



Common Sense Initiative

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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 6B – Packaging and Labeling Requirements for Cannabis Intended for Direct Customer Sale

Rule Number(s): OAC 1301:18-4-04 (NEW), OAC 1301:18-4-06 (NEW), OAC 1301:18-4-19 (NEW), OAC 1301:18-4-20 (NEW), OAC 1301:18-4-21 (NEW), OAC 1301:18-4-23 (NEW).

Date of Submission for CSI Review: 9/26/2025

Public Comment Period End Date: 10/13/2025

Rule Type/Number of Rules:

New/ 6 rules

No Change/ rules (FYR?)

Amended/ rules (FYR?)

Rescinded/ rules (FYR?)

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

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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 1301:18-4-04: Requirements for Universal THC Symbol (NEW)

- Each cannabis licensee must ensure that all of the following contain or outline the universal THC symbol to ensure all consumers, law enforcement agencies, and anyone looking at the item are aware the contents of the package contain licensed, regulated tetrahydrocannabinol (“THC”):
 - Each portion, dose, and serving size of cannabis products sold to consumers;
 - Any portable, hand-held device used to administer cannabis that would cause a reasonable person to believe the device does not contain cannabis;
 - Each package of bulk cannabis material intended for transfer to another licensed entity;
 - Each package of cannabis intended for direct customer sale; and
 - Certain advertisements.

OAC 1301:18-4-06: Limitations on Packages of Cannabis Intended for Direct Customer Sale (NEW)

- The rule establishes restrictions on the quantity or amount of cannabis that may be contained within packages intended for direct customer sale and sold at licensed dispensaries.

OAC 1301:18-4-19: Pre-Approval Requirements for Packaging and Labeling Intended for Direct Customer Sale (NEW)

- The rule requires that cannabis licensees submit certain information for review and approval by the Division related to packaging and labeling for cannabis intended for direct customer sale to ensure certain public health and safety standards (e.g., packages of cannabis are child resistant and tamper evident) are met prior to production and sale to customers.

OAC 1301:18-4-20: Packaging and Labeling for Cannabis Intended for Direct Customer Sale (NEW)

- The rule requires that cannabis licensees disclose certain product information to ensure consumer awareness on all cannabis packaging and labeling intended for direct customer sale.

OAC 1301:18-4-21: Additional Limitations on Packaging and Labeling Intended for Direct Customer Sale (NEW)

- This rule prohibits a licensee from using a package that is attractive to children, false or misleading, obscene, a health-related statement, or encourages over consumption or intoxication, among other prohibitions. The rule also specifically prohibits cannabis products that reference or resemble cartoon characters, fictional characters, or pop culture icons whose target audience is children or youth.

OAC 1301:18-4-23: Single Serving Units (NEW)

- This rule requires that cannabis processors adhere to certain state-required testing, packaging, and labeling requirements for raw and infused single serving units intended for direct customer sale.

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, 3780.03, 3780.20

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)?

The Division wishes to implement the present consumer protection rules to dissuade underage consumption, prevent accidental ingestion, and ensure proper patient and non-medical consumer awareness of the contents and other relevant information of cannabis products. Furthermore, the present rules establish certain standards for cannabis to allow consumers and law enforcement agencies to easily differentiate between regulated cannabis and unregulated products.

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, consumer safety, public awareness of regulated, licensed cannabis versus unregulated 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 to cannabis license holders soliciting feedback from December 6, 2024 to December 16, 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?

In response to early stakeholder feedback, the Division made the following amendments to the proposed rules:

