Common Sense Initiative

Mike DeWine, *Governor*
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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Commerce, Division of Cannabis Control

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Regulation/Package Title (a general description of the rules' substantive content):

Rule Package 6 – Provisional Licenses, Fees, Employee Training, Record Keeping, Business to Business Transfers, Forms & Methods of Administration, Advertising, Product Registration, Inventory Control, Cultivator and Processor Operations, Testing Lab Accreditation and Surveillance, Product Recalls, Dispensary Discounts and Returns, Enforcement Authority

Rule Number(s): OAC 1301:18-1-01 (AMENDED), 1301:18-2-07 (NEW), 1301:18-2-09 (NEW), 1301:18-3-10 (NEW), 1301:18-3-14 (NEW), 1301:18-3-16 (NEW), 1301:18-3-18 (NEW), 1301:18-4-01 (NEW), 1301:18-4-02 (NEW), 1301:18-4-03 (NEW), 1301:18-4-05 (NEW), 1301:18-2-07 (NEW), 1301:18-2-08 (NEW), 1301:18-2-09 (NEW), 1301:18-2-10 (NEW), 1301:18-4-12 (NEW), 1301:18-4-16 (NEW), 1301:18-4-17 (NEW), 1301:18-4-18 (NEW), 1301:18-4-22 (NEW), 1301:18-5-03 (NEW), 1301:18-5-04 (NEW), 1301:18-5-06 (NEW), 1301:18-6-03 (NEW), 1301:18-6-05 (NEW), 1301:18-7-04 (NEW), 1301:18-7-05 (NEW), 1301:18-7-06 (NEW), 1301:18-8-04 (NEW), 1301:18-8-06 (NEW), 1301:18-8-08 (NEW), 1301:18-8-09 (NEW), 1301:18-8-10 (NEW), 1301:18-8-11 (NEW), 1301:18-8-12 (NEW), 1301:18-9-04 (NEW), 1301:18-9-05 (NEW), 1301:18-10-03 (NEW),
3796:2-1-09 (RESCIND), 3796:2-2-01 (RESCIND), 3796:2-2-04 (RESCIND), 3796:2-2-08 (RESCIND), 3796:3-2-04 (RESCIND), 3796:3-2-08 (RESCIND), 3796:4-1-05 (RESCIND), 3796:4-1-09 (RESCIND), 3796:4-2-07 (RESCIND), 3796:5-5-01 (RESCIND), 3796:5-6-01 (RESCIND), 3796:5-7-01 (RESCIND), 3796:6-3-06 (RESCIND), 3796:6-3-07 (RESCIND), 3796:6-3-12 (RESCIND), 3796:6-3-18 (RESCIND), 3796:6-3-19 (RESCIND), 3796:6-3-21 (RESCIND), 3796:6-3-24 (RESCIND), 3796:6-4-01 (RESCIND), 3796:6-4-04 (RESCIND), 3796:6-4-05 (RESCIND), 3796:6-4-06 (RESCIND), 3796:6-4-07 (RESCIND), 3796:6-4-08 (RESCIND), 3796:6-4-09 (RESCIND), 3796:8-2-01 (RESCIND), 3796:8-2-02 (RESCIND), 3796:8-3-01 (RESCIND), 3796:2-2-06 (RESCIND), 3796:2-2-07 (RESCIND), 3796:3-1-04 (RESCIND), 3796:3-1-05 (RESCIND), 3796:3-2-01 (RESCIND), 3796:3-2-06 (RESCIND), 3796:3-2-07 (RESCIND), 3796:3-3-01 (RESCIND), 3796:4-1-03 (RESCIND), 3796:4-1-04 (RESCIND), 3796:4-1-07 (RESCIND), 3796:5-1-01 (RESCIND), 3796:5-2-04 (RESCIND), 3796:6-3-01 (RESCIND)

Date of Submission for CSI Review: 12/06/2024

Public Comment Period End Date: 12/23/2024

Rule Type/Number of Rules:

New/ 37 **rules** | **No Change/** ____ **rules (FYR?** ___**)**

Amended/ 1 **rules (FYR?** N**)** | **Rescinded/** 43 **rules (FYR?** Y**)**

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

d. ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.
Please include the key provisions of the regulation as well as any proposed amendments.

OAC 1301:18-1-01 Definitions (AMENDED)

- This rule establishes various definitions of terms used throughout 1301:18.

OAC 1301:18-2-07 Provisional Licenses (NEW)

- This rule outlines general requirements for provisional licensure. A provisional license does not permit the holder to cultivate, process, test, or sell cannabis, but is simply issued as a placeholder while provisional licensees work to meet the requirements to obtain a Certificate of Operation.

OAC 1301:18-2-09 Fee Schedule (NEW)

- This rule lays out the fees for all licensees related to licensing, renewals, and employee badging. Fees also cover product registration, and change requests including ownership, relocation, and major facility modifications.

OAC 1301:18-3-10 Employee Training and Qualification Requirements (NEW)

- Foundational training is required for all employees at each facility before they can begin working. Additionally, licensees must ensure, at least annually, that their training materials are updated, and employees are trained on any updates.
- Training includes topics such as policies and procedures related to the employee's assigned function, use and proper documentation of all cannabis maintained at the licensed premises in the state inventory tracking system, preparation for regulatory inspections, employee badging requirements, all applicable statutes and regulations pertaining to Ohio cannabis law, and responsible use training and available addiction services resources.
- The rule also prescribes training requirements for specific facility license types and/or employees performing certain functions, including training for security, OSHA, food safety, and dispensing cannabis.

OAC 1301:18-3-14 Cannabis Entity Record Keeping (NEW)

- This rule details the records that licensees must maintain for two years, and which must be maintained in an auditable format that is available to the Division for immediate inspection.

OAC 1301:18-3-16 Business to Business Transfers Generally (NEW)

- This rule establishes the parameters around transfers of cannabis from one licensed entity to another, including the packaging, labeling, and manifest requirements for those shipments.

OAC 1301:18-3-18 Business to Business Transfers – Cannabis Packaged for Direct Customer Sale (NEW)

- This rule establishes the parameters around transfers of cannabis and cannabis products from one licensed entity to another, including the forms that may be transferred and requirements that the packaging and labeling is compliant with those rules.

OAC 1301:18-4-01 Cultivator and Processor Good Manufacturing Processes (NEW)

- This rule requires cultivators and processors to comply with good manufacturing practices (GMPs), which are based on the federal code requirements. These practices set standards for the safe, sanitary, and clean cultivation and manufacturing of cannabis, including in areas such as personal cleanliness and disease control, maintenance of the facility and grounds, pest control and appropriate storage of chemicals, potable water supply, clean ingredients, and sanitary utensils and equipment.

OAC 1301:18-4-02 Authorized Cannabis Forms & Methods of Administration (NEW)

- Cannabis may be sold in the forms and methods of administration authorized by this rule, which includes those mandated by ORC 3780.
- Smoking is prohibited for registered medical marijuana patients. Vaporization is prohibited for medical marijuana patients under 18 years old.
- Forms intended for vaporization or smoking are prohibited from containing characterizing flavors, except those intended to mimic the strain.

OAC 1301:18-4-03 Petition for Additional Forms & Methods (NEW)

- Anyone may submit a request to the Division to add a new form or method of administration. An application must demonstrate that multiple scientific experts (with specialized knowledge) support the addition of the form or method of administration, the extent to which the prospective form or method of administration is generally accepted by the medical community, information or studies regarding any benefit or adverse effects from the use of the proposed form or method of administration, and benefits to approving the proposed form or method of administration.

OAC 1301:18-4-05 Limitations on THC Content for Cannabis Intended for Direct Customer Sale

- THC content is limited by the statute at 35% for both medical and non-medical plant material, and 70% for medical cannabis extracts and 90% for non-medical cannabis extracts. This rule establishes those limitations as well.

OAC 1301:18-4-07 Limitations on Cannabis Strain Names

- This rule prohibits a licensee from using a strain name that is attractive to children, false or misleading, obscene, a health-related statement, or encourages over consumption or intoxication, among other prohibits. The rule also specifically prohibits strain names that infer cartoon characters, fictional characters, or pop culture icons whose targe audience is children or youth, or a commercially available candy product.

OAC 1301:18-4-08 Limitations on Cannabis Products

- Similar to proposed OAC 1301:18-4-07, this rule prohibits a licensee from making a cannabis product that is attractive to children, false or misleading, obscene, contains a health-related statement, or encourages over consumption or intoxication, among other prohibits. The rule also specifically prohibits products that infer cartoon characters, fictional characters, or pop culture icons whose target audience is children or youth, a commercially available candy product, or a realistic or fictional human, animal, or fruit.

- Products intended for vaporization or smoking are prohibited from containing characterizing flavors, except those intended to mimic the cannabis strain.

OAC 1301:18-4-09 Pre-Approval Requirement for Product Registration

- This rule requires that licensees seek and obtain approval prior to manufacturing a new product and register each product with the Division.

OAC 1301:18-4-10 State-Required Testing Generally (NEW)

- This rule sets the baseline requirement for cannabis to be tested and meet the Division's testing standards prior to transfer to a dispensary for sale to a medical marijuana patient or consumer, and for this information to be tracked in the state inventory tracking system.

OAC 1301:18-4-12 Transfer Manifests for Test Samples (NEW)

- Prior to the transportation of a testing sample to a testing laboratory, a transfer manifest must be prepared in the state inventory tracking system. The rule outlines the items required in the manifest.

OAC 1301:18-4-16 Certificates of Analysis (NEW)

- A certificate of analysis must be uploaded by the testing laboratory to the state inventory tracking system for all tests conducted.

OAC 1301:18-4-17 Research and Development Testing by Testing Laboratory Licensed Pursuant to 1301:18 of the Administrative Code (NEW)

- This rule permits cultivators and processors to submit cannabis samples to a testing laboratory licensed by the Division for the purposes of specific research and development, if done so in the manner outlined by the rule.

OAC 1301:18-4-18 Research by Testing Laboratory Licensed by Division 4729:5-16 of the Administrative Code (NEW)

- This rule permits a cannabis licensee to make a request to the Division to transfer cannabis samples to a testing laboratory licensed by the State of Ohio Board of Pharmacy to possess dangerous drugs and controlled substances solely for scientific, clinical, research, or development purposes.

OAC 1301:18-4-22 Advertising (NEW)

- This rule lays out the types of advertisements that are prohibited, including those that are attractive to children, promote excessive use, intoxication, or overconsumption, or otherwise promote use of cannabis in a manner not approved by the law.
- Advertising on billboards, radio or television, internet programming, or in ways with a high likelihood of reaching persons under the age of 18 is prohibited.
- Any online presence must be age gated.
- Licensees are permitted to market, sell, or license merchandize only to individuals over 18 years old as long as the merchandise contains only branding previously approved by the Division.
- All advertisements must include the universal THC symbol and the Division's seal.

OAC 1301:18-5-03 Cultivator Operating Procedures and Quality Assurance (NEW)

- Cultivators are required to establish, maintain, and comply with written policies and procedures for the daily operation and cultivation of cannabis. This rule prescribes certain requirements for the cultivation facility premises, areas within the facility, and employees, and sets requirements for licensees that wish to make a major modification to the facility.
- Additionally, this rule outlines the acceptable use of fertilizers, pesticides, herbicides, and other similar chemicals.

OAC 1301:18-5-04 Cultivation Area Expansion (NEW)

- A cultivator may submit a request to the Division to expand its cultivation area if it is utilizing the totality of its current cultivation area. Cultivators may request the expansion as follows based on license type:
    - Level 1 Cultivator – up to 100,000 square feet
    - Level II Cultivator – up to 15,000 square feet
- A cultivator may request to locate a portion of its cultivation area within another facility that must be approved by the Division.

OAC 1301:18-5-06 Cultivator Inventory and Control (NEW)

- Cultivators are also required to establish, maintain, and comply with written policies and procedures for proper and secure inventory control of all cannabis maintained at the premises. These policies must mitigate the risk of theft, loss, and diversion of cannabis.
- This includes processes for accepting cannabis deliveries and preparing transfers to another facility, storing securely, tracking accurately in the state inventory tracking system, and conducting regular inventories.

OAC 1301:18-6-03 Processor Operating Procedures and Quality Assurance (NEW)

- Processors are required to establish, maintain, and comply with written policies and procedures for the daily operation and processing of cannabis. This rule prescribes certain requirements for the processing facility premises, areas within the facility, and employees, and sets requirements for licensees that wish to make a major modification to the facility.

OAC 1301:18-6-05 Processor Inventory and Control (NEW)

- Processors are required to establish, maintain, and comply with written policies and procedures for proper and secure inventory control of all cannabis maintained at the premises. These policies must mitigate the risk of theft, loss, and diversion of cannabis.
- This includes processes for accepting cannabis deliveries and preparing transfers to another facility, storing securely, tracking accurately in the state inventory tracking system, and conducting regular inventories.

OAC 1301:18-7-04 Testing Laboratory Accreditation (NEW)

- All cannabis testing laboratories must be accredited to ISO 17025 standards by a non-profit accreditation body. Accreditation must be achieved within two calendar years of the date of issuance of a provisional license, unless otherwise approved by the Division.

OAC 1301:18-7-05 Proficiency Testing Program (NEW)

- At least once every renewal cycle, or more often if required by the Division, each testing laboratory must successfully participate in a proficiency testing program. The proposed rule specifies the requirements for such participation.

