

Preventing Unintentional Ingestion of Marijuana by Children: A Health Impact Assessment of Packaging Regulations in Retail Marijuana Establishments in Colorado

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Jodi K. Duke, MPH CPH – Jodi.Duke@ucdenver.edu

Katherine Collins

Robin Kimbrough-Melton, JD

Heidi Baskfield, JD

Gregory J. Tung, MPH PhD

This Health Impact Assessment is a joint effort between the Pediatric Injury Prevention Education and Research Program at the Colorado School of Public Health and the Children's Health Advocacy Institute at Children's Hospital Colorado



Children's Hospital Colorado



**Pediatric Injury Prevention, Education
and Research Program (PIPER)**

COLORADO SCHOOL OF PUBLIC HEALTH

UNIVERSITY OF COLORADO **ANSCHUTZ MEDICAL CAMPUS**

The following organizations endorse the recommendations of this Health Impact Assessment:



Executive Summary

The legalization of recreational marijuana by the State of Colorado raises concerns about the unintentional ingestion of marijuana by children. In July and August of 2013, the Colorado State Licensing Authority formed working groups to develop the final regulatory structure for retail marijuana in the state. To inform this process, we conducted a Health Impact Assessment focused on the issue of preventing unintended ingestion of marijuana by children and the potential role that the use of child-resistant packaging could play at mitigating the problem. After reviewing the scientific evidence and incorporating stakeholder input, we make the following recommendations:

1. All retail marijuana and marijuana products should leave retail establishments in child-resistant packaging as defined by ASTM International and the Poison Prevention Packaging Act of 1970 (PPPA)
2. All child-resistant packaging should be opaque
3. All child-resistant packaging should be re-closeable
4. Allowances should be made to re-use appropriate child-resistant packages

Background

Preventing accidental ingestion of marijuana by children is a high priority for Colorado and the state's citizens. Following the legalization of medical marijuana in Colorado in 2000 and the Federal Government's decision in 2009 not to prosecute in medical marijuana states, Children's Hospital Colorado saw a large increase in the number of pediatric patients who presented to the Emergency Room with marijuana-related health consequences.¹ From January 2005 to September 2009, of 790 children under 12 years of age screened for marijuana, none were found to be positive for exposure to marijuana.¹ From October 2009 to December 2011, when medical marijuana expanded significantly in Colorado, 14 of 588 children under 12 years of age tested positive for marijuana exposure.¹

In 2012, Amendment 64 was passed in Colorado legalizing and regulating recreational marijuana sales to adults over the age of 21. It is anticipated that this measure will further increase the availability of marijuana and marijuana-products (i.e. loose-leaf products, candies, baked goods, infused fruit drinks, etc.) throughout the state and further increase the risk of and number of unintentional ingestions of marijuana by children. Given this concern, the state of Colorado has a responsibility to take steps to prevent unintentional ingestion of marijuana by children.

On May 28th, 2013, Governor John Hickenlooper signed into law a number of pieces of legislation, including HB 13-1317, that took steps to establish the legal and regulatory structure for marijuana in Colorado. HB 13-1317 created the State Licensing Authority which was responsible for regulating medical and retail marijuana. The bill also specified that regulations should require packaging similar to those required by the Poison Prevention Packaging Act of 1970.

On July 1, 2013, a set of emergency rules were adopted by the State Licensing Authority to regulate the retail marijuana industry. These emergency rules were put into place with the intention of protecting public safety and preventing the diversion of marijuana to minors. On July 15th, 2013, the State Licensing Authority initiated the process of developing the State's permanent regulations related to marijuana. As part of the final rule making process, five working groups were formed including the Labeling, Packaging, Product Safety, and Marketing Working Group, which was responsible for developing regulations related to child resistant and poison prevention packaging. The final rule-making period concludes with formal public hearings from August 20th through the 22nd, 2013.

This Health Impact Assessment (HIA) provides a set of evidence-based recommendations for the packaging of retail marijuana products to reduce unintentional ingestion by children. These recommendations are based on a review of relevant scientific evidence, expert opinion, and stakeholder input. This HIA also provides recommended regulatory language specific to product packaging that incorporates the recommendations of this report (See Appendix).

What is a Health Impact Assessment?

Evidence-Based Decision Making

An HIA is a combination of procedures, methods, and tools used to make recommendations to decision-makers on programs or policies to maximize positive and minimize negative health impacts. Evidence from a variety of sources can be gathered and synthesized including scientific evidence, independent analysis, expert opinions, and evaluations of other similar policies. HIAs also incorporate stakeholder input, and balance that input with other evidence allowing a recommendation not only to be evidence-based, but also sensitive to the needs, beliefs, and opinions of the community.