- OAC 1301:18-4-04 Requirements for Universal THC symbol: in response to stakeholder feedback, the Division amended its proposed rules to clarify which advertisements and which devices need to display the universal THC symbol.
- OAC 1301:18-4-06 Limitations on Packages of Cannabis Intended for Direct Customer Sale: based upon stakeholder feedback, the Division amended the proposed per package limitations to ensure that packages of infused single serving units intended for direct customer sale and the accompanying limitations on THC do not lead to overconsumption and accurately reflect the naturally occurring THC content. Furthermore, the Division amended the proposed rules to clarify the differing requirements for total THC content, versus overall net weight package limitations, for cannabis intended for direct customer sale.
- OAC 1301:18-4-19 Pre-Approval Requirements: in response to stakeholder feedback, the Division has removed the requirement for a “photograph of the entirety of the package.” The intention at this phase of the product registration process is gathering sufficient information about the package, which may include images of the plain package and renderings of package.
- OAC 1301:18-4-20 Packaging and Labeling requirements for Cannabis Intended for Direct Customer Sale: in response to stakeholder feedback, the Division amended the proposed rule to ensure the associated cannabis packaging and labeling provides accurate product information for consumer awareness without creating unduly burdensome and costly disclosures that would unnecessarily adversely affect licensees. The Division has modified the previously proposed requirement to include a disclaimer on labels if the licensee has used a “technology solution” on plant material and instead will permit licensees that do not use such technology to display a seal or verbiage prescribed by the Division. Finally, the Division clarified that licensees may list more than three terpenes on product labels, but must include at least the top three if terpenes are present.

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 strives to establish 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. For the purposes of packaging and labeling, prescriptive standards are necessary to ensure packages are child-resistant and that the information provided to consumers is accurate and standardized, similar to federal food or alcohol labeling requirements. 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 rules require that licensees submit an application; however, this is not a new requirement, as under current rules licensees are already required to submit all aspects of packaging and labeling for review and approval prior to use. There is no application fee for packaging and labeling; however, the cost associated with all proposed packaging and labeling rules contained herein will be staff time and effort to submit the application, and the amount dependent upon each individual licensee and the associated volume and quantity requested and produced.

Placing the universal THC symbol on each portion of products, such as edibles, is a continuation of current rule requirements and is typically not overly costly or burdensome. Placing the symbol is usually achieved by using molds that are pre-made with the symbol inside. Similarly, many licensees have already been in the practice of placing the THC symbol on transfers, product packages, and advertisements. Placing the THC symbol on devices, such as vapes, may add additional expense due to customization of the devices ordered. However, this requirement is limited to devices in which a reasonable person would not believe the device contains cannabis. This cost will vary depending on the device, the supplier, the quantity ordered, and the method used to place the symbol on the device.

Finally, while these rules do not directly impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action for failure to comply with their terms, the Division does have authority to enforce all rules – that enforcement may include imposing penalties or other sanctions for failure to comply. The Division’s enforcement authority is in a separate rule that is not part of this rule package.

- 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.

- 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. All of the rules associated with these impacts seek to balance fair regulations for business while protecting public health and safety. Specifically, these rules are aimed at protecting children by ensuring that packaging is child-resistant, clearly labeled as containing cannabis, and neither packaging nor products are attractive to children. Additionally, requiring transparency on the label in regard to ingredients of the products and manufacturing processes provides a customer awareness and education, which in turn helps to ensure products are consumed safely and responsibly.

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 priority are intended to create 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.

DCC Rule Package 6B

18-4-04 Requirements for Universal THC Symbol

18-4-06 Limitations on Packages of Cannabis Intended for Direct Customer Sale

18-4-19: Pre-Approval Requirements for Packaging and Labeling Intended for Direct Customer Sale

18-4-20 Packaging and Labeling for Cannabis Intended for Direct Customer Sale

18-4-21 Additional Limitations on Packaging and Labeling Intended for Direct Customer Sale

18-4-23 Single Serving Units

OAC 1301:18-4-04 Requirements for Universal THC Symbol

- **(A)** Each licensee shall place the universal THC symbol in a form and manner prescribed by the division of cannabis control and as outlined by division 1301:18 of the Administrative Code.
 - **(1)** The THC symbol must be a contrasting color to the surface or background upon which it is printed, or permanently affixed on the package in a manner that cannot be removed, and be at least ¼ inch by ¼ inch in size.
- **(B)** The universal THC symbol shall be clearly visible and conspicuously placed on all of the following:
 - **(1)** In accordance with rule 1301:18-6-06 of the Administrative Code, each portion, serving size, or unit of a cannabis product;
 - **(2)** Any portable, hand-held **cannabis device** used to administer cannabis that would cause a reasonable person to believe the device does not contain cannabis;
 - **(3)** In accordance with rule 1301:18-3-16 of the Administrative Code, each **package** intended for bulk cannabis transfer to another licensed entity;
 - **(4)** In accordance with rule 1301:18-4-20 of the Administrative Code, each **package intended for direct customer sale**; and
 - **(5)** In accordance with rule 1301:18-4-22 of the Administrative Code, advertisements.

