

Rulemaking Cover Sheet

MAPA-1

TO: **Secretary of State**
ATTN: **Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333.**

1. **Agency:** Office of Cannabis Policy, Department of Administrative and Financial Services
2. **Agency umbrella and unit number:** 18-691
(2 digit umbrella # and 3 digit unit #)
3. **Title of rule:** Compliance Rules for Adult Use Cannabis Establishments
4. **Chapter number assigned to the rule:** Chapter 30
(must be 3 digits or less)
5. **Date(s)/method(s) of notice:** E-mail and social media notice to interested parties list on August 15, 2023; Official SoS Notice of Rulemaking Published in Newspapers August 15, 2023.
6. **Date(s)/place(s) of hearing(s):** Wednesday, September 6, 2023; 10:00 a.m.; Office of Cannabis Policy, 19 Union St., Augusta, Maine, 3rd Floor, Room 325.
7. **Type:** new rule partial amendment(s) of existing rule
 suspension of existing rule repeal of rule emergency rule
 repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.
8. **Name/phone of agency contact person:** Gabi Pierce; Office of Cannabis Policy, 162 State House Station, Augusta, ME 04333; Phone: (207) 530-0507; Fax (207) 287-2671; e-mail: Gabi.Pierce@maine.gov
9. **If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following**
 Provisional adoption **Final adoption**
(prior to Legislative review)
 emergency adoption of major-substantive rule

10. **Certification Statement:** I, Kirsten LC Figueroa hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by

the Dept. of Administrative + Financial Services on 01-08-2024.
(name of agency) (date)

I further certify that all portions of this rule are adopted in compliance with the requirements of the Maine Administrative Procedure Act.

Signature: Kirsten LC Figueroa
(original signature, personally signed by the head of agency)

Printed name & title: Kirsten LC Figueroa, Commissioner

11. Approved as to form and legality by the Attorney General on 1/2/2024.
(date)

Signature Nancy Maciowski.
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Nancy Maciowski.

Notice of Agency Rulemaking Adoption

AGENCY: Office of Cannabis Policy

CHAPTER NUMBER AND TITLE: 18-691 CMR, ch. 30
Compliance Rules for Adult Use Cannabis Establishments

ADOPTED RULE NUMBER: 20xx.xxx
(LEAVE BLANK - ASSIGNED BY SECRETARY OF STATE)

CONCISE SUMMARY

The Department of Administrative and Financial Services, Office of Cannabis Policy, is promulgating the *Compliance Rules for Adult Use Cannabis Establishments*, along with the *Rules for the Administration of the Adult Use Cannabis Program*, 18-691 CMR, ch. 10, the *Rules for the Licensure of Adult Use Cannabis Establishments*, 18-691 CMR, ch. 20, and the *Rules for the Testing of Adult Use Cannabis*, 18-691 CMR, ch. 40 in anticipation of fully repealing the *Adult Use Cannabis Program Rule*, 18-691 CMR, ch. 1, once those four rules have been finally adopted. The Office of Cannabis Policy (OCP) has the authority to “promulgate rules necessary to implement, administer and enforce [the Cannabis Legalization Act].” 28-B MRS § 104.

This rule is comprised of the compliance requirements from the original *Adult Use Cannabis Program Rule*, and incorporates statutory changes since the last time that rule was revised, specifically, PL 2023, ch. 6, Emergency (Signed March 15, 2023), PL 2023, ch. 408 and PL 2023, ch. 396. This rule also incorporates changes to clarify provisions addressed in guidance documents previously issued by the Office, changes identified by the Office through regulatory lookback, as well as changes identified by stakeholders through public comments during the public comment period for this rule.

EFFECTIVE DATE:
(TO BE FILLED IN BY SECRETARY OF STATE)

AGENCY CONTACT PERSON: Gabi Pierce

AGENCY NAME: Office of Cannabis Policy

ADDRESS: 162 State House Station, Augusta, ME 04333

TELEPHONE: 207-530-0507

Notice of Agency Rulemaking Proposal

AGENCY: 18-691 – Office of Cannabis Policy, Department of Administrative and Financial Services

CHAPTER NUMBER AND TITLE: Ch. 30 - Compliance Rules for Adult Use Cannabis Establishments

TYPE OF RULE (*check one*): Routine Technical Major Substantive

PROPOSED RULE NUMBER (*leave blank; to be assigned by Secretary of State*):

BRIEF SUMMARY: This rulemaking updates the compliance requirements necessary to implement statutory changes made to the Cannabis Legalization Act, 28-B MRS, including PL 2023, ch. 6, Emergency (Signed March 15, 2023), and PL 2023, ch. 408, PL 2023, ch. 396, specifically changes to the authorized activity of tier 1, tier 2, and nursery cultivation facilities and products manufacturing facilities allowing for the sales of cannabis and cannabis products to consumers by delivery (except that nursery cultivation facilities may sell only immature cannabis plants, seedlings, cannabis seeds and agricultural or gardening supplies relating to the cultivation of cannabis); permitting the delivery of cannabis and cannabis products by authorized licensees to consumers at hotels or other private businesses, provided that the delivering licensee has obtained written consent from the owner or other authorized agent of the business to conduct such deliveries; permitting the return of cannabis or cannabis products from licensee to the licensee that transferred the cannabis or cannabis products to the returning licensee and provides for the testing of such returned cannabis or cannabis products; permitting the use of vehicle wraps by licensees; increasing the per package limit for edible cannabis products from 100 mg per package to 200 mg per package and increasing the possession limit for cannabis concentrates from 5 grams to 10 grams; creation of new definitions for the terms “permitted premises for a specified event,” “specified event,” and “specified event permit”; amendments to the application requirements for the issuance of a permit for cannabis stores to conduct sales at specified events; amendments to the limitations and conditions for cannabis stores to conduct sales at events – including repealing the prohibition on the sale of “smokable” cannabis or cannabis products at specified event; establishment of criteria for suspension/revocation of permit to conduct sales at an event; established criteria for DAFS’s approval or denial of a permit application for cannabis stores to conduct sales at a specified event to allow denial of such applications for “good cause”; and amendments to the requirements that the Department issue guidance to cannabis stores.

This rulemaking is being conducted in preparation to repeal the Adult Use Cannabis Program Rule, 18-691 CMR, ch. 1, once this rule, and 18-691 CMR, chapters 10, 20 and 40 are finally adopted.

Date, time and location of PUBLIC HEARING (*if any*): September 6, 2023; 10:00 a.m.; Office of Cannabis Policy, 19 Union Street., Augusta, Maine, 3rd Floor, Room 325.

COMMENT DEADLINE: Sunday, September 17, 2023 at 11:59 p.m.

CONTACT PERSON FOR THIS FILING (*include name, mailing address, telephone, fax, TTY, email*): Gabi Pierce; Office of Cannabis Policy, 162 State House Station, Augusta, ME 04333; Phone: (207) 530-0507; Fax: (207) 287-2671; gabi.pierce@maine.gov.

CONTACT PERSON FOR SMALL BUSINESS IMPACT STATEMENT (*if different*): N/A

FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES (*if any*): None

STATUTORY AUTHORITY FOR THIS RULE: Title 28-B, Chapter 1 (Cannabis Legalization Act), including PL 2023, ch. 6, Emergency (Signed March 15, 2023), and PL 2023, ch. 408, PL 2023, ch. 396

BASIS STATEMENT FOR
COMPLIANCE RULES FOR ADULT USE CANNABIS ESTABLISHMENTS
18-691 CMR, CH. 30

The Department of Administrative and Financial Services, Office of Cannabis Policy, is promulgating the *Compliance Rules for Adult Use Cannabis Establishments*, along with the *Rules for the Administration of the Adult Use Cannabis Program*, 18-691 CMR, ch. 10, the *Rules for the Licensure of Adult Use Cannabis Establishments*, 18-691 CMR, ch. 20, and the *Rules for the Testing of Adult Use Cannabis*, 18-691 CMR, ch. 40 in anticipation of fully repealing the *Adult Use Cannabis Program Rule*, 18-691 CMR, ch. 1, once those four rules have been finally adopted.¹ The Office of Cannabis Policy (OCP) has the authority to “promulgate rules necessary to implement, administer and enforce [the Cannabis Legalization Act].” 28-B MRS § 104.