OAC 1301:18-7-06 Testing Laboratory Minimum Security and Surveillance Requirements (NEW)

- Each testing laboratory must establish, maintain, and comply with written policies and procedures that ensure adequate security, surveillance, and control of the licensed premises that prevent diversion, theft, or loss while meeting the minimum requirements outlined under the rule.

OAC 1301:18-8-04 Dispensary General Sanitary Requirements (NEW)

- Similar to the clean and sanitary operations requirements for cultivators and processors in the proposed GMP rule, dispensaries must ensure they have procedures in place for the safe, sanitary, and clean distribution of cannabis. This includes requirements for the building, grounds, and equipment, and personnel cleanliness and disease control.

OAC 1301:18-8-06 Dispensary Inventory and Control (NEW)

- Dispensaries are required to establish, maintain, and comply with written policies and procedures for the receipt, storage, tracking, and proper and secure inventory control of all cannabis maintained at the premises. These policies must mitigate the risk of theft, loss, and diversion of cannabis.
- This includes processes for accepting cannabis deliveries and preparing transfers to another facility, storing securely, documentation of each sale and tracking accurately in the state inventory tracking system, and conducting regular inventories.

OAC 1301:18-8-08 Dispensing Adult-Use Cannabis (NEW)

- This rule reiterates a dispensary's obligation to check identification and ensure that no one under the age of 21 purchases cannabis.
- Per statutory restrictions in ORC 3780, the rule limits sales to a non-medical cannabis consumer to no more than 2.5 ounces of plant material and 15 grams of extract per day.
- The proposed rule also outlines requirements for cannabis to be tracked in the state inventory tracking system and that all sales adhere to applicable tax laws.
- Finally, the rule requires a receipt to be provided to the consumer outlining, at a minimum, the dispensary's information, the time and date of sale, a complete description of the items purchased, any discounts applied, all sales and excise taxes, and the dispensary's return policy.

OAC 1301:18-8-09 Dispensing Medical Cannabis (NEW)

- The proposed rule requires a dispensary to check the patient or caregiver's identification and patient or caregiver card to ensure they are eligible to purchase medical cannabis.
- A dispensary is required to, first and foremost, dispense medical cannabis in an amount and manner consistent with any instructions provided by the patient's recommending physician. Otherwise, the rule sets limits on the amount of medical cannabis that may be purchased per day and how that information must be tracked in both the prescription monitoring program as well as the state inventory tracking system.

OAC 1301:18-8-10 Dispensing Errors (NEW)

- Dispensaries must have written policies and procedures to detect, identify, and prevent dispensing errors.

OAC 1301:18-8-11 Dispensary Discounts (NEW)

- This rule permits dispensaries to offer discounts, as long as any discount is also offered to patients who are registered with veteran or indigent status. Additionally, if a discount is being offered to non-medical consumers, it must also be offered to all medical patients.
- Licensees are permitted to offer a discount to their employees who are medical patients as well as long as the discount doesn't exceed one offered to veteran or indigent patients.

OAC 1301:18-8-12 Dispensary Returns (NEW)

- Each dispensary must adopt written policies and procedures to accept returns.
- At a minimum, a dispensary must accept cannabis that is returned by a customer because it is defective, it doesn't match the item stated on the receipt, or it is mislabeled. A dispensary may accept other returns if it is outlined in their written policies and procedures.
- The dispensary must provide a refund at the time of return and, if applicable, revise the patient's days' supply.

OAC 1301:18-9-04 Product Alerts and Recalls (NEW)

- All licensees must have written policies and procedures to conduct product alerts and recalls.
- If a product alert or recall directs a customer to return the affected product to a dispensary, the dispensary must accept the return of unused product and provide a refund, and if the customer is a medical marijuana patient the dispensary must revise the patient's days' supply.

OAC 1301:18-9-05 Ohio Division of Cannabis Control Enforcement Authority (NEW)

- This rule establishes the Division's authority to inspect, investigate, and take enforcement action against a licensee or holder of an employee badge whenever it appears that the entity or individual engaged in, or is about to engage in, any prohibited conduct or conduct not authorized by the Revised Code of Administrative Code.

OAC 1301:18-10-03 Patient and Caregiver General Requirements (NEW)

- The proposed rule prohibits patients under the age of 18 from purchasing medical cannabis. It also sets purchase and possession limits for patients, storage requirements for the cannabis, and certain prohibitions including prohibiting the transfer, sale, or distribution of medical cannabis to another person.

The Division is also proposing to rescind several of the current medical marijuana rules under Chapter 3796 which the new rules under Chapter 1301 in this package will replace. Those include 3796 rules regarding cultivation area expansion, cultivator operations, cultivator, processor, and dispensary inventory control, cultivator and processor record keeping, testing laboratory security and surveillance, enforcement authority, advertising, dispensary errors, employee training requirements recall procedures, and forms and methods of administration. Other rule rescissions include Chapter 3796 rules regarding testing laboratory financial responsibility, winding down, cannabis facility distance from prohibited facility, and release of records related to patient transactions. Updated rules regarding those topics were submitted in earlier rule packages.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   Authorized By: R.C. 3796.03, 3780.03, 3780.20
   Amplifies: R.C. 3796.03, 3796.06, 3796.061, 3796.14, 3780.03, 3780.04, 3780.20, 3780.21, 3780.26

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   No

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   n/a

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   Regarding proposed advertising regulations, the state has a compelling interested 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 statute or rules, and is not attractive to children.

   Cannabis entity employees need to be trained to understand how to follow the policies and procedures adopted by the entity they work for, safe and sanitary work practices, as well as how to follow the Division's rules and interact with the Division during inspections. Additionally, while the Division's rules no longer require an armed security guard as dispensaries were previously required to have, the DCC does feel it is important and necessary that certain functions be conducted by an individual with security training. This includes accessing secured areas where video surveillance and security equipment is held, and monitoring and assisting with curbside pick-up. Dispensary employees also need to be trained on products and appropriate dispensing requirements prior to fulfilling those duties.

   The maintenance of certain records by the licensed entity is required for the purposes of any necessary inspections, investigations, or audits.

   By implementing good manufacturing practices, the Division is ensuring licensees are meeting standards set by the federal code for other manufacturing facilities and aligns with many other state cannabis regulations. These standards help ensure that cannabis distributed to a dispensary for sale to a patient or consumer are safe.

   The Division also believes it is important to provide a rule allowing for the transfer of cannabis from a licensed entity to a testing laboratory licensed by the Board of Pharmacy to research dangerous drugs and controlled substances, and to appropriately ensure those transfers are approved and overseen by the Division.

The initiated statute approved by Ohio voters, as well as the medical marijuana statute, outlines the approved forms and methods of administration and the process to get additional ones approved. The Division's rule amplifies those statutory requirements.

The fees established support the costs of administration and licensure for the Division.

Operational rules as well as inventory control and storage requirements are aimed at ensuring that cannabis products are safe and free from harmful contaminants, and prevent the diversion, theft, and loss of cannabis.

The proposed testing requirements, including laboratory proficiency testing, help to ensure that cannabis products sold to patients and consumers are safe.

A product alert or recall is sometimes necessary when the cannabis product is not compliant with the Division's rules or statute. The purpose of this rule is to ensure licensees have a process in place to effectuate a recall.

Finally, the authority to take enforcement action when a licensee or individual has engaged in any prohibited conduct or conduct not authorized by the Revised Code of Administrative Code is in the interest of public health and safety.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   The success of the regulations will be measured by compliance, safe products, and the prevention of theft, loss, and diversion.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

   No

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   The Division posted the proposed rules for early stakeholder feedback on its website and sent a direct email soliciting feedback to cannabis license holders from June 12, 2024 – June 26, 2024. The Division has also received stakeholder feedback during many meetings, including with individual licensees and advocacy groups, as well as with associations representing license holders.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

    Employee Training – licensees broadly expressed concerns with the Division's original proposal requiring OSHA training. Based on the feedback provided, the Division updated the rule to require the

training for at least one registered responsible party or other person in a safety supervisory or managerial role completes the thirty-hour OSHA course, or for the licensee to maintain a contract with a third-party OSHA safety consultant approved by the division to provide all registered employees regular trainings and safety audits.

Record keeping – the Division updated the record keeping rule to require the records be maintained for two years instead of the previously-proposed five years. Additionally based on stakeholder feedback, the Division clarified the only complaints received by a licensee that must be reported to the Division are those that claim the cannabis directly caused a negative health or adverse event *resulting in serious bodily harm to the complainant*.

Transfers – following requests and feedback from licensees, the Division updated the proposed rule regarding business to business transfers to ensure that a processor that manufactures a product pursuant to an agreement with a cultivator (often referred to as a "white-labeling" agreement) can send that product back to the cultivator for the cultivator to distribute it directly to dispensaries.

GMPs – the Division updated the rule to provide a pathway for existing facilities to request an exemption from certain requirements that would require a major modification of an immutable, structural aspect. The licensee must demonstrate that the requested exemption is not otherwise statutorily required, will not be contrary to the public interest, no party would be injured, and the rule is unreasonable or unnecessarily burdensome.

Advertising – the Division updated the prohibition on the use of pop culture icons from "Includes any image or text referencing or resembling a cartoon character, fictional character whose target audience is children or youth, or pop culture icon," to "Includes any image or text referencing or resembling a cartoon character, fictional character, or pop culture icon whose target audience is children or youth."

Cultivator and Processor Operating Procedures – based on stakeholder feedback, the Division removed the previously-proposed timeline for major modifications which required them to be submitted at least 60 days prior to implementation. Instead, the rule requires major modifications to be submitted and written approval provided by the Division prior to implementation. Additionally, the Division has made significant updates to the requirements for the use of pesticides, fertilizers, and other similar chemicals to clarify requirements and ensure they are practical.

Inventory and Control – based on stakeholder feedback, the Division has updated the requirements for the acceptance of deliveries and the completion of inventories from requiring a responsible party to complete to ensuring that a responsible party oversees the tasks. Additionally, based on broad industry feedback, the Division updated the proposed rules to clarify that if a transfer is rejected, it must be immediately documented in the state inventory tracking system, as opposed to the previous language that required notification to the Division within 48 hours, which led to some concerns about duplicative work.

Cultivation Area Expansion – based on licensee feedback, the Division removed the previously proposed restriction only permitting a cultivator to submit one expansion application per year.

11. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

    Other state cannabis markets and regulations were studied and identified best practices were used to help develop these rules.

12. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?** ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

    The Division is establishing standard-based, performance-based regulations. The goal is to allow businesses the flexibility in how they meet the Division's standards set in the rules, unless more prescriptive requirements are necessary to help ensure the public health and safety. Additional provisions considered but updated are described in the answer to question ten above.

13. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

    The initiated statute approved by voters in O.R.C. 3780 places sole regulatory authority over the non-medical cannabis industry with the Division of Cannabis Control.

14. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

    All licensees must comply with the Division's rules. The Division regularly issues industry guidance documents to communicate rule requirements and how to maintain compliance, emails those updates out to licensees, and posts them on the Division's website.

Adverse Impact to Business

15. **Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**
    a. **Identify the scope of the impacted business community, and**
    b. **Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**
    The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.

The impacted business community includes currently licensed cannabis entities, as well as any other businesses who may become licensed in the future.

The proposed rules prescribe various application and licensure fees. This includes fees for initial licensure application that range from $2,000 - $20,000 depending on license type. Fees for the issuance of a Certificate of Operation range from $18,000 - $180,000 per license type. Fees for the renewal of a Certificate of Operation range from $20,000 - $200,000 annually. New and renewal employee applications are $100. Application fees for change of ownership, change of location, or a major modification are $1,000 each, application for change of business or trade name is $500, and product registration is $100.

Employee training requirements necessitate expenditure of employer time and effort to prepare materials, and may include additional monetary costs if the licensee chooses to work with another entity to prepare or conduct training. The security training is free; however, the course takes roughly two hours to complete. The OSHA training course costs about $160 and is 30 hours. The food safety manager training is about $180 and 8 hours to complete.

Licensees are required to maintain certain records for two years. The cost of maintaining these records is dependent upon the volume of required records created in the licensee's course of business, as well as the manner in which the licensee chooses to maintain the records.

While the Division anticipates that the vast majority of licensees have a facility and practices that are currently in line with the proposed GMP requirements, there may be additional costs to implement these updated rules. For example, SOPs may need to be updated, which costs staff time. While that cost is likely minimal, any larger updates that a licensee may need to make (e.g., facility structure changes, equipment) could be more costly; however, this varies by licensee.

Licensees are required to submit new products through the product registration process, which requires staff time to complete the necessary form. The product registration fee is $100.

These rules also require cultivators and processors to establish written policies and procedures in compliance with the proposed operations and quality assurance requirements, and cultivators, processors, and dispensaries must do the same to ensure inventory control. Any changes to these policies or procedures must be submitted to the Division, which may require staff time and effort to submit the appropriate Change of Operations request.

Proposed rules in this package also require a cultivator that wishes to expand their allowable cultivation area to submit a request for Division approval to do so. This application will take some time and effort to complete.

Testing laboratories must complete proficiency testing as required by the Division. There are costs involved with these tests, which includes the samples, process for the proficiency testing, and the assessment. The costs will vary depending on the frequency required and the matrices subject to the proficiency test.

