
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 shall be rendered unusable and unrecognizable prior to being transported.				
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.				

Grower/Processor Operational Checklist

Management and Disposal of Medical Marijuana Waste (cont'd).				
Operation Requirements Regulations: 28 Pa. Code § 1151.40	Timeline	Grower/Processor Completed	Department Notified	Department Approval
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.				
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.				

Grower/Processor Operational Checklist

Management and Disposal of Medical Marijuana Waste (cont'd).

Operation Requirements Regulations: 28 Pa. Code § 1151.40	Timeline	Grower/Processor Completed	Department Notified	Department Approval
Some medical marijuana waste may be composted and beneficially used at the grower/processor facility through a permit-by-rule. The grower/processor shall submit the required notice 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.				

Inventory Data.

Generally: A grower/processor shall establish inventory controls and procedures to conduct inventory reviews and comprehensive inventories at its facility.				
Operational Requirement Regulations: 28 Pa. Code § 1151.30	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall conduct inventory reviews monthly of medical marijuana plants in the process of growing and medical marijuana and medical marijuana products that are being stored for future sale.				
The grower/processor shall conduct comprehensive inventories of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products at least annually.				
The grower/processor shall create and maintain a written or electronic record of each inventory review and comprehensive inventory conducted 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.				

Grower/Processor Operational Checklist

Start-up Inventory.				
Generally: 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.				
Operational Requirement Regulation: 28 Pa. Code § 1151.24	Timeline	Grower/Processor Complete	Department Notified	Department approval
The grower/processor is permitted to obtain seeds or immature medical marijuana plants from outside of this Commonwealth within 30 days from the date that the Department determines that the grower/processor is operational.				
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.				
After the 30-day period, the 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.				
The grower/processor acknowledges that it may not obtain medical marijuana plants from outside of this Commonwealth at any time.				

Grower/Processor Operational Checklist

Inventory Data.				
Generally: The grower/processor shall maintain inventory data in its electronic tracking system.				
Operational Requirements Regulations: 28 Pa. Code § 1151.30	Timelines	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall account for and identify the following inventory data in its electronic tracking system:				
(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.				

Grower/Processor Operational Checklist

Transportation of Medical Marijuana.				
Generally: A grower/processor may transport and deliver medical marijuana to a medical marijuana organization or an approved laboratory in this Commonwealth in accordance with the temporary regulations.				
Operational Requirements Regulations: 28 Pa. Code § 1151.35	Timeline	Grower/Processor Complete	Department Notified	Department Approval
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.				
A grower/processor may contract with a third-party contractor for delivery so long as the contractor complies with this section.				
A grower/processor may not transport medical marijuana to any location outside of this Commonwealth.				
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.				
Vehicles.				
Operational Requirements Regulations: 28 Pa. Code § 1151.35	Timeline	Grower/Processor Complete	Department Notified	Department Approval
Transport vehicles permitted to transport medical marijuana must:				
Be equipped with a secure lockbox or locking cargo area.				
Have no markings that would either identify or indicate that the vehicle is being used to transport medical marijuana.				
Be capable of being temperature-controlled for perishable medical marijuana, as appropriate.				
Display current State inspection stickers and maintain a current State vehicle registration.				
Be insured in an amount that is commercially reasonable and appropriate.				

Grower/Processor Operational Checklist

Staffing Transport Vehicles.				
Operational Requirements Regulations: 28 Pa. Code § 1151.35	Timeline	Grower/Processor Complete	Department Notified	Department Approval
A transport vehicle must be staffed with a delivery team consisting of at least two individuals and comply with the following:				
At least one delivery team member shall remain with the vehicle at all times that the vehicle contains medical marijuana.				
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.				
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.				
Each delivery team member shall have a valid driver's license.				
While on duty, a delivery team member may not wear any clothing or symbols that may indicate ownership or possession of medical marijuana.				
Medical marijuana stored inside the transport vehicle may not be visible from the outside of the transport vehicle.				
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.				
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.				