This rule is comprised of the compliance requirements from the original *Adult Use Cannabis Program Rule*, and incorporates statutory changes since the last time that rule was revised, specifically, PL 2023, ch. 6, Emergency (Signed March 15, 2023), PL 2023, ch. 408 and PL 2023, ch. 396. This rule also incorporates changes to clarify provisions addressed in guidance documents previously issued by the Office, changes identified by the Office through regulatory lookback, as well as changes identified by stakeholders through public comments during the public comment period for this rule.

In addition, the Office has attached to this basis statement a complete list of all comments received by the Office during the public comment period and the agency’s response to the same. Also attached for readers’ convenience is a list of those public comments accepted by the Office and integrated into the provisionally adopted rule. Finally, attached to this basis statement is an e-mail chain and attachments from Dr. David Nathan, on behalf of Doctors for Cannabis Regulation, regarding the changes made to the department-required warning statement to be included on the labels of cannabis and cannabis products, that is discussed in the “changes identified through regulatory lookback” section below.

Statutory Changes

An Act to Clarify State Policy Regarding Cannabis Paraphernalia in the Maine Medical Use of Cannabis Act and the Cannabis Legalization Act, PL 2023, ch. 6, Emergency (Signed March 15, 2023) amended the Cannabis Legalization Act (and the Maine Medical Use of Cannabis Act, Title 22, ch. 558-C) to include definitions of “cannabis paraphernalia” and distinguished that “cannabis paraphernalia” from “tobacco products” as defined in 22 MRS § 1551. One of the consequences of that change was an expansion of the kinds of adult use cannabis and cannabis

¹ With the exception of the *Rules for the Testing of Adult Use Cannabis*, 18-691 CMR, ch. 40, all other rules, Chapters 10, 20, and 30, are designated “major substantive” under the *Cannabis Legalization Act*, Title 28-B, ch. 1. 18-691 CMR, ch. 40 is exclusively related to mandatory testing in the Adult Use Cannabis Program, and those rules are designated “routine technical”. The Office intends to finally adopt Chapter 40 in late 2023 and will finally adopt Chapters 10, 20, and 30 following action by the 131st Legislature in 2024. Following final adoption of all four rules, the Office will take the steps required under the *Maine Administrative Procedures Act*, Title 5, ch. 375, necessary to repeal 18-691 CMR, ch. 1, the *Adult Use Cannabis Program Rule*.

products that can be delivered to consumers. Previously, because items like pre-rolled cannabis cigarettes (commonly referred to as “joints”), rolling papers, or cannabis concentrate cartridges (commonly referred to as “vapes” or “vape carts”) could not be delivered to consumers because those cannabis items also fell under the definition of “tobacco products”, and tobacco products may not be delivered to consumers. As a result, the *Compliance Rules for Adult Use Cannabis Establishments* removed restrictions included in the *Adult Use Cannabis Program Rule* regarding the delivery of so-called “tobacco products”, allowing delivery of the same inventory available at cannabis stores operating in the program.

An Act to Clarify the Requirements for Off-Premises Sales by Cannabis Store Licensees, PL 2023, ch. 408, amended the *Cannabis Legalization Act* to update the requirements applicable to the conduct of off-premises sales by cannabis store licensees at “specified events” outside of the licensed premises of cannabis stores. Specifically, that law amends the compliance requirements regarding permits for cannabis stores to conduct sales at specified events by:

1. Amending the limitations and conditions for cannabis stores to conduct sales at events – including repealing the prohibition on the sale of “smokable” cannabis or cannabis products at specified events;
2. Establishing criteria for suspension or revocation of permits to conduct sales at a specified event; and
3. Identifying the criteria for DAFS’ approval or denial of a permit application for cannabis stores to conduct sales at a specified event, including provisions allowing denial of such applications for “good cause”.

In response, OCP included in this rule security and inventory tracking requirements regarding the conduct of sales by cannabis stores at specified events. Also included in this rule are provisions regarding suspension and revocation of specified event permits, as well as a process for reciprocal suspension or revocation of such permits in the event that landowner or municipal authority to conduct these events is revoked.

An Act to Amend the Adult Use Cannabis Laws, PL 2023, ch. 396, amended the *Cannabis Legalization Act* in a number of ways, including expanding the authorized activities for tier 1, tier 2 and nursery cultivation facilities and products manufacturing facilities, changes to the advertising and marketing restrictions of the law, and changes to the potency limits for packages of edible cannabis products and an increase in the amount of cannabis concentrate an adult consumer may possess. Specifically, the law amended the *Cannabis Legalization Act* as follows:

1. Permitting tier 1, tier 2, and nursery cultivation facilities and products manufacturing facilities to conduct sales of cannabis and cannabis products to consumers by delivery (except that nursery cultivation facilities may sell only immature cannabis plants, seedlings, cannabis seeds and agricultural or gardening supplies relating to the cultivation of cannabis);
2. Permitting delivery of cannabis and cannabis products by authorized licensees to adult use consumers at hotels or other private businesses, provided that the delivering licensee has obtained written consent from the owner or other authorized agent of the business to conduct such deliveries;

3. Permitting the return of cannabis or cannabis products from a licensee to the licensee that transferred the cannabis or cannabis products to the returning licensee and providing for the testing of such returned cannabis or cannabis products;
4. Requiring the Department to specify in rule limitations on signs, advertising and marketing necessary to limit the appeal of such materials to individuals under 21 years of age;
5. Permitting the use of “vehicle wraps” by licensees; and
6. Increasing the per package THC limit for edible cannabis products from 100 mg per package to 200 mg per package and increasing the possession limit for cannabis concentrates from five grams to ten grams.

In response, OCP included in this rule provisions:

1. Regarding the newly authorized activities of tier 1, tier 2 and nursery cultivation facilities, as well as products manufacturing facilities, to include compliance requirements for retail sales of cannabis and cannabis products to consumers by delivery, including requirements that cultivation facility and products manufacturing facility licensees conducting such retail sales separate their inventory for delivery from that intended for wholesale transfers to other licensees;
2. Requiring licensees that intend to conduct retail sales to consumers by delivery at businesses, including hotels and motels, obtain and retain written consent from a business owner or their agent on forms provided by the Department;
3. Regarding the inventory tracking, testing and packaging, and as applicable, resale, of cannabis and cannabis products returned by a cultivation facility, products manufacturing facility and cannabis store licensees to the licensee that originally transferred the cannabis or cannabis products to it;
4. Implementing the Office’s new definition of “appealing to individuals under 21 years of age” included in 18-691 CMR, ch. 1, in the advertising and marketing requirements applicable to licensees;
5. Removing a prohibition from the *Adult Use Cannabis Program Rule* regarding the use of so-called “vehicle wraps” for advertising and marketing purposes; and
6. Adjusting the per package potency limit of edible cannabis products from 100 mg of THC per package to 200 mg of THC per package, and adjusting the retail sales limits to reflect the increase in the personal possession limit for cannabis concentrate from five grams per person to ten grams per person.

Changes Based Upon Previously Issued Guidance²

As the Office has implemented the requirements of and amendments to the *Cannabis Legalization Act*, Title 28-B, ch. 1, it has made a practice of periodically issuing guidance to clarify provisions of the rules promulgated pursuant to that law in response to repeated inquiries from program participants, as well as findings of licensee noncompliance by OCP’s compliance team.

² “Guidance Documents”, Office of Cannabis Policy Website, available at: <https://www.maine.gov/dafs/ocp/resources/guidance-documents> (Accessed November 6, 2023).

This rule reflects guidance issued by OCP clarifying the implementation of “group tracking” of “groups” of cannabis plants as required by P.L. 2021, ch. 628, based upon the reconfiguration of the inventory tracking system to accommodate that new plant tracking option. The rule also includes provisions necessary to clarify the packaging requirements for single-serve cannabis drinks to ensure that such edible cannabis products are child resistant and tamper evident.

Changes Identified Through Regulatory Lookback

In addition to the integration of guidance documents indicated above, in order to clarify program requirements and reduce compliance costs for program participants, the Office engaged in a process of regulatory lookback before drafting these rules. Through that process, OCP identified that single-serve cannabis drink packaging issue discussed above. OCP also identified through this process improvements to the warning statements required to be printed on the labels of all cannabis and cannabis products.