Dispensaries are required to report dispensing errors to the Division. The amount of time to compile the necessary report may depend upon the complexity of the error.

Testing laboratories must maintain ISO accreditation. This is a standard requirement for many different types of labs. According to a 2017 report by the Association of Public Health Laboratories, the annual

average cost of ISO 17025 accreditation was $311,485; however, the report notes the costs are heavily dependent on several variables such as location and volume of testing.

Testing laboratories are required by the rules in this package to meet the Division's standards for security and surveillance, which include, at a minimum, things like an alarm system with point of entry alarms, motion detectors, and silent alarm, and a video surveillance system which must be accessible remotely in real time by the Division and all video must be stored for at least 45 days. The cost of these systems can vary depending on the size of the facility, and the vendor, software, and equipment the licensee has chosen.

Finally, rules in this package allow the Division to take enforcement action against a licensee who violates cannabis laws or rules. Enforcement action may include, but is not limited to, fines, sanctions, and license suspension or revocation.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. *(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).*

The rules proposed here are new pursuant to O.R.C. 3780; however, they will replace the rules adopted under O.R.C. 3796, which were specific to the regulation of the Medical Marijuana Control Program. The new rules apply to both medical and non-medical cannabis.

The current medical marijuana rule regarding employee training requires that all training materials be submitted and approved by the Division. The new updated rule does not require this submission or approval.

The current medical marijuana record keeping rule requires the records to be maintained for five years. The new updated rule requires them to be maintained for two years.

Currently, only cultivators may submit cannabis samples for research and development testing. The proposed rules allow processors to do so as well within the parameters outlined.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The adverse impacts created by the proposed rules mostly include the report of information or certain expenditures, and possible enforcement action. All of the rules associated with these impacts seek to balance fair regulations for business while protecting public health and safety.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

These rules are largely focused on public health and safety, and the requirements that must be met to ensure that there is a level playing field for all licensees.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The DCC works diligently to ensure that all licensees understand all applications, forms, and compliance requirements. The Division does not fine licensees for simple paperwork violations, but does work with licensees who encounter challenges to ensure they have the information necessary to comply with all laws and rules.

20. What resources are available to assist small businesses with compliance of the regulation?

The DCC regularly issues guidance to licensees and posts those documents and other helpful information on its website: www.com.ohio.gov/cannabiscontrol. Additionally, the DCC has a team of inspectors who work closely with all licensees to ensure they are able to achieve and maintain compliance with program regulations

Rules Package 6
General Provisions

1301:18-1-01: Definitions

For purposes of these rules, the following definitions shall apply:

- **(A) Abandoned application** means an application submitted pursuant to division 1301:18 of the Administrative Code which does not meet the minimum eligibility requirements for review, or is otherwise deemed abandoned pursuant to these rules, and is removed from the application process.
- **(B) Adult-Use consumer:** means an individual who is at least twenty-one years of age.
- **(C) Adulterated cannabis** means marijuana as defined by division (A)(1) of section 3796.01 of the Revised Code in which any of the following applies:
    - (1) A substance has been mixed or packed with the cannabis so as to reduce the quality or strength or the substance has been substituted wholly or in part for the cannabis;
    - (2) It consists, in whole or in part, of any filthy, putrid, or decomposed substance, including mold, mildew, and other contaminants;
    - (3) It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or
    - (4) Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.
- **(D) 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.
- **(E) Batch number** means a unique numeric or alphanumeric identifier assigned prior to testing to allow for inventory tracking and traceability.
- **(F) Bona fide physician-patient relationship** has the same meaning as used in the rule promulgated by the state medical board of Ohio under section 4731.301 of the Revised Code.
- **(G) Cannabis clone** means a non-flowering cannabis plant cut from a mother plant that is no taller than twelve (12) inches and is capable of developing into a new plant.
- **(H) Cannabis container:** a sealed, hard or soft-bodied receptacle in which cannabis or cannabis products are directly placed.
    - (1) A cannabis container that is not subsequently placed into any secondary package as defined by this rule, shall adhere to all packaging and labeling requirements outlined under rule 1301:18-4-20 of the Administrative Code.
    - (2) A cannabis container does not mean:
        - (a) Inner wrapping or lining;
        - (b) Any associated device used to administer the cannabis;
        - (c) An exit package; or
        - (d) Packaging used to transfer cannabis in bulk from one licensee or to another.

- **(I) Cannabis Device** means any portable, hand-held cannabis mechanism sold with cannabis or cannabis products utilized for administering the materials contained within. This includes, vaporizers, cannabis inhalers, oral syringe used to administer oil for cannabis extracts intended for oral administration, paper or other materials intended for use in a raw or infused single serving units, and other similar materials.
- **(J) Cannabis inhalers** means a device to administer aerosolized cannabis extract and does not further decarboxylate THCA by heated vaporization or combustion.
- **(K) Cannabis product** means any product manufactured by a cannabis processor that is in the final form intended for consumption. A cannabis product contains cannabis extract or dried cannabis plant material, which may be in combination with other approved ingredients to create the final product. This includes, but is not limited to, oils, tinctures, edibles, patches, single serving units, combination inhalable products, vaporization solutions, and any forms approved under 1301:18 of the Administrative Code.
- **(L) Church** means a church as defined by section 1710.01 of the Revised Code.
- **(M) Combination Inhalable Product** means a product created by combining one or more cannabis products, including cannabis extracts, with dried plant material into a final form which is intended for inhalation. Combination inhalable products may only be created using cannabis products and dried plant material which passed all state-required testing just prior to use as a component.
- **(N) Complete Registration:** means the following
    - (1) Patient full name;
    - (2) Patient residential address;
    - (3) Patient telephone number;
    - (4) Patient date of birth;
    - (5) Patient qualifying condition;
    - (6) State-issued identification number (such as driver's license number) or other identification approved by the division;
    - (7) Patient registration number;
    - (8) Recommending physician's full name (first name and last name);
    - (9) Recommending physician's drug enforcement administration identification number;
    - (10) Recommending physician's medical license number issued by the state medical board;
    - (11) Recommending physician's certificate to recommend identification issued by the state medical board;
    - (12) Date recommendation was issued by the recommending physician;
    - (13) Recommending physician's business address, telephone number, and email address;
    - (14) Indication whether the recommendation is new or a refill;
    - (15) Number of the refill being dispensed; and
    - (16) Date order written, which shall be the date the written recommendation was issued.
- **(O) Control** means the ability to make or significantly influence the strategic policies or management decisions ordinarily reserved for the majority owners or board of directors of a “person” as defined under these rules. Control may be established through ownership, contract, or otherwise; provided control will not be imputed on a bank or licensed lending institution that holds a mortgage or other lien on the person acquired in the ordinary course of business.
    - **(1)** When determining whether a person is exercising control, or has the ability to exercise control, over another, the division may consider, among other factors, whether, and to what extent, the person has any power to do the following on behalf of another:

        - **(a)** Adopt or amend governance documents, including articles of incorporation, articles of organization, bylaws, operating agreements, or buy-sell agreements.
        - **(b)** Cause or prevent a merger, dissolution, equity sale, or asset sale.
        - **(c)** Elect or remove directors or officers; or elect or remove other positions that exercise authority similar to those of a director or an officer in an Ohio corporation.
        - **(d)** Exercise voting power similar to a shareholder in an Ohio corporation.
        - **(e)** Exercise voting power similar to a director in an Ohio corporation.
        - **(f)** Call meetings of the directors or owners.
        - **(g)** Regulate the authority of the owners, directors, or officers.
        - **(h)** Issue shares, membership interest, or similar equity.
        - **(i)** Declare dividends or distributions.
        - **(j)** Enter into contractually binding agreements.
        - **(k)** Authorize a mortgage, pledge, lien or deed of trust on any real property or personal property.
        - **(l)** Hire or fire organizations that manage day-to-day operations.
    - **(2)** In addition to the listed factors, the division may consider any other factors listed under paragraph (1) it deems relevant. Control may be established whether one, any or none of the factors listed are present.
- **(P) Cultivation Area** means the boundaries of the enclosed areas in which adult use cannabis is cultivated during the vegetative stage and flowering stage of the cultivation process. For purposes of calculating the cultivation area square footage, enclosed areas used solely for the storage and maintenance of mother plants, clones, or seedlings shall not be included.
- **(Q) Customer:** means an adult-use consumer or registered medical patient or caregiver within the context of purchasing cannabis at a licensed dispensary.
- **(R) Disqualifying offense** means a conviction or plea of guilty, including conspiracy to commit, attempt to commit, or aiding and abetting another in committing, the following:
    - **(1)** Any offense set forth in chapters 2925, 3719, or 4729 of the Revised Code, the violation of which constitutes a felony or a misdemeanor of the first degree;
    - **(2)** Any theft offense set forth under division (K) in section 2913.01 of the Revised Code, the violation of which constitutes a felony;
        - **(a)** Any violation for which a penalty was imposed under section 3715.99 of the Revised Code;
        - **(b)** A crime of moral turpitude as defined in section 4776.10 of the Revised Code; or
        - **(c)** A violation of any former law of this state, any existing or former law of another state, any existing or former law applicable in a military court or Indian tribal court, or any existing or former law of any nation other than the United States that is or was substantially equivalent to any of the offenses listed in paragraphs (a)(iv) to (a)(iv) of this definition.
    - **(3)** Any first degree misdemeanor offense listed in paragraphs (a)(i) to (a)(v) of this definition will not automatically disqualify an applicant from licensure if the applicant was convicted of or pleaded guilty to the offense more than five years before the date the application for licensure is filed.
    - **(4)** Notwithstanding paragraph (1) or (2) of this definition, no misdemeanor offense, including misdemeanors of the first degree, related to cannabis possession, cannabis trafficking, illegal cultivation of cannabis, illegal use or possession of drug paraphernalia

or cannabis drug paraphernalia, or other cannabis related crimes shall be considered a disqualifying offense.

- **(S) Dual-use license** means a license issued by the division that allows:
    - **(a)** A cultivator to engage in all permissible activities outlined under sections 3796.18, 3780.12, and 3780.13 of the Revised Code.
    - **(b)** A processor to engage in all permissible activities outlined under sections 3796.19 and 3780.14 of the Revised Code.
    - **(c)** A testing laboratory to engage in all permissible activities outlined under sections 3796.21 and 3780.16 of the Revised Code.
    - **(d)** A dispensary to engage in all permissible activities outlined under sections 3796.20 and 3780.15 of the Revised Code.
- **(T) Facility visitor** means any individual seeking to enter the premises of a licensed entity who does not maintain a valid employee badge pursuant to rule 1301:18-3-09 of the Administrative Code and is not a registered patient, caregiver, or adult-use consumer within a dispensary's retail area.
- **(U) Final Form** means the form of cannabis as manicured, trimmed, manufactured, or processed and intended for customer sale.
    - The intended form of cannabis immediately prior to submission to a testing laboratory licensed pursuant to 1301:18 of the Administrative Code for all state-required testing. For purposes of submission of final form cannabis for any state-required testing, final form cannabis may, but is not mandated to be, placed in a container or package.
- **(V) Financial interest** means any actual or future right to ownership, or investment, with another person, either directly or indirectly, through business, investment, spouse, parent, or child, in licensed cannabis business. Financial interest does not include ownership of investment securities in a publicly-held corporation that is traded on a national securities exchange or over-the-counter market in the United States, provided the investment securities held by the person and the person's spouse, parent, or child, in the aggregate, do not exceed ten percent ownership in the licensed cannabis entity.
- **(W) Flowering stage** means the stage of cultivation where and when a cannabis plant is cultivated to produce plant material for products. This includes mature plants which are identified by:
    - (1) If greater than two stigmas are visible at each internode of the plant; or
    - (2) If the cannabis plant is in an area that has been intentionally deprived of light for a period of time intended to produce flower buds and induce maturation, from the exact moment the light deprivation has started to occur and for the remainder of the cannabis plant growth cycle in such area.
- **(X) 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.