OAC 1301:18-4-06 Limitations on Packages of Cannabis Intended for Direct Customer Sale

- **(A)** Prior to any transfer or sale, each licensee shall place all cannabis directly into a single **cannabis container**. A cannabis container by itself may constitute the **package intended for direct customer sale**.
 - **(1)** A cannabis container that is placed into secondary packaging, the secondary packaging would then constitute the **packaging intended for direct customer sale**.
 - **(2)** Cannabis sold to customers within a **device** must be placed into a cannabis container.
- **(B)** Each **package of cannabis intended for direct customer sale** shall adhere to the following requirements:
 - **(1)** Cannabis Plants:
 - **(a)** Cannabis clones and live plants must adhere to the requirements outlined under OAC 1301:18-1-01 and shall only be in a vegetative state. A clone or live plant that proceeds to the flowering stage, shall not be sold.
 - **(b)** Each package shall not exceed six (6) clones
 - **(c)** Each package shall not exceed six (6) live plants
 - **(d)** Each package shall not exceed six (6) seeds.
 - **(2)** Cannabis Plant Material
 - **(a)** Each package shall not exceed one (1) ounce of cannabis plant material.
 - **(3)** Raw single serving units:
 - **(a)** Each raw single-serving unit shall not exceed one (1) gram of cannabis plant material.

- **(b)** Each package of raw single single-serving units shall not exceed five (5) single-serving units
- **(4) Cannabis Vaporizers**
 - **(a)** Each package is limited to two (2) vape devices or two (2) vape cartridges, as applicable.
 - **(b)** The net weight of each vape device shall not exceed two (2) grams.
 - **(c)** The THC content per vape device shall not exceed 900mg.
 - **(d)** The serving size is one (1) inhalation lasting two (2) seconds per serving.
- **(5) Cannabis Inhalers:**
 - **(a)** Each package is limited to one (1) inhaler device.
 - **(b)** The net weight of each inhaler device shall not exceed one (1) gram
 - **(c)** The THC content per inhaler device shall not exceed 800mg
 - **(d)** The serving size is one (1) inhalation lasting 2 seconds per serving.
- **(6) Other Cannabis Extracts intended for vaporization or combustion:**
 - **(a)** Each package is limited to one (1) container of cannabis extract.
 - **(b)** The net weight of each container of cannabis extracts shall not exceed one (1) gram.
 - **(c)** The THC content per container shall not exceed 900 mg
 - **(d)** The serving size is one (1) inhalation lasting 2 seconds per serving.
- **(7) Infused single serving unit:**
 - **(a)** The net weight for each infused single-serving unit shall not exceed one (1) gram.
 - **(b)** The total THC content per infused single-serving unit shall not exceed 500mg.
 - **(c)** The THC content per package of infused single-serving units shall not exceed 1,500mg
- **(8) Other combination Inhalable Products**
 - **(a)** The total THC content per package shall not exceed 900mg
 - **(b)** The serving size is one (1) inhalation lasting 2 seconds per serving.
- **(9) For cannabis edibles, the following:**
 - **(a)** For adult-use cannabis edibles:
 - **(i)** The THC content per portion or serving shall not exceed 10mg and
 - **(ii)** The THC content per package shall not exceed 100mg
 - **(b)** For medical cannabis edibles:
 - **(i)** The THC content per portion or serving shall not exceed 55mg; and
 - **(ii)** Each package shall not exceed 10 servings per package
- **(10) Cannabis Beverages:**
 - **(a)** The total THC content per container shall not exceed 10mg
 - **(b)** Each package is limited to six (6) containers per package
- **(11) Oral pouches and oral strips**
 - **(a)** The total THC content per unit shall not exceed 10mg
 - **(b)** The total THC content per package shall not exceed 100mg
- **(12) Capsules and pills:**
 - **(a)** The total THC content per capsule or pill shall not exceed 50mg
 - **(b)** The total THC content per package shall not exceed 500mg
- **(13) Oral Sprays**
 - **(a)** Each package is limited to one (1) container.
 - **(b)** The net weight of each container shall not exceed one (1) gram
 - **(c)** The total THC content per container shall not exceed one (1) gram

