

Ohio Division of Cannabis Control Rules Package 6

(All section numbers and citations subject to change)

Rules Applicable to all Cannabis Entities

1301:18-2-09 Fee schedule

- (A) The following non-refundable fees shall be paid to the division of cannabis control:
 - o (1) Initial Applications
 - (a) Level I Cultivators: twenty thousand dollars
 - (b) Level II Cultivators: two thousand dollars
 - (c) Processors: ten thousand dollars
 - (d) Testing Laboratories: two thousand dollars
 - (e) Dispensaries: five thousand dollars
 - o (2) Issuance of a certificate of operation
 - (a) Level I Cultivators: one hundred eighty thousand dollars
 - (b) Level II Cultivators: eighteen thousand dollars
 - (c) Processors: ninety thousand dollars
 - (d) Testing Laboratories: eighteen thousand dollars
 - (e) Dispensaries: seventy thousand dollars
 - o (3) Renewal of certificate of operation
 - (a) Level I Cultivators: two hundred thousand dollars
 - **(b)** Level II Cultivators: twenty thousand dollars
 - (c) Processors: fifty thousand dollars
 - (d) Testing Laboratories: twenty thousand dollars per year, which may be paid in one sum of forty-thousand dollars prior to renewal.
 - **(e)** Dispensaries: thirty-five thousand dollars per year, which may be paid in one sum of seventy thousand dollars prior to renewal.
 - o (4) Employees
 - (a) Initial Applications:
 - (i) Responsible party badge: one hundred dollars
 - (ii) Owner or officer badge: one hundred dollars
 - (iii) Employee badge: one hundred dollars
 - **(b)** Renewal of badge certificate:
 - (i) Responsible party badge: one hundred dollars
 - (ii) Owner or officer badge: one hundred dollars
 - (iii) Employee badge: one hundred dollars
 - o (5) Change of Ownership: one thousand dollars
 - o (6) Change of Business or Trade Name: five hundred dollars
 - o (7) Change of Location: one thousand dollars
 - o (8) Major Modification: one thousand dollars
 - o (9) Product Registration: one hundred dollars

- o (10) Packaging or Labeling:
 - (a) Pursuant to its license fee outlined in paragraph (A)(2) and (A)(3) of this rule, each licensee may submit a total of one hundred packaging or labeling submissions per calendar year for review by the division with no additional fee.
 - **(b)** Review of any package or label in excess of one hundred submissions per calendar year are one hundred dollars per additional submission.
- **(B)** Any fees due and payable to the division shall be submitted via credit card, electronic transfer utilizing the Automated Clearing House network ("ACH"), a certified check or money order payable to the "Treasurer, State of Ohio," or by such other means as approved by the division.

1301:18-3-10 Employee Training and Qualification Requirements

- **(A)** Pursuant to section 3780.03 of the Revised Code, each licensee shall establish and oversee an employee training program.
 - (1) Each licensee shall submit in a manner prescribed by the division evidence of ongoing compliance with this rule and ensure:
 - (a) All training is reviewed annually and updated as necessary and appropriate;
 - **(b)** All employees regularly receive training on all applicable materials.
- **(B) Foundational Training.** Prior to commencing business, all individuals registered pursuant to rule 1301:18-3-09 of the Administrative Code, shall receive foundational training on the following:
 - o **(1)** All applicable written policies and procedures associated with their respective assigned function.
 - (2) Use and proper documentation of all cannabis maintained at the licensed premises in the state inventory tracking system established pursuant to sections 3780.05 and 3796.07 of the Revised Code;
 - (3) Preparation for regulatory inspections;
 - (4) Mandates for maintaining their respective badge certificate pursuant to rule 1301:18-3-09 of the Administrative Code;
 - o (5) All applicable statutes and regulations pertaining to Ohio cannabis law; and
 - (6) Responsible use training and available resources for addiction services established pursuant to section 3780.30 of the Revised Code.
- **(C)** Additional Requirements: in addition to the foundational training outlined under paragraph (A), each licensee shall train all applicable employees as follows:
 - o (1) OSHA training. Each licensee shall ensure on an annual basis:
 - (a) All employees complete the ten-hour OSHA course; and
 - **(b)** At least one registered responsible party completes the thirty-hour OSHA course.
 - (2) Security Personnel. Prior to gaining access to the licensed premises' designated security and surveillance area, or commencing any security or surveillance function, each authorized registered employee shall successfully complete the Ohio homeland security private investigators and security guards ("PISGS") training:
 - (a)https://homelandsecurity.ohio.gov/private-investigators-and-security-guards/training-opportunities/online-training
 - o (3) Processors.
 - (a) Each processor shall ensure at least one employee is available during all
 operating hours when cannabis products are prepared or packaged, who is a
 certified food protection manager through a program accepted by the Ohio

- department of health, or a nationally recognized accrediting agency as approved by the division.
- (b) A processor using hydrocarbon solvent-based or carbon dioxide extraction methods shall designate at least one individual to train and supervise employees engaged in extracting cannabis, producing cannabis products, or the handling of such products on the proper, sanitary, and safe use of extraction equipment and associated solvents.
 - (i) The supervisor shall meet the following minimum qualifications:
 - (A) A bachelor's degree in engineering or physical sciences from an accredited university; or
 - (B) At least three years of experience operating the same or similar processing and extraction equipment utilized at the facility.

(4) Testing Laboratories.

- (a) Each testing laboratory shall employ a scientific director responsible for supervising all laboratory employees and ensuring that the laboratory achieves and maintains quality standards of practice.
- **(b)** Each testing laboratory's scientific director shall meet the following minimum qualifications:
 - (i) A doctorate degree in chemical, environmental, or biological sciences from an accredited college or university and two years of post-degree laboratory experience;
 - (ii) A master's degree in chemical, environmental, or biological sciences from an accredited college or university and four years of post-degree laboratory experience; or
 - (iii) A bachelor's degree in chemical, environmental, or biological sciences from an accredited college or university and eight years of post-degree laboratory experience.
- (c) All individuals employed at a testing laboratory shall meet the education and experience guidelines pursuant to ASTM D8347 21a: "Standard Guide for Requirements for Analytical Laboratory Related Professions Within the Cannabis and Hemp Industries," adopted herein.
- **(e)** Prior to testing independently without supervision, each testing analyst shall demonstrate they can perform a testing method that renders reliable and accurate results.

(5) Dispensaries.

- (a) Prior to commencing business, all dispensary employees with access to confidential patient information or the patient registry shall receive foundational training pertaining to the confidentiality requirements pursuant to rule 1301:18-8-08 of the Administrative Code;
- **(b)** Prior to dispensing cannabis, all dispensary employees dispensing cannabis shall receive the following training:
 - (i) Relevant registration and training on the drug database established pursuant to section 4729.75 of the Revised Code;
 - (ii) Instruction on the different forms and methods of administration;
 - (iii) Instruction on qualifying conditions for medical cannabis patients;

- (iv) Authorized uses of medical cannabis in the treatment of qualifying conditions;
- (v) Guidelines for providing information to patients and caregivers related to patients' symptoms and risks associated with medical cannabis, including possible drug interactions;
- (vi) Recognizing signs and symptoms of substance abuse; and
- **(vii)** Guidelines for refusing to provide cannabis to an individual who appears to be impaired or abusing cannabis.
- **(D)** Pursuant to [OAC Records Rule], each licensee shall document all training pursuant to this rule and include the following:
 - (1) Names and qualifications of the persons responsible for training content;
 - o (2) A set of training materials, to be provided to each participant; and
 - (3) Date(s) of training.

Consumer Protection and Product Safety

1301:18-4-01 Good Manufacturing Processes

Each licensee shall establish, maintain, and comply with written policies and procedures for the safe, sanitary, and clean cultivation, manufacturing, testing, and distribution of cannabis at the licensed premises. Each licensee shall ensure all policies and procedures ensure the following:

• (A) Personnel:

- o **(1) Disease control.** Any employee who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of cannabis, cannabis-contact surfaces, or cannabis-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (*e.g.*, by an impermeable cover).
 - (a) Personnel must be instructed to report such health conditions to their supervisors.
- (2) Cleanliness. All employees working in direct contact with cannabis, cannabis-contact surfaces, and cannabis-packaging materials must conform to hygienic practices while engaged in employment activities to the extent necessary to protect against allergen cross-contact and against contamination of cannabis. The methods for maintaining cleanliness include:
 - (a) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of cannabis, cannabis-contact surfaces, or cannabis-packaging materials.
 - (b) Maintaining adequate personal cleanliness.
 - (c) Removing all unsecured jewelry and other objects that might fall into cannabis, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which cannabis is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the cannabis, cannabis-contact surfaces, or cannabis-packaging materials.

- (d) Maintaining gloves, if they are used in cannabis handling, in an intact, clean, and sanitary condition.
- **(e)** Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
- **(f)** Storing clothing or other personal belongings in areas other than where cannabis is exposed or where equipment or utensils are washed.
- (g) Confining the following to areas other than where cannabis may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
- (h) Taking any other necessary precautions to protect against allergen crosscontact and against contamination of cannabis, cannabis-contact surfaces, or cannabis-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

(3) Hand washing.

- (a) Each employee shall clean their hands and the exposed portions their arms using a cleaning compound in a hand-washing sink that is appropriately equipped, at the following times:
 - (i) Immediately before working with cannabis plants;
 - (ii) Immediately before preparing or packaging cannabis products, including, without limitation, working with exposed cannabis products, clean equipment and utensils or unwrapped single-service and single-use articles;
 - (iii) After touching any bare human body parts other than their clean hands and exposed portions of arms, including, without limitation, surrogate prosthetic devices for hands and arms;
 - (iv) After using the toilet facilities;
 - (v) After coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating or drinking;
 - (vi) After handling soiled equipment or utensils;
 - (vii) During preparation or packaging of cannabis, as often as necessary to remove soil and contamination and to prevent cross- contamination when changing tasks;
 - (viii) Before donning gloves for working with cannabis; and
 - (ix) After engaging in other activities that contaminate the hands.
- **(b)** Each employee shall use the following cleaning procedure in the order stated to clean their hands and the exposed portions of their arms, including, without limitation, surrogate prosthetic devices for hands and arms:
 - (i) Rinse under clean, running warm water.
 - (ii) Apply an amount of cleaning compound recommended by the manufacturer of the cleaning compound.
 - (iii) Rub together vigorously for at least 15 seconds while:
 - (A) Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure; and
 - (B) Creating friction on the surfaces of the hands and arms, fingertips and areas between the fingers.
 - (iv) Thoroughly rinse under clean, running warm water; and

• (v) Immediately follow the cleaning procedure with thorough drying using a clean paper towel.

• (B) Facility and grounds.