Specifically, OCP determined, based upon feedback from Dr. David Nathan, on behalf of Doctors for Cannabis Regulation, that the warning statement included in the *Adult Use Cannabis Program Rule* should be updated to better conform with the standards for cannabis labels identified by Doctors for Cannabis Regulation and other medical professionals: readability, warnings based upon scientific evidence, and brevity. To correct this deficiency, OCP changed the language of the warning statement to conform with the ASTM International consensus standard “ASTM D8441” for the International Intoxicating Cannabinoid Product Symbol. An e-mail and attached memorandum from Dr. Nathan are included as an appendix to this basis statement. As indicated on the attached public comments and responses document, OCP received several comments and questions from the public regarding the implementation of this new warning statement. In response, OCP indicated that it would provide more detailed guidance regarding the implementation of the warning statement at the time these rules are finally adopted, however, it is the intention of the Office to permit licensees to use up any existing packaging with the current warning statement for at least one year after the effective date for this new rule.

Changes Based Upon Public Comments

In response to public comments, which mirrored industry feedback over the past two years, OCP updated this rule to allow cultivation facility licensees to accept transfers of gifts of seeds in addition to the seedlings those licensees were already authorized to accept under the *Adult Use Cannabis Program Rule*.

In response to public comments indicating confusion regarding the definition of “appealing to individuals under 21 years of age” included in 18-691 CMR, ch. 10 (in response to a statutory directive that OCP make rules regarding the same) that impacted provisions of this rule, OCP made changes to that definition in 18-691 CMR, ch. 10 to clarify and narrow the scope of that definition. While those comments were submitted in response to this rule, the changes necessitated were incorporated into 18-691 CMR, ch. 10.

Additionally, OCP accepted comments from Jill Polster, Esq. and Alex McMahan regarding the addition of a “knowing” *mens rea* before the prohibition on allowing adult use consumers to open packaging containing cannabis or cannabis products on the licensed premises of a cannabis store.

In an attempt to simplify packaging requirements and reduce packaging waste, OCP originally proposed in this rule the elimination of so-called “exit packaging”. However, OCP a number of comments from the public that licensees wanted the flexibility of meeting the opacity and tamper evident requirements for packaging either through the retail packaging for each individual retail unit or the exit packaging used by cannabis store licensees. In response, OCP revised the rule to allow the opacity and tamper evident requirements to be met using either retail packaging or exit packaging.

Conclusion

In general, these rules reflect the good governance practice of regulatory lookback and continue the practice of rightsizing compliance requirements for program participants while ensuring that OCP has the ability to protect public health and safety.

Small Business Impact Statement required pursuant to 5 MRS § 8052(5-A):

The following businesses may be impacted by the requirements of this rule: All adult use cannabis licensees. As of November 2023, that includes: 88 cultivation facility licensees, 67 products manufacturing facility licensees, 132 cannabis store licensees, and 4 cannabis testing facility licensees.

The projected reporting and record-keeping costs of this rule are related to compliance with the inventory tracking requirements of this rule and those costs amount to: \$40/month fee to access the state’s inventory tracking system, Metrc; and 45¢ per plant for plant tags (for cultivation facility licensees) and 25¢ per package tag (for cultivation facility and products manufacturing facility licensees).

The probable impact of these costs is negligible, as licensees are already required to comply with these requirements under existing program rules and recordkeeping through the state’s inventory tracking system is a statutory requirement under 28-B MRS § 105.

Seed-to-sale inventory tracking is standard across regulated cannabis markets in the United States, at this time, there are no less costly, reasonable alternatives to the state’s inventory tracking system. The contract for the state’s inventory tracking system vendor was awarded through the state’s competitive procurement process.

Name	Source	Affiliation	Company name	Comments - Ch. 30, Sec. 1 - General Compliance	Reference	Department Response (except accept in part, reject)	Reasoning
Victor Cole	Email	OCP		<p>This conflicts with definition of material changes in prior paragraph. Can this be included in definition of material changes above and omitted from this paragraph? (A material change includes without limitation: changes to operations, including cultivation or security practices; changes to the licensed premises including changes to the floor plan, security equipment, manufacturing equipment, display cases or any other area of the licensed premises where cannabis is cultivated, manufactured, stored or sold; the addition or removal of curbside pickup locations – including those curbside pickup locations outside the licensed premises but immediately adjacent to the primary public ingress and egress of the cannabis store; the commencement or cessation of delivery activities and seasonal or temporary cessation of authorized activities at a licensed cannabis establishment in excess of 30 days;...” (2) No licensee shall make material changes to operations, including cultivation or security practices, until the application for changes to the facility plan have been approved by the Department.”</p>	Chapter 30, Section 1(3) - General Compliance: General Conduct	Accept	
Victor Cole	Email	OCP		<p>(4) The type, number and weight of each sample storage container used to store sample increments collected; Add: The date and time the sample was collected and placed into the container. (5) The total weight of the composite sample and the weight of any additional sample increments collected for homogeneity testing; (5) The seal numbers for every tamper evident seal affixed to a sample container used in the sample collection event; Numbered seals are not typically used- Suggest = (5) The type of tamper evident seal that was affixed to the sample container used in the sample collection event;</p>	Chapter 30, Section 1(11) - General Compliance: Recordkeeping Requirements for Sample Collection, Transport and Receipt	Accept	
James Judge	Online		Theory Wellness	<p>C. Authorized Sources of Cannabis Plants and Seeds The restrictions limiting cultivation licenses to receive only 5 seedlings from an individual in a 90-day period is extremely constraining to achieving a diverse genetic stock. Furthermore, limiting the gifting to only seedlings as opposed to seeds themselves is not preferable due to the possibility of seedlings being contaminated with mold and other pathogens which could adversely affect a cultivation facility. We ask that these limitations be revisited to allow for the gifting of seeds at a number which would allow for phenotype hunting; at least ten seeds per strain, with no limit on the number of strains; if this request cannot be met, we ask that the limit of 5 seedlings per giftee, per quarter be removed entirely.</p>	Chapter 30, Section 1(5) - General Compliance: Requirements Applicable to Cultivation Facilities	Accept	See revisions to § 1(5)(C)
Michael DiPersia	Online		All Purpose Flower LLC	<p>There needs to be an allowance for individuals to gift cultivators actual seeds and not seedlings. The problem with seedlings is contamination. Taking plants in from just any individual could introduce both pests and pathogens to a cultivation facility. Please allow this distinction as the seedling requirement is too risky for businesses.</p>	Chapter 30, Section 1(5) - General Compliance: Requirements Applicable to Cultivation Facilities	Accept	See revisions to § 1(5)(C)
Michael DiPersia	Online		All Purpose Flower LLC	<p>These requirements will create hardship and increased labor cost on licensees. I understand testing is important. I fully support it and support more so the department doing spot testing at retailers and live leaf tests. The record keeping requirement is incredibly burdensome and redundant. We use Metrc. This tracks all our samples including who enters the sample, who delivers it, who receives it and what it was analyzed for. The container seal number is pointless, having a witness is added labor and unnecessary (we are all on camera anyway) the writing down temperature, container used, humidity have no bearing on results. The weight is entered in Metrc so that is redundant. The temperature and humidity is irrelevant because most people will be taking a sample from an airtight source bag and placing it into an airtight container once sampled. This section adds unnecessary work and is redundant. Using Metrc captures enough of the information and this is an overreach and unnecessary.</p>	Chapter 30, Section 1(11) - General Compliance: Recordkeeping Requirements for Sample Collection, Transport and Receipt	Accept in part	Seal numbers stricken from requirements, other issues (container, temp, etc) addressed are necessary for integrity of mandatory testing process and identifying reasons for testing failures
Michael DiPersia	Online		All Purpose Flower LLC	<p>There needs to be an allowance for individuals to gift seeds to licensed cultivators instead of just seedlings. The problem with seedlings is the potential for introducing pests and pathogens into a facility. Seeds would be a more sterile way to propagate new genetics. Please allow this distinction as it will help cultivators maintain their cultural practices while also spurring innovation.</p>	Chapter 30, Section 1(5) - General Compliance: Requirements Applicable to Cultivation Facilities	Accept	See revisions to § 1(5)(C)