- **(Y) Indigent Status** means an individual 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 or other documentation as determined by the division.
- **(Z) Infused single serving unit** is a combination inhalable product that consists of dried plant material and cannabis extract, wrapped in rolling paper. The cannabis extract may be included in the product by combining with the dried plant material, applying to the rolling paper, or both. A lot of infused single serving units may not exceed 35,000 units.
- **(AA) Licensed premises** means the real property, including any facility, building, storage areas, parking lot or areas, and any surrounding curtilage, to which any person licensed pursuant to 1301:18 of the Administrative Code maintains ownership or control over via a valid lease or other formal written agreement and as represented to the division of cannabis control pursuant to an application for a license to cultivate, process, test, or dispense cannabis and reflected on the person's certificate of operation.
- **(BB) Live Plants** means cannabis plants that are no greater than five feet in height and are still in the vegetative state and not flowering;
- **(CC) Mother plant** means a cannabis plant that is cultivated or maintained for the purpose of generating clones, and that will not be used to produce plant material for sale to a processor or dispensary.
- **(DD) Ownership** means a person's, direct or indirect, present ownership interest in a person, including membership interest in a limited liability company, shares of stock in a corporation, or similar equity interests in any other corporate person; or a person's beneficial interest or proprietary interest in an individual or group of individuals. The definition of ownership does not include passive equity interest of less than ten percent in a licensed cannabis business which is for investment purposes only.
- **(EE) Packaging intended for Direct Customer Sale:** the final cannabis packaging as presented, displayed, and sold to customers at a licensed dispensary. Packaging for direct customer sale, may include a cannabis container and secondary packaging, depending on the product type. All packaging for direct customer shall adhere to all mandates outlined for rule 1301:18-4-20 of the Administrative Code.
- **(FF) Person** includes, but is not limited to, an individual or a combination of individuals; a sole proprietorship, a firm, a company, a joint venture, a partnership of any type, a joint-stock company, a corporation of any type, a corporate subsidiary of any type, a limited liability company, a business trust, or any other business entity or organization; an assignee; a receiver; a trustee in bankruptcy; an unincorporated association, club, society, or other unincorporated entity or organization; entities that are disregarded for federal income tax purposes; and any other nongovernmental, artificial, legal entity that is capable of engaging in business.
- **(GG) Product Alert:** A notice issued from the Division to the public when it is determined that a cannabis product is not compliant with chapters 3780 or 3796 of the Revised Code, or these rules, and has been sold to the public, but the deficiency does not reasonably constitute the product being unfit for consumption or a risk to public health and safety.
- **(HH) Product Recall:** A notice issued from the Division to the public when it is determined that a cannabis product which is not compliant with chapters 3780 or 3796 of the Revised Code, or these rules, has been sold to the public, and the deficiency may cause serious adverse health consequences.
- **(II) Prohibited facility** means a school, church, public library, public playground, or public park, as defined by this rule.

- **(JJ) Provisional license** means a temporary license issued to a license applicant that establishes certain conditions that must be met by the provisional licensee before it may be issued a cultivator, processor, testing laboratory, or dispensary certificate of operation and engage in any authorized activity outlined under division 1301:18 of the Administrative Code.
- **(KK) Public library** means a library provided for under chapter 3375 of the Revised Code.
- **(LL) Public park** means a park established by the state or a political subdivision of the state including a county, township, municipal corporation, or park district.
- **(MM) Public playground** means a playground established by the state or a political subdivision of the state including a county, township, municipal corporation, or park district.
- **(NN) Range of total THC Content** means: within 10% of the total THC as defined by 1301-1-01 of the Administrative Code as reflected by the associated certificate of analysis.
- **(OO) Raw single serving unit** means a unit that is packed with dried plant material (such as trim, shake or ground flower) and wrapped in rolling paper. A raw single serving unit contains only dried plant material and must be batch specific. A batch of raw single serving units must be wrapped in rolling paper prior to regulatory compliance testing.
- **(PP) Recommending physician** means a physician, as defined by division (A)(5) of section 3796.01 of the Revised Code, that holds a valid certificate to recommend medical marijuana issued by the state medical board of Ohio under section 4731.30 of the Revised Code.
- **(QQ) Secondary Packaging:** if applicable, packaging that holds the cannabis container and does not come into direct contact with any cannabis or cannabis products. The packaging as presented for direct customer sale.
- **(RR) School** means a public or nonpublic primary school or secondary school and includes a childcare center as defined under section 5104.01 of the Revised Code, and a preschool, as defined section 2950.034 of the Revised Code.
- **(SS) Shake** means the loose, fragmented pieces of cannabis flower that accumulate at the bottom of a bag or container. It consists of fragmented buds, broken leaves, and resinous trichomes (kief) that naturally separate during transportation or handling.
- **(TT) Single day supply:** means 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 cannabis products with a total THC content of no more than 15,000mg.
- **(UU) Test Sample Collector:** means an individual who is a registered employee pursuant to rule 1301:18-9-01 of the Administrative Code who retrieves test samples from a licensed entity, conducts all required test sample collection, and adheres to all mandates pertaining to test sample collection on behalf of a testing laboratory licensed pursuant to 1301:18 of the Administrative Code.
- **(VV) Tetrahydrocannabinol or THC** means the sum of the amount of delta-9 tetrahydrocannabinol (THC)and 87.7 per cent of the amount of delta-9-tetrahydrocannabinolic acid (THCA) present in the product or plant material. THC does not include minor cannabinoids.
- **(WW) Tetrahydrocannabinol content** means tetrahydrocannabinol as defined by this rule and any artificially or naturally derived tetrahydrocannabinols, or any structural, optical or geometric isomers, or analogs of tetrahydrocannabinols derived cannabinoid with an intoxicating or psychoactive effect, as determined by the division of cannabis control.
- **(XX) Trim** means the sugar leaves and small pieces of cut-off buds that are intentionally pruned from the cannabis plant post-harvest as part of the trimming or manicuring phase, as well as the resinous trichomes (kief) that are dislodged from the cannabis plant incidental to trimming and manicuring activities.
- **(YY) Veteran status** means an individual that may provide the following:

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

- **(ZZ) Vegetative stage** means the stage of cultivation where and when a cannabis plant is propagated to produce additional cannabis plants or reach a sufficient size for production. This includes "seedlings," "clones," "mothers," and other immature cannabis plants identified by: (a) having no more than two stigmas visible at each internode of the cannabis plant and if the cannabis plant is in an area that has not been intentionally deprived of light for a period of time intended to produce flower buds and induce maturation; or (b) any cannabis plant that is cultivated solely for the purpose of propagating clones and is never used to produce any cannabis intended for customer sale.

OAC 1301:18-2-07 Cannabis Entity Provisional Licenses

- **(A)** The division of cannabis control may issue a provisional license to a license applicant if it demonstrates, at a minimum:
  - **(1)** Compliance with all mandates outlined in the application for licensure;
  - **(2)** Compliance with all applicable tax laws within the state of Ohio;
  - **(3)** Proper, accurate, and appropriate disclosure of all information outlined under rule 1301:18-3-04 of the Administrative Code;
  - **(4)** Applicant owns, or maintains a valid lease for, the property upon which the proposed licensed premises is located;
  - **(5)** The proposed facility site is not within five hundred feet of the end boundaries of a parcel of real estate having situated on it a prohibited facility as outlined under rule 1301:18-3-01 of the Administrative Code;
  - **(6)** The licensed premises is:
    - **(a)** Not subject to a local moratorium or other action that would prohibit operation;
    - **(b)** Compliant with all applicable local ordinances, rules, and regulations adopted by the locality in which the facility is located including:
      - **(i)** Local building standards adopted pursuant to chapters 3781 and 3791 of the Revised Code; and
      - **(ii)** Local approval to operate as a cannabis business.
  - **(7)** An applicant will be non-compliant with this paragraph if any of the above-referenced mandates are subject to ongoing negotiations, litigation, or other un-resolved inquiry.
- **(B)** Upon determination that a license applicant met all mandates for a provisional license, the division may issue the provisional license outlining the business entity and licensed premises as specified in its application for licensure.
  - **(1)** In addition to the requirements outlined under this paragraph, a provisional license shall be issued only to the persons and individuals disclosed pursuant to paragraph (A)(3) of this rule.
  - **(2)** Unless otherwise authorized by the division, all provisional licenses issued pursuant to division 1301:18 of the Administrative Code are non-transferable.

- **(C)** The division reserves the right to cancel a notice of an open application period pursuant to rule 1301:18-2-01 of the Administrative Code prior to issuance of a provisional license.

OAC 1301:18-2-09 Fee schedule

- **(A)** The following non-refundable fees shall be paid to the division of cannabis control:
    - **(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
    - **(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: forty thousand dollars
        - **(d)** Testing Laboratories: eighteen thousand dollars
        - **(e)** Dispensaries: seventy thousand dollars
    - **(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.
    - **(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
    - **(5)** Change of Ownership: one thousand dollars
    - **(6)** Change of Business or Trade Name: five hundred dollars
    - **(7)** Change of Location: one thousand dollars
    - **(8)** Major Modification: one thousand dollars
    - **(9)** Product Registration: one hundred dollars
- **(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.

OAC 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 of cannabis control evidence of ongoing compliance with this rule and ensure:
    - **(a)** All training is reviewed annually and updated as necessary and appropriate; and
    - **(b)** All employees regularly receive training on all applicable materials.

- **(B) Foundational Training.** Prior to commencing business, each person registered pursuant to rule 1301:18-3-09 of the Administrative Code, shall receive foundational training on the following:
    - **(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;
    - **(5)** All applicable statutes and regulations pertaining to Ohio cannabis law; and
    - **(6)** Responsible use training and available associated 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 (B) of this rule, each licensee shall train all applicable employees as follows:
    - **(1) 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 located at:
        - **(a)** https://homelandsecurity.ohio.gov/private-investigators-and-security-guards/training-opportunities/online-training
    - **(2) OSHA training.** Each cultivator and processor shall ensure on an annual basis:
        - **(a)** At least one registered responsible party or other person in a safety supervisory or managerial role completes the thirty-hour OSHA course; or
        - **(b)** The licensee maintains a contract with a third-party OSHA safety consultant approved by the division to provide all registered employees regular trainings and safety audits.
    - **(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 person 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.
    - **(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 1301:18-8-07 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 rule 1301:18-3-14 of the Administrative Code, each licensee shall document all training pursuant to this rule and include the following:
    - **(1)** Names and qualifications of the person responsible for training content;
    - **(2)** A set of training materials, to be provided to each participant; and
    - **(3)** Date(s) of training.

OAC 1301:18-3-14: Cannabis Entity Record Keeping

- **(A)** Each licensee shall maintain upon the licensed premises all books, records, policies, procedures, and documentation evidencing the daily operations and business transactions conducted at the licensed premises.
    - **(1)** All records shall be maintained in an auditable format and immediately available for inspection and duplication upon the division of cannabis control's request.
    - **(2)** A licensee may use an electronic system for storage and retrieval of records so long as the system meets the following:
        - **(a)** Guarantees the confidentiality of the information stored in the system;
        - **(b)** Is capable of providing safeguards against erasures and unauthorized changes; in data after the information has been entered and verified by the licensee;
        - **(c)** Can implement an administrative hold for investigative or inspection purposes; and
        - **(d)** Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.
    - **(3)** Any loss of electronically maintained records shall not mitigate any violations of this rule.

- **(B)** Documentation maintained within the normal course of business and as required by paragraph (A) of this rule shall be retained for the current calendar year, and the preceding calendar year, and include the following:
    - **(1)** Any and all written policies and procedures utilized at the licensed premises including those mandated by division 1301:18 of the Administrative Code, including:
        - **(a)** Standard operating procedures;
        - **(b)** Cleaning and sanitization procedures of the licensed premises;
        - **(c)** In accordance with rule 1301:18-3-12 of the Administrative Code, waste disposal records;
        - **(d)** Inventory records;
        - **(e)** Security and surveillance records;
        - **(f)** Production records;
        - **(g)** Packaging and labeling records;
        - **(h)** Records of all test samples sent to a licensed testing laboratory and the associated certificate of analysis for each batch or lot;
        - **(i)** In accordance with rule 1301:18-3-13 of the Administrative Code, transportation records;
        - **(j)** In accordance with rule 1301:18-9-04 of the Administrative Code, product alerts and recall procedures; and
        - **(k)** In accordance with rule 1301:18-3-11 of the Administrative Code, visitor logs.
    - **(2)** If applicable:
        - **(a)** Dispensing records, as required by chapter 1301:18-8 of the Administrative Code;
        - **(b)** Records of any theft, loss, or other unaccountability of any cannabis as required by rule 1301:18-9-02 of the Administrative Code;
        - **(c)** All complaints received pertaining to the quality or efficacy of the licensee's cannabis cultivated, processed, tested, or dispensed at the licensed premises; and
        - **(d)** All complaints received alleging the cannabis cultivated, processed, tested, or dispensed at the licensed premises, directly caused a negative health or adverse event resulting in serious bodily harm to the complainant, as required by rule 1301:18-9-02 of the Administrative Code.
    - **(3)** Business records, including:
        - **(a)** Licensee's ownership list and capitalization table;
        - **(b)** An organizational chart identifying all owners, officers, and board members of the licensee;
        - **(c)** For each owner, officer, and board member:
            - **(i)** Full legal name;
            - **(ii)** Mailing address;
            - **(iii)** Date of birth, evidencing the individual is at least twenty-one years of age or older; and
            - **(iv)** The individual's role with the licensee.
        - **(d)** A list of any person with a direct or indirect financial interest in, the licensee;
        - **(e)** A list of any person with direct or indirect control over, the licensee;
            - **(i)** This applies to any current or future right to control.
        - **(f)** A list of any of the following regardless of whether they meet the definition of ownership, financial interest, or control:

- **(i)** Option agreement, debt conversion, or other agreement which creates a current or future right in equity in the licensee, regardless of whether such modification is contingent upon certain acts or omissions.

- **(g)** A copy of any executed merger, sale, option to purchase, letter of intent, consulting, management, support, administrative services, or other similar agreements between applicant and any other person or that person's affiliates; and
- **(h)** Any other documentation evidencing the ownership structure, financial interest, or control of the licensee.