- (1) Grounds. The grounds about the licensed premises under the control of the licensee must be kept in a condition that will protect against the contamination of cannabis. The methods for adequate maintenance of grounds must include:
 - (a) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the facility that may constitute an attractant, breeding place, or harborage for pests.
 - **(b)** Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where cannabis is exposed.
 - **(c)** Adequately draining areas that may contribute contamination to cannabis by seepage, foot-borne filth, or providing a breeding place for pests.
 - (d) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where cannabis is exposed.
 - (e) If the licensed premises grounds are bordered by grounds not under the licensee's control and not maintained in the manner described in paragraphs (B)(1)(a) through (e) of this rule, care must be exercised in the facility by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of cannabis contamination.
- (2) Facility construction and design. The facility must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for cannabis-production purposes (i.e., manufacturing, processing, packing, and holding). The facility must:
 - (a) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe cannabis.
 - **(b)** Reduce the potential for allergen cross-contact and for contamination of cannabis, cannabis-contact surfaces, or cannabis-packaging materials with microorganisms, chemicals, filth, and other extraneous material.
 - (i) The potential for allergen cross-contact and for contamination may be reduced by adequate cannabis safety controls and operating procedures or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.
 - (c) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate cannabis, cannabis-contact surfaces, or cannabis-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating cannabis, cannabis-contact surfaces, or cannabis-packaging materials with clothing or personal contact.
 - (d) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where cannabis is harvested, examined, manufactured, processed, packed, tested, or held and where equipment or utensils are cleaned; and provide shatter-resistant light bulbs, fixtures, skylights,

- or other glass suspended over exposed cannabis in any step of preparation or otherwise protect against cannabis contamination in case of glass breakage.
- (e) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate cannabis; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating cannabis, cannabis-packaging materials, and cannabis-contact surfaces.
- **(f)** Provide, where necessary, adequate screening or other protection against pests.

• (C) Sanitary Operations

- (1) General maintenance. Buildings, fixtures, and other physical facilities of the licensed premises must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent cannabis from becoming adulterated.
 - (a) Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of cannabis, cannabis-contact surfaces, or cannabis-packaging materials.
- o (2) Substances used in cleaning and sanitizing; storage of toxic materials.
 - (a) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use.
 - (i) Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination.
 - **(b)** Only the following toxic materials may be used or stored in a facility where cannabis is processed or exposed:
 - (i) Those required to maintain clean and sanitary conditions;
 - (ii) Those necessary for use in the facility's operations;
 - (iii) Those necessary for use in laboratory testing procedures; and
 - (iv) Those necessary for facility and equipment maintenance and operation.
 - (c) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of cannabis, cannabis-contact surfaces, or cannabis-packaging materials.
- o (3) Pest control. Pests must not be allowed in any area of a cannabis facility.
 - (a) Guard, guide, or pest-detecting dogs may be allowed in some areas of a facility
 if the presence of the dogs is unlikely to result in contamination of cannabis,
 cannabis-contact surfaces, or cannabis-packaging materials.
 - **(b)** Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of cannabis on the premises by pests.
 - (c) The use of pesticides to control pests in the facility is permitted only under precautions and restrictions that will protect against the contamination of cannabis, cannabis-contact surfaces, and cannabis-packaging materials.
- (4) Sanitation of cannabis-contact surfaces. All cannabis-contact surfaces, including
 utensils and cannabis-contact surfaces of equipment, must be cleaned as frequently as

necessary to protect against allergen cross-contact and against contamination of cannabis.

- (a) Cannabis-contact surfaces used for cultivating, manufacturing, processing, testing, packing, or holding low-moisture cannabis must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.
- (b) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into cannabis, all cannabis-contact surfaces must be cleaned and sanitized before use and after any interruption during which the cannabis-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and cannabis-contact surfaces of the equipment must be cleaned and sanitized as necessary.
- (c) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of cannabis, cannabis-contact surfaces, or cannabis-packaging materials.
- (5) Non-cannabis-contact surfaces of equipment used in the operation of a cannabis facility must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of cannabis, cannabis-contact surfaces, and cannabis-packaging materials.
- (6) Cleaned and sanitized portable equipment with cannabis-contact surfaces and utensils
 must be stored in a location and manner that protects cannabis-contact surfaces from
 allergen cross-contact and from contamination.

• (D) Sanitary facilities and controls

- (1) Each facility must be equipped with adequate sanitary facilities and accommodations including:
 - (a) The water supply must provide potable water that meets the standards prescribed in the Primary Drinking Water Regulations, 40 C.F.R. Part 141 and be adequate for the operations intended and derived from an adequate source.
 - (i) Any water that contacts cannabis, cannabis-contact surfaces, or cannabis-packaging materials must be safe and of adequate sanitary quality.
 - (ii) All running water must be a suitable temperature, and under pressure as needed, in all areas where required for the cultivation, manufacture, and processing of cannabis, for the cleaning of equipment, utensils, and cannabis-packaging materials, or for employee sanitary facilities.
 - **(b)** Plumbing must be of adequate size and design and adequately installed and maintained to:
 - (i) Carry adequate quantities of water to required locations throughout the facility.
 - (ii) Properly convey sewage and liquid disposable waste from the facility.
 - (iii) Avoid constituting a source of contamination to cannabis, water supplies, equipment, or utensils or creating an unsanitary condition.
 - (iv) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

- (v) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for cannabis or cannabis manufacturing.
- **(c)** Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.
- **(d) Toilet facilities.** Each facility must provide employees with adequate, readily accessible toilet facilities.
 - (i) Toilet facilities must be kept clean and must not be a potential source of contamination of cannabis, cannabis-contact surfaces, or cannabis-packaging materials.
- (e) Each facility where employees will have direct contact with cannabis, cannabis-contact surfaces, and cannabis-packaging materials must contain a fully-stocked hand-washing sink limited to hand washing only with the following:
 - (i) Disposable, single-use paper towels in a mounted dispenser;
 - (ii) Hand washing soap contained in a dispenser; and
 - (iii) A trash can conveniently located near the sink.
- (f) Waste disposal. Waste must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of cannabis, cannabis-contact surfaces, cannabis-packaging materials, water supplies, and ground surfaces.

• (E) Equipment and utensils

- (1) All cannabis not in packaging intended for distribution to consumers shall be maintained in food grade containers.
- (2) All facility equipment and utensils used in cultivating, manufacturing, processing, testing, packing, or holding cannabis must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.
 - (a) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of cannabis with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.
 - **(b)** Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.
 - (c) Cannabis-contact surfaces must be corrosion-resistant when in contact with cannabis.
 - (e) Cannabis-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of cannabis, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.
 - **(f)** Cannabis-contact surfaces must be maintained to protect cannabis from allergen cross-contact and from being contaminated by any source, including unlawful indirect cannabis additives.
- (3) Seams on cannabis-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of cannabis particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

- (4) Equipment that is in areas where cannabis is cultivated, manufactured, processed, tested, packed, or held and that does not come into contact with cannabis must be so constructed that it can be kept in a clean and sanitary condition.
- o **(5)** Trimming, holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.
- (6) Each freezer and cold storage compartment used to store and hold cannabis capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.
- (7) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in cannabis must be accurate and precise and adequately maintained, and adequate in number for their designated uses.
- (8) Compressed air or other gases mechanically introduced into cannabis or used to clean cannabis-contact surfaces or equipment must be treated in such a way that cannabis is not contaminated with unlawful indirect cannabis additives.

• (F) Processes and controls

- (1) All operations in the cultivation, manufacturing, processing, testing, dispensing, packing, and holding of cannabis (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.
 - (a) Appropriate quality control operations must be employed to ensure that cannabis is suitable for human consumption and that cannabis-packaging materials are safe and suitable.
 - **(b)** Overall sanitation of the facility must be under the supervision of one or more competent individuals assigned responsibility for this function.
 - (c) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.
 - (d) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and cannabis contamination.
 - **(e)** All cannabis that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.
- (2) Raw materials and other ingredients. Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into cannabis and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration.
 - (a) Raw materials must be washed or cleaned as necessary to remove soil or other contamination.
 - **(b)** Water used for washing, rinsing, or conveying cannabis must be safe and of adequate sanitary quality.
 - (i) Water may be reused for washing, rinsing, or conveying cannabis if it
 does not cause allergen cross-contact or increase the level of
 contamination of the cannabis.

- (c) Raw materials and other ingredients must either not contain levels of microorganisms that may render the cannabis injurious to the health of humans, or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.
- (d) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished cannabis.
- (e) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing cannabis.
- **(f)** Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen crosscontact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the cannabis from becoming adulterated. Material scheduled for rework must be identified as such.
- **(g)** Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.
- **(h)** Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.
- (i) Raw materials and other ingredients that are cannabis allergens, and rework that contains cannabis allergens, must be identified and held in a manner that prevents allergen cross-contact.
- (3) Manufacturing operations. Equipment and utensils and cannabis containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.
 - (a) All cannabis cultivation, manufacturing, processing, packing, testing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen crosscontact, contamination of cannabis, and deterioration of cannabis.
 - (b) Cannabis that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the cannabis from becoming adulterated during cultivation, manufacturing, processing, packing, testing, and holding.
 - (c) Measures such as sterilizing, irradiating, cooking, freezing, refrigerating, controlling pH, or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent cannabis from being adulterated.
 - (d) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.
 - (e) Effective measures must be taken to protect finished cannabis from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse.

- (i) When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated cannabis.
- (ii) During transportation, cannabis must be protected against allergen cross-contact and against contamination as necessary.
- (f) Equipment, containers, and utensils used to cultivate, process, manufacture, test, convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other cannabis must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.
- **(g)** Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in cannabis.
- (h) Cannabis, raw materials, and other ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other cannabis;
- (i) Steps such as washing, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect cannabis against allergen crosscontact and against contamination.
- (j) Cannabis must be protected from contaminants that may drip, drain, or be drawn into the cannabis.
- **(k)** Heat blanching, when required in the preparation of cannabis products capable of supporting microbial growth, must be effected by heating the cannabis to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the cannabis or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.
- (I) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.
- (m) Filling, assembling, packaging, and other operations must be performed in such a way that the cannabis is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.
- (n) Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.
- (o) Cannabis that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.
- **(p)** When ice is used in contact with cannabis, it must be made from water that is safe and of adequate sanitary quality in accordance with this rule and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

• (G) Cannabis storage and distribution

(1) Storage and transportation of cannabis must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of cannabis, as well as against deterioration of the cannabis and the container.