Michael DiPesa	Online		All Purpose Flower LLC	These requirements will create hardship and increased labor cost on licensees. I understand testing is important. I fully support it and support OCP doing live leaf testing at cultivation facilities as well as spot testing at retail. The record keeping requirement is incredibly burdensome and redundant, we use Metrc. This tracks all our samples including who enters the sample, who delivers it, who receives it and what it is analyzed for. The container seal number is a pointless piece of record as this will become trash. Everyone is on camera so writing down the temperature, humidity has no actual bearing on results. The weight of the sample is tracked in Metrc so this is redundant. The temperature and humidity have no relevance because licensees pull samples from source bags which are usually stored in airtight containers, sampled from them immediately place into airtight containers. The requirement for a witness as well as signature increases labor cost and takes a second person who we pay to now not do other necessary work at the facility. Again we are on camera and everything is tracked so these added requirements contribute to testing becoming overly costly beyond what the labs charge.	Chapter 30, Section 1(11) - General Compliance: Recordkeeping Requirements for Sample Collection, Transport and Receipt	Accept in part	Seal numbers stricken from requirements, other issues (container, temp, etc) addressed are necessary for integrity of mandatory testing process and identifying reasons for testing failures
Jill Cohen	Online	Cohen Law Maine PLLC		(C) (24) is it possible to add "knowingly" to the beginning of this prohibition? Otherwise a consumer could open a product while sitting in their car in the parking lot outside a retail store and the licensee could be held accountable for that.	Chapter 30, Section 1(8) - General Compliance: Requirements Applicable to Cannabis Stores and Nursery Cultivation Facilities	Accept	
Alex McMahhan	Email		MedCo.	1.1.C.3.d. - This is inconsistent with Chapter 20 1.C. It is missing "or visitor"	Chapter 30, Section 1(3) - General Compliance: Premises	Accept	
Alex McMahhan	Email		MedCo.	1.7.B.2.e - Any additive can be considered appealing to persons under 21 years of age (sugar, chocolate, flavoring, butter, etc).	Chapter 30, Section 1(7) - General Compliance: Requirements Applicable to Products Manufacturing Facilities	Accept in part	See revised definition of "appealing to individuals under 21 years of age"
Alex McMahhan	Email		MedCo.	1.7.E.2.e & 1.7.E.2.f - These seem to be inconsistent with the legislation that passed in the 130th legislative session regarding acceptable variance.	Chapter 30, Section 1(7) - General Compliance: Requirements Applicable to Products Manufacturing Facilities	Accept in part	See 18-691 CMR, ch. 30, §(5)(4)(B) - the variance in question only affects labeling requirements, as low potency edibles will not exceed per-serving potency limits but the allowable variance may impact labeling requirements.
Alex McMahhan	Email		MedCo.	1.6.C.24 - Should be struck completely, but also begs the following question: What happens if a customer opens a package in an operator's parking lot ("area that the licensee controls"? The operator just broke the law.	Chapter 30, Section 1(8) - General Compliance: Requirements Applicable to Cannabis Stores and Nursery Cultivation Facilities	Accept in part	See addition of "knowingly or negligently" to this paragraph

Name	Source	Affiliation	Company name	Comments - Ch. 30, Sec 2, Track, Trans., Trans	Reference	Department Response (except, accept in part, reject)	Reasoning
Lynsi Shecker			Average Holdings	<p>Regulation: 18-691 C.M.R., Chapter 30, Section 2(10) Sales Delivery Manifest: A sales delivery manifest, generated by the tracking system, is required for all deliverer of cannabis or cannabis products by a cannabis store, tier 1, tier 2 or nursery cultivation facility, or products manufacturing facility/ licensee to an adult use consumer. Comment: Clarification should be made that prepackaged, intact items sent for delivery that are refused by the consumer (i.e. never leave the transporter's possession) can be returned to the facility and resold.</p>	Chapter 30, Section 2(2) - Tracking, Transportation, Returns, and Records Retention: Transportation	Accept	
Elisa Ellis	Online	OCP		<p>Please consider expanding transportation to be by more than motor vehicle. Being a state with many islands, transportation by boat may be a necessity as it is for one pending application OCP has that can not currently move forward with this limitation to be able supply his store with product.</p>	Chapter 30, Section 2(2) - Tracking, Transportation, Returns and Records Retention: Transportation	Accept	See new allowance for transport by watercraft in certain circumstances

Name	Source	Affiliation	Company name	Comments - Ch. 30, Sec. 3, Advertising	Reference	Department Response (accept, accept in part, reject)	Reasoning
Jill Cohen	Online	Cohen Law Maine PLC		<p>I will join in feedback I expect you will receive from other attorneys suggesting that OCP adopt the definition of "cartoon", prohibited on tobacco advertising, from the Tobacco Settlement Claims Act for use in defining "appealing to individuals under 21"; "[a] drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria: (1) the use of comically exaggerated features; (2) the attribution of human characteristics to animals, plants or other objects; or the similar use of anthropomorphic technique; or (3) the attribution of unnatural or extra-human abilities, such as improvisationalism to pain or injury, X-ray vision, tunneling at very high speeds or transformation."</p> <p>As written, the advertising prohibitions in the proposed rule still are quite ambiguous and do not provide certainty to licensees as they make decisions related to brand development and advertising.</p>	Chapter 30, Section 3(1) - Advertising Prohibitions	Accept in part	See revised definition of "appealing to individuals under 21 years of age" in 18-691 CMR, ch. 10
Karleena Stoner	Online		Stoner & Co.	<p>To allow our ideal target market to know us, like us and trust us enough to become a customer, advertising, promotion, publicity, PR, sales and marketing is an essential component of a business strategy. An organization cannot tell a brand story without these platforms. Please amend your rules to allow cannabis companies to responsibly participate in business strategies that are essential for competitiveness and success. The language in section C3 of the rules states that we cannot utilize television, radio, print media or internet advertising in cases where there is a high likelihood it will reach persons under the age of 21; this language essentially forbids us from using these platforms at all. We suggest instead of using the words "No licensee or agent of a licensee may utilize television, radio, print media or internet advertising in cases where there is a high likelihood it will reach persons under the age of 21" you use language that says, "No licensee or agent of a licensee may intentionally use television, radio, print media or internet advertising to target persons under the age of 21." Additionally, because this statement leaves much up to interpretation, it may be beneficial to include language that states, "the use of animal mascots, logos or language is prohibited, referencing characters, fonts or terminology from programming, products or literature geared toward children is prohibited."</p>	Chapter 30, Section 3(1) - Advertising Prohibitions	Accept in part	See revised definition of "appealing to individuals under 21 years of age" in 18-691 CMR, ch. 10
Karleena Stoner	Online		Stoner & Co.	<p>We strongly believe that it is our responsibility to serve our community. We serve our community by being season sponsors of community theater, softball teams and golf events, just to name a few. With the current language, those sponsorships would be prohibited as they could inadvertently be seen by various age groups. We suggest changing the language to allow us to continue sponsoring community endeavors without targeting children.</p>	Chapter 30, Section 3(4) - Advertising, Branding and Logos	Accept in part	See revised definition of "appealing to individuals under 21 years of age" in 18-691 CMR, ch. 10
Richelle Grossi	Online		Highrow	<p>Similar to our response in regards to the "appealing to those under 21, we find these restrictions prevent us from doing philanthropy in the communities in which we operate. This applies to all of the advertising language that is proposed.</p>	Chapter 30, Section 3(1) - Advertising Prohibitions	Accept in part	See revised definition of "appealing to individuals under 21 years of age" in 18-691 CMR, ch. 10
Alex McManahan	Email		MedCo.	<p>3.6.A.4 - type: missing the word "or" in between "conveyed" and "consumers".</p>	Chapter 30, Section 3(6) - Advertising: Marketing Between Licensees and Employee Samples	Accept	

Name	Source	Affiliation	Company name	Comments - Ch. 30 Sec. 4, Waste Management	Reference	Department Response (accept, accept in part, reject)	Reasoning