Grower/Processor Operational Checklist

Staffing Transport Vehicles (cont'd).				
Operational Requirement Regulations: 28 Pa. Code § 1151.35	Timeline	Grower/Processor Complete	Department Notified	Department Approval
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.				
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.				
Transport Manifest.				
Operational Requirement Regulations: 28 Pa. Code § 1151.36	Timeline	Grower/Processor Complete	Department Notified	Department Approval
A grower/processor shall generate a printed transport manifest from the electronic tracking system or electronic transport manifest that accompanies every transport vehicle.				
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.				

Grower/Processor Operational Checklist

Transport Manifest (cont'd).				
Operational Requirement Regulations: 28 Pa. Code § 1151.36	Timeline	Grower/Processor Complete	Department Notified	Department Approval
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).				
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.				
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.				
Transportation of Seeds, Immature Medical Marijuana Plants and Medical Marijuana Plants.				
Operational Requirements Regulations: 28 Pa. Code § 1151.37	Timeline	Grower/Processor Complete	Department Notified	Department Approval
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).				

Grower/Processor Operational Checklist

Evidence of Adverse Loss During Transport.				
Operational Requirements Regulations: 28 Pa. Code § 1151.38	Timeline	Grower/Processor Complete	Department Notified	Department Approval
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 by electronic communication, and to the appropriate law enforcement authorities.				
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 by electronic communication, and to law enforcement.				
If a grower/processor discovers a discrepancy in the transport manifest, the grower/processor shall conduct an investigation.				
A grower/processor shall amend its 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.				
During an investigation, the grower/processor shall submit the following reports to the Department:				
A written preliminary report of the investigation shall be submitted to the Department within 7 days of discovering the discrepancy.				
A final written report of the investigation shall be submitted to the Department within 30 days of discovering the discrepancy.				

Grower/Processor Operational Checklist

Pesticides.				
Generally: 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 the temporary regulations.				
Operational Requirements Regulations: 28 Pa. Code § 1151.43	Timeline	Grower/Processor Completed	Department Notified	Department Approval
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.				

Grower/Processor Operational Checklist

Pesticides (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.43	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor shall complete a record required to be kept under this section 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.				
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.				
A grower/processor shall only use the pesticide active ingredients in Appendix A in the growing and processing of medical marijuana.				

Grower/Processor Operational Checklist

Approved Laboratories and Testing.				
Generally: Prior to conducting any testing of a sample at the request of a grower/processor, an approved laboratory shall enter into a written contract with the grower/processor for testing services.				
Operational requirement Regulations: 28 Pa. Code Chapter 1171	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The grower/processor has contracted with an approved laboratory that is posted on the Department's web site.				
The grower/processor has submitted the names of the approved laboratories that they have contracted with to the Department for entry into the electronic tracking system.				
The grower/processor has protocols that will allow an employee of an approved laboratory to enter a facility for the purpose of identifying and collecting samples and shall have access to limited access areas in the facility for these purposes.				
The grower/processor has a process to accept the test results that meet the testing requirements established by the Department.				
The grower/processor acknowledges that it shall only rely on test results that are entered into the electronic tracking system.				
The grower/processor should have a re-test procedure that allows the same approved laboratory or a different approved laboratory to conduct a re-test of a sample that fails.				
The grower/processor verifies that none of its principals, owners, financial backers or employees has a management or a direct or indirect financial or other ownership interest in any approved laboratory.				
The grower/processor acknowledges that an approved laboratory shall provide a copy of the contract to the Department within 2 days following the Department's request.				