1301:18-4-02 Requirements for Cannabis Strains and Cannabis Products

- (A) No licensee shall create, use, or distribute, or cause to be created, used, or distributed, any cannabis strain name or cannabis product that is any of the following:
 - (1) False or misleading;
 - o (2) Obscene or indecent;
 - o (3) Attractive to children;
 - o (4) Resembles any of the following:
 - (i) A cartoon character, fictional character whose target audience is children or youth, or pop culture icon;
 - (ii) A product available for consumption as a commercially available candy; or
 - (iii) A realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
 - (5) Encourages the consumption of cannabis in a manner that leads to excessive use, intoxication, overconsumption, or in combination or conjunction with other intoxicants, illegal substances, or in a method not otherwise authorized by this chapter;
 - o (6) Contains a depiction of cannabis consumption or administration;
 - (7) Departs from the cannabis registered name, including, slang terms, and similar references;
 - (8) Contains a health-related statement unless documentation meeting the standards set by the division demonstrates that the specific health-related statement is supported by substantial evidence or substantial clinical data;
 - (9) Suggests, or otherwise indicates, that the product has been approved or endorsed by the division, the state of Ohio or any person or entity associated with the state of Ohio, or any other person without their consent;
 - o (10) Violates state of Ohio or federal trademark or copyright law; or
 - (11) Otherwise violates any provision of chapters 3780 and 3796 of the Revised Code or the rules promulgated pursuant to chapters 3780 and 3796 of the Revised Code.

1301:18-4-03 Authorized cannabis forms and methods of administration

- **(A)** Pursuant to sections 3780.04 and 3796.06 of the Revised Code, approved cannabis products include the following forms and methods of administration:
 - (1) For adult-use cannabis:
 - (a) Smoking, Combustion, or Vaporization:
 - (i) Seeds;
 - (ii) Live plants;
 - (iii) Clones;
 - (iv) Plant material; and
 - (v) Extracts.
 - o (2) For medical cannabis:
 - (a) Vaporization:
 - (i) Seeds;

- (ii) Live plants;
- (iii) Clones;
- (iv) Plant material; and
- (v) Extracts.
- (3) Oral administration:
 - (a) Capsules;
 - (b) Pills;
 - (c) Tablets;
 - (d) Drops;
 - (e) Oils;
 - (f) Edibles; and
 - (g) Beverages.
- o (4) Topical administration:
 - (a) Salves;
 - (b) Ointments;
 - (c) Lotions or similar cosmetic products; and
 - (d) Topical sprays.
- o **(5)** Transdermal administration:
 - (a) Patches
- o (6) Inhalation:
 - (a) Inhalers
- o (7) Sublingual or Oromucosal:
 - (a) Lozenges;
 - (b) Oral pouches;
 - (c) Oral strips;
 - (d) Oral sprays; and
 - (e) Tinctures.
- o (8) Rectal:
 - (a) Suppositories
- **(B)** The following limitations apply:
 - o (1) For medical cannabis:
 - (a) The smoking or combustion of medical cannabis is prohibited.
 - **(b)** Vaporization is not an authorized method of administration for registered patients under the age of eighteen.
 - (2) Products intended for vaporization cannot contain characterizing flavors, except those intended to mimic cannabis strains.

1301:18-4-04 Petition for Additional Forms and Methods

- (A) An individual seeking to add a form or method of administration shall apply in a manner prescribed by the division of cannabis control and include the following:
 - o (1) Multiple scientific experts supporting the addition of the form or method of administration.
 - (a) The scientific experts must have specialized knowledge acquired through experience, education or observation, or study that is not possessed by the average layperson.
 - (2) The extent to which the prospective form or method of administration is generally accepted by the medical community;

- (3) Information or studies known to the petitioner regarding any benefit or adverse effects from the use of the proposed form or method of administration; and
- o (4) Benefits to approving the proposed form or method of administration.
- **(B)** In addition to information provided in a petition, the division may examine scientific, medical, or other evidence and research pertaining to the petition and may gather information, in person or in writing, from other persons knowledgeable about the form or method of administration included in the petition.

• (C) Division review of application.

- (1) Upon receipt of an application pursuant to paragraph (A) of this rule, the division will
 review the application and within sixty calendar days may:
 - (a) Approve the form or method;
 - **(b)** Deny the application; or
 - (c) Advise in writing that the applicant failed to meet all application requirements.
- (2) Upon determination by the division that an applicant failed to meet all requirements
 of paragraph (A) of this rule, the division will notify the applicant in writing of all
 deficiencies contained within the application.
- (3) Within ten business days of receipt of written notification from the division, the applicant shall ensure that all deficiencies outlined are alleviated and submit any further documentation requested by the division.
- (4) Should an applicant fail to cure all application deficiencies, the application shall be deemed abandoned.
- **(D)** If a form or method has been previously considered and rejected by the division, or is determined by the division to be substantially similar to a rejected form or method of administration, the division may deny the petition without first considering the appropriateness, unless new scientific research supporting the request is included in the petition.

1301:18-4-05 THC Content, Portions, and Units of cannabis

- (A) Limitations on THC Content.
 - o (1) The tetrahydrocannabinol content for adult-use cannabis shall not exceed:
 - (a) Thirty-five percent for plant material; and
 - **(b)** Ninety percent for extracts.
 - (2) The tetrahydrocannabinol content for medical cannabis shall not exceed:
 - (a) Thirty-five percent for plant material; and
 - (b) Seventy percent for extracts.

• (B) Requirements for Cannabis Intended for Direct Consumer Sale.

- (1) Limitations on portion sizes and units per package.
 - (a) Each portion of cannabis shall be clearly demarked in a way that enables a reasonable person to intuitively determine the amount of product that constitutes a single portion.
 - **(b)** Each portion in patch form must be individually marked with the total target THC content indicated pursuant to [Product Registration].
 - (c) Each portion of cannabis shall contain not less than ninety per cent or no more than one hundred ten per cent of the concentration of total target THC content indicated pursuant to [Product Registration].
 - (d) Each licensee shall package all cannabis in a single package for sale to consumers. Each single package shall not exceed the following:
 - (i) Plant material: one ounce per package

- (ii) Capsules and pills: 100mg per serving and 1000mg per package
- (iii) Drops for oral administration: 10mg per serving and 1000mg per package
- (iv) Edibles: 10mg per serving and 100mg per package
- (v) Beverages: 10mg per container
- (vi) Extracts for oral administration: 1000mg per package
- **(vii)** Topical sprays, salves, lotions, or other similar cosmetic products: 1000mg per package
- (viii) Patches for transdermal administration: 100mg per serving and 1000mg per package
- (ix) Inhalers: 800mg per device
- (x) Lozenges, oral pouches, oral strips, oral sprays, and tinctures for sublingual or oromucosal administration: 100mg per portion and 1000mg per package
- (xi) Rectal: Suppositories for rectal administration: 100mg per serving and 1000mg per package
- **(e)** The serving size for concentrates for vaporization is 1 inhalation lasting 2 seconds per serving.

(2) Requirement for Universal THC symbol.

- (a) Each cannabis product that is divided into portions shall:
 - **(1)** Apply a universal symbol that denotes that the product contains cannabis to each portion of the cannabis product;
 - (2) If the cannabis product is presented as separate single portions, the processor shall apply the universal symbol to each single portion;
 - (3) If the cannabis product is presented as a single unit comprised of more than one portion, the processor shall make clearly visible lines of demarcation between portions and apply the universal symbol to each portion; and
 - (4) The size of the universal symbol marking is determined by the size of the portion instead of the overall product size, and shall not be less than one-fourth inch by one-fourth inch.

1301:18-4-08 Advertising Definitions:

- "Advertisement" or "advertising" means any written or verbal statement, illustration, or depiction created, intended, or otherwise calculated to induce sales, through a combination of letters, pictures, objects, lighting effects, illustrations, or other similar means, regardless of form, location, or medium.
- "Health-related statement" means any statement, term, reference, or claim related to health and includes statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption or administration of cannabis, or any compound, ingredient, additive, or any combination thereof, found within a cannabis product, and health benefits or effects on health. This includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of cannabis. This also includes anything that implies a physical, physiological, or psychological sensation or effect resulting from the consumption or administration of cannabis. Health-related statement also includes statements, symbols, vignettes, or other forms of communication that suggest, within the

- context in which they are presented, that a relationship exists between the consumption or administration of cannabis and any alleged health benefit.
- The state of Ohio has a compelling state interest to ensure that any advertisement, or marketing campaign related to cannabis, does not encourage or promote excessive use, intoxication, overconsumption, or use of cannabis in a manner not authorized by this chapter and chapter 3780 of the Revised Code, and is not attractive to children.
- (A) No licensee shall create, use, or disseminate, or cause to be created, used, or disseminated, an advertisement that is any of the following:
 - (1) False or misleading;
 - (2) Obscene or indecent;
 - (3) Attractive to children;
 - (4) Includes any image or text referencing or resembling a cartoon character, fictional character whose target audience is children or youth, or pop culture icon;
 - (5) Encourages the consumption of cannabis in a manner that leads to excessive use, intoxication, overconsumption, or in combination or conjunction with other intoxicants, illegal substances, or in a method not otherwise authorized by this chapter;
 - (6) Contains a depiction of cannabis consumption or administration;
 - (7) A departure from the cannabis registered name, including, slang terms, and similar references;
 - (8) Disparaging to a competitor's products;
 - (9) Contains a health-related statement unless documentation meeting the standards set by the division demonstrates that the specific health-related statement is supported by substantial evidence or substantial clinical data;
 - (10) Suggests, or otherwise indicates, that the advertisement has been approved or endorsed by the division, the state of Ohio or any person or entity associated with the state of Ohio, or any other person without their consent;
 - o (11) Violates state of Ohio or federal trademark or copyright law; or
 - (12) Or otherwise violates any provision of chapter or the rules promulgated pursuant to chapters 3780 or 3796 of the Revised Code.
- **(B)** No licensee shall place or maintain, or cause to be placed or maintained, an advertisement for cannabis, whether medical or adult-use, cannabis products, or cannabis-related paraphernalia, in any form or through any of the following medium:
 - o (1) On a medium with a high likelihood of reaching persons under the age of eighteen;
 - (2) Within five hundred feet of the end boundaries of a parcel of real estate having situated on it a prohibited facility;
 - (3) On a billboard;
 - (4) On a radio or television broadcast or internet programming;
 - o (5) Left upon any private property without the consent of the property owner;
 - o (6) On or in a public transit vehicle or public transit shelter;
 - o (7) On or in a stadium or arena;
 - o (8) On or in a publicly owned or operated property; or
 - (9) At any scheduled event, which includes conferences, trade shows, or similar events, which a licensee plans to attend, participate, or sponsor, whether it be educational or otherwise, unless the licensee provides written notification to the division of its intent to attend at least ten business days prior to the event.
- **(C)** A licensee may market, sell, or license merchandise to individuals eighteen years of age or older so long as the licensee ensures the following:

- (1) Any merchandise sold contains only depictions, representations, or branding previously approved by the division.
- (2) No licensee shall market, distribute, offer, sell, license, or cause to be marketed, distributed, offered, sold, or licensed any merchandise related to any entity licensed under this chapter, cannabis, or cannabis paraphernalia, to an individual under eighteen years of age.
- **(D)** A licensee may develop a website or otherwise establish a web presence advertising the name, business address, contact information, and services provided by the licensee which requires age affirmation of at least eighteen years of age by the user before gaining access to licensee's website. A licensee operating a website shall not do any of the following:
 - (1) Provide a medium for website users to transmit website content to individuals under the age of eighteen; and
 - (2) Display or otherwise post content that violates chapter 3780 or 3796 of the Revised Code. or these rules.
- **(E)** A licensee may utilize a sign that is located within the external boundaries of the parcel on which the licensee is located.
- **(F)** A licensee may photograph, record, or create other media depicting the licensed premises so long as the licensee ensures:
 - o (1) The confidentiality of all patients, caregivers, and adult-use consumers; and
 - o (2) No media compromises the safety and security of the licensed premises.
- **(G)** No licensee shall license, encourage, or otherwise authorize any affiliated or third party to use or advertise in a manner prohibited by this division.
- **(H)** Should the division determine that a licensee's advertisement violates any of the regulations outlined under this chapter the division may:
 - (1) Require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the advertisement would be false or misleading without such a disclosure;
 - (2) Make recommendations with respect to changes that are necessary to protect the public health, safety, and welfare;
 - o (3) Prohibit the use of the advertisement; or
 - (4) Investigate and proceed with any action as permitted by [Enforcement Authority].
- (I) A licensee may submit in a manner prescribed by the division an advertisement for review prior to use or disbursement to ensure the advertisement complies with all requirements with this rule.

Cultivators

1301:18-5-02 Cultivator Operating Procedures and Quality Assurance

- (A) Each cultivator shall establish, maintain, and comply with written policies and procedures for the daily operation and cultivation of cannabis. The cultivator's standard operating policies and procedures shall ensure the safe cultivation and distribution of cannabis and compliance with all mandates under division 1301:18 of the Administrative Code.
- (B) Major Modifications
 - (1) Any proposed major renovation or modification of the licensed premises shall be submitted to the division at least sixty calendar days prior to implementation.
 - (2) The division will review the proposed modification and may do any of the following:
 - (a) Approve the submission;
 - (b) Deny the submission; or

- (c) Mandate updates to the submission to ensure compliance with this chapter.
- (3) The division may inspect the licensed premises pursuant to any proposed major renovation or modification.
- **(C)** Each cultivator shall ensure the licensed premises:
 - (1) Conforms with all relevant local ordinances, zoning and planning requirements, and fire codes;
 - o (2) Prominently displays its certificate of operation and license seal issued by the division;
 - (3) Contains sufficient lighting to ensure visibility, security, and proper surveillance;
 - (4) Maintains proper cleanliness, ventilation, temperature control, and sanitation of the facility to ensure safe and consistent inventory;
 - (5) Conducts routine calibration of all scales, balances, or other weight or mass measuring devices using "National Institute of Standards and Technology" (NIST)-traceable reference weights, at least annually, by an independent third party approved by the division.
 - o (6) Documents the following utilized at the licensed premises:
 - (a) Cultivation methods and standards;
 - **(b)** Cannabis strains with respective cannabinoid profiles cultivated at the facility;
 - **(c)** If applicable, cannabis remediation methods, including remediation by irradiation, gas treatment such as ozone, radiofrequency, and UV light.

• (D) Designated Areas within the Facility.

- (1) Each cultivator shall designate areas within the facility that are compartmentalized based upon function and restricts movement between the different production areas by personnel based on access credentials assigned by the facility.
- (2) Each cultivator shall maintain the following designated, secure limited access areas accessible only by authorized registered employees:
 - (a) A cannabis cultivation area;
 - (b) A storage area for all cannabis;
 - (c) A security area for all security and surveillance systems and equipment;
 - (d) A preparation and packaging area for all cannabis intended for distribution;
 - (e) A cannabis destruction and disposal area that complies with rule 1301:18-3-16 of these rules: and
 - (f) An area for receipt of all deliveries to the facility.

• (E) Employees

- (1) Prior to commencing employment, each cultivator shall ensure all employees are registered with the division pursuant to rule 1301:18-3-09 of the Administrative Code and receive adequate education and training on standard operating procedures and as mandated by rule 1301:18-3-10 of the Administrative Code.
- (2) All registered employees are to display their employee badge at all times during working hours.
- (3) A registered responsible party as outlined by rule 1301:18-3-09 of the Administrative Code is to be present at the licensed premises at least twenty hours per week.

• (F) Requirements for pesticides, fertilizers, and other chemicals.

- (1) The division may maintain a list of pesticides that are approved for use during the cultivation process.
- (2) Unless otherwise authorized pursuant to paragraph (F)(1) of this rule, a cultivator shall not utilize any pesticides, fertilizers, or other chemicals during the cultivation process without prior approval by the division. All pesticides, fertilizers, and other chemicals shall be properly stored and in a manner that protects against contamination and ensure the following:

(a) Pesticides:

- (i) The pesticide is registered with the Ohio division of agriculture and is either:
 - (A) Registered with the United States environmental protection agency under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 - 136y (2012); or
 - (B) Exempt from registration under 40 C.F.R. 152.25(f) (2015) and the active inert ingredients of the pesticide product are authorized for use on crops or plants intended for human consumption by the United States environmental protection agency.

(b) Fertilizers:

- (i) Any specialty fertilizer, as defined in division (Q) of section 905.31 of the Revised Code, is registered with the Ohio division of agriculture pursuant to section 905.33 of the Revised Code.
- (c) All individuals applying pesticides, fertilizers, or other chemicals adhere to all use requirements outlined on the product label and utilize all applicable personal protective equipment.
- (d) Disposal of all unused pesticides, fertilizers, and other chemicals complies with all state and federal laws and regulations and complies with all directions outlined on the product label.
- (3) Unless otherwise authorized by the division, foliar application of approved pesticides, fertilizers, or other chemicals shall not occur after the twenty-first day following the date that a plant is moved into the flowering stage of growth.
- (4) Pursuant to [OAC Records Rule] each cultivator shall document all pesticide, fertilizer, or other chemical applications utilized during the cultivation process and include the following information for each application:
 - (a) Date and time of application;
 - (b) Stage of cultivation process;
 - **(c)** Date when the plants in the application area were moved to the flowering stage, if applicable;
 - (d) United States environmental protection agency registration number, if applicable;
 - (e) Analysis of the fertilizer applied;
 - **(f)** Application site, which shall be identified by the location legend maintained by the cultivator;
 - (g) Name of the product being applied;
 - (h) Amount applied;
 - (i) Unique plant identifier or other information that identifies which plants received the application;
 - (j) Size of the application area;
 - (k) Name of individual making the application; and
 - (I) Comments or special conditions related to the application.

1301:18-5-03 Cultivator Inventory and Control

• (A) Each cultivator shall establish, maintain, and comply with written policies and procedures for proper and secure inventory control of all cannabis maintained at the licensed premises. The

cultivator's inventory control policies and procedures shall mitigate the risk of theft, loss, and diversion of cannabis and ensure the following:

- (1) Before accepting a delivery of cannabis, a responsible party must inspect and ensure the delivery:
 - (a) Meets all relevant packaging and labeling requirements; and
 - **(b)** The contents within the shipment conform with all representations outlined in the transfer manifest from the originating entity.
 - (c) In the event the shipment fails to meet the requirements outlined under paragraph (A) of this rule, the cultivator shall:
 - (i) Refuse to accept the non-conforming batch or lot;
 - (ii) Return the batch or lot to the originating entity; and
 - (iii) Within forty-eight hours of discovery, notify the division in writing.
- (2) All information related to cannabis maintained at the licensed premises is accurately
 and contemporaneously recorded in the state inventory tracking system from the time of
 receipt until distribution or disposal.
- (3) All inventory is stored in a secure, limited access storage area that meets the requirements of rule 1301:18-5-05 of the Administrative Code accessible only by authorized employees.
- (4) Ongoing, regular, and comprehensive inventories of all cannabis maintained at the licensed premises that includes the following:
 - (a) Upon discovery, each cultivator shall notify the division in writing of any discrepancies and submit a written plan of corrective action prior to making any adjustments to the state inventory tracking system.
 - **(b)** Prior to commencing business, each cultivator shall conduct an initial comprehensive inventory of all cannabis at the licensed premises.
 - (i) If the cultivator commences business with no cannabis at the licensed premises, the cultivator shall record this fact as the initial inventory.
 - (c) When a cannabis plant reaches twelve inches in height or is transplanted from a cloning medium or apparatus into a growth medium or apparatus intended for the vegetative or flowering stages of growth cycle, whichever occurs sooner, securely attach a state inventory tracking system tag to the plant or the plant's container that includes the following information:
 - (i) The cultivator's name and license number;
 - (ii) The registered name of the strain; and
 - (iii) The unique plant identifier.
 - (d) A registered responsible party shall conduct a weekly inventory and document an audit of the licensed premises' daily inventory to ensure the physical inventory matches the information documented in the cultivator's internal inventory system and state inventory tracking system. The weekly is to include the following:
 - (i) The date of the inventory;
 - (ii) The amount of cannabis maintained at the licensed premises, and include the following:
 - (A) The total number of cannabis plants, whether in the flowering, vegetative, or clone phase of growth, organized by the room in which the plants are grown;
 - (B) Each batch of plant material including the associated batch number, weight, and strain name quarantined for:

- (1) Required testing as outlined under [OAC testing];
- (2) Research and development;
- (3) Destruction or disposal in accordance with rule 1301:18-3-12 of the Administrative Code;
- (4) Packaged, labeled, and prepared for transfer, distribution, or sale; and
- **(5)** The total number of plants and every unique plant identifier that have been harvested, but are not yet associated with a batch.
- (iii) The amount of cannabis sold or distributed since the previous weekly inventory, and include the following:
 - (A) The date of sale or distribution;
 - (B) The license number and name of the licensed entity to which the cannabis was sold; and
 - (C) The batch number, registered product name, and quantity of cannabis sold.
- (iv) The date, quantity, and method of disposal of cannabis, if applicable;
- (v) A summary of the inventory findings; and
- **(vi)** The name, signature, and title of the employees who conducted the inventory and oversaw the inventory.
- **(e)** Prior to the renewal of its certificate of operation, a registered responsible party for each cultivator shall do the following:
 - (i) Create an annual inventory report generated by the state inventory tracking system; and
 - (ii) Conduct a full, comprehensive, manual inventory of the cannabis at the licensed premises and compare the findings to the annual inventory report created pursuant to paragraph (4)(a) of this rule.
- **(5)** Prior to any transfer of cannabis, a transfer manifest is prepared utilizing the state inventory tracking system that includes the following for each transfer:
 - (a) The names and addresses of the cannabis entities sending and receiving the shipment;
 - **(b)** The names of the employees transporting the cannabis and their respective badge number as provided by rule 1301:18-3-09 of the Administrative Code;
 - (c) The time of departure and estimated time of arrival;
 - **(d)** Within each transfer the following information for each individual package:
 - (i) A description of each individual package that is part of the shipment;
 - (ii) The total number of individual packages;
 - (iii) The unique identifying number generated within the state inventory tracking associated with the package;
 - (iv) The units of measure as reported within the state inventory tracking system as follows:
 - (A) The weight of the cannabis contained within the shipment; or
 - o (B) The quantity of units contained within the shipment.
 - **(e)** The unique identifying number generated within the state inventory tracking system associated with the transfer manifest; and
 - (f) If applicable:

- (i) The license plate number and vehicle type that will transport the shipment; and
- (ii) The specific delivery route, which includes street names and distances.
- (g) Prior to the delivery, provide a copy of the transfer manifest to the division.
- o **(6)** Any and all information the division determines necessary for maintaining and tracking cannabis is documented and submitted into the state inventory tracking system.
- (7) All inventories, procedures, and other documents required by this rule are maintained at the licensed premises and pursuant to [OAC Records and Reporting] and available for immediate review and duplication upon the division's request.