- **(14)** Drops for oral administration:
 - **(a)** The total THC content per serving shall not exceed 10mg
 - **(b)** The total THC content per package shall not exceed one 1 gram
- **(15)** Topical sprays, salves, lotions, or other similar cosmetic products:
 - **(a)** The total THC content per package shall not exceed one (1) gram
- **(16)** Patches for transdermal administration:
 - **(a)** The total THC content per patch shall not exceed 50mg
 - **(b)** The total THC content per package shall not exceed 500mg
- **(17)** Suppositories for rectal administration:
 - **(a)** The total THC per suppository shall not exceed 100mg
 - **(b)** The total THC content per package shall not exceed one (1) gram

OAC 1301:18-4-19 Pre-Approval Requirements for Packaging and Labeling Intended for Direct Customer Sale

- **(A)** Prior to utilizing any **packaging intended for direct customer sale**, each cultivator and processor shall petition the division of cannabis control solely as outlined by this rule.
- **(B)** In accordance with paragraph A of this rule, each licensee shall evidence in a form and manner prescribed by the division each of the following for any package intended for direct customer sale:
 - **(1)** The package is tamper-evident;
 - **(2)** The package is child resistant in accordance with 16 CFR 1700;
 - **(3)** At a minimum, renderings of the entirety of the package;
 - **(4)** In accordance with rule 1301:18-4-04 of the Administrative Code, the universal THC symbol, which shall be affixed in a form and manner that clearly and immediately indicates to a reasonable person that the product contains cannabis;
 - **(5)** The division of cannabis control seal, as prescribed by the division; and
 - **(6)** Any other information deemed necessary by the division.
- **(C)** Upon receipt of an application, the division may:
 - **(1)** Approve the application;
 - **(2)** Approve the application, subject to certain mandates or limitations;
 - **(3)** Advise the licensee in writing that further information is needed; or
 - **(4)** Deny the application.
- **(D)** Upon receipt of written approval by the division, a licensee may sell cannabis only within the associated packaging intended for direct customer sale.

OAC 1301:18-4-20: Packaging and Labeling Requirements for Cannabis Intended for Direct Customer Sale

- **(A)** Each cultivator and processor shall establish, maintain, and comply with written policies and procedures to ensure all cannabis intended for **direct customer sale** complies with the packaging and labeling requirements outlined under rule 1301:18-4-19 of the Administrative Code and this rule.
 - **(1)** Except as specified and required by rule 1301:18-4-19 of the Administrative Code, a licensee may but is not required to request approval prior to utilizing packaging intended for direct customer sale.
 - **(2)** However, licensees are mandated to adhere to all restrictions as further outlined in this rule. In the event the division determines that a licensee fails to comply with these rules, it may proceed with any action as outlined under chapter 1301:18-9 of the Administrative Code.
 - **(3)** The package shall maintain the integrity and stability of the cannabis contained within.