Grower/Processor Operational Checklist

Packaging and Labeling of Medical Marijuana.				
Generally: A grower/processor shall package and label at its facility each form of medical marijuana prepared for sale.				
Operational Requirements Regulations: 28 Pa. Code § 1151.34	Timeline	Grower/Processor Completed	Department Notified	Department approval
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.				
A grower/processor shall package the medical marijuana in a package that minimizes exposure to oxygen and that is:				
Child-resistant.				
Tamper-proof or tamper-evident.				
Light-resistant and opaque.				
Re-sealable.				
A grower/processor shall identify each process lot of medical marijuana with a unique identifier.				
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:				
Be easily readable.				
Made of weather-resistant and tamper-resistant materials.				
Be conspicuously placed on the package.				
Include the name, address and permit number of the grower/processor.				
List the form, quantity and weight of medical marijuana included in the package.				
List the amount of individual doses contained within the package and the species and percentage of THC and CBD.				
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.				

Grower/Processor Operational Checklist

Packaging and Labeling of Medical Marijuana (cont'd).				
Operational Requirements Regulations: 28 Pa. Code § 1151.34	Timeline	Grower/Processor Completed	Department Notified	Department approval
Each label must:				
Include the date the medical marijuana was packaged.				
State the employee identification number of the employee preparing the package and packaging the medical marijuana.				
State the employee identification number of the employee shipping the package, if different than the employee preparing the package and packaging the medical marijuana.				
Contain the name and address of the dispensary to which the package is to be sold.				
List the date of expiration of the medical marijuana.				
Include instructions for proper storage of the medical marijuana in the package.				
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.				
Contain a warning that the medical marijuana must be kept in the original container in which it was dispensed.				
Contain a warning that unauthorized use is unlawful and will subject the purchaser to criminal penalties.				

Grower/Processor Operational Checklist

Labeling Prohibitions.				
Operational Requirements Regulations: 28 Pa. Code § 1151.34	Timeline	Grower/Processor Completed	Department Notified	Department approval
Labeling by a grower/processor of any medical marijuana may not contain any of the following:				
Any resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available food or beverage product.				
Any statement, artwork or design that could reasonably lead an individual to believe that the package contains anything other than medical marijuana.				
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.				
Any cartoon, color scheme, image, graphic or feature that might make the package attractive to children.				

Grower/Processor Operational Checklist

Quarterly Reports.				
Generally: A grower/processor shall submit reports to the Department on forms prescribed by the Department.				
Operational Requirements Regulations: 28 Pa. Code § 1141.46	Timeline	Grower/Processor Completed	Department Notified	Department approval
A grower/processor shall submit the following reports at the end of the first 12-month period following the issuance of a permit, and as of the end of each 3-month period thereafter:				
(i) The amount of medical marijuana sold by the grower/processor during the period for which the report is being submitted.				
(ii) The per-dose price of an amount of medical marijuana sold by the grower/processor to a medical marijuana organization in a unit of measurement as determined by the Department.				
The grower/processor acknowledges that the Department may require ongoing reporting of operational and financial information in a form and manner prescribed by the Department.				
The grower/processor acknowledges that the Department may require additional reports as necessary to carry out its responsibilities under the Medical Marijuana Act and the temporary regulations.				

Grower/Processor Operational Checklist

Diversity Goals.				
Generally: As part of each application to renew a permit submitted to the Department, a grower/processor shall include information of its efforts to meet the diversity goals of the Medical Marijuana Act and the effectiveness of its diversity plan.				
Operational Requirements Regulations: 28 Pa. Code § 1141.32	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The report must include information regarding the following, as applicable:				
(1) Representation of diverse participants in the grower/processor's workforce.				
(2) Efforts to reach out to and recruit diverse participants for employment, including for executive and managerial positions.				
(3) Employee retention efforts.				
(4) A list of all contracts entered into or transactions conducted by the grower/processor for goods or services with diverse groups.				
The grower/processor may demonstrate achievement of its diversity goals by employing diverse participants or transacting business with diverse groups.				
The Department will review the diversity plan and provide the grower/processor with advice regarding activities that should be undertaken by the grower/processor to improve its efforts to encourage and promote participation by diverse participants and diverse groups to comply with the diversity goals of the Medical Marijuana Act.				