Team Discus	Name	Source	Affiliation	Company name	Comments - Ch. 30, Sec. 5, Packaging and Labeling	Reference	Department Response (except, accept in part, reflect)	Reasoning
Yes	Michael DiPersia	Online	Dentons	All Purpose Flower LLC	<p>I oppose this section entirely and want to discuss the implications this will have on cannabis businesses in the State. Currently the statute requirements of inhaled cannabis products being child resistant and opaque CAN be met at the point of sale at the retail level. I would like to see that part of the regulations to continue to be allowed by OCP. In the proposed rule it now removes this option of a child resistant exit package using non child resistant and non opaque packaging which would then only be allowed to be sold to a consumer after it is placed in a child resistant exit package (at the point of sale). Cultivators have invested millions of dollars into packaging and branding. This would force them to redesign and lose millions of dollars in the process. There is not any reason from a public safety perspective to make this change as all cannabis products in our current regulations still are sold to all customers in child resistant containers but the distinction being that they are allowed to be non child resistant until the point of sale where a child resistant exit package can be used is an important distinction.</p> <p>Opaque packaging also will increase the cost for the retailer. Most customers want the opportunity to visually see the cannabis flower they are purchasing prior to sale. A visual inspection can aid a consumer in making a much more transparent purchasing decision and determine if the product looks visually like something they would like or find to be the correct value. At this time under the control of retail staff or in display cases across the state consumers are able to see the cannabis flower through glass jars or mylar bags without opening them or breaking a tamper evident seal. This allows the products to be sold compliantly into the future. If this proposed rule is not changed then every retail employee will have to spend an increased amount of time with each customer. The only way a customer could see products would be if a retail employee opens an opaque package to show them this would render it unable to be sold once the tamper evident seal is broken and the product would have to be destroyed. This increase in time at each point of sale will cost all store owners. This increase labor cost will also increase the amount of time each transaction takes. This increase in time will lead to the need to hire more labor to sell the same amount of products as previously done. All these additional costs will eliminate any potential savings from eliminating exit packaging.</p> <p>Consumer safety and law can be met currently using child resistant exit packaging as well as meet the requirement of being opaque. This option should be allowed to continue as an option. If a retailer wants to stock a non child resistant non opaque option and take on the expense of a child resistant exit bag then this should be allowed as the new regulation does not add any additional public safety and only increases costs to all licensees. I understand that there may have been a reason to want to eliminate exit packaging from an environmental perspective-but regardless of regulations all retailers will still have to offer shoppers a shopping bag of some kind at the point of sale. People will continue to want to leave with their products in a bag like any other traditional retail business. We can maintain public safety as well as labor costs by allowing the child resistant and opaque requirement be met at the point of sale through exit packaging. I think the option to also meet this requirement before point of sale could also be a reasonable option for some.</p> <p>I oppose this section and would like to discuss the implications this will have on cannabis businesses in the State. Currently the statute requirements of inhaled cannabis products being child resistant and opaque CAN be met at the point of sale through child resistant exit packaging at the retail level. I would like to see this to continue to be allowed to meet this requirement.</p> <p>In the proposed rule it now removes this option which currently allows a cultivation licensee to use non child resistant non opaque packaging which would then be required to be paid into the proposed child resistant bag at the point of sale. Cultivators have invested millions of dollars into packaging and branding. This change would force most to redesign their packaging and to collectively lose millions of dollars. Our industry simply cannot afford this when it will not add to public safety.</p> <p>There is no reason from a public safety perspective to make this change as all cannabis products under our current regulations cannot leave a retail store with a customer without being child resistant and opaque which exit packaging at the point of sale accomplishes this for many.</p> <p>Opaque packaging will also increase the labor cost for the retailer. Most customers want the opportunity to visually see the cannabis flower they are purchasing prior to sale. A visual inspection can aid a consumer in this heavily regulated market in making a more informed decision about their purchase. It can help them judge value, quality and lead to transparency as well as trust. It shows the cultivator has nothing to hide. At this time under the control of retail staff or in display cases across the state consumers are able to see the cannabis flower through clear jars and mylar bags (without the need to break a tamper evident seal and open them). If this proposed rule is not changed then every retail employee will have to spend an increased amount of time with each customer. The only way a customer could see products a opaque packaging is required would be by opening the container and showing them. This would render that product unable to be sold and eventually destroyed. This increase in time at each point of sale will cost store owners more money for each transaction. This increase in labor cost will also require the store to hire more employees. In the current rule if a retailer is required to operate would increase with the added time each transaction will now take. This creates even more added labor cost. All these added costs will eliminate any cost savings not needed exit packaging will have.</p> <p>Consumer safety and the law can be met currently by using opaque child resistant exit packaging. This option should continue to be allowed by the rules. If a retailer wants to stock a non child resistant and non opaque product and take on the expense of child resistant exit packaging that should be a permitted option allowed in the rules. Telling this away does not create more public safety and will increase the costs to all licensees. I understand OCP had a reason for this but not allowing exit packaging will not eliminate the need for all retailers to still offer some sort of shopping bag at the point of sale. Many customers will still want a bag for numerous reasons including ease of transport, concealing branding/products, as well as carrying etc but like all retail purchases. Please continue to allow child resistant exit packaging as a way to meet the opaque and child resistant requirements on inhaled products.</p>	<p>Chapter 30, Section 5(1)(B)(3) - Packaging and Labeling for Retail Sale of Inhaled Cannabis Products</p>	Accept	Exit packaging permitted and can satisfy opacity requirements
Yes	Hannah King	Online	Dentons	All Purpose Flower LLC	<p>Chapter 30, Section 5(1)(B)(3) - WARNING STATEMENT</p> <p>If the Department is going to adopt an entirely new warning statement, which in many cases will be pre-printed on product packaging, we recommend specifying a period of time in the rule during which either the previous required warning statement or the new warning statement will be viewed as compliant. This will allow for a sell down period and will avoid a situation where all packaging immediately needs to have a sticker added to it with the new required information, particularly where retail stores do not have the authority to label products with required information.</p>	<p>Chapter 30, Section 5(1) - Packaging and Labeling: General Packaging and Labeling Requirements for Retail Sale</p>	Accept	Licensees will be allowed at least one year after rule implementation to phase out the use of noncompliant packaging