- **(4)** All financial records reasonably related to operations, including but not limited to:
  - **(a)** Records that clearly reflect all financial transactions and the financial condition of the business, including contracts for services performed or received that relate to the licensee;
  - **(b)** Purchase invoices, bills of lading, manifests, sales records, copies of bills of sale, and any supporting documents, including the items and/or services purchased, from whom the items were purchased, and the date of purchase;
  - **(c)** Accounting and tax records related to the licensee and all investors in the licensee;
  - **(d)** Bank statements;
  - **(e)** Cancelled checks; and
  - **(f)** Third-party vendor contracts.
- **(5)** All advertising records related to advertising, promotional, or other marketing materials;
- **(6)** Employee records, including:
  - **(a)** Employee hiring records, including the applicable background evaluation conducted by the licensee pursuant to rule 1301:18-3-09(B)(1) of the Administrative Code;
  - **(b)** An employee list of all current and former employees, outlining the following information:
    - **(i)** Full legal name, address, phone number, and electronic mail address;
    - **(ii)** Badge certificate number pursuant to rule 1301:18-3-09 of the Administrative Code;
    - **(iii)** Access designation credentials;
    - **(iv)** Date of hire; and
    - **(v)** If applicable:
      - **(A)** Date and rationale for separation; and
      - **(B)** History of disciplinary actions.
  - **(c)** Salary and wages paid to each employee, and any executive compensation, bonus, benefit, or item of value paid to any individual affiliated with any cannabis entity, including members of a non-profit corporation, if any; and
  - **(d)** Training and educational records, pursuant to rule 1301:18-3-10 of the Administrative Code.

OAC 1301:18-3-16 Business to Business Transfers Generally

- **(A) Bulk Packaging:**

- **(1)** Prior to transfer to another licensee, each cultivator and processor shall place the cannabis in a separate, clean food-grade package that is tamper-evident and maintains the integrity and stability of the cannabis contained within.

- **(B) Bulk Shipping Label:** Each cultivator and processor shall ensure all cannabis intended for transfer to another licensed entity is affixed with a label on the exterior of every bulk package and states in legible English at least the following information, as applicable:
  - **(1)** The name and license number of the cultivator where the plant material was cultivated and harvested;
  - **(2)** The name and license number of the processor where the cannabis products were manufactured;
  - **(3)** The batch or lot number that corresponds with the batch or lot number associated with all state-required testing;
  - **(4)** The net weight of the cannabis contained within the package or the quantity of units contained within the package;
  - **(5)** The universal THC symbol;
  - **(6)** The division seal, as prescribed by the division;
  - **(7)** The following warning: This Product Contains Cannabis, Keep out of reach of children; and
  - **(8)** If the plant material or cannabis product was mislabeled by the originating licensee, or is damaged, defective, or adulterated, a disclaimer that states as such.
- **(C) Transfer Manifests.** Prior to any transfer, sale, or distribution to another licensed entity, the originating licensee shall prepare a transfer manifest utilizing the state inventory tracking system and include the following information for each transfer:
  - **(1)** The names and addresses of the cannabis entities sending and receiving the shipment;
  - **(2)** The time of departure and estimated time of arrival;
  - **(3)** Within each transfer the following information for each individual package:
    - **(a)** A description of each individual package that is part of the shipment;
    - **(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:
      - **(i)** The weight of the cannabis contained within the shipment; or
      - **(ii)** 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 names of the registered employees transporting the cannabis and their respective badge certificate number as provided by rule 1301:18-3-09 of the Administrative Code;
      - **(ii)** The license plate number and vehicle type that will transport the shipment; and
      - **(iii)** The specific delivery route, which includes street names and distances.
  - **(4)** Prior to the delivery, provide a copy of the transfer manifest to the recipient licensee and the division, via the state inventory tracking system.

- **(D)** Prior to receipt, each licensee shall ensure that all cannabis received from another licensee adheres to the following:
    - **(1)** Meets all standards for all applicable state-required testing;
    - **(2)** Meets all packaging and labeling standards; and
    - **(3)** The accompanying certificate of analysis is uploaded in the state inventory tracking system with each batch or lot.

OAC 1301:18-3-18: Business to Business Transfers - cannabis packaged for direct customer sale.

- **(A)** A cultivator, processor, or dispensary licensed pursuant to division 1301:18 of the Administrative Code may transfer cannabis **packaged for direct customer sale** in accordance with the following:
    - **(1)** A licensee is not required to test the cannabis or cannabis products again prior to transferring to another licensee so long as the cannabis complies with the following:
        - **(a)** The cannabis met all standards established by the division and 1301:18 of the Administrative Code for all state-required testing; and
        - **(b)** The cannabis is contained within the unopened, sealed packaging intended for direct customer sale in accordance with rule 1301:18-4-20 of the Administrative Code.
    - **(2)** Except as permitted by 1301:18 of the Administrative Code, any cannabis that is removed from **packaging intended for direct customer sale** is considered **adulterated** and is to be immediately destroyed pursuant to rule 1301:18-3-12 of the Administrative Code.
- **(B) Allowable Transfers.**
    - **(1)** A **cultivator** may transfer cannabis contained within **packaging for direct customer sale** as follows:
        - **(a)** To another cultivator licensed pursuant to division 1301:18 of the Administrative Code:
            - **(i)** Seeds, clones, live plants; and
            - **(ii)** Cannabis plant material
        - **(b)** To a processor licensed pursuant to division 1301:18 of the Administrative Code:
            - **(i)** Cannabis plant material
        - **(c)** To a dispensary licensed pursuant to division 1301:18 of the Administrative Code:
            - **(i)** Seeds, clones, live plants; and
            - **(ii)** Cannabis plant material
    - **(2)** A **processor** may transfer cannabis contained within **packaging for direct customer sale** as follows:
        - **(a)** To a cultivator licensed pursuant to division 1301:18 of the Administrative Code:
            - **(i)** Cannabis plant material; and
            - **(ii)** Cannabis products pursuant to a valid contract or agreement between the two licensed entities.
        - **(b)** To another processor licensed pursuant to division 1301:18 of the Administrative Code:
            - **(i)** Cannabis plant material; and
            - **(ii)** Cannabis products

        - **(c)** To a dispensary licensed pursuant to division 1301:18 of the Administrative Code:
            - **(i)** Cannabis plant material; and
            - **(ii)** Cannabis products
    - **(3)** A **dispensary** may transfer cannabis contained within **packaging for direct customer sale** as follows:
        - **(a)** To a cultivator licensed pursuant to division 1301:18 of the Administrative Code:
            - **(i)** Cannabis plant material
        - **(b)** To a processor licensed pursuant to division 1301:18 of the Administrative Code:
            - **(i)** Cannabis plant material; and
            - **(ii)** Cannabis products
        - **(c)** To another dispensary licensed pursuant to division 1301:18 of the Administrative Code:
            - **(i)** Cannabis plant material; and
            - **(ii)** Cannabis products

Consumer Protection and Product Safety

OAC 1301:18-4-01 Cultivator and Processor Good Manufacturing Processes

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

- **(A) Personnel:**
    - **(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, is to 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 are to 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 are to 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 cross-contact 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 is to 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 is to 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 are to be kept in a condition that will protect against the contamination of cannabis. The methods for adequate maintenance of grounds are to 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 is to 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 is to be suitable in size, construction, and design to facilitate maintenance and sanitary operations for cannabis-production purposes (i.e., cultivating, manufacturing, processing, packing, and holding). The facility is to:
        - **(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 are to be maintained in a clean and sanitary condition and be kept in repair adequate to prevent cannabis from becoming adulterated.
    - **(a)** Cleaning and sanitizing of utensils and equipment are to be conducted in a manner that protects against allergen cross-contact and against contamination of cannabis, cannabis-contact surfaces, or cannabis-packaging materials.
  - **(2)** Substances used in cleaning and sanitizing; storage of toxic materials.
    - **(a)** Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures are to be free from undesirable microorganisms and safe and adequate under the conditions of use.
      - **(i)** Cleaning compounds and sanitizing agents are to be used in accordance with the labeling requirements.
      - **(ii)** Processors are to use food-safe sanitizers for all utensils and contact surfaces.
    - **(b)** Only the following toxic materials may be used or stored in a facility where cannabis is processed or exposed:
      - **(i)** Those necessary 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 are to be identified, held, and stored in a manner that protects against contamination of cannabis, cannabis-contact surfaces, or cannabis-packaging materials.
  - **(3) Pest control.** Pests are not 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 are to 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, are to 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 are to be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they are to be, when necessary, 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 are to 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) are to 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 are to 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 are to 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 is to be equipped with adequate sanitary facilities and accommodations including:
        - **(a)** The water supply is to 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 is to be safe and of adequate sanitary quality.
            - **(ii)** All running water is to 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 is to 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 is to be disposed of into an adequate sewerage system or disposed of through other adequate means.
        - **(d) Toilet facilities.** Each facility is to provide employees with adequate, readily accessible toilet facilities.
            - **(i)** Toilet facilities are to be kept clean and cannot 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 are to 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.** In accordance with rule 1301:18-3-12 of the Administrative Code, 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 contained within packaging intended for direct customer sale is to be maintained in food grade containers.
    - **(2)** All facility equipment and utensils used in cultivating, manufacturing, processing, testing, packing, or holding cannabis are to be so designed and of such material and workmanship as to be adequately cleanable, and adequately maintained to protect against allergen cross-contact and contamination.
        - **(a)** Equipment and utensils are to 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 is to be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.
        - **(c)** Cannabis-contact surfaces are to be corrosion-resistant when in contact with cannabis.

        - **(e)** Cannabis-contact surfaces are to 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 are to 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 are to 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 is to be so constructed that it can be kept in a clean and sanitary condition.
    - **(5)** Trimming, holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, is to 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 is to 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 are to 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 are to 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) are to be conducted in accordance with adequate sanitation principles.
        - **(a)** Appropriate quality control operations are to 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 are to be under the supervision of one or more competent individuals assigned responsibility for this function.
        - **(c)** Adequate precautions are to 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 are to 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 are to be inspected and segregated or otherwise handled as necessary to ascertain that they are

clean and suitable for processing into cannabis and stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration.

- **(a)** Raw materials are to be washed or cleaned as necessary to remove soil or other contamination.
- **(b)** Water used for washing, rinsing, or conveying cannabis are to 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 are to 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 are to 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 are to 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 are to be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and 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 are to be kept frozen. If thawing is required prior to use, it to 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 are to 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, are to be identified and held in a manner that prevents allergen cross-contact.

- **(3) Manufacturing operations.** Equipment and utensils and cannabis containers are to be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment is to be taken apart for thorough cleaning.
    - **(a)** All cannabis cultivation, manufacturing, processing, packing, testing, and holding are to be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of cannabis, and deterioration of cannabis.
    - **(b)** Cannabis that can support the rapid growth of undesirable microorganisms is to 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 are to be adequate under the conditions of manufacture, handling, and distribution to prevent cannabis from being adulterated.
- **(d)** Work-in-process and rework is to be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.
- **(e)** Effective measures are to 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 cannot 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 is to 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 is to 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 are to 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 are to 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 is to be performed so as to protect cannabis against allergen cross-contact and against contamination.
- **(j)** Cannabis is to 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, is to be effected by heating the cannabis to the required temperature, holding it at this temperature for the necessary time, and then either rapidly cooling the cannabis or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers is to be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.
- **(l)** Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time are to 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 are to 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 is to 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 is to be monitored and maintained at a pH of 4.6 or below.
        - **(p)** When ice is used in contact with cannabis, it is to be made from water that is safe and of adequate sanitary quality in accordance with this rule and 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 is to 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.
- **(H)** A cultivator or processor may request exemption of a specific mandate outlined under this rule so long as the following apply:
    - **(1)** The division issued the licensee a certificate of operation prior to the initial effective date of this rule; and
    - **(2)** The licensee demonstrates the following:
        - **(a)** The specific mandate would require a major modification of an immutable, structural aspect of the licensed premises; and
        - **(b)** All other factors outlined under rule 1301:18-9-06 of the Administrative Code.

OAC 1301:18-4-02 Authorized cannabis forms and methods of administration

- **(A)** Pursuant to sections 3780.04 and 3796.06 of the Revised Code, and in accordance with all mandates outlined under chapters 3780 and 3796 of the Revised Code and 1301:18 of the Administrative Code, a cultivator or processor shall only produce 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)** Cannabis extracts.
    - **(2)** For medical cannabis:
        - **(a)** Vaporization:
            - **(i)** Seeds;
            - **(ii)** Live plants;
            - **(iii)** Clones;
            - **(iv)** Plant material; and
            - **(v)** Cannabis extracts.
    - **(3)** Oral administration:
        - **(a)** Capsules;
        - **(b)** Pills;

        - **(c)** Tablets;
        - **(d)** Drops;
        - **(e)** Oils;
        - **(f)** Edibles; and
        - **(g)** Cannabis Beverages.
    - **(4)** Topical administration:
        - **(a)** Salves;
        - **(b)** Ointments;
        - **(c)** Lotions or similar cosmetic products; and
        - **(d)** Topical sprays.
    - **(5)** Transdermal administration:
        - **(a)** Patches
    - **(6)** Inhalation:
        - **(a)** Inhalers
    - **(7)** Sublingual or Oromucosal:
        - **(a)** Lozenges;
        - **(b)** Oral pouches;
        - **(c)** Oral strips;
        - **(d)** Oral sprays; and
        - **(e)** Tinctures.
    - **(8)** Rectal:
        - **(a)** Suppositories
- **(B)** The following limitations apply:
    - **(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.

OAC 1301:18-4-03: Petition for Additional Forms and Methods

- **(A)** A person seeking to add an approved form or method of administration as outlined under rule 1301:18-4-03 of the Administrative Code shall apply in a manner prescribed by the division of cannabis control and demonstrate the following:
    - **(1)** Multiple scientific experts support 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
    - **(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.