Grower/Processor Operational Checklist

Permit Renewal Applications.				
Generally - A grower/processor wishing to renew its permit shall submit to the Department a permit renewal application not more than 6 months, nor less than 4 months, prior to the current permit's expiration.				
Operational Requirement Regulations: 28 Pa. Code § 1141.36	Timeline	Grower/Processor Completed	Department Notified	Department Approval
A grower/processor shall include the following in the permit renewal application:				
Information regarding any charge, or any initiated, pending or concluded investigation, during the period of the initial permit or prior renewal period, by any governmental or administrative agency with respect to:				
(i) Any incident involving the theft, loss or possible diversion of medical marijuana by the grower/processor or from the grower/processor's facility.				
(ii) Compliance by the grower/processor with the laws of the Commonwealth with respect to any substance in section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).				
Information concerning the grower/processor's ability to carry on the activity for which the permit was issued, including medical marijuana product shortages or wait lists occurring during the 12 months prior to the date the renewal permit application was submitted.				
The grower/processor's history of compliance with the Medical Marijuana Act and temporary regulations.				

Grower/Processor Operational Checklist

Application for Approval of a Change in Ownership of a Grower/Processor.				
Generally: In the event of an impending change in ownership of a grower/processor from the ownership listed in the initial permit application or a permit renewal application, the grower/processor shall submit an application for approval of a change in ownership, on a form prescribed by the Department, to the Department together with the fee required under § 1141.28 (relating to fees).				
Operational Requirements Regulations: 28 Pa. Code § 1141.39	Timeline	Grower/Processor Completed	Department Notified	Department Approval
The Department, in its sole discretion, may permit a grower/processor to incorporate by reference all of the information in the grower/processor's initial permit application, and any previously submitted permit renewal application, into the application for approval of a change in ownership.				
A grower/processor's application for approval of a change in ownership will not be considered complete by the Department until all portions of the application are completed and the appropriate application fee is submitted.				
The Department may reject an incomplete application.				
If the Department determines that an application for approval of a change in ownership is lacking sufficient information upon which, to make a determination, the Department will notify the grower/processor in writing of the factors that require additional information and documentation. The grower/processor shall have 30 days from the mailing date of the notice to provide the requested information and documentation to the Department. A grower/processor's failure to provide the requested information to the Department by the deadline may be grounds for denial of approval for the requested change in ownership.				

Grower/Processor Operational Checklist

Application for Approval of a Change in Location of a Facility.

Generally: A grower/processor wishing to change the location of a site or facility authorized under a permit issued to the grower/processor and determined operational shall submit an application for approval of a change in location to the Department together with the fee required under § 1141.28 (relating to fees).

Operational Requirement Regulations: 28 Pa. Code § 1141.40	Timeline	Grower/Processor completed	Department Notified	Department approval
A change in location of a facility authorized by a permit may not occur until the Department approves the change, in writing, under this section.				
The grower/processor shall submit an application for approval of a change in location on a form prescribed by the Department.				
An application for approval of a change in location must include the reason for requesting the change and other information about the new location as the Department may require.				
The Department will not approve a change of location that is outside the boundaries of the region for which the initial permit was issued.				

Grower/Processor Operational Checklist

Application for Approval of Alteration of a Facility.				
Generally: After the issuance of a permit, a grower/processor may not make a physical change, alteration or modification of the facility that materially or substantially alters the facility or its usage as listed in the plot plans originally approved by the Department.				
Operational Requirement Regulations: 28 Pa. Code § 1141.41	Timeline	Grower/Processor Completed	Department Notified	Department Approval
A grower/processor wishing to make any of the following alterations to the facility for which its permit was issued shall submit an application for approval of alteration of a facility, on a form prescribed by the Department, to the Department together with the fee required under § 1141.28 (relating to fees):				
(1) An increase or decrease in the total square footage of the facility.				
(2) The sealing off, creation of or relocation of a common entryway, doorway, passage or other means of public ingress or egress when the common entryway, doorway or passage alters or changes limited access areas.				
(3) Any of the following made to enhance activities authorized under the permit:				
(i) Additional electric fixtures or lighting equipment.				
(ii) The lowering of a ceiling.				
(iii) Electrical modifications that require inspection by the local municipality.				