1301:18-5-06 Cultivation Area Expansion

- (A) A cultivator shall not expand its cultivation area without prior approval from the division of cannabis control.
- **(B)** Upon utilization of the totality of its cultivation area, a cultivator may apply in a manner prescribed by the division for an initial cultivation area expansion subject to the following restrictions:
 - o (1) A Level I cultivator may request to expand up to one hundred thousand square feet;
 - o (2) A Level II cultivator may request to expand up to fifteen thousand square feet;
 - o (3) A cultivator may submit only one request for expansion each calendar year; and
 - **(4)** A cultivator's total cultivation area is calculated per license, regardless of whether a cultivator is approved for an expansion at more than one location.
- (C) Prior to expanding its cultivation area, a cultivator shall submit the following to the division:
 - (1) A complete and accurate application on a form prescribed by the division evidencing the following:
 - (a) The proposed location of expanded cultivation area;
 - **(b)** The associated plans and specifications for the proposed expansion that includes:
 - (i) Plans and specifications for the proposed expansion in compliance with rule 1301:18-5-02 of the Administrative Code;
 - (ii) A timeline for completion of the proposed expansion, which, if approved, will become a mandatory condition; and
 - (iii) Evidence that the cultivator has a history of compliance with division 1301:18 of the Administrative Code.
 - (c) Supporting documentation that the cultivator has maintained an uninterrupted supply of cannabis plant material pursuant to rule 1301:18-5-03 of the Administrative Code; and
 - (d) Evidence the proposed expansion meets all applicable requirements under rule 1301:18-5-02 of the Administrative Code;
 - **(e)** The licensee will remain in compliance with division 1301:18 of the Administrative Code; and
 - **(f)** Any supporting documentation evidencing the requirements outlined under this paragraph.
 - (2) Within ninety calendar days of receipt of an expansion request pursuant to this rule, the division will review the application and may:
 - (a) Approve the application;
 - (b) Deny the application; or

- (c) Advise the cultivator in writing that the applicant failed to meet all application requirements.
- (3) Upon receipt of written approval, the cultivator may construct and prepare the expanded cultivation area.
- **(D)** In addition to the mandates outlined under paragraph (C) of this rule, a cultivator requesting to re-locate all or a portion of its cultivation area to more than one facility site shall also comply with the following:
 - (1) Once the expanded cultivation area is fully constructed and prepared to commence all business, the cultivator shall submit in a manner prescribed by the division a proposed transition plan outlining the following:
 - (a) A proposed procedure for the safe and secure transfer all inventory and other materials maintained at the original location to the proposed location within ninety calendar days as outlined under this paragraph;
 - **(b)** Confirmation that the cultivator's transition plan will ensure proper security and surveillance of the original location and the proposed location during the transition period that mitigate the risk of theft, loss, and diversion; and
 - **(c)** Assurance the cultivator will maintain ongoing compliance with all requirements outlined under these rules.
 - (2) Upon receipt of a cultivator's proposed transition plan, the division will:
 - (a) Review the proposed transition plan and advise of any necessary modifications: and
 - **(b)** Conduct an inspection pursuant to rule 1301:18-9-01 of the Administrative Code.
 - (3) Unless otherwise authorized by the division, the cultivator shall have ninety calendar
 days from the date the cultivator passes the inspection pursuant to paragraph (D) of this
 rule to transfer all inventory.
 - (a) No inventory may be transferred prior to the beginning date of the approved transition period;
 - **(b)** The cultivator shall notify the division once the transfer of inventory is complete and business may commence at the new location.
 - (c) Pursuant to rule 1301:18-9-01 of the Administrative Code, the division may conduct an inspection at the original location and the proposed location to ensure compliance with all requirements outlined under these rules.
 - (4) After verification by the division that the expanded cultivation area is in full compliance
 with these rules, the division will issue a modified certificate of operation reflecting the
 new location.
 - (a) The cultivator shall not operate at the new location until the division approves and issues an amended certificate of operation outlining the new location.
 - **(b)** A cultivator's modified certificate of operation has the same expiration date as the previously issued license.
 - **(c)** Upon receipt of the modified certificate of operation, the cultivator may commence business.
- **(E)** If the division approves a cultivator's request for expansion pursuant to this rule, the cultivator will be bound to the terms in the request for expansion.
- **(F)** After issuance of initial cultivation expansion requests pursuant to paragraph (C) of this rule, should the division determine that additional cultivation area is necessary to meet the demand for cannabis, it may solicit requests for cultivation expansion plans from cultivators licensed pursuant to these rules.

- (1) The division will examine the following when determining the necessity of additional cultivation area:
 - (a) Program-wide capacity;
 - (b) Total population of this state;
 - (c) Data from the inventory tracking system regarding demand for cannabis; and
 - (d) Any other information the division deems appropriate.
- (2) Should the division determine that additional expansion is necessary pursuant to this paragraph, the division will:
 - (a) Issue a formal solicitation for expansion plans to licensed cultivators; and
 - (b) Provide notice of all expansion area plan application requirements.

Processors

1301:18-6-02 Processor Operating Procedures and Quality Assurance

• (A) Each processor shall establish, maintain, and comply with written policies and procedures for the daily operation and processing of cannabis. The processor's standard operating policies and procedures shall ensure the safe processing, extracting, manufacturing, and distribution and compliance with all mandates under division 1301:18 of the Administrative Code.

• (B) Major Modifications

- o **(1)** Any proposed major renovation or modification of the licensed premises shall be submitted to the division at least sixty calendar days prior to implementation.
- o (2) The division will review the proposed modification and may do any of the following:
 - (a) Approve the submission;
 - **(b)** Deny the submission; or
 - (c) Mandate updates to the submission to ensure compliance with this chapter.
- (3) The division may inspect the licensed premises pursuant to any proposed major renovation or modification.
- **(C)** Each processor shall ensure the licensed premises:
 - (1) Conforms with all relevant local ordinances, zoning and planning requirements, and fire codes;
 - (2) Complies with all applicable OSHA regulations, fire, safety, and building codes
 pertaining to the use and storage of the equipment and solvents used in the manufacture
 of cannabis products and pass all associated inspections;
 - (3) Prominently displays its certificate of operation and license seal issued by the division;
 - o (4) Contains sufficient lighting to ensure visibility, security, and proper surveillance;
 - (5) Maintains proper cleanliness, ventilation, temperature control, and sanitation of the facility to ensure safe and consistent inventory;
 - (6) Conducts routine calibration of all scales, balances, or other weight or mass measuring devices using "National Institute of Standards and Technology" (NIST)-traceable reference weights, at least annually, by an independent third party approved by the division.
 - (7) Documents the following utilized at the licensed premises:
 - (a) Processing records, which at a minimum shall include:
 - (i) The form and types of medical marijuana maintained at the facility on a daily basis; and
 - (ii) Production records, including extraction, refining, manufacturing, packaging, and labeling, and all ingredients used in the production of each batch or lot of marijuana product.
- (D) Designated Areas within the Facility.

- (1) Each processor shall designate areas within the facility that are compartmentalized based upon function and restricts movement between the different production areas by personnel based on access credentials assigned by the facility.
- (2) Each processor shall maintain the following designated, secure limited access areas accessible only by authorized registered employees:
 - (a) A cannabis extraction area;
 - (b) A storage area for all cannabis;
 - (c) A security area for all security and surveillance systems and equipment;
 - (d) A preparation and packaging area for all cannabis intended for distribution;
 - **(e)** A cannabis destruction and disposal area that complies with rule 1301:18-3-16 of the Administrative Code; and
 - **(f)** An area for receipt of all deliveries to the facility.

• (E) Employees

- (1) Prior to commencing employment, each processor shall ensure all employees registered with the division pursuant to rule 1301:18-3-09 of the Administrative Code and receive adequate education and training on standard operating procedures and as mandated by rule 1301:18-3-10 of the Administrative Code.
- (2) All registered employees are to display their employee badge at all times during working hours.
- (3) A registered responsible party as outlined by rule 1301:18-3-09 of the Administrative Code is to be present at the licensed premises at least twenty hours per week.
- **(F)** Unless otherwise authorized by the division, a processor shall only utilize the following methods, equipment, solvents, and gases in the manufacture of cannabis products:
 - (1) Hydrocarbon solvent-based extraction methods in a spark-free and properly ventilated environment, isolated from any open flame or ignition source, and may use the following solvents, at a minimum of ninety-nine per cent purity, in a professional grade, closed-loop extraction system designed to recover the solvents:
 - (a) Propane;
 - (b) N-butane;
 - (c) Isobutane;
 - (d) Heptane; or
 - **(e)** Other solvents exhibiting minimal potential toxicity to humans with the approval of the department.
 - (2) Carbon dioxide-based extraction methods using food grade carbon dioxide at a minimum of ninety-nine per cent purity in a professional grade, closed-loop system in which each vessel is rated to a minimum pressure to accommodate the specific extraction protocol, including supercritical, liquid, and subcritical.
 - (3) Ethanol at a minimum of ninety-nine per cent purity to produce extracts for use in the manufacture of cannabis products.
 - (4) Food grade glycerin, ethanol, and propylene glycol in the manufacture of cannabis products.
 - (5) Non-solvent extraction methods involving the mechanical separation of cannabinoids from plant material to produce cannabis extracts for use in the manufacture of cannabis products.
- **(G)** Prior to an issuance or renewal of a certificate of operation, each processor shall complete an inspection with the Ohio department of agriculture, or an equivalent body, evidencing compliance with the manufacturing standards established by the division.