Yes	Hannah King	Online	Dentons		<p>OPAQUE PACKAGING</p> <p>Reference to "exit packaging" were removed in sections throughout the proposed rules. Getting rid of environmentally unfriendly child-resistant and tamper evident exit packaging is sound policy, although, similar to changes in the warning label, the rule should provide for a sufficient period of time for companies who developed and purchased packaging based on the existing law.</p> <p>Additionally, removing the option to use any form of exit packaging (specifically, the ability to have products packaged for sale with a window or clear portions of the packaging providing a view of the product and to meet the requirement that packaging be opaque through exit packaging at the point of sale) will adversely impact consumers and OCP compliance efforts. Requiring that the products displayed in the store be packaged in opaque packaging will prevent customers from being able to view the products they are purchasing and impact their ability to determine that the product is of the quality that they desire prior to purchase. This could very well lead to increased, unnecessary returns and destruction. It also will prevent OCP during retail store inspections from being able to view products that are being sold. This will make it more difficult to determine, for example, whether an edible product is stamped or embossed with a universal symbol in compliance with state law without opening the packaging. Having to open packaging to determine product compliance will require licenses to unnecessarily destroy product.</p> <p>We would recommend continuing to allow businesses to check the box for "opaque" packaging specifically at the point of sale. This can be as simple as placing the tamper-evident, child-resistant cannabis product in a paper bag prior to completing the sale. This is an environmentally sustainable practice and will not result in undue waste. We do not see a strong policy rationale for prohibiting this conduct (particularly given that the policy goal of requiring opaque packaging is preventing individuals under 21 from viewing the product, and individuals under the age of 21 are prohibited from entering an adult use cannabis store).</p> <p>If the Department does move forward with this new requirement, then we request that the Department establish a sell-down period such as six months after the rule goes into effect.</p>	Chapter 30, Section 5(3) - Packaging and Labeling for Retail Sale of Inhaled Cannabis Products	Accept in part	Exit packaging is permitted and may satisfy opacity requirement
Yes	Jill Cohen	Online	Cohen Law Mahre PLLC		<p>(A) (1) (c) and (d) Opaque and child-resistant? This change is not prompted by a change in state law. Why is exit packaging no longer sufficient as it is still authorized by statute?</p> <p>This section does not contemplate the use of exit packaging which is still authorized by state law.</p> <p>(B) (2) This section needs further review, supplements. The "amount of a cannabis product" that is customarily consumed by adults is dependent on the individual and the dosage. It is not the same as the particular food item's non-cannabis counterpart, because they are not the same thing.</p> <p>This section does not contemplate the use of exit packaging which is still authorized by state law.</p>	Chapter 30, Section 5(3) - Packaging and Labeling for Retail Sale of Inhaled Cannabis Products	Accept in part	Exit packaging permitted
Yes	Jill Cohen	Online	Cohen Law Mahre PLLC		<p>This section does not contemplate the use of exit packaging which is still authorized by state law.</p> <p>(B) (2) This section needs further review, supplements. The "amount of a cannabis product" that is customarily consumed by adults is dependent on the individual and the dosage. It is not the same as the particular food item's non-cannabis counterpart, because they are not the same thing.</p> <p>This section does not contemplate the use of exit packaging which is still authorized by state law.</p>	Chapter 30, Section 5(4) - Packaging and Labeling for Retail Sale of Edible Cannabis Products	Accept in part	Exit packaging permitted
	Jill Cohen	Online	Cohen Law Mahre PLLC		<p>This section does not contemplate the use of exit packaging which is still authorized by state law.</p> <p>(B) (2) This section needs further review, supplements. The "amount of a cannabis product" that is customarily consumed by adults is dependent on the individual and the dosage. It is not the same as the particular food item's non-cannabis counterpart, because they are not the same thing.</p> <p>This section does not contemplate the use of exit packaging which is still authorized by state law.</p>	Chapter 30, Section 5(5) - Packaging and Labeling for Retail Sale of Topical Cannabis Products	Accept in part	Exit packaging permitted
	Kameron James	Online			<p>This seems very bad for the businesses that have already invested in packaging that met previous requirements when exit packaging was in the law. Making the requirement for packaging of product to be opaque removes the ability of customers to visually inspect product that they are purchasing which is very important when comparing quality between different brands.</p> <p>Overall it's bad for business, quality, and the customers. This seems to benefit multi state operators that have had to meet these requirements for other states and add excess regulation on smaller businesses trying to compete in the market.</p> <p>Strongly oppose this rule change. Retailers should have the option to continue to meet the current requirement of inhaled cannabis products being child resistant and opaque at the point of sale through the use of child resistant exit packaging.</p> <p>The proposed changes would prevent customers from being able to see product through clear packaging while making their selections. Product will have to be opened for customers to see it and ultimately degraded out. Transactions will take much longer. This will create frustration for customers and added expenses of increased retail labor costs and damaging out now unusable product.</p> <p>Respectfully, mylar bags lend themselves to a lower quality product and give customers a subpar experience. Brands invest so much in unique packaging in hopes of creating a better experience for the customer and to set themselves apart. The proposed changes would lead to a potentially devastating financial loss on already ordered custom packaging, and create an added expense of designing and purchasing all new packaging. This change would force most stakeholders to redesign their packaging and collectively lose millions of dollars. Our industry simply cannot afford this, especially when there is absolutely no benefit to public safety or customer experience.</p>	Chapter 30, Section 5(3) - Packaging and Labeling for Retail Sale of Inhaled Cannabis Products	Accept in part	Exit packaging permitted and OCP will allow licenses at least one year from the date of implementation to phase out the use of noncompliant packaging
	Gina A	Online			<p>I would like to see businesses who choose to remediate using potentially harmful techniques be required to make consumers aware of these practices. The voluntary labeling and packaging approval I would like to see the department be required to answer operators who ask if their product is ready for the market. I have sent field investigators and other members of OCP pictures of our packaging and labeling, before sending it to a retail establishment, and received great advice and guidance. I would be disappointed if I got no response.</p>	Chapter 30, Section 5(1) - Packaging and Labeling for Retail Sale	Accept in part	See new labeling requirements for remanufactured cannabis flower and trim. Because OCP has not been authorized to assess a fee for label review, it must the balance review of labels with the other responsibilities of the office.
Yes	Ryan Parker	Online	Stoner & Co.		<p>I believe that the warning statement in the proposed rule will inhibit potential customers from trying these products, this could also make products from medical, or illicit markets seem safer. The safer product to use is in the adult use program. We also have to take into account all the operators who purchase their packaging in bulk. Almost all packaging is produced internationally, and so the only way to cut costs per unit is to order in large quantities. What are operators to do with packaging that is deemed unfit?</p>	Chapter 30, Section 5(3) - Packaging and Labeling for Retail Sale of Inhaled Cannabis Products	Accept in part	Warning statement not changed but OCP will allow licenses at least one year from the date of implementation to phase out the use of noncompliant packaging

Renele Brosi	Online	Highlow	The proposed "opaque packaging" is a large concern for not only us, but other large, local cannabis companies. To remain competitive in today's market, we have to plan our packaging for the year and at times (right) to reduce overall cost to deliver a quality, safe, enjoyable product to our consumer. Based on what we have on hand, how long it takes to receive packaging, how challenging it is to source appropriate packaging and how the loss we will take on our year's worth of exit packaging, we are looking at approximately a 40% loss in packaging alone. This does not take into account the work/cost to update all our labels that have been printed and product on the shelf with the proposed new warning statement. We do see that exit packaging has been removed from these requirements, however many companies have already designed and purchased enough of this to last the entire year or more. We have to plan in this manner due to massive market fluctuations and excessive taxation & regulation. This statement also applies to our view on the proposed changes for drinks and topicals. In addition to cost, we feel this is taking away one of the very few ways a company can differentiate itself with the creativity put into packaging and labeling. This proposal doesn't appear take any of this into consideration	Chapter 30, Section 5(9) - Packaging and Labeling for Retail Sale of Inhaled Cannabis Products	Accept in part	OCP will allow exit packaging and licenses will have at least one year from the date of implementation to phase out the use of noncompliant packaging.
Alex Mckahan	Email	MedCo.	5.3.A.1.c & 5.3.A.1.d - The striking of the exit packaging is problematic, and was not prompted by the legislature. Also exit packaging is allowed in statute.	Chapter 30, Section 5(9) - Packaging and Labeling for Retail Sale of Inhaled Cannabis Products	Accept	
Alex Mckahan	Email	MedCo.	5.4.A - The striking of "unless otherwise specified" is problematic, and was not prompted by the legislature. Also exit packaging is allowed in statute.	Chapter 30, Section 5(4) - Packaging and Labeling for Retail Sale of Edible Cannabis Products	Accept in part	Exit packaging permitted
Alex Mckahan	Email	MedCo.	5.4.A.6 & 5.4.A.7 - The striking of the exit packaging is problematic, and was not prompted by the legislature. Also exit packaging is allowed in statute.	Chapter 30, Section 5(4) - Packaging and Labeling for Retail Sale of Edible Cannabis Products	Accept	
Alex Mckahan	Email	MedCo.	5.5.A.4 - The striking of the exit packaging is problematic, and was not prompted by the legislature. Also exit packaging is allowed in statute.	Chapter 30, Section 5(5) - Packaging and Labeling for Retail Sale of Topical Cannabis Products	Accept	

Pierce, Gabi

From: Malloch, Vernon
Sent: Thursday, May 4, 2023 9:11 AM
To: Hudak, John; Roberts, Lisa; Pierce, Gabi
Subject: FW: Cannabis Warning Labels
Attachments: IICPS with text for Maine (ME).pdf; Standardized Warnings for Cannabis Packages 2023-05-03.pdf

Hi All

As part of our regulatory look back I reached out to Dr. Nathan from Doctors for Cannabis Regulation for more information on updating our universal symbol and warning statement. This is what he provided.

In our meeting he made a good case for updating our universal symbol and the examples he provides of a warning statement are interesting too.

If we do adopt/change either or both we should have a one year overlap to account for packaging already ordered and current inventory.