Grower/Processor Operational Checklist

General Penalties and Sanctions.

Regulations: 28 Pa. Code § 1141.47. General penalties and sanctions.

- (a) In addition to any other penalty imposed by law for violations of the Medical Marijuana Act or the temporary regulations, the Department may take one or more of the following actions:
- (1) Suspend or revoke a permit if any of the following occur:
 - (i) The grower/processor fails to maintain effective control against diversion of medical marijuana from its facility or under its control.
 - (ii) The grower/processor violates a provision of the Medical Marijuana Act or the temporary regulations, or an order issued under the Medical Marijuana Act or the temporary regulations.
 - (iii) The grower/processor violates a provision of other State or local laws regarding the operation of its facility.
 - (iv) The grower/processor engages in conduct, or an event occurs, that would have disqualified the grower/processor from being issued a permit or having its permit renewed.
 - (2) Impose a civil penalty of not more than \$10,000 for each violation and an additional penalty of not more than \$1,000 for each day of a continuing violation. In determining the amount of each penalty, the Department will take the following into consideration:
 - (i) The gravity of the violation.
 - (ii) The potential harm resulting from the violation to patients, caregivers or the general public.
 - (iii) The willfulness of the violation.
 - (iv) Previous violations, if any, by the grower/processor being assessed.
 - (v) The economic benefit to the grower/processor being assessed resulting from the violation.
 - (3) Suspend or revoke a permit pending the outcome of a hearing if the Department determines that the health, safety or welfare of the public, a patient or a caregiver is at risk.
 - (4) Order the restitution of funds or property unlawfully obtained or retained by a grower/processor.
 - (5) Issue a cease and desist order to immediately stop or restrict the operations of a grower/processor conducted under the permit to protect the public's health, safety and welfare. The following apply:
 - (i) An order may include a requirement that a grower/processor cease or restrict some or all of its operations. In addition, the order may prohibit the use of some or all of the medical marijuana grown, processed or to be sold by the grower/processor.
 - (ii) An order may be issued by an authorized agent of the Department immediately upon completion of an inspection or investigation if the agent observes or suspects an operational failure or determines that the conditions will likely create a diversion of medical marijuana, contamination of medical marijuana, or a risk to patients or the public.

Grower/Processor Operational Checklist

General Penalties and Sanctions (cont'd).

Regulations: 28 Pa. Code § 1141.47. General penalties and sanctions.

(iii) An order may include:

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

(B) A quarantine of some or all of the medical marijuana found at the facility.

(C) The suspension of the sale or shipment of some or all of the medical marijuana found at the facility.

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

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

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

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

(c) Before the Department may act under subsection (a) or (b), the Department will provide the grower/processor or other person with written notice specifying the nature of the alleged violation or conduct. The notice will fix a time and place for a hearing. The hearing will be scheduled at least 10 days after the date of the notice. This subsection supersedes 1 Pa. Code §§ 35.102 and 35.121 (relating to hearing calendar; and initiation of hearings).

(d) Notwithstanding subsection (c), for violations of the Medical Marijuana Act or the temporary regulations, the Department may require a grower/processor to develop and adhere to a plan of correction approved by the Department. The Department will monitor compliance with the plan of correction. Failure to comply with the plan of correction may result in the Department's taking action under applicable provisions of this section as it deems appropriate.

(e) The Department's actions under subsections (a), (b) and (c) are subject to 2 Pa.C.S. Chapter 5, Subchapter A (relating to practice and procedure of Commonwealth agencies).