- **(B) Each package of cannabis intended for direct customer sale** shall prominently, conspicuously, clearly, and plainly display in an unobstructed manner when viewing the package the following in legible English:
 - **(1)** The net weight or volume of the contents contained within the package;
 - **(2)** In accordance with rule 1301:18-4-09 of the Administrative Code, the name of the product variation as approved by and registered with the division;
 - **(3)** In accordance with rules 1301:18-4-04 and 1301:18-4-19 of the Administrative Code, the universal THC symbol as approved and registered with the division;
 - **(4)** The division of cannabis control seal, as prescribed by the division;
 - **(5)** For edible products, the phrase “cannabis-infused” or “marijuana-infused.”
- **(C) Labeling Requirements.** In addition to the requirements outlined in paragraph (B) of this rule, each package of cannabis intended for direct customer sale shall be affixed with a label that includes the following information in legible English:
 - **(1) Cannabis Plant Material**
 - **(a)** The name and license number of the cultivator that cultivated and harvested the plant material;
 - **(b)** If different than the entity outlined pursuant to paragraph (C)(1)(a) of this rule, the name and license number of the licensee that packaged the plant material;
 - **(c)** The date the plant material was harvested;
 - **(d)** The date the plant material was packaged for direct customer sale;
 - **(e)** In accordance with rule 1301:18-4-09 of the Administrative Code, the unique identifying product registration number, as provided by the division;
 - **(f)** In accordance with rule 1301:18-4-07 of the Administrative Code, the cannabis strain name, as reflected in and consistent with the cannabis strain name submitted by the licensee into the state inventory tracking system;
 - **(g)** The net weight in grams and ounces of the plant material contained within each package;
 - **(h)** In accordance with rule 1301:18-4-05 of the Administrative Code, the approved range of THC content, as prescribed by the division;
 - **(i)** The name and license number of the testing laboratory that conducted all state-required testing;
 - **(j)** The date the associated batch of plant material was submitted to all state-required testing;
 - **(k)** The state inventory tracking number associated with the specific batch of plant material submitted to all state-required testing as outlined under division 1301:18 of the Administrative Code;
 - **(l)** The following as reflected on the associated certificate of analysis:
 - **(i)** The following cannabinoids, at a minimum:
 - **(A)** Cannabidiol (CBD);
 - **(B)** Cannabidiolic acid (CBDA);
 - **(C)** THCv; and
 - **(D)** Any other cannabinoid deemed necessary by the division.
 - **(ii)** At a minimum, the top three terpenes by percentage
 - **(iii)** The label shall not include:
 - **(A)** Results for THC content other than the approved range prescribed by the division;
 - **(B)** Any sum total of terpenes or cannabinoids;
 - **(C)** Delta-9 THC results;

- **(D)** Delta-8 THC results; or
 - **(E)** THCA results
- **(m)** A statement with the following language: “WARNING: Keep out of reach of children. **There is limited information on the side effects and medication interactions and there may be health risks associated with the use of this product.** This product may cause impairment and may be habit-forming. There may be **additional health risks** associated with the use of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant. **Consult your physician prior to use of this product.** It is against the law to drive or operate machinery when under the influence of this product. This product may be unlawful outside the state of Ohio.”
- **(n)** Any other requirements the division deems necessary.
- **(2) Cannabis Products Generally**
 - **(a)** The name and license number of the processor that manufactured the cannabis product;
 - **(b)** If different than the entity outlined pursuant to paragraph (C)(2)(a) of this rule, the name and license number of the licensee that packaged the cannabis product;
 - **(d)** The date the cannabis product was manufactured;
 - **(e)** The date the cannabis product was packaged for direct customer sale;
 - **(g)** The expiration date, which shall not exceed one calendar year from the date of manufacture;
 - **(e)** In accordance with rule 1301:18-4-09 of the Administrative Code, the unique identifying product registration number as provided by the division;
 - **(f)** The net weight in grams and ounces of cannabis or volume in fluid ounces and milliliters in each package, as outlined for serving size;
 - **(c)** The state inventory tracking number associated with the specific lot submitted to state-required testing as outlined 1301:18 of the Administrative Code;
 - **(h)** In accordance with rule 1301:18-4-02 of the Administrative Code, the intended method of administration;
 - **(i)** If applicable, the serving size;
 - **(j)** The name and license number of the testing laboratory that conducted all state-required testing;
 - **(k)** The date the associated lot of cannabis products was submitted to all state-required testing;
 - **(m)** The following as reflected on the associated certificate of analysis, in total milligrams per package:
 - **(i)** The following cannabinoids:
 - **(A)** The THC content as defined by rule 1301:18-1-01 of the Administrative Code;
 - **(B)** Delta-8-tetrahydrocannabinol;
 - **(C)** Delta-9-tetrahydrocannabinol;
 - **(D)** Delta-9-tetrahydrocannabinolic acid;
 - **(E)** Cannabidiol (CBD);
 - **(F)** Cannabidiolic acid (CBDA);
 - **(G)** THCV; and
 - **(H)** Any other cannabinoid deemed necessary by the division.
 - **(ii)** At a minimum, the top three terpenes by percentage
 - **(A)** The label shall not include any sum total of terpenes.