Vernon W. Malloch

Deputy Director of Operations | Office of Cannabis Policy
Maine Department of Administrative and Financial Services
162 State House Station | Augusta, ME 04330-0162
Tel: (207) 624-7308 | Fax: (207) 287-2671



From: David L. Nathan <dnathan@dfcr.org>
Sent: Wednesday, May 3, 2023 8:53 PM
To: Malloch, Vernon <Vernon.Malloch@maine.gov>
Subject: Re: Cannabis Warning Labels

EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vern. Great to hear from you. Yes, I remember meeting you on the call with John Hudak.

I'm happy to help with your requests. Here are my thoughts about the product symbol and product warnings, which I can put in a memo if that's a better format for your office...

The Symbol

There are a number of text options to go with the symbol:

1. [NO TEXT]. I learned last week that [South Dakota](#) mandates use of the IICPS with *no* added text. There are warnings elsewhere, and the symbol speaks for itself ("Caution: Cannabis"). So, I think that's reasonable.

2. CONTAINS THC. Of course, that's what you have now. Vermont plans to switch to the IICPS, and they think they'll retain that text. The problem with this option is the existence of other intoxicating cannabinoids, such as HHC, which are *not* subtypes of THC (unlike Delta-8, Delta-9, Delta-10, etc.). Products containing HHC will need to be regulated sooner or later, and they should bear the symbol. At that point, the text would need to change.

3. MARIJUANA or CANNABIS. Montana's Legislature required use of "MARIJUANA" with the IICPS, purportedly as a deterrent to underage use, and [that is what they now use](#). The Montana Cannabis Control Division has discussed changing to "CANNABIS". Of the two options, I also would recommend "CANNABIS" over "MARIJUANA".

4. NOT SAFE FOR KIDS. This is used in the complex NJ symbol that uses the IICPS (with tiny images and text), but it can be done neatly and legibly with just the IICPS. My concern with that text is that it could stigmatize families of kids who actually *do* need medical cannabis. It's a small but legitimate group.

5. Other options, such as "21+", "ME", "MAINE", "THC", etc.

Please find attached illustrations of these options.

When switching from the current symbol to the IICPS, I suggest giving businesses a grace period (perhaps 6-12 months) to change their package design and let them use up their existing packaging inventory.

Product Warnings

This is a timely question, as a new standard for labeling was released recently. Please find attached an updated version of a working document on this subject, which addresses the new standard (ASTM D8449).

Please let me know if this is what you need, and feel free to ask any other questions.

Regards,
David

David L. Nathan, MD, DFAPA
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On May 3, 2023, at 2:52 PM, Malloch, Vernon <Vernon.Malloch@maine.gov> wrote:

Hello Dr. Nathan

I hope you are well. We met briefly on February 21 on a video conference call with the Maine Office of Cannabis Policy. The meeting was very helpful and we are now about to review our regulations. I will be discussing with my team your suggestion that we adopt the recommended universal symbol. I was able to locate it on the DFCR website. I recall that you also had some recommended language for label warnings that was comprehensive and concise but I am not able to locate it now. Could you please forward any recommendations you may have for us?

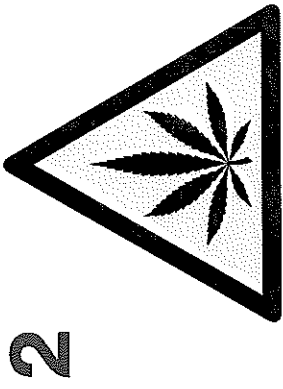
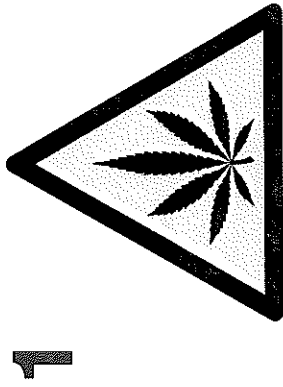
Currently we require “There may be health risks associated with the use of this product. There may be additional health risks associated with the use of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant. Do not drive a motor vehicle or operate heavy machinery while using this product.”
I recall you had a better suggestion.

Thank you for any assistance you can provide.

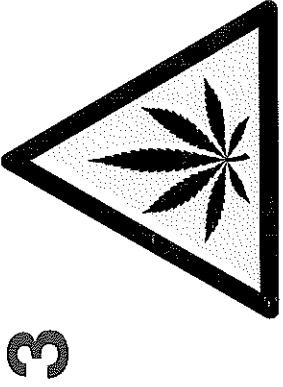
Best, Vern

Sent from [Mail](#) for Windows

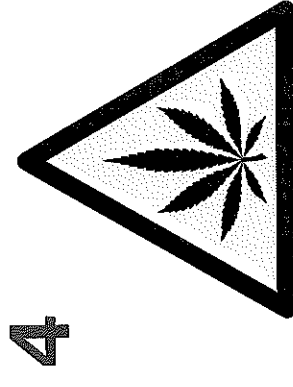
**IICPS (ASTM D8441) with and without
optional text for MAINE**



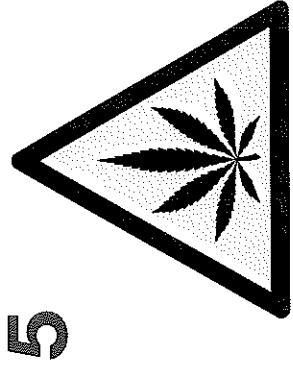
CONTAINS THC



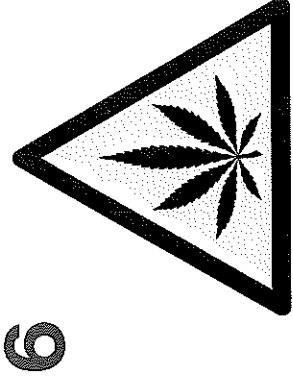
CANNABIS



**NOT SAFE
FOR KIDS**



ME • 21+



MAINE

STANDARDIZED WARNINGS FOR CANNABIS PACKAGES IN THE UNITED STATES OF AMERICA

David L. Nathan, MD, DFAPA
May 3, 2023

INTRODUCTION

This is a working document and an iterative process that summarizes the consensus among scientists and physicians regarding the health risks of cannabis about which all cannabis consumers and patients should be told through product warning labels. At the end, it addresses the 2023 consensus standard ASTM D8449, which I believe will need revising.

There are three guiding principles that should shape standardized warnings for cannabis product packages:

1. **Readability** – The text of warnings should use language simple enough to be understood by all literate English speakers and easily translated into other languages.
2. **Evidence** – While this goes without saying, there should be sufficient peer-reviewed scientific evidence (and preferably a consensus among scientists) to justify the inclusion of a particular warning. An exception is in pregnancy and breastfeeding, which lacks data and therefore merits inclusion in basic warnings.
3. **Brevity** – Fewer words allow for larger text in the allotted space on a package, so every *letter* counts. Standardized warnings should be as succinct as possible to maximize the likelihood that patients and consumers will actually read and remember them. Package warnings should be selected to maximize their impact on public health and safety, focusing on populations at greatest risk.

Here is a proposed list of populations most at risk from cannabis consumption:

- All patients and consumers (at risk for addiction and less common side effects)
- Patients and consumers who want to drive or operate heavy machinery (at risk for accidents)
- Patients and consumers who are new to cannabis (at risk for overconsumption)
- Small children and pets (at risk for accidental consumption)
- Minors (at risk for intentional non-medical consumption)
- Adults with or at risk for psychiatric disorders (including psychosis and substance use disorders)
- Pregnant and breastfeeding people (given a relative lack of safety data)

We may want to recommend rotating warnings, as seen on tobacco products and Canadian cannabis products, but we should first work out the basic warnings. Also, packages should have a QR code (i.e., a 2D barcode) or web address that links to more detailed warnings, but that's the subject of another conversation.

PROPOSED PRODUCT WARNING TEXT FOR ALL CANNABIS PRODUCTS

WARNING: Keep out of reach of children and pets. Do not drive or operate machinery while intoxicated. This product can be addictive. Use of this product may be harmful, especially if you are under 21, inexperienced with cannabis, pregnant, breastfeeding, or at risk for psychiatric problems.

ADDITIONAL WARNINGS FOR PARTICULAR PRODUCT FORMS

1. Inhaled concentrates:

Inhale cannabis concentrates with caution to avoid overconsumption. Start low & go slow.

2. Oral concentrates and edibles:

Exceeding the serving size [or dose] can make you sick. Intoxicating effects can be delayed by 2 hours or more and can last 8 hours or more.