OAC 1301:18-4-05 Limitations on THC Content for Cannabis Intended for Direct Customer Sale.

- In accordance with sections 3780.03 and 3796.06 of the Revised Code the following limitations apply:
- **(A)** For adult-use cannabis:
  - **(1)** Cannabis plant material shall not contain a tetrahydrocannabinol content of more than thirty-five (35) percent; and
  - **(2)** Cannabis extracts shall not contain a tetrahydrocannabinol content of more than ninety percent (90) percent.
- **(B)** For medical cannabis:
  - **(1)** Cannabis plant material shall not contain a tetrahydrocannabinol content of more than thirty-five (35) percent; and
  - **(2)** Cannabis extracts shall not contain a tetrahydrocannabinol content of more than seventy percent (70) percent.
- **(C)** In accordance with rule 1301:18-4-09 of the Administrative Code, each package of cannabis intended for direct customer sale shall not contain less than ninety percent or more than one hundred ten per cent of the concentration of total target THC content as provided in the product registration pursuant to rule 1301:4-06 of the Administrative Code.
- **(D)** For cannabis plant material, a THC content of less than three-tenths of one per cent will be considered as having zero percent THC content.
- **(E)** For cannabis products, there is no zero percent threshold for THC content in cannabis products.

OAC 1301:18-4-07 Limitations on Cannabis Strain Names

- **(A)** No licensee shall create, use, or distribute, or cause to be created, used, or distributed, any cannabis strain name that is any of the following:
  - **(1)** False or misleading;
  - **(2)** Obscene or indecent;
  - **(3)** Attractive to children;
  - **(4)** Is named after or references, either directly or by inference, any of the following:

        - **(i)** A cartoon character, fictional character, or pop culture icon whose target audience is children or youth;
        - **(ii)** A product available for consumption as a commercially available candy; or
        - **(iii)** A health-related statement.
    - **(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)** 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;
    - **(7)** Violates state of Ohio or federal trademark or copyright law; or
    - **(8)** 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.

OAC 1301:18-4-08 Limitations on Cannabis Products

- **(A)** No licensee shall manufacture, process, or distribute, or cause to be created, used, or distributed, any cannabis product that is any of the following:
    - **(1)** False or misleading;
    - **(2)** Obscene or indecent;
    - **(3)** Attractive to children;
    - **(4)** Resembles any of the following:
        - **(i)** A cartoon character, fictional character, or pop culture icon whose target audience is children or youth;
        - **(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;
    - **(6)** Departs from the registered product name as submitted pursuant to [product registration], including, slang terms, and similar references;
    - **(7)** Contains a health-related statement;
    - **(8)** Suggests, or otherwise indicates, that the product has been approved or endorsed by the division of cannabis control, the state of Ohio or any person or entity associated with the state of Ohio, or any other person without their consent;
    - **(9)** Violates state of Ohio or federal trademark or copyright law; or
    - **(10)** 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.
- **(B)** Products intended for smoking, combustion, or vaporization cannot contain characterizing flavors, except those intended to mimic the cannabis strain.

OAC 1301:18-4-09: Pre-Approval Requirement for Product Registration

- **(A)** Each cultivator and processor shall not package, produce, transfer, distribute, or sell cannabis plant material or a cannabis product variation without prior written approval from the division of cannabis control.
- **(B)** Each cannabis product variation shall be registered and designated by a unique identifying number to the product variation by the division.

- **(C)** Prior to packaging, producing, transferring, distributing, or selling a cannabis product, each licensee shall apply in a manner prescribed by the division.
- **(D)** Pursuant this rule, the division may:
    - **(1)** Pursuant to rule 1301:18-9-01 of the Administrative Code, conduct an inspection at the licensed premises and review any proposed product or associated procedure or equipment;
    - **(2)** Require testing or process verification pertaining to the new product;
    - **(3)** Approve the product registration;
    - **(4)** Deny the product registration; or
    - **(5)** Advise the licensee in writing that it failed to meet all mandates as established by the division.
- **(E)** Upon receipt of written approval, the licensee may proceed with cultivating, manufacturing, and distributing the proposed product variation.

OAC 1301:18-4-10: State-Required Testing Generally

- **(A)** Each cultivator and processor shall establish, maintain, and comply with written policies and procedures to ensure all cannabis cultivated, processed, manufactured, transferred, and distributed pursuant to chapters 3780 and 3796 of the Revised Code is safe for medical patients and public consumption alike. Each licensee shall ensure all written policies and procedures include the following:
    - **(1)** Prior to any transfer or sale of cannabis, each licensee shall submit all cannabis in its final form to a testing laboratory licensed pursuant to division 1301:18 of the Administrative Code;
    - **(2)** All cannabis is subjected to all applicable test panels and associated analytes as outlined under division 1301:18 of the Administrative Code;
    - **(3)** All cannabis meets or exceeds all testing standards established by the division;
    - **(4)** Prior to any test sample collection, each licensee submits a request in writing in a form and manner prescribed by the division to the testing laboratory conducting the state-required testing;
    - **(5)** Each batch or lot of cannabis maintained at the licensed premises does not exceed the allowable weight, size, or amount outlined under 1301:18 of the Administrative Code;
    - **(6)** The entire batch or lot is presented to the test sample collector during test sample collection;
        - **(a)** If the batch or lot is stored in multiple containers or trays, the test sample must be comprised of increments from each container or tray as equally as possible.
    - **(7)** Each test sample is statistically representative of its respective batch or lot and in accordance with rules 1301:18-4-13, 1301:18-3-14, and 1301:18-4-15 of the Administrative Code, as applicable;
    - **(8)** Each test sample is documented in the state inventory tracking system and in accordance with the following:
        - **(a)** All test samples are created in the state inventory tracking system contemporaneously with the test sample collector's test sample collection;
        - **(b)** The licensee accurately records the test sample amount and as provided by the test sample collector;
        - **(c)** Each associated batch or lot is accurately recorded in the state inventory tracking system; and
        - **(d)** The accompanying certificate of analysis is uploaded in the state inventory tracking system for each batch or lot.

- **(9)** All test samples are collected at the originating licensee and transported solely by the test sample collector to the testing laboratory conducting the testing.

OAC 1301:18-4-11: Transfer Manifests for Test Samples

- **(A)** Prior to a test sample collector transporting a test sample to a testing laboratory, the originating licensee shall prepare a transfer manifest utilizing the state inventory tracking system. Each transfer manifest shall include the following for each transfer:
  - **(1)** The names and facility addresses of the cannabis entities sending and receiving the shipment;
  - **(2)** The time of departure and estimated time of arrival;
  - **(3)** Within each transfer the following information for each individual package:
    - **(a)** A description of each individual test sample that is part of the transport;
    - **(b)** The total number of individual test samples;
    - **(c)** The unique identifying number generated within the state inventory tracking associated with the test sample;
    - **(d)** The units of measure as reported within the state inventory tracking system as follows:
      - **(i)** The net weight of the cannabis contained within the test sample; or
      - **(ii)** The quantity of units contained within the test sample.
    - **(e)** The unique identifying number generated within the state inventory tracking system associated with the transfer manifest; and
    - **(f)** The names of the registered employees transporting the cannabis and their respective badge certificate number as provided by rule 1301:18-3-09 of the Administrative Code;
    - **(g)** The license plate number and vehicle type that will transport the shipment; and
    - **(h)** The specific delivery route, which includes street names and distances.
  - **(4)** Prior to the delivery, each licensee is to provide a copy of the transfer manifest to the test sample collector and the division, via the state inventory tracking system.

OAC 1301:18-4-16: Certificates of Analysis

- **(A)** Each licensee shall ensure all test samples submitted to state-required testing are documented in the state inventory tracking system and the associated unique certificate of analysis for each batch or lot tested is uploaded into the state inventory tracking system. Each certificate of analysis shall include the following information, at a minimum:
  - **(1)** The name and license number of the testing laboratory;
  - **(2)** The name and license number of the originating licensee;
  - **(3)** The registered name of the cannabis strain or cannabis product;
  - **(4)** A unique batch or lot number that matches the cannabis sample;
  - **(5)** The date or dates on which each test was performed;
  - **(6)** A grid or table outlining all required tests performed, and indicating "pass" or "fail" for each, as prescribed by the division;
  - **(7)** The cannabinoid potency of the sample;
  - **(8)** The signature of the laboratory manager or scientific director certifying the analysis; and
  - **(9)** A photograph of the test sample, as received, captured at the time of receipt in the testing laboratory.
- **(B)** The certificate of analysis may contain the following:

- **(1)** Results of quantitative analysis of additional cannabinoids for which the laboratory is able to obtain a commercially available certified reference standard for comparison; and
- **(2)** Results of quantitative analysis of terpenes for which the laboratory is able to obtain a commercially available certified reference standard for comparison.

OAC 1301:18-4-17: Research and Development Testing by Testing Laboratory Licensed Pursuant to 1301:18 of the Administrative Code

- **(A)** Prior to any sale, transfer, or distribution of cannabis to another licensed entity, a cultivator or processor may request a testing laboratory licensed pursuant to 1301:18 of the Administrative Code to conduct scientific or clinical based research or development subject to the following limitations:
  - **(1)** The research is limited to cannabis cultivated or processed as authorized by 1301:18 of the Administrative Code;
  - **(2)** The cultivator or processor does not sell, transfer, or distribute any cannabis tested pursuant to this rule to another licensee, patient, caregiver, or adult-use consumer.
  - **(3)** A cultivator may request research pertaining to:
    - **(a)** Developing new strains of cannabis; or
    - **(b)** Cultivation techniques.
  - **(4)** A processor may request validation for new matrixes pertaining to potency, or to allow a testing laboratory to obtain samples for validation of a new matrix;
  - **(5)** All tests performed on the test sample are documented in the state inventory tracking system with the accompanying certificate of analysis; and
  - **(6)** The resulting certificate of analysis is clearly marked with the phrase "For research and development only. Not for sale."
- **(B)** Any and all associated cannabis tested pursuant to this rule must be solely intended for scientific or clinical research or development.
  - **(1)** A licensee shall not utilize this rule to:
    - **(a)** Submit any test sample to a testing laboratory prior to any state-required testing.
    - **(b)** Obtain test results from more than one laboratory for purposes of comparing results.
    - **(c)** In place or a substitution of, any state-required testing as outlined under division 1301:18 of the Administrative Code.
    - **(d)** Attempt to circumvent any standards or mandates established by the division pertaining to state-required testing, including any procedures, requirements, or directives.

OAC 1301:18-4-18: Research by Testing Laboratory Licensed by Chapter 4729:5-16 of the Administrative Code

- **(A)** Prior to any sale, transfer, or distribution of cannabis pursuant to this rule, a cultivator or processor may request in a manner prescribed by the division to sell cannabis to a laboratory licensed under chapter 4729:5-16 of the Administrative Code, to possess dangerous drugs and controlled substances solely for scientific, clinical, research, or development purposes.
- **(B)** Upon receipt of a request the division may:
  - **(1)** Approve the request;
  - **(2)** Approve the request, subject to certain mandates or limitations;
  - **(3)** Advise the licensee in writing that further information is needed; or
  - **(4)** Deny the request.

- **(C)** Upon receipt of written approval by the division, a licensee may proceed and sell cannabis pursuant to this rule.
- **(D)** A licensee seeking to sell cannabis pursuant to this rule is to apply to the division for each sale of cannabis.
- **(E)** Any and all associated cannabis tested pursuant to this rule must be solely intended for scientific or clinical research or development.
    - **(1)** A licensee shall not utilize this rule to:
        - **(a)** Submit any test sample to a testing laboratory prior to any state-required testing.
        - **(b)** In place or a substitution of, any state-required testing as outlined under division 1301:18 of the Administrative Code.
        - **(c)** Attempt to circumvent any standards or mandates established by the division pertaining to state-required testing, including any procedures, requirements, directives.
- **(F)** Unless and until a licensee receives written approval from the division, a licensee shall not transfer, sell, or distribute cannabis pursuant to this rule.
- **(G)** Pursuant to rule 1301:18-3-14 of the Administrative Code, any cannabis transferred, sold, or distributed pursuant to this rule must be recorded in the state inventory tracking system.

OAC 1301:18-4-22 Advertising

- 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, or pop culture icon whose target audience is children or youth;
    - **(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;
    - **(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;
    - **(11)** Violates state of Ohio or federal trademark or copyright law; or
    - **(12)** 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.

- **(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:
    - **(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;
    - **(5)** Left upon any private property without the consent of the property owner;
    - **(6)** On or in a public transit vehicle or public transit shelter;
    - **(7)** On or in a stadium or arena;
    - **(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 prominently and conspicuously displays the division of cannabis control seal and 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 of real estate upon 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:
    - **(1)** The confidentiality of all patients, caregivers, and adult-use consumers;
    - **(2)** No media compromises the safety and security of the licensed premises; and
    - **(3)** Unless authorized by the division, the media will not depict any secure, limited access area.
- **(G)** No licensee shall license, encourage, or otherwise authorize any affiliated or third party to use or advertise in a manner prohibited by 1301:18 of the Administrative Code.
- **(H)** Each licensee is to ensure all advertising contains the following as prescribed by the division:
    - **(1)** The universal THC symbol, outlined in a contrasting color than the surface or background upon which it is placed as to ensure it is clearly visible; and
    - **(2)** The division of cannabis control seal,

- **(3)** If an advertisement depicts any cannabis packaging or labeling, it must depict the THC and division seal accurately, and in the precise location displayed on the respective packaging and labeling presented in the advertisement.