- **(n)** A statement with the following language: “WARNING: Keep out of reach of children. **There is limited information on the side effects and medication interactions and there may be health risks associated with the use of this product.** This product may cause impairment and may be habit-forming. There may be **additional health risks** associated with the use of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant. **Consult your physician prior to use of this product.** It is against the law to drive or operate machinery when under the influence of this product. This product may be unlawful outside the state of Ohio.”
- **(3) Specific Mandates for Certain Cannabis Products.** In addition to the requirements outlined under paragraphs (C)(1) and (2) of this rule, each package of cannabis products intended for direct customer sale shall also include the following additional information on the label, as applicable:
 - **(a)** For edibles or cannabis beverages, the following:
 - **(i)** In accordance with 21 CFR 101, a list of all ingredients and sub-ingredients;
 - **(ii)** In accordance with 21 USC 343, a list of all major food allergens; and
 - **(iii)** A statement with the following language: "Caution: When eaten or swallowed, effects and impairment may be delayed."
 - **(b)** For cannabis inhalers, a statement with the following language: “Not approved by the FDA.”
 - **(c)** For any product intended for vaporization or combustion:
 - **(i)** A list of all ingredients, sub-ingredients, and additives included and added to the cannabis extract to create the cannabis product.
 - **(ii)** A statement with the following language: “Smoking is hazardous to your health.”
 - **(d)** If a **solvent-based cannabis concentrate** was used in the manufacture of the product, a disclosure of the type of extraction process and any solvent, gas, or other chemical used in the extraction and manufacturing process or any other compound added to the extract;
 - **(e)** If the product was manufactured using hemp-derived ingredients as outlined under rule 1301:18-6-06 of the Administrative Code:
 - **(i)** The following information related to the originating licensed and regulated source that manufactured the hemp-derived ingredients:
 - **(A)** The business name of the source; and
 - **(B)** The type of extraction process and any solvent, gas, or other chemical used by the originating source in the extraction and manufacturing process or other compound added to the extract.
 - **(ii)** A statement with the following language: “This product contains hemp-derived ingredients.”
 - **(f)** If the plant material was not subjected to any technology solutions, including remediation by irradiation, gas treatment such as ozone, radiofrequency, and UV light, the licensee may indicate as such, as prescribed by the division.
 - **(g)** Any other requirements the division deems necessary.
- **(4) Seeds, clones, and live plants.**
 - **(a)** The name and license number of the cultivator that cultivated the seeds, clones, or live plants;

- **(b)** If different than the entity outlined pursuant to paragraph (C)(4)(a) of this rule, the name and license number of the licensee that packaged the materials;
- **(c)** The date the material was packaged for direct customer sale;
- **(d)** In accordance with rule 1301:18-4-09 of the Administrative Code, the unique identifying product registration number as provided by the division;
- **(e)** In accordance with rule 1301:18-4-07 of the Administrative Code, the cannabis strain name, as reflected in and consistent with the cannabis strain name submitted by the licensee into the state inventory tracking system;
- **(f)** For seeds:
 - **(i)** The date the seeds were harvested by the originating cultivator;
 - **(ii)** The net weight in grams and ounces of the seeds in each package;
 - **(iii)** The total number of seeds contained within the package.
- **(g)** For clones and live plants,
 - **(i)** The date planted by the originating cultivator;
 - **(ii)** The height in inches of the clone or live plant when packaged; and
 - **(iii)** The total number of clones or live plants contained within the package.
- **(h)** "WARNING: Keep out of reach of children. **This product was NOT subjected to state-required consumer health and safety testing as outlined by 1301:18 of the Administrative Code.** This product may be unlawful outside the state of Ohio."

OAC 1301:18-4-21 Additional Limitations on Packaging and Labeling Intended for direct customer sale

- **(A)** No licensee shall manufacture, process, or distribute, or cause to be created, used, or distributed, any **cannabis packaged for direct customer sale** 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 cannabis is 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.