• **(H)** Unless otherwise authorized by the division, a processor shall not manufacture potentially hazardous foods as defined by section 3715.01 of the Revised Code.

• (I) Non-marijuana ingredients

- (1) The division may prohibit the use of certain non-marijuana ingredients if the division determines that there is reasonable probability that use in the manufacture of cannabis products is, or would be, in violation of chapters 3780 or 3796 of the Revised Code or use or exposure to the ingredient constitutes a risk to public health or safety.
- (2) Except as required pursuant to paragraph (I)(3) of this rule, non-marijuana ingredients may be used in the manufacture of cannabis products provided they meet the following conditions:
 - (a) The non-marijuana ingredients are obtained from licensed and regulated sources that comply with the requirements of federal and state laws and regulations;
 - (b) The non-marijuana ingredients are nontoxic and safe for human consumption;
 and
 - (c) The non-marijuana ingredients were not prepared or stored in a private residence.
- (3) Hemp-derived ingredients may be used in the manufacture of cannabis products provided they meet the following conditions:
 - (a) The ingredients are obtained from a state-licensed and regulated source that comply with federal and state laws and regulations;
 - **(b)** The ingredients are obtained from the source in extracted, distillate form;
 - (c) The ingredients contain an accompanying certificate of analysis evidencing compliance with all required testing; and
 - (d) Each batch or lot of hemp-derived ingredients, along with the accompanying certificate of analysis is recorded in the state inventory tracking system.

1301:18-6-04 Processor Inventory and Control

- (A) Each processor shall establish, maintain, and comply with written policies and procedures for proper and secure inventory control of all cannabis maintained at the licensed premises. The cultivator's inventory control policies and procedures shall mitigate the risk of theft, loss, and diversion of cannabis and ensure the following:
 - (1) Before accepting a delivery of cannabis, a responsible party must inspect and ensure the delivery:
 - (a) Meets all relevant packaging and labeling requirements; and
 - **(b)** The contents within the shipment conform with all representations outlined in the transfer manifest from the originating entity.
 - (c) In the event the shipment fails to meet the requirements outlined under paragraph (A)(1) of this rule, the dispensary shall:
 - (i) Refuse to accept the non-conforming batch or lot;
 - (ii) Return the batch or lot to the originating entity; and
 - (iii) Within forty-eight hours of discovery, notify the division in writing.
 - (2) All information related to the cannabis maintained at the licensed premises is accurately and contemporaneously recorded in the state inventory tracking system from the time of receipt until distribution or disposal.

- (3) All inventory is stored in a secure, limited access storage area that meets the requirements of 1301:18-6-05 of the Administrative Code accessible only by registered employees.
- Ongoing, regular, and comprehensive inventories of all cannabis maintained at the licensed premises that includes the following:
 - (a) Upon completion of each iteration of an extraction process, the processor attaches a label to the container of cannabis extract that includes the following information:
 - (i) The processor's name and license number;
 - (ii) The batch numbers of any batches of plant material used in the extraction;
 - (iii) The registered strain names of any plant material used during the extraction;
 - (iv) The batch number assigned to the batch of medical marijuana extract;
 - (v) The date of extraction; and
 - **(vi)** The net weight and volume of medical marijuana extract.
 - (b) Upon completion of each iteration of a manufacturing process, the processor attaches a label to the container of cannabis products that includes the following information:
 - (i) The processor's name and license number;
 - (ii) The registered product name;
 - (iii) The batch numbers of any batches of extract used in the manufacturing process;
 - (iv) The date of manufacture; and
 - (v) The net weight and unit count of cannabis products prepared or packaged for sale.
 - (c) A registered responsible party shall conduct a weekly inventory and document an audit of the licensed premises' daily inventory to ensure the physical inventory matches the information documented in the processor's internal inventory system and state inventory tracking system. The weekly inventory is to include the following:
 - (i) The date of the inventory;
 - (ii) The amount of cannabis at the licensed premises and include:
 - (A) The net weight of plant material;
 - o **(B)** The net weight and volume of cannabis extract;
 - (C) The net weight and unit count of cannabis products prepared or packaged for sale or distribution;
 - (D) The results from a testing laboratory indicating the amounts of tetrahydrocannabinol (THC) and cannabidiol, if available; and
 - (E) The registered strain or product names and batch or lot numbers of plant material, cannabis extract, and cannabis products.
 - (iii) The amount of cannabis sold or distributed since the previous weekly inventory, and include the following:
 - o (A) The date of sale or distribution:
 - (B) The license number and name of the licensed entity to which the cannabis was sold; and

- o **(C)** The batch or lot number, registered product name, and quantity of cannabis sold.
- (iv) The date, quantity, and method of disposal of cannabis, if applicable;
- (v) A summary of the inventory findings; and
- **(vi)** The name, signature, and title of the employees who conducted the inventory and oversaw the inventory.
- **(d)** Prior to the renewal of its certificate of operation, a registered responsible party for each processor shall do the following:
 - (i) Create an annual inventory report generated by the state inventory tracking system; and
 - (ii) Conduct a full, comprehensive, manual inventory of the cannabis at the licensed premises and compare the findings to the annual inventory report created pursuant to paragraph (4)(a) of this rule.
- (e) Upon discovery, each processor shall notify the division in writing of any discrepancies and submit a written plan of corrective action prior to making any adjustments to the state inventory tracking system.
- o **(5)** Prior to any transfer of cannabis, preparation of a transfer manifest utilizing the state inventory tracking system that includes the following for each transfer:
 - (a) The names and addresses of the cannabis entities sending and receiving the shipment;
 - (b) The names of the registered employees transporting the cannabis and their respective badge number as provided by rule 1301:18-3-09 of the Administrative Code; and
 - (c) The time of departure and estimated time of arrival;
 - **(d)** Within each transfer the following information for each individual package:
 - (i) A description of each individual package that is part of the shipment;
 - (ii) The total number of individual packages;
 - (iii) The unique identifying number generated within the state inventory tracking associated with the package;
 - (iv) The units of measure as reported within the state inventory tracking system as follows:
 - o (A) The weight of the cannabis contained within the shipment; or
 - (B) The quantity of units contained within the shipment.
 - **(e)** The unique identifying number generated within the state inventory tracking system associated with the transfer manifest; and
 - (f) If applicable:
 - (i) The license plate number and vehicle type that will transport the shipment; and
 - (ii) The specific delivery route, which includes street names and distances.
 - (g) Prior to the delivery, provide a copy of the transfer manifest to the division.
- o **(6)** Any and all information the division determines necessary for maintaining and tracking cannabis is documented and submitted into the state inventory tracking system.
- (7) All inventories, procedures, and other documents required by this rule are maintained at the licensed premises and pursuant to [OAC Records and Reporting] and available for immediate review and duplication upon the division's request.

Dispensaries

1301:18-8-04 Dispensary Inventory and Control

- (A) Each dispensary shall establish, maintain, and comply with written policies and procedures for the receipt, storage, tracking, and distribution of cannabis, cannabis paraphernalia, and other inventory at the licensed premises. The dispensary's inventory control policies and procedures shall mitigate the risk of theft, loss, and diversion and ensure the following:
 - (1) Before accepting a delivery of cannabis, a responsible party must inspect and ensure the delivery:
 - (a) Meets all relevant packaging and labeling requirements; and
 - **(b)** The contents within the shipment conform with all representations outlined in the transfer manifest from the originating entity.
 - (c) In the event the shipment fails to meet the requirements outlined under paragraph (A)(1) of this rule, the dispensary shall:
 - (i) Refuse to accept the non-conforming batch or lot;
 - (ii) Return the batch or lot to the originating entity; and
 - (iii) Within forty-eight hours of discovery, notify the division in writing.
 - (2) All information related to the cannabis maintained at the licensed premises is accurately and contemporaneously recorded in the state inventory tracking system from the time of receipt until distribution or disposal.
 - (3) All inventory is stored in a secure, limited access storage area that meets the requirements of rule 1301:18-8-05 of the Administrative Code and accessible only by registered employees.
 - o (4) Documentation of each sale of cannabis in the state inventory tracking system.
 - o **(5)** Ongoing regular, comprehensive inventories of all cannabis at the licensed premises and in compliance with this rule.
 - (a) Upon discovery, each dispensary shall notify the division in writing of any discrepancies and submit a written plan of corrective action prior to making any adjustments to the state inventory tracking system.
 - **(b)** A dispensary responsible party shall conduct a weekly inventory and document an audit of the facility's daily inventory to ensure the physical inventory matches the information documented in the dispensary's internal inventory system and state inventory tracking system. The weekly is to include the following:
 - (i) The date of the inventory;
 - (ii) The amount of cannabis maintained at the licensed premises;
 - (iii) The amount of cannabis sold since the previous monthly inventory, and include the following:
 - (A) The date of sale;
 - (B) The license number and name of the licensed entity to which the cannabis was sold; and
 - **(C)** The batch or lot number, registered product name, and quantity of cannabis sold.
 - (iv) The date, quantity, and method of disposal of cannabis, if applicable;
 - (v) A summary of the inventory findings; and
 - **(vi)** The name, signature, and title of the employees who conducted the inventory and oversaw the inventory.
 - (c) A registered responsible party shall conduct an annual inventory and do the following:

- (i) Create an annual inventory report generated by the state inventory tracking system; and
- (ii) Conduct a full, comprehensive, manual inventory of the cannabis at the licensed premises and compare the findings to the annual inventory report.
- o (6) Prior to any transfer of cannabis, each dispensary shall
 - (a) Shipping cannabis from the facility, a responsible party must inspect and acknowledge that the delivery meets relevant packaging and labeling requirements outlined under [OAC packaging and Labeling]
 - **(b)** Prepare a transfer manifest utilizing the state inventory tracking system and include the following for each transfer:
 - (i) The names and addresses of the cannabis entities sending and receiving the shipment;
 - (ii) The time of departure and estimated time of arrival;
 - (iii) Within each transfer the following information for each individual package:
 - (A) A description of each individual package that is part of the shipment;
 - o **(B)** The total number of individual packages;
 - (C) The unique identifying number generated within the state inventory tracking associated with the package;
 - (D) The units of measure as reported within the state inventory tracking system as follows:
 - (1) The weight of the cannabis contained within the shipment; or
 - (2) The quantity of units contained within the shipment.
 - (iv) The unique identifying number generated within the state inventory tracking system associated with the transfer manifest; and
 - (v) If applicable:
 - (A) The names of the registered employees transporting the cannabis and their respective badge number as provided by rule 1301:18-3-09 of the Administrative Code; and
 - **(B)** The license plate number and vehicle type that will transport the shipment.
 - (C) The specific delivery route, which includes street names and distances.
 - **(vi)** Prior to the delivery, provide a copy of the transfer manifest to the division;
- (7) Any and all information the division determines necessary for maintaining and tracking cannabis is documented and submitted into the state inventory tracking system.
- (8) All inventories, procedures, and other documents required by this rule are maintained on the premises and pursuant to [OAC Records and Reporting] and available for immediate review and duplication upon the division's request.