- **(I)** 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;
  - **(3)** Prohibit the use of the advertisement; or
  - **(4)** Investigate and proceed with any action as permitted by rule 1301:18-9-05 of the Administrative Code.

Cultivator Rules

OAC 1301:18-5-03 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 prior to implementation.
  - **(2)** The division of cannabis control 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 these rules.
  - **(3)** The division may inspect the licensed premises pursuant to any proposed major renovation or modification.
  - **(4)** A cultivator shall not proceed with any major modification unless and until the division provides the cultivator written approval to do so.
- **(C)** Each cultivator shall ensure the licensed premises:
  - **(1)** Conforms with all relevant local ordinances, zoning and planning requirements, and fire codes;
  - **(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.
  - **(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 technology solutions, 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 **fertilizers** and **pesticides, herbicides, and other similar chemicals.**
    - **(1)** Each cultivator shall ensure all fertilizers, pesticides, herbicides, and other similar chemicals:
        - **(a)** Are properly stored and in a manner that protects against contamination; and
        - **(b)** Are disposed of in compliance with all state and federal laws and regulations and complies with all directions outlined on the product label.
    - **(2)** Any person applying the above-referenced chemicals or materials is to adhere to all use requirements outlined on the product label and utilize all applicable personal protective equipment.
    - **(3)** Pursuant to rule 1301:18-3-14 of the Administrative Code, each cultivator shall document all fertilizers and pesticides, herbicides, and other similar 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
        - **(l)** Comments or special conditions related to the application.
        - **(m)** Each cultivator shall maintain these records in a manner so they are readily available upon request of a dispensary or customer.
    - **(4) Fertilizers:** in addition to the other mandates outlined under this paragraph, any specialty fertilizer, as defined in division (Q) of section 905.31 of the Revised Code, is to be registered with the Ohio division of agriculture pursuant to section 905.33 of the Revised Code.
    - **(5) Pesticides, herbicides, growth regulators, and other similar chemicals:**
        - **(a)** The division may maintain a list of pesticides, herbicides, growth regulators, and other similar chemicals that are approved for use during the cultivation process.
        - **(b)** Unless otherwise authorized by the division list pursuant to paragraph (F)(5)(a) of this rule, foliar application of approved pesticides, herbicides, growth regulators, or other similar chemicals shall not occur after the twenty-first day following the date that a plant is moved into the flowering stage of growth.
        - **(c)** Unless otherwise permitted on the division's list pursuant to paragraph (F)(5)(a) of this rule, a cultivator shall not utilize any pesticides, herbicides, growth regulators, or other similar chemicals during the cultivation process without prior approval by the division.
            - **(i)** A cultivator seeking to utilize a new pesticide not on the list maintained by the division must submit the request on a form prescribed by the division. The new pesticide or other similar chemical must be registered with the Ohio division of agriculture and be one of the following:
                - **(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.

OAC 1301:18-5-04 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:
    - **(1)** A Level I cultivator may request to expand up to one hundred thousand square feet;
    - **(2)** A Level II cultivator may request to expand up to fifteen thousand square feet; and
    - **(3)** 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 in a manner prescribed by the division the following:
    - **(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 division 1301:18 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 1301:18-5-02 of the Administrative Code; and
        - **(d)** Evidence the proposed expansion meets all applicable requirements under division 1301:18 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.

OAC 1301:18-5-06 Cultivator Inventory Control and Storage

- **(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 oversee 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)** Immediately document the rejection in the state inventory tracking system and outline the reason for rejecting the non-conforming batch or lot; and
- **(iii)** Return the batch or lot to the originating entity.

- **(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 cannabis strain name filed with the division; and
    - **(iii)** The unique plant identifier.
  - **(d)** A registered responsible party shall oversee 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 inventory 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)** State-required testing as outlined under these rules;
        - **(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 the registered responsible party that oversaw the review.
- **(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)** In accordance with rule 1301:18-3-16 of the Administrative Code, prior to any transfer, sale, or distribution to another licensed entity, the licensee prepares a transfer manifest utilizing the state inventory tracking system for each transfer; and
- **(6)** Any and all information the division deems necessary for maintaining and tracking cannabis is documented and submitted into the state inventory tracking system.
- **(7)** In accordance with rule 1301:18-3-14 of the Administrative Code, all inventories, procedures, and other documents required by this rule are maintained at the licensed premises and available for immediate review and duplication upon the division's request.

Processor Rules

OAC 1301:18-6-03 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**
    - **(1)** Any proposed major renovation or modification of the licensed premises shall be submitted to the division prior to implementation.
    - **(2)** The division of cannabis control 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 these rules.
    - **(3)** The division may inspect the licensed premises pursuant to any proposed major renovation or modification.

- **(4)** A processor shall not proceed with any major modification unless and until the division provides the processor written approval to do so.

- **(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;
  - **(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)** In accordance with rule 1301:18-3-14 of the Administrative Code, documents the following processes utilized at the licensed premises:
    - **(i)** The form and types of cannabis maintained at the facility on a daily basis;
    - **(ii)** Production records, including extraction, refining, manufacturing, records;
    - **(iii)** All ingredients used in the production of each lot of cannabis products, documented in a manner that reconciles the identity and amount of cannabis and all other ingredients used with each lot; and
    - **(iv)** The vendor name, part number and lot identifier of the vaporization units for each lot of vaporization solution that is manufactured.

- **(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.

OAC 1301:18-6-05 Processor Inventory Control and Storage

- **(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 processor'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 oversee 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 processor shall:
            - **(i)** Refuse to accept the non-conforming batch or lot;
            - **(ii)** Immediately document the rejection in the state inventory tracking system and outline the reason for rejecting the non-conforming batch or lot; and
            - **(iii)** Return the batch or lot to the originating entity
    - **(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.
    - **(4)** 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 lot number assigned to the lot of cannabis extract;
            - **(v)** The date of extraction; and
            - **(vi)** The net weight and volume of cannabis 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 lot numbers of any lots 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.
        - **(d)** A registered responsible party shall oversee 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 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;
  - **(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:
  - **(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 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.

- **(5)** In accordance with rule 1301:18-3-16 of the Administrative Code, prior to any transfer, sale, or distribution to another licensed entity, the licensee prepares a transfer manifest utilizing the state inventory tracking system for each transfer; and
- **(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 rule 1301:18-3-14 of the Administrative Code and available for immediate review and duplication upon the division's request.

Testing Laboratory Rules

1301:18-7-04: Testing Laboratory Accreditation

- **(A)** Within two calendar years of the date of issuance of a provisional license, each testing laboratory shall receive accreditation to the ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" standard by a non-profit accreditation body that is signatory to the "International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA)" and which operates in accordance with ISO/IEC 17011 "General Requirements for accreditation Bodies Accrediting Conformity Assessment Bodies."
    - **(1)** Each testing laboratory shall ensure the accrediting agency provides a copy of all inspections and reports pertaining to certification and accreditation directly to the division.
- **(B)** A testing laboratory may petition the division to toll computation of the timeframes provided in paragraph (A) of this rule. Such a petition shall be in writing and provide:
    - **(1)** An explanation of the facts and circumstances that prevent the laboratory's compliance with paragraph (A) of this rule; and
    - **(2)** A written plan, outlined in specific detail with the laboratory's intended actions and projected timeline, to ensure the laboratory complies with this rule.
    - **(3)** Upon receipt of a petition under this paragraph, the division may stay the requirement of paragraph (A) of this rule for the laboratory. A division order staying the requirement of paragraph (A) of this rule will state the date upon which the stay is lifted.

OAC 1301:18-7-05: Proficiency Testing Program

- **(A)** The division of cannabis control may require a testing laboratory to participate in third-party proficiency testing programs.
    - **(1)** In the event the division determines that proficiency testing is necessary, each testing laboratory shall adhere to all mandates outlined under this rule.
- **(B)** At least once every twenty-four months, each testing laboratory is to successfully participate in a proficiency testing program for all test analytes outlined under these rules.
    - **(1)** A third-party proficiency program mandated pursuant to paragraph (A) of this rule, is to be administered by an organization accredited to ISO/IEC 17043 "Conformity Assessment - General Requirements for Proficiency Testing" and provide rigorously controlled and standardized analysis of the following:
        - **(a)** Proficiency testing samples;
        - **(b)** Reports of associated proficiency testing directly to the laboratory and the division; and
        - **(c)** Statistical evaluation of the collective demographics and results of all cannabis testing facilities.
    - **(2)** Successful participation includes an acceptable score for each and every target analyte that the testing laboratory reports to include quantitative results when applicable.
        - **(a)** Failure to provide a result for a required analyte will be considered an unacceptable result.
- **(C)** Pursuant to third-party proficiency testing, each testing laboratory is to:
    - **(1)** Analyze proficiency testing samples utilizing the same procedures, including the number of replicate analyses, standards, testing analysts, and equipment, as used for routine required testing pursuant to these rules at the licensed premises.
    - **(2)** When possible, integrate all proficiency testing samples within the day-to-day operations of the laboratory.
- **(D)** All proficiency testing results are to be reviewed by the scientific director and appropriate employees and:

    - **(1)** Evaluate the testing laboratory's performance and perform corrective action for any unsatisfactory results received; and
    - **(2)** If applicable:
        - **(a)** Investigate any unsatisfactory results, to include a retrospective review of potentially affected cannabis samples.
        - **(b)** Document the investigation findings and any resultant corrective actions.
- **(E)** A testing laboratory who fails to achieve an acceptable score for any state-required test mandated pursuant to division 1301:18 of the Administrative Code shall do the following:
    - **(1)** Notify the division in writing within 24 hours of receipt of the score; and
    - **(2)** Unless authorized by the division, repeat the proficiency testing of any failed tests within 30 calendar days of receipt of the failed score.
    - **(3)** If the testing laboratory fails to perform satisfactorily for the same state-required testing in two consecutive proficiency testing events, or two out of three proficiency testing events, the testing laboratory may be required to cease the performance of testing for those analytes until it demonstrates to the satisfaction of the division that the nonconformances have been corrected in such a manner as to ensure that they will not recur.
- **(F)** Prior to the renewal of its certificate of operation, each testing laboratory is to ensure proficiency testing includes each matrix within the scope of their ISO accreditation.
- **(G)** A testing laboratory shall not:
    - **(1)** Communicate with another licensed laboratory about proficiency testing samples until after the deadline for submission of results to the proficiency testing provider.
    - **(2)** Refer proficiency testing samples to another testing laboratory for analysis; or
    - **(3)** Accept proficiency testing samples from other testing laboratory for analysis.

OAC 1301:18-7-06: Testing Laboratory Minimum Security and Surveillance Requirements

- **(A)** Each testing laboratory shall establish, maintain, and comply with written policies and procedures that ensure adequate security, surveillance, and control of the licensed premises that prevent diversion, theft, or loss and meet the minimum requirements outlined under this rule.
    - **(1)** Pursuant to rule 1301:18-7-02 of the Administrative Code each testing laboratory shall petition the division prior to implementing any major modification to the facility's security procedures, systems, or equipment.
- **(B)** Prior to the commencement of business, each testing laboratory shall meet the following security and surveillance requirements that ensure compliance with all standards established by the division:
    - **(1)** Designate a secure, limited access area for all equipment maintained pursuant to this rule that is accessible only by authorized registered laboratory employees with foundational training in security and surveillance;
    - **(2)** Maintain or construct fencing to prevent unauthorized entry or access to waste disposal containers, disposal areas or compost areas located outside the facility;
    - **(3)** Install a security alarm system with commercial grade equipment that includes the following:
        - **(a)** An access alarm on all entry points and windows;
        - **(b)** Motion detectors that identify unauthorized access into the facility; and
        - **(c)** A silent alarm, which may be utilized during instances of duress that sends a pre-recorded voice message to the facility's designated security personnel and law enforcement, public safety, or emergency services requesting dispatch, which

includes the capability to enter a designated code into an arming station to signal that the alarm user is being forced to turn off the system.

- **(4)** Install a video surveillance system that complies with the following:
  - **(a)** Capable of electronic monitoring of the facility and real-time access by the division;
  - **(b)** Collects twenty-four-hour live video feed with motion-activated recording capabilities for all video cameras that record in at least fifteen frames per second;
  - **(c)** Archives and retains recordings for at least forty-five calendar days;
  - **(d)** Contains a display monitor with a minimum screen size of twelve inches;
  - **(e)** Exports still images in an industry standard format that guarantees authentication and prevents alteration of the recorded images;
  - **(f)** Produces clear color still photographs that are a minimum of 600 x 600 dpi from any camera image, live or recorded;
  - **(g)** Embeds a date and time stamp on all recordings; and
  - **(h)** Includes a failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system.
- **(5)** Install unobstructed, tamper-evident cameras that capture the entirety of the licensed premises and clearly identify all individuals and activities within the surveilled area;
- **(6)** Camera placement at all the following locations:
  - **(a)** All points of ingress and egress;
  - **(b)** All secure, limited access areas;
  - **(c)** Any area where cannabis is tested, stored, or handled;
  - **(d)** Any area that stores cannabis or facility inventory;
  - **(e)** The facility's cannabis destruction and disposal area; and
  - **(f)** All areas where sales proceeds are stored or transferred.
- **(7)** Daily records of all registered employees' access to any secure, limited access area;
- **(8)** Develop emergency policies and procedures for securing all inventory and currency in the event of diversion, theft, or loss; and
- **(9)** Any other requirements the division deems necessary to maintain proper security and surveillance and ensure public safety.