OAC 1301:18-4-23: Requirements for Single Serving Units

- **(A)** Each processor shall establish, maintain, and comply with written policies and procedures to ensure all single serving units intended for **direct customer sale** comply with this rule.
- **(B) State-Required Testing**
 - **(1)** Prior to creating a lot of final form raw single serving units intended for direct customer sale, each processor shall ensure each batch of cannabis plant material adheres to the limitations outlined under rule 1301:18-1-01 of the Administrative Code and meets all standards for state-required testing as provided by rule 1301:18-4-13(B) and (C) of the Administrative Code.
 - **(a)** After the cannabis plant material meets all standards for state required testing outlined under rule 1301:18-4-13(B) and (C), the processor **shall** produce the final form single-serving units, including any paper and any other consumable parts of the single serving unit.
 - **(b)** A processor **may** use a **single batch** of cannabis plant material to create a lot of final form single serving units **or may combine** batches of cannabis plant material to create the lot of final form raw single serving units.
 - **(c)** Each lot of final form single serving units shall meet all requirements outlined under rule 1301:18-1-01 of the Administrative Code and cannot exceed 10,000 production units, created using the same operating procedures and same batch or batches of starting plant material.
 - **(d)** The minimum allowable test sample size for each lot is 0.5% of the net weight of the lot, or fifty-seven (57) grams, whichever is smaller.
 - **(i)** Each sample increment equals one (1) gram.
 - **(e)** Each test sample shall be tested, at a minimum, for the following:
 - **(i)** Microbial contaminants, including:
 - **(A)** Total yeast and mold;
 - **(B)** Total Enterobacteriaceae;
 - **(C)** Salmonella;
 - **(D)** Shiga toxin-producing E. Coli (“STEC”); and
 - **(E)** Any other contaminant the division deems necessary;
 - **(ii)** Mycotoxins;
 - **(iii)** Moisture content;
 - **(iv)** Water activity;
 - **(v)** Foreign matter contamination;
 - **(vi)** Heavy metals;
 - **(vii)** Pesticide, herbicides, and growth regulators;
 - **(viii)** Cannabinoid potency, including, at a minimum:
 - **(A)** Delta-9-tetrahydrocannabinolic acid (THCA);
 - **(B)** Delta-9-tetrahydrocannabinol;
 - **(C)** Delta-8-tetrahydrocannabinol;
 - **(D)** Cannabidiolic acid (CBDA);
 - **(E)** Cannabidiol (CBD);
 - **(F)** Tetrahydrocannabivarin (THCV);
 - **(G)** Cannabinoid (CBN);
 - **(H)** Cannabigerolic acid (CBGA);
 - **(I)** Cannabigerol (CBG);
 - **(J)** Cannabichromenic acid (CBCA);
 - **(K)** Cannabichromene (CBC);

- **(L)** Cannabidivarinic acid (CBDVA);
 - **(M)** Cannabidivarin (CBDV); and
 - **(N)** Any other cannabinoid determined by the division.
- **(ix)** Terpenes, including, at a minimum:
 - **(A)** Alpha-bisabolol;
 - **(B)** Alpha-humulene;
 - **(C)** Alpha-pinene;
 - **(D)** Terpinolene;
 - **(E)** Beta-caryophyllene;
 - **(F)** Beta-myrcene;
 - **(G)** Beta-pinene;
 - **(H)** Caryophyllene oxide;
 - **(I)** Limonene; and
 - **(J)** Linalool
- **(x)** Residual solvents if a **solvent-based extract** is used as an ingredient in the **infused single serving unit**, including solvents used during winterization.
- **(C) Packaging Requirements**
 - **(1)** Each package of single serving units shall prominently, conspicuously, clearly, and plainly display the following in legible English, in an unobstructed manner when viewing the package:
 - **(a)** The net weight in grams and ounces of the contents contained within the package;
 - **(b)** In accordance with rule 1301:18-4-09 of the Administrative Code, the name of the product variation as approved by and registered with the division;
 - **(c)** In accordance with rules 1301:18-4-04 and 1301:18-4-19 of the Administrative Code, the universal THC symbol approved and registered with the division; and
 - **(d)** The division of cannabis control seal, as prescribed by the division.
- **(D) Labeling Requirements**
 - **(1)** In addition to the requirements outlined in paragraph (B) of this rule, each package of single serving units intended for direct customer sale shall be affixed with a label that includes the following information in legible English:
 - **(a)** The name and license number of the processor that manufactured the final product;
 - **(b)** If different than the entity outlined pursuant to paragraph (D)(1)(a) of this rule, the name and license number of the licensee that packaged the cannabis product;
 - **(c)** The date the single serving units were manufactured;
 - **(d)** The date the single serving units were packaged for direct customer sale;
 - **(e)** In accordance with rule 1301:18-4-09 of the Administrative Code, the unique identifying product registration number as provided by the division;
 - **(f)** The date the associated lot was submitted to all state-required testing;
 - **(g)** The state inventory tracking number associated with the specific lot submitted to state-required testing as outlined 1301:18 of the Administrative Code;
 - **(h)** A list of all ingredients, sub-ingredients, and additives utilized to manufacture the single serving units, including the materials used to create the paper and any other consumable parts of the single serving unit;