1301:18-8-06 Dispensing cannabis

- Definitions
 - Complete Registration:

- (a) Patient full name;
- (b) Patient residential address;
- (c) Patient telephone number;
- (d) Patient date of birth;
- (e) Patient qualifying condition;
- (f) State-issued identification number (such as driver's license number) or other identification approved by the division;
- (g) Patient registration number;
- (h) Recommending physician's full name (first name and last name);
- (i) Recommending physician's drug enforcement administration identification number;
- (j) Recommending physician's medical license number issued by the state medical board;
- (k) Recommending physician's certificate to recommend identification issued by the state medical board;
- (I) Date recommendation was issued by the recommending physician;
- (m) Recommending physician's business address, telephone number, and email address;
- (n) Indication whether the recommendation is new or a refill;
- (o) Number of the refill being dispensed; and
- (p) Date order written, which shall be the date the written recommendation was issued.

Single day supply:

For purposes of calculation of days and days' supply pursuant to section 3796.03(B)(10), a single day supply shall be up to 2.5 ounces of plant material and 15 grams of extract.

Veteran:

- (a) Department of defense identification card (active, retired, temporary disability retirement list (TDRL);
- (b) DD214, DD215, or national guard bureau (NGB) military discharge certificate indicating disposition of discharge;
- (c) Report of separation from the national archives national personnel records center in St. Louis, Missouri; or
- (d) Veterans identification card from the department of veterans affairs.
- Other documentation as determined by the division.

Indigent

- Enrolled in the federal "Social Security Disability Income" (SSDI) or the "Supplemental Security Income" (SSI) disability programs, a copy of a letter or other documentation from the United States social security administration with the individual's identification.
- Other documentation as determined by the division.
- (A) Each dispensary shall ensure the following when dispensing cannabis:
 - o (1) Each sale of cannabis sold is documented in the state inventory tracking system.
 - (2) Each package of cannabis sold:
 - (a) Is in the original, child resistant and tamper evident containers or packaging as delivered by the originating entity;
 - (b) Is affixed with the dispensary's business name and license number; and

- (c) The contents contained within the package.
- o (3) All adult-use cannabis sales adhere to applicable taxes.
- (4) Upon completion of each sale, each customer is furnished with a receipt evidencing the following information:
 - (a) The dispensary's business name;
 - **(b)** The dispensary's license number;
 - (c) The dispensary's business address and telephone number;
 - (d) The time and date of sale;
 - **(e)** A complete description of all items purchased;
 - (f) A complete description of any discounts applied;
 - (g) As applicable, a separate line evidencing the following:
 - (i) The associated sales tax; and
 - (ii) The associated excise tax; and
 - (h) The dispensary's return policy; and
 - (i) Any other information deemed necessary by the division.

• (B) Adult-Use Cannabis.

- (1) Prior to any sale, or the transfer of possession of any cannabis, a registered dispensary employee shall review the individual's valid, government-issued photographic identification containing the individual's date of birth and confirm the following:
 - (a) The individual is at least twenty-one years of age or older;
 - **(b)** The information contained on the individual's identification matches the individual presenting the identification; and
 - **(c)** The information contained on the individual's identification matches the information provided in the order.
- o (2) Each dispensary shall not dispense to each adult-use consumer more than the following amounts of cannabis per day:
 - (a) 2.5 ounces of plant material; and
 - (b) 15 grams of extract

• (C) Medical cannabis

- (1) Prior to any sale, or the transfer of possession of any cannabis, a registered dispensary employee shall review the individual's:
 - (a) Valid, government-issued photographic identification containing the individual's date of birth and confirm the following:
 - (i) The individual is a patient is at least eighteen years of age or older or a caregiver at least twenty-one years of age or older;
 - (ii) The information contained on the individual's identification matches the individual presenting the identification; and
 - (iii) The information contained on the individual's identification matches the information provided in the order.
 - (b) Documentation evidencing the individual is a registered patient or caregiver;
 and
 - (c) If applicable, a veteran or indigent status.
- (2) Notwithstanding any other provision, a dispensary shall dispense cannabis in an amount and manner consistent with any instructions for use as determined by the recommending physician.

- O (3) Unless otherwise limited by a patient's recommending physician pursuant to paragraph (C)(2) of this rule, each dispensary shall not dispense more than the following amount of medical cannabis per day:
 - (a) To each registered patient:
 - (i) 10 ounces of plant material; and
 - (ii) 60 grams of extract
 - **(b)** To each registered caregiver:
 - (i) 2.5 ounces of plant material; and
 - (ii) 15 grams of extract
- o (4) The dispensary shall record all patient purchases of cannabis as follows:
 - (a) For transactions that are at or below 2.5 ounces of plant material and 15 grams of extract, a dispensary shall record the following information by close of business of the date of the transaction:
 - (i) All recommendations are serially numbered;
 - **(A)** There is a complete accounting of all numbers used in the serial numbering system.
 - (B) All recommendations which are not refillable, either because
 of the dispensing of all refills or the length of time since issuance,
 shall be assigned a new serial number upon an authorization for
 additional dispensing by a recommending physician.
 - (ii) Each recommendation is complete.
 - (iii) Pursuant to [OAC Records], the patient record is updated for each sale with the following information:
 - (A) Dispensary license number;
 - (B) Dispensary name;
 - (C) Dispensary address;
 - (D) Dispensary telephone number;
 - (E) Date order filled, which shall be the date cannabis is dispensed;
 - (F) Order number, which shall be the serial number assigned to each cannabis product dispensed to a patient;
 - o (G) Quantity;
 - (H) Days' supply;
 - (1) Any amount in excess of a whole day as defined in paragraph (C)(2), shall be rounded to the next full day.
 - (I) Product identifier;
 - o (J) Payment code for either cash or third-party provider; and
 - o **(K)** Drug name, which shall be the brand name of the cannabis.
 - **(b)** For purchases in excess of 2.5 ounces of plant material and 15 grams of extract, each dispensary shall record all information outlined pursuant to this paragraph, contemporaneously with the transaction.
- **(D)** A dispensary may offer discounts in accordance with a written discount policy and ensure the following:
 - (1) Any discount offered to an adult-use consumer or a registered employee of a licensed entity must also be offered to all registered patients and caregivers.
 - o (2) Any discount offered to registered patients and caregivers, must also be offered to all patients and caregivers who are a veteran or indigent status.

• (E) Returns.

- o (1) Each dispensary shall establish, maintain, and comply with written policies and procedures to accept returned cannabis as follows:
 - (a) Each dispensary must accept the following cannabis returned by a customer:
 - (i) Defective product, that shall be destroyed and disposed of by the dispensary in accordance with rule 1301:18-3-12 of the Administrative Code:
 - (ii) Product that does not match the item stated on the purchase receipt;
 or
 - (iii) Mislabeled cannabis by the cultivator or processor of the product.
 - (A) All cannabis returned to a dispensary due to mislabeling by a cultivator or processor must be reported to the division in a manner prescribed by the division.
 - **(b)** A dispensary may accept other cannabis returned by a customer so long as the dispensary establishes, maintains, and complies with written policies and procedures for such returns.
 - (c) Each dispensary shall provide the customer a refund of the purchase price of the product contemporaneously with the return, and, if applicable, revise the patient's days' supply to reflect the returned product.
- **(F)** Each dispensary shall not do the following:
 - (1) Dispense expired, damaged, deteriorated, misbranded, adulterated, or opened cannabis.
 - **(2)** Possess or dispense any cannabis requiring refrigeration or hot-holding or other any potentially hazardous food.
 - o (3) Provide free samples of cannabis to customers.

1301:18-8-07 Dispensing Errors.

- (A) Each dispensary shall establish, maintain, and comply with written policies and procedures for quality assurance that detect, identify, and prevent dispensing errors. A dispensary's quality assurance procedure shall include:
 - (1) Protocols to determine the cause of a dispensing error and the appropriate response and notification to the division within forty-eight hours of detection;
 - (2) Pursuant to [OAC records,] documentation of each quality assurance review with the following information:
 - (a) The date of review;
 - **(b)** The pertinent data and other information related to the dispensing error;
 - (c) Documentation of contact with all applicable consumers, patients, caregivers, and recommending physicians;
 - (d) The findings and determinations generated by the quality assurance review;
 - **(e)** If applicable, recommended changes to dispensary policy, procedure, systems or processes to prevent similar dispensing errors.
 - (3) Communication to the following individuals outlining the details of a dispensing error:
 - (a) All dispensary employees; and
 - **(b)** All applicable consumers, patients, caregivers, and recommending physicians.
 - (c) The communication is to include methods of correcting the dispensing error or reducing the negative impact of the error on qualifying patients.

- (4) Displaying a sign concerning the reporting of dispensing errors in a conspicuous location visible to customers. The sign shall:
 - (a) Measure a minimum of eight inches in height and ten inches in width and the lettering shall be in a size and style that allows such sign to be read without difficulty;
 - **(b)** Read: "If you have a concern that an error may have occurred in the dispensing of your cannabis, you may contact the state of Ohio division of cannabis control, using the contact information found at www.com.ohio.gov/cannabiscontrol."

Enforcement

1301:18-9-04 Product Advisories and Recalls

- (A) Each licensee shall establish, maintain, and comply with written policies and procedures to conduct product advisories and recalls of cannabis and ensure the following:
 - (1) All recall procedures shall be established in accordance with the most recent version of ASTM D8220 Standard Guide for Conducting Recall/Removal Procedures for Products in the Cannabis Industry.
 - (2) Appropriately address product advisories and recalls, whether initiated by the licensee or by the division.
 - o **(3)** All affected product is immediately quarantined from other viable inventory intended for distribution and maintained in a secure location.
 - (4) The licensee notifies the following individuals about the advisory or recall:
 - (a) All associated licensees that cultivated, processed, or dispensed the affected cannabis;
 - **(b)** All customers who have, or likely have, obtained the affected product;
 - **(c)** The communication must include information on the process for return of the recalled product; and
 - **(d)** If applicable, notification to the division within twenty-four hours of initial determination that a recall is necessary and proper.
 - **(5)** Pursuant to paragraph (A)(4), the licensee contains the following information within the notice:
 - (a) The name and license number of all licensed entities that received the affected product;
 - (b) The product identity;
 - (c) Product description;
 - (d) Net contents; and
 - (e) Batch or lot number.
 - o **(6)** In the event of a product advisory or product recall directs a customer to return the affected product to a dispensary, the dispensary shall do the following:
 - (a) Accept the return of unused affected product;
 - **(b)** Provide the customer a refund of the purchase of the product contemporaneously with the return if the product is returned within thirty calendar days of the product notice; and
 - (c) If applicable, revise the patient's days' supply to reflect the returned product.