3. Topicals:

For external use only.

OTHER WARNINGS FOR CONSIDERATION

A. Interactions with other drugs:

Intoxication and other effects can increase greatly when this product is combined with alcohol or other drugs.

B. Tachycardia:

This product may cause rapid heart rate.

A NEW CONSENSUS STANDARD: ASTM D8449

ASTM D8449 is a labeling standard released in spring 2023, and it addresses product warnings. Most of the requirements are summarized here:

Adult-use and medicinal-use cannabis flowers shall be labeled with the following warning statements or similar wording that expresses the facts:

“Do not consume during pregnancy or while breastfeeding.”

“This product may impair the ability to drive or operate heavy machinery.”

“Keep out of reach of children and pets.”

Cannabis flowers containing more than 3000 ppm total THC by weight or volume:

“This product contains THC. Consume at your own risk.”

Cannabis flowers containing more than 10 000 ppm total cannabinoids by weight or volume:

“This product contains cannabinoids. Consume at your own risk.”

Additional warning statements required by the authority having jurisdiction.

ASTM D8449 also mentions text for specific products, like “Do not eat” for topicals.

I personally think the language of ASTM D8449 needs to be improved, but that requires changing the standard. I think some at risk populations need to be added to the ASTM D8449 standard, such as people at risk for psychiatric problems. I also believe language like “Consume at your own risk” is unnecessary.

Note that the National Technology Transfer and Advancement Act of 1995 (NTTAA) requires the U.S. federal government to adopt available consensus standards into federal regulations. So, it’s likely that a standard like ASTM D8449, along with its requirements for product warnings, will eventually be mandated at the national level once cannabis is federally legalized. In the meantime, the product warnings in ASTM D8449 should be improved for brevity and content.

FINAL THOUGHTS

Please get involved and offer your feedback on proposed label warnings. Good people disagree on almost every aspect of labeling for regulated cannabis products, so obviously not all contributions can be incorporated into the final product. But who knows?... Your input just might show up on cannabis packages at the state and/or federal regulatory level!

**PLEASE SEND ANY FEEDBACK TO LABELING@DFCR.ORG.
THANKS FOR YOUR INPUT!**

Administrative Procedure Act

CHECKLIST

Agency: Office of Cannabis Policy, Department of Administrative and Financial Services

Chapter Number and Title of Rule: Ch. 30 - Compliance Rules for Adult Use Cannabis Establishments

PROPOSED RULE:

1. Was this rule listed on the last regulatory agenda? Yes
2. Date of notification of: Anyone on mailing list: August 15, 2023
Any trade, industry or professional group _____
Any trade publications _____
3. Date Notice of Rulemaking Proposal (MAPA-3) sent to Secretary of State: August 8, 2023
4. Date Fact Sheet sent to Executive Director of Legislative Council: August 9, 2023
5. Date of publication in Secretary of State's rulemaking ad.: August 16, 2023
6. Date of hearing(s): September 6, 2023 7. Comment deadline: September 17, 2023

ADOPTED RULE:

8. Was comment deadline extended or comment period reopened? No.
If yes, date of second notice publication in Secretary of State's rulemaking ad: _____
9. Is adopted rule consistent with what was proposed? See comments and responses.
(If not, please address the changes in the comments and responses section of your filing.)
10. Is the person signing the Certification Statement (MAPA-1, #9) authorized to do so as stated in your statutes or in 5 MRSA, c.71? Yes.
11. Was the rule adopted within 120 days of the comment deadline? Yes.
12. Was the rule approved and signed by the Office of the Attorney General within 150 days of the comment deadline? Yes.
13. Is a Basis Statement included? Yes. Is a copy of the Fact Sheet included? Yes.
Are comments, with names and organizations, and your responses included? Yes.

Rulemaking Fact Sheet

(5 MRS §8057-A)

AGENCY: 18-691 – Office of Cannabis Policy, Department of Administrative and Financial Services

NAME, ADDRESS, PHONE NUMBER, EMAIL OF AGENCY CONTACT PERSON: Gabi Pierce; Office of Cannabis Policy, 162 State House Station, Augusta, ME 04333; Phone: (207) 530-0507; Fax: (207) 287-2671; gabi.pierce@maine.gov.

CHAPTER NUMBER AND RULE TITLE: Ch. 30 - Compliance Rules for Adult Use Cannabis Establishments

TYPE OF RULE (*check one*): Routine Technical Major Substantive

STATUTORY AUTHORITY: Title 28-B, Chapter 1 (Cannabis Legalization Act)

DATE, TIME AND PLACE OF PUBLIC HEARING: September 6, 2023; 10:00 a.m.; Office of Cannabis Policy, 19 Union Street., Augusta, Maine, 3rd Floor, Room 325.

COMMENT DEADLINE: Sunday, September 17, 2023 at 11:59 p.m.

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: [*see* §8057-A(1)(A)&(C)]

This rulemaking updates the compliance requirements necessary to implement statutory changes made to the Cannabis Legalization Act, 28-B MRS, including PL 2023, ch. 6, Emergency (Signed March 15, 2023), and PL 2023, ch. 408, PL 2023, ch. 396, specifically changes to the authorized activity of tier 1, tier 2, and nursery cultivation facilities and products manufacturing facilities allowing for the sales of cannabis and cannabis products to consumers by delivery (except that nursery cultivation facilities may sell only immature cannabis plants, seedlings, cannabis seeds and agricultural or gardening supplies relating to the cultivation of cannabis); permitting the delivery of cannabis and cannabis products by authorized licensees to consumers at hotels or other private businesses, provided that the delivering licensee has obtained written consent from the owner or other authorized agent of the business to conduct such deliveries; permitting the return of cannabis or cannabis products from licensee to the licensee that transferred the cannabis or cannabis products to the returning licensee and provides for the testing of such returned cannabis or cannabis products; permitting the use of vehicle wraps by licensees; increasing the per package limit for edible cannabis products from 100 mg per package to 200 mg per package and increasing the possession limit for cannabis concentrates from 5 grams to 10 grams; creation of new definitions for the terms “permitted premises for a specified event,” “specified event,” and “specified event permit”; amendments to the application requirements for the issuance of a permit for cannabis stores to conduct sales at specified events; amendments to the limitations and conditions for cannabis stores to conduct sales at events – including repealing the prohibition on the sale of “smokable” cannabis or cannabis products at specified event; establishment of criteria for suspension/revocation of permit to conduct sales at an event; established criteria for DAFS’s approval or denial of a permit application for cannabis stores to conduct sales at a specified event to allow denial of such applications for “good cause”; and amendments to the requirements that the Department issue guidance to cannabis stores.

This rulemaking is being conducted in preparation to repeal the Adult Use Cannabis Program Rule, 18-691 CMR, ch. 1, once this rule, and 18-691 CMR, chapters 10, 20 and 40 are finally adopted.

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? YES NO [§8056(1)(B)]

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [*see* §8057-A(1)(B)&(D)]

This rulemaking updates the compliance requirements necessary to implement statutory changes made to the Cannabis Legalization Act, 28-B MRS, including PL 2023, ch. 6, Emergency (Signed March 15, 2023), and PL

2023, ch. 408, PL 2023, ch. 396, in preparation to repeal the Adult Use Cannabis Program Rule, 18-691 CMR, ch. 1, once this rule, and 18-691 CMR, chapters 10, 20 and 40 are finally adopted.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE
(including up to 3 primary sources relied upon) [see §§8057-A(1)(E) & 8063-B]

Previous guidance issued by OCP

Public hearings and work sessions for PL 2023, ch. 6, Emergency (Signed March 15, 2023), and PL 2023, ch. 408, PL 2023, ch. 396.

Public comments

ESTIMATED FISCAL IMPACT OF THE RULE: [see §8057-A(1)(C)]

This rule should not have any impact on existing state resources.

FOR EXISTING RULES WITH FISCAL IMPACT OF \$1 MILLION OR MORE, ALSO INCLUDE:

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS:
[see §8057-A(2)(A)]

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED
AND HOW THEY WILL BE AFFECTED: [see §8057-A(2)(B)]

BENEFITS OF THE RULE: [see §8057-A(2)(C)]

Note: If necessary, additional pages may be used.