Scope & Purpose

Packaging of Retail Marijuana

The scope of this HIA is packaging of retail marijuana products to reduce unintentional ingestion by children, resulting with a set of recommendations and corresponding model regulatory language. While it is known that children are also influenced by labeling and marketing, due to time and resource constraints, the scope of this HIA was limited to packaging of retail marijuana products.

This report targets all children under the age of 21 in Colorado. For this HIA, we determined that children should be divided into two general age groups - those under 5 and those between 5 and 20. These groups have different cognitive, developmental, and physical abilities possibly requiring unique recommendations.

Recommendations

The following are our recommendations related to packaging of marijuana and marijuana products based on scientific evidence, expert opinion, and stakeholder input.

- 1. All retail marijuana and marijuana products should leave retail establishments in child-resistant packaging as defined by ASTM International and the Poison Prevention Packaging Act of 1970 (PPPA)**

Under this recommendation, existing child-resistant packaging that meets ASTM and PPPA classification and testing standards qualify and no additional testing need be done. As specified in the existing emergency regulations, the label “Keep Away from Children” must appear on the packaging itself. This recommendation is specific to marijuana and marijuana products leaving a dispensary. This recommendation does not include a requirement that marijuana or marijuana products be displayed in child-resistant packaging while in a marijuana dispensary.

- 2. All child-resistant packaging should be opaque**

Marijuana and marijuana products should not be visible when inside child-resistant packaging. Child-resistant packaging should be sufficiently opaque so that the product is not visible, or an integral part of the packaging should be sufficiently opaque to prevent the product from being visible. For example, blister packs that are enclosed within an opaque box comply with this recommendation.

- 3. All child-resistant packaging should be re-closeable**

All marijuana and marijuana products that contain multiple servings or could be consumed during multiple instances should be packaged in child-resistant and re-closable packaging. Marijuana products that could not reasonably be consumed over multiple instances may be packaged in child-resistant packaging, such as blister packs, that keeps unconsumed product in a child-resistant state.

- 4. Allowances should be made to re-use appropriate child-resistant packages**

This recommendation states that regulations should be put in place to allow consumers to re-use compliant child-resistant packages in a manner that is consistent with the recommendations of the package’s manufacturer.

Model Regulations

We have provided model regulations that incorporate these recommendations in the Appendix.

Supporting Evidence and Justification

This section details the scientific evidence and stakeholder input that was used to support and justify the recommendations of this HIA which are summarized in Table 1.

Table 1: HIA Recommendations and Justifications

Recommendation	Justification	Anticipated Magnitude of Health Impact*	Quality of Evidence**
Child Resistant Packaging	Scientific Evidence and Stakeholder Input	Strong	Strong
Opaque Packaging	Scientific Evidence and Stakeholder Input	Medium	Medium
Re-closeable Packaging	Scientific Evidence and Stakeholder Input	Medium	Medium
Reusable Packaging	Stakeholder Input	Low	Low

**Impact Magnitude was considered Strong if it was a primary barrier to accessing item, Medium if was a secondary barrier to accessing item, and Low if it was a tertiary barrier OR post-access recommendation*

***Quality of Evidence was considered Strong if at least 4 peer-reviewed articles were published, Medium if 2-3 peer-reviewed articles were published, and Low if 1 was published OR recommended by expert opinion*

Scientific Evidence

Child-Resistant and Re-closeable Packaging

Evidence supporting the effectiveness of specific child-resistant packaging is strong and long-standing. This literature also supports the use of re-closable packaging. Since the inception of the PPPA, numerous studies have shown the efficacy and effectiveness of child resistant packaging in reducing child poisonings.²⁻¹⁰ Child resistant packaging as defined by ASTM International and the PPPA is often considered a gold standard both in the US and internationally. A vast body of evidence suggests that the implementation of child resistant packages has been highly successful in reducing accidental ingestion by children under the age of 5.²⁻¹³

Implementing a subset of rules and regulations for retail marijuana sales in Colorado based on the PPPA could reduce resulting childhood poisonings by 45%.¹⁴ Use of child resistant containers and packaging is an effective way to reduce accidental ingestions, especially among children under the age of 5 years old who do not yet possess the sensorimotor development and cognitive ability of older children and adults. While children under the age of 5 are a major consideration, so are those between 5 and 21. Because child resistant packages will not prevent older children from opening them, it is also important to reduce the appeal of these products.