- **(C)** Each testing laboratory shall inspect and test all security and surveillance equipment at least once per thirty calendar days to ensure functionality.
  - **(1)** Pursuant to rule 1301:18-3-14 of the Administrative Code, each laboratory shall record and maintain of all security and surveillance equipment tests.
  - **(2)** Each laboratory shall immediately notify the division of any failure in the facility's security or surveillance system or equipment.
    - **(a)** Any necessary repair or replacement shall occur within twenty-four hours of identification.
  - **(3)** Each laboratory shall keep all security equipment in good-working order and the systems shall be inspected and all devices tested on an annual basis by a third party.
- **(D)** In the event a testing laboratory is made aware of any pending criminal, civil, or administrative investigations or legal proceedings for which a video recording may contain relevant information, the testing laboratory shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the laboratory that it is not necessary to retain the recording.

Dispensary Rules

OAC 1301:18-8-04 Dispensary General Sanitary Requirements

- **(A)** Each dispensary shall establish, maintain, and comply with written policies and procedures for the safe, sanitary, and clean distribution of cannabis at the licensed premises. Each dispensary shall ensure all policies and procedures ensure the following:
    - **(1)** Each dispensary is equipped as to land, buildings, and equipment to properly carry on the business of a cannabis dispensary.
    - **(2)** Any building or equipment used for the storage or sale of cannabis is maintained in a clean, orderly, and sanitary condition, free from infestation by insects, rodents, birds, or pests.
    - **(3)** The facility and equipment used by a dispensary for the storage or sale of cannabis is to be cleaned in a manner and as frequently as necessary to protect against contamination of cannabis.
    - **(4)** Personnel:
        - **(a)** 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, are to 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).
        - **(b)** Personnel are to be instructed to report such health conditions to their supervisors.
    - **(5) Cleanliness.** All employees are to maintain adequate personal cleanliness while engaged in employment activities.
        - **(a)** Each employee is to 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 at a minimum: after using the toilet facilities, after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking, and after engaging in other activities that contaminate the hands.
    - **(6) Grounds.** The grounds about the licensed premises under the control of the licensee is to be kept in a condition that will protect against the contamination of cannabis. The methods for adequate maintenance of grounds are to 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)** Adequately draining areas that may contribute contamination to cannabis by seepage, foot-borne filth, or providing a breeding place for pests.
        - **(c)** Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination.
        - **(d)** If the licensed premises grounds are bordered by grounds not under the licensee's control and not maintained in the manner described by this paragraph, care is to 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.

- **(7) Facility.** A dispensary facility is to be the suitable in size, construction, and design to facilitate maintenance and sanitary operations for storing and distributing cannabis and to do the following:
    - **(b)** Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the distribution of safe cannabis.
    - **(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; 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.
    - **(d)** Each facility is to provide employees with adequate, readily accessible toilet facilities.
    - **(e)** Toilet facilities are to be kept clean and cannot be a potential source of contamination of cannabis.
    - **(f)** Each facility is to contain a sink fully stocked 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.
    - **(g)** In accordance with rule 1301:18-3-12 of the Administrative Code, waste is to 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.

OAC 1301:18-8-06 Dispensary Inventory Control and Storage

- **(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.
    - **(4)** Documentation of each sale of cannabis in the state inventory tracking system.

- **(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 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 weekly 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.
- **(6)** Prior to any transfer of cannabis, a responsible party must inspect and acknowledge that the delivery meets relevant packaging and labeling requirements outlined under rule 1301:18-4-20 of the Administrative Code.
    - **(a)** If the dispensary intends to transfer cannabis that is mislabeled, defective, damaged, or adulterated, the dispensary must provide written notification in a form and manner prescribed by the division prior to initiating the transfer.
- **(7)** In accordance with rule 1301:18-3-16 of the Administrative Code, prior to any transfer, sale, or distribution to another licensed entity, the licensee prepares a transfer manifest utilizing the state inventory tracking system for each transfer; and
- **(8)** Any and all information the division determines necessary for maintaining and tracking cannabis is documented and submitted into the state inventory tracking system.
- **(9)** All inventories, procedures, and other documents required by this rule are maintained on the premises and pursuant to rule 1301:18-3-14 of the Administrative Code and available for immediate review and duplication upon the division's request.

OAC 1301:18-8-08 Dispensing Adult-Use Cannabis

- **(A)** Each dispensary shall ensure the following when dispensing 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)** If applicable, the information contained on the individual's identification matches the information provided in the order.
- **(2)** Each dispensary shall not dispense to an adult-use consumer more than the following amounts of cannabis per day:
  - **(a)** 2.5 ounces of plant material; and
  - **(b)** Cannabis products with a total THC content of no more than 15,000mg.
  - **(c)** For purposes of section 3780.36 of the Revised Code and this paragraph the following applies:
    - **(i)** When calculating 2.5 ounces of plant material, the following forms apply:
      - **(A)** Cannabis plant material; and
      - **(B)** Raw-single serving units.
    - **(ii)** Except as provided by this paragraph, all other products apply towards the adult-use consumer's cannabis product limitation of 15,000mg of total THC content.
- **(3)** Each package of cannabis sold is in the original, child resistant and tamper evident packaging intended for direct customer sale as delivered by the originating entity;
- **(4)** Each package of cannabis sold is affixed with the following information:
  - **(a)** The dispensary's business name or registered tradename; and
  - **(b)** The dispensary's license number.
- **(5)** Any and all cannabis sold by the dispensary is documented in the state inventory tracking system;
- **(6)** All sales adhere to all applicable taxes; and
- **(7)** Upon completion of each sale, each adult-use consumer 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)** A separate line evidencing the following:
    - **(i)** The associated sales tax; and
    - **(ii)** The associated excise tax.
  - **(h)** The dispensary's return policy; and
  - **(i)** Any other information deemed necessary by the division.

OAC 1301:18-8-09 Dispensing Medical Cannabis

- **(A)** Each dispensary shall ensure the following when dispensing 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)** If applicable, 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 patient's recommending physician.
    - **(3)** Unless otherwise limited by a patient's recommending physician pursuant to paragraph (A)(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 medical cannabis plant material; and
            - **(ii)** Cannabis products with a total THC content of 60,000 milligrams
        - **(b)** To each registered caregiver:
            - **(i)** 2.5 ounces of plant material; and
            - **(ii)** Cannabis products with a total THC content of 15,000 milligrams
        - **(c)** For purposes of sections 3780.36 and 3796.03 of the Revised Code and this paragraph, the following applies:
            - **(i)** When determining plant material, the following forms apply:
                - **(A)** Cannabis plant material; and
                - **(B)** Raw-single serving units.
            - **(ii)** Except as provided in this paragraph, all other cannabis products apply towards the medical patient or registered caregiver's cannabis products limitation for total THC content.
    - **(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 cannabis products with a total THC content of 15,000mg, a dispensary shall record the following information by close of business of the date of the transaction:
            - **(i)** All recommendations are serially numbered;
                - **(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 rule 1301:18-3-14 of the Administrative Code, 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;
        - **(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;
        - **(J)** Payment code for either cash or third-party provider; and
        - **(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 cannabis products with a total THC content of 15,000 milligrams, each dispensary shall record all information outlined pursuant to this paragraph, contemporaneously with the transaction.
- **(5)** Any and all cannabis sold by the dispensary is documented in the state inventory tracking system.
- **(6)** Each package of cannabis sold is in the original, child resistant and tamper evident packaging intended for direct customer sale as delivered by the originating entity;
- **(7)** Each package of medical cannabis is affixed with the following information:
    - **(a)** The dispensary's business name or registered tradename;
    - **(b)** The dispensary's license number;
    - **(c)** The patient's legal name;
    - **(d)** The patient's designated registry number; and
    - **(e)** If applicable, the name of the patient's designated caregiver.
- **(8)** 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;
    - **(h)** The dispensary's return policy; and
    - **(i)** Any other information deemed necessary by the division.

OAC 1301:18-8-10 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 rule 1301:18-3-14 of the Administrative Code, 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; and
        - **(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;
        - **(b)** All applicable patients, caregivers, and recommending physicians; and
        - **(c)** If known, all applicable adult-use consumers.
        - **(d)** 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."

OAC 1301:18-8-11 Dispensary Discounts

- **(A)** A dispensary may offer discounts in accordance with the following mandates:
    - **(1)** The dispensary establishes, maintains, and complies with written policies and procedures for discounts that ensure:
        - **(a)** Any discount is offered to all patients registered as indigent or veteran; and
        - **(b)** Any discount offered to an adult-use consumer is also offered to all registered patients and caregivers.
        - **(c)** All patients registered under 1301:18 of the Administrative Code who are also a registered employee of a licensed entity under 1301:18 of the Administrative Code and:
            - **(i)** The employee presents their employee identification card in addition to the identification required under rule 1301:18-10-01; and
            - **(ii)** The discount does not exceed the discount offered in accordance with paragraph (A)(1)(a) of this rule.
- **(B)** Dispensary employees shall not receive rebates or discounts on cannabis offered by a cultivator, processor, or third-party entity.

OAC 1301:18-8-12: Dispensary Returns

- **(A)** Each dispensary shall establish, maintain, and comply with written policies and procedures to accept returned cannabis as mandated by this rule.
- **(B)** Each dispensary must accept the following cannabis returned by a customer:
    - **(1)** Defective product, that shall be destroyed and disposed of by the dispensary in accordance with rule 1301:18-3-12 of the Administrative Code;
    - **(2)** Product that does not match the item stated on the purchase receipt; or
    - **(3)** 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.

- **(C)** 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.
- **(D)** 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.

Enforcement

OAC 1301:18-9-04 Product Alerts and Recalls

- **(A)** Each licensee shall establish, maintain, and comply with written policies and procedures to conduct product alerts and recalls of cannabis and ensure the following:
    - **(1)** A designated recall coordinator is trained and prepared to manage complaint and product investigations. The designated recall coordinator is responsible for:
        - **(a)** Communicating timely and accurate information to the division of cannabis control.
        - **(b)** Maintaining up-to-date communication and contact lists for the licensee's recall team members.
    - **(2)** Each of the following elements are included:
        - **(a)** Identification of the product name, unique product identification, description, batch or lot number;
        - **(b)** Identification of any reports or complaints made to the licensee about the product;
        - **(c)** Inventory and sales review of the affected products including products in the licensee's inventory, products transferred, dispensaries transferred to, and products sold;
        - **(d)** Adequate product quarantine steps.
        - **(e)** Notification templates for the groups described in paragraph (A)(4) of this rule.
    - **(3)** Appropriately address product alerts and recalls, whether initiated by the licensee or by the division.
    - **(4)** All affected product is immediately quarantined from other viable inventory intended for distribution and maintained in a secure location.
    - **(5)** The licensee notifies the following individuals about the alert or recall:
        - **(a)** All associated licensees that cultivated, processed, or dispensed the affected cannabis;
        - **(b)** All patients who have, or likely have, obtained the affected product;
        - **(c)** All customers who have, or may have, obtained the affected product are notified via a conspicuous posting at the dispensary of the alert or recall notice by each dispensary where the product was sold.
        - **(c)** The communication must include information on the process for return of the recalled product; and
        - **(d)** If the alert or recall is initiated by a licensee, notification to the division immediately after initial determination that an alert or recall is necessary and proper.
    - **(6)** Pursuant to paragraph (A)(5), 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.
    - **(7)** In the event of a product alert 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.

OAC 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 these rules is found to be invalid, the remaining portion of these 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;

- **(6)** Investigate activities which are, or are suspected to be, prohibited;
- **(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.
- **(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;
- **(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;

    - **(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; and
    - **(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.
    - **(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:
    - **(1)** Adhere to the requirements outlined pursuant to rule 1301:18-3-15 of the Administrative Code; and
    - **(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.

Patient and Caregiver Rules

OAC 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 purchase, possess, and maintain medical 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 the following amount of cannabis 2.5 ounces of medical cannabis plant material and cannabis products with a total THC content of 15,000mg at any time except as follows:
    - **(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)** Cannabis products with a total THC content of 60,000mg
    - **(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 and cannabis products with a total THC content of 15,000mg at any time.
- **(E)** All medical cannabis shall be maintained as follows:
    - **(1)** In a secure location to prevent theft, loss, access by unauthorized individuals; and
    - **(2)** In the original package intended for direct customer sale with an unaltered dispensary label in accordance with rule 1301:18-8-09 of the Administrative Code until administered to or by a patient.
- **(F)** Patients and caregivers are precluded from engaging in the following activities:
    - **(1)** Operating a vehicle, streetcar, trackless trolley, watercraft, or aircraft under the influence of medical cannabis
    - **(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.
    - **(3)** Using or maintaining medical cannabis in a manner that puts others at risk.
    - **(4)** Transferring, selling, or distributing medical cannabis to any other person, with or without renumeration.