• (d) Unless otherwise authorized by the division, the dispensary shall destroy and dispose of any cannabis returned pursuant to this rule in accordance with rule 1301:18-3-12 of the Administrative Code.

1301:18-9-05 Ohio Division of Cannabis Control Enforcement Authority

- Pursuant to chapters 3780 and 3796 of the Revised Code, the rules set forth in division 1301:18 of the Administrative Code establish standards for the oversight and enforcement of the cultivation, processing, testing, and dispensing of cannabis.
 - Division 1301:18 of the Administrative Code also establishes legal standards for the denial, suspension, or revocation of licenses issued by the division of cannabis control pursuant to chapters 3780 and 3796. of the Revised Code.
 - If any portion of the rules is found to be invalid, the remaining portion of the rules shall remain in full force and effect.
- **(A)** The Ohio division of cannabis control has the following authority over all cultivators, processors, testing laboratories, and dispensaries issued a provisional license or certificate of operation, and employees issued a provisional badge or badge certificate whenever it appears to the division that a cannabis entity or individual engaged in, is engaged in, or is about to engage in any prohibited conduct or conduct otherwise not authorized by chapters 3780 and 3796. of the Revised Code or the rules promulgated in accordance with chapters 3780 and 3796. of the Revised Code, or when the division believes that it is necessary for the program's administration, implementation, and enforcement:
 - (1) Pursuant to rule 1301:18-9-01 of the Administrative Code, at any time, with or without notice, conduct an inspection to ensure compliance with all representations made to the division, state and local law, chapters 3780 and 3796. of the Revised Code, and the rules promulgated in accordance with Chapters 3780 and 3796. of the Revised Code.
 - (2) Inspect, examine, or investigate any premises or motor vehicle where cannabis is grown, stored, cultivated, harvested, transported, processed, extracted, manufactured, tested, distributed, transferred, or dispensed and any inventory, equipment, instruments, and records in any way connected with any such activity;
 - (3) Issue requests for information, to which licensees are to respond in a manner prescribed by the division;
 - (4) Obtain samples of any cannabis or any other material maintained at the licensed premises;
 - (5) Obtain samples for testing of any cannabis maintained at the licensed premises, media used to grow cannabis, chemicals and ingredients utilized at the licensed premises, any labels or containers for cannabis, or any raw packaged cannabis.
 - o **(6)** Investigate activities which are, or are suspected to be, prohibited;
 - o (7) Refuse to issue a provisional license or certificate of operation;
 - (8) Refuse to renew a certificate of operation;
 - (9) Refuse to issue a provisional badge pursuant to rule 1301:18-3-09 of the Administrative Code:
 - (10) Refuse to issue a badge certificate pursuant to rule 1301:18-3-09 of the Administrative Code;
 - (11) Refuse to renew badge certificate pursuant to rule 1301:18-3-09 of the Administrative Code;
 - (12) Suspend or revoke a license or registration issued pursuant to chapters 3780 and 3796. of the Revised Code or the rules promulgated in accordance with chapters 3780 and 3796. of the Revised Code;

- (13) Upon finding clear and convincing evidence that continued distribution of cannabis presents a danger of immediate and serious harm to others, suspend without prior hearing a license or registration issued under chapters 3780 or 3796 of the Revised Code.
- (14) Issue a cease and desist order;
- (15) Serve all summonses, subpoenas, administrative orders, notices, or other processes concerning the enforcement of laws regulating cannabis and cannabis products;
- (16) Issue either administrative subpoenas ad testificandum or subpoenas duces tecum, or both, to compel the testimony of witnesses or the production of any books and records, in paper or electronic format, to be served by personal service or by certified mail, return receipt requested;
 - (a) If the subpoena is returned because of inability to deliver, or if no return is received within thirty calendar days of the date of mailing, the subpoena may be served by ordinary mail.
 - (i) If no return of ordinary mail is received within thirty calendar days after the date of mailing, service shall be deemed perfected and effectuated.
 - (ii) If the subpoena is returned because of inability to deliver, the division may designate a person or persons to effect either personal or residence service upon the witness.
 - **(b)** The person designated to effect personal or residence service under this paragraph may be the sheriff of the county in which the witness resides or may be found or may be any other duly designated person.
 - (c) The fees and mileage of the person serving the subpoena shall be the same as those allowed by the courts of common pleas in criminal cases, and will be paid from the funds of the division.
- o (17) Place conditions on an applicant, license, licensee, or registrant;
- (18) Issue guidance on the requirements outlined pursuant to the rules promulgated pursuant to chapters 3780 and 3796 of the Revised Code.
- o **(19)** To prevent destruction of evidence, diversion, or other threats to public safety, order an administrative hold of cannabis or any books and records of any licensee.
- (20) Initiate and require a product advisory or recall of any cannabis when the division determines that there is reasonable probability that the cannabis is in violation of chapters 3780 or 3796 of the Revised Code.
- (21) Implement and mandate a recall of any cannabis when the division determines that there is reasonable probability that the cannabis is in violation of chapters 3780 or 3796 of the Revised Code and use or exposure to the cannabis at issue constitutes a risk to public health or safety.
- o (22) Initiate, mandate, and implement the destruction of cannabis upon determination violates any requirement under chapters 3780 or 3796 of the Revised Code.
- (23) Assess the costs of an investigation, including travel and the time of any and all division employees, to a licensee.
- (24) Impose a civil penalty in an amount not to exceed fifty thousand dollars for each violation, for any violation of Chapters 3780 and 3796. of the Revised Code or the rules promulgated in accordance with Chapters 3780 and 3796. of the Revised Code;
- (25) Exercise any other power or duty authorized by Chapters 3780 and 3796. of the Revised Code or the rules promulgated in accordance with Chapters 3780 and 3796. of the Revised Code.
- (26) Sanctions described under this rule are not mutually exclusive and may be imposed in any combination.

- (27) Adjudicatory hearings will be conducted pursuant to Chapter 119. of the Revised Code.
- **(B)** Upon receipt of a notice of deficiency by the Ohio department of taxation for failure to comply with all applicable taxes, the Ohio division of cannabis control shall suspend without prior hearing a license or registration issued under chapters 3780 or 3796 of the Revised Code.
 - (1) The division will lift the suspension upon notification that a license or registrant is in compliance with all applicable taxes.
 - (2) In the event that all tax deficiencies are not alleviated within thirty calendar days of the suspension, the division will revoke the license or registration.
- (C) If the division suspends, revokes, or refuses to renew any license issued under chapters 3780
 or 3796 of the Revised Code or determines that there is clear and convincing evidence of a danger
 of immediate and serious harm to any individual, the division may place under seal all cannabis
 owned by or in the possession, custody, or control of the associated licensed entity.
- (D) If a license is voluntarily surrendered or is not renewed, the division may impose other penalties permitted by Chapter 3796. of the Revised Code or the rules promulgated in accordance with Chapter 3796. of the Revised Code, on any such license or licensee.
- **(F)** A licensee whose certificate of operation has been suspended shall not sell, offer for sale, transport, or conduct any operations outside the facility related to cannabis.
 - o (1) Employees of the facility may enter the premises of the facility for the necessary care and maintenance of the premises and any cannabis and cannabis products.
 - (2) The removal of cannabis from a cultivator, processor, or testing laboratory is strictly prohibited during an active suspension under this chapter.
 - (3) During a suspension, a licensee may, at the direction and discretion of the division, update the state inventory tracking system.
- **(G)** A licensee whose certificate of operation has been revoked shall:
 - o **(1)** Adhere to the requirements outlined pursuant to rule 1301:18-3-17 of the Administrative Code;
 - (2) Close the facility and prohibit anyone from entering the facility, other than employees
 with the division, law enforcement, or other individuals carrying out official duties related
 to the revocation of the certificate of operation.
 - (3) The revocation of a provisional license or certificate of operation shall immediately terminate the employee identification cards of persons employed by the licensee.
- **(H)** Whenever the division revokes or suspends a cannabis entity license, it will notify local law enforcement, and county sheriff's office with applicable jurisdiction.
- (I) Division employees will not serve as expert witnesses in private litigation. In addition, the division may move to quash any subpoena that seeks fact testimony from division employees in private litigation. The division may certify as to the status of any person as a licensee or registered employee of a licensee. Such certification shall be admissible in any court as prima-facie evidence as to the status of the person.

Patients and Caregivers

1301:18-10-03 Patient and Caregiver General Requirements

- (A) No patient under eighteen years of age shall purchase medical cannabis.
- **(B)** Notwithstanding any other provision, patients and caregivers shall possess cannabis in an amount, form, and manner consistent with any instructions or limitations as determined by the recommending physician.

- **(C)** Unless otherwise limited pursuant to paragraph (B) of this rule, a patient shall not purchase, possess, or maintain more than 2.5 ounces of medical cannabis plant material or 15 grams of extract at any time except as follows:
 - o **(1)** When transporting medical cannabis from a dispensary to their primary residence with the associated proof of purchase or receipt from the dispensary:
 - (a) 10 ounces of plant material; and
 - **(b)** 60 grams of extract
 - **(2)** At their primary residence, not more than a ninety-day supply of medical cannabis within a ninety-day period.
 - (a) A patient's ninety-day recommendation is divided into two forty-five-day fill periods, except that the first fill period of a patient's new recommendation shall be forty-six days.
- **(D)** A caregiver shall not purchase, possess, or maintain more than 2.5 ounces of medical cannabis plant material or 15 grams of extract at any time.
- **(E)** All medical cannabis shall be maintained as follows:
 - o (1) In a secure location to prevent theft, loss, access by unauthorized individuals; and
 - (2) In the original dispensing package with an unaltered dispensary label in accordance with rule 1301:18-8-06 of the Administrative Code until administered to or by a patient.
- **(F)** Patients and caregivers are precluded from engaging in the following activities:
 - o **(1)** Operating a vehicle, streetcar, trackless trolley, watercraft, or aircraft under the influence of medical cannabis
 - o (2) Possessing or administering medical cannabis on federal property or in federal buildings, or at any public or private place where medical cannabis is prohibited.
 - o (3) Using or maintaining medical cannabis in a manner that puts others at risk.