- (i) If the plant material was not subjected to any technology solutions, including remediation by irradiation, gas treatment such as ozone, radiofrequency, and UV light, the licensee may indicate as such, as prescribed by the division;
- (j) A statement with the following language:
 - (i) "WARNING: Keep out of reach of children. **There is limited information on the side effects and medication interactions and there may be health risks associated with the use of this product.** This product may cause impairment and may be habit-forming. There may be **additional health risks** associated with the use of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant. **Consult your physician prior to use of this product.** It is against the law to drive or operate machinery when under the influence of this product. This product may be unlawful outside the state of Ohio."; and
 - (ii) "Smoking is hazardous to your health."
- (2) **Raw Single Serving Units.** In addition to the requirements outlined in paragraph (D)(1) of this rule, each processor shall ensure each lot of raw single serving units contains the following information on the label:
 - (a) In accordance with rule 1301:18-4-07 of the Administrative Code, the cannabis strain name, as reflected in and consistent with the cannabis strain name submitted by the licensee into the state inventory tracking system;
 - (b) In accordance with rule 1301:18-4-05 of the Administrative Code, the approved range of THC content, as prescribed by the division;
 - (c) The following as reflected on the associated certificate of analysis:
 - (i) The following cannabinoids, at a minimum:
 - (A) Cannabidiol (CBD);
 - (B) Cannabidiolic acid (CBDA);
 - (C) THCV; and
 - (D) Any other cannabinoid deemed necessary by the division.
 - (ii) At a minimum, the top three terpenes by percentage
 - (iii) The label shall not include:
 - (A) Results for THC content other than the approved range prescribed by the division;
 - (B) Any sum total of terpenes or cannabinoids;
 - (C) Delta-9 THC results;
 - (D) Delta-8 THC results; or
 - (E) THCA results
- (3) **Infused Single Serving Units.** In addition to the requirements outlined in paragraph (D)(1) of this rule, each processor shall ensure each lot of infused single serving units contains the following information on the label:
 - (a) The expiration date, which shall not exceed one calendar year from the date of manufacture;
 - (b) In accordance with rule 1301:18-4-07 of the Administrative Code, the cannabis strain name, as reflected in and consistent with the cannabis strain name submitted by the licensee into the state inventory tracking system;
 - (c) The following as reflected on the associated certificate of analysis, in total milligrams per package:
 - (i) The following cannabinoids:

- **(A)** The THC content as defined by rule 1301:18-1-01 of the Administrative Code;
 - **(B)** Delta-8-tetrahydrocannabinol;
 - **(C)** Delta-9-tetrahydrocannabinol;
 - **(D)** Delta-9-tetrahydrocannabinolic acid;
 - **(E)** Cannabidiol (CBD);
 - **(F)** Cannabidiolic acid (CBDA);
 - **(G)** THCv; and
 - **(H)** Any other cannabinoid deemed necessary by the division.
- **(ii)** At a minimum, the top three terpenes by percentage. The label shall not include any sum total of terpenes.
- **(d)** If a **solvent-based cannabis concentrate** was used in the manufacture of the infused single serving unit:
 - **(i)** A disclosure of the type of extraction process and any solvent, gas, or other chemical used in the extraction and manufacturing process or any other compound added to the extract; and
 - **(ii)** A list of all ingredients, sub-ingredients, and additives included and added to the cannabis extract to create the infused single serving units.
- **(e)** If the product was manufactured using hemp-derived ingredients as outlined under rule 1301:18-6-06 of the Administrative Code:
 - **(i)** The following information related to the originating licensed and regulated source that manufactured the hemp-derived ingredients:
 - **(A)** The business name of the source; and
 - **(B)** The type of extraction process and any solvent, gas, or other chemical used by the originating source in the extraction and manufacturing process or other compound added to the extract.
 - **(ii)** A statement with the following language: “This product contains hemp-derived ingredients.”