Opaque Packaging

Cognitive and developmental psychologists generally agree that 8-24 months is the approximate time a child understands object permanence (he/she knows an object is there without seeing it) and 2-7 years is the time when thinking is centered on a single aspect of a situation (i.e. drinking a toxic substance without noticing other aspects of the situation such as a warning label).¹⁵ Furthermore, marketing research has found that one of the best ways to increase food appeal to adolescents is to provide packaging that allows them to view the item.¹⁶ These findings formed the scientific foundation for our recommendation that all child-resistant packages should be opaque.

Stakeholder Input

The Colorado State Licensing Authority, Labeling, Packaging, Product Safety, and Marking Working Group consisted of a wide range of stakeholders; chemical testing facilities, pharmacists, marijuana retailers, consumer advocacy groups, and government employees. There were a total of 14 working group members. Each stakeholder/working group member brought a unique perspective to the issue of product packaging. In order to incorporate their input the HIA team contacted each working group member separately for interview. Interviews were conducted using semi-structured interviewing techniques. A number of considerations and themes emerged:

- Child resistant packaging for children under 5 years of age
- Adoption of regulations from Poison Prevention Packaging Act of 1970
- How to reduce appeal to children over 5 years
- Add a Poison Control statement on all containers
- Child resistant packaging for edible items
- Child resistant packaging for flower-based products
- Environmental impact of packaging
- Cost of packaging
- Health outcomes experienced by children who ingest marijuana

In addition, a number of other topics arose in the interviews including labeling and marketing that were beyond the scope of this HIA. This does not diminish the importance of these topics nor the potential health effects of regulations related to them.

Child-Resistant Packaging and Warning Label

There was broad support from all stakeholders for the introduction of regulations requiring child-resistant packaging compliant with ASTM and PPPA requirements and the inclusion of a warning label on packaging. All stakeholders noted the importance of preventing unintentional ingestion of marijuana by children. Marijuana industry representatives also noted the importance of legitimizing the industry and that the use of child-resistant packaging and this type of responsible conduct could help the retail marijuana industry build trust and acceptance among its community members.

Opaque packaging

When considering input from stakeholders, the HIA team considered the needs of both industry and consumers. For example, when considering opaque packaging, the HIA team contacted ASTM and PPPA compliant package producers through websites and emails to determine price differences in color scheme. We concluded that requiring opaque packaging would not be cost prohibitive or represent an unreasonable burden on marijuana dispensaries. Upon further discussion, all stakeholders, including industry representatives, agreed that opaque packaging could be an important way to reduce appeal to children.

Re-use of Child Resistant Packages

Stakeholder interviews also revealed that the potential environmental impact of child-resistant packaging was a concern. Often child-resistant packages are many times larger than the product it holds, and if discarded after each use the environmental impact might be significant. To mitigate this, we recommend the addition of regulatory language that would allow consumers to bring in their own container as long as it adheres to all other standards of child-resistance and opaque coloring.

Discussion

This HIA focused on the issue of preventing the unintentional ingestion of marijuana by children and limited its scope to the packaging of marijuana and marijuana products. We also focused our efforts on making recommendations with the assumption that recreational use of marijuana would become a legal activity in the state of Colorado and that the industry would be unrestricted in the type of infused marijuana products they could produce. These assumptions are not an endorsement of the legalization of recreational marijuana use or the fact that, at the time this HIA was conducted, there were no restrictions on the type of products that could be infused with marijuana.

We attempted to make our recommendations sensitive to practical industry considerations. We felt it was important that our recommendations protect children and be evidence-based, while not creating an unreasonable burden on industry. By recommending child-resistant packing standards that parallel the existing ASTM and PPPA standards, the marijuana industry can choose from an extensive number of ASTM and PPPA child-resistant classified and compliant packages already available. A partial list of ASTM and PPPA child-resistant compliant packages can be found at: www.cpsc.gov/Regulations-Laws--Standards/Statutes/Poison-Prevention-Packaging-Act/CRP-ASTM-Type.

Our recommendations are evidence-based, sensitive to stakeholder concerns, and take into account practical industry considerations. As such, we encourage the State of Colorado to include our recommendations into the final regulations related to retail marijuana. To help facilitate the inclusion of our recommendations, we have drafted model regulatory language that incorporates our recommendations included as an appendix to this report.

The recommendations of this HIA are based on the available scientific evidence about which child-resistant packaging standards will likely help address the issue of unintentional ingestion of

marijuana by children. Additional research and evaluation efforts should be undertaken to monitor the extent of unintentional ingestion of marijuana by children in the future and which measures, including those recommended here, are most effective at addressing the problem.

Acknowledgements

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Colorado Department of Revenue

Marijuana Enforcement Division

1 CCR 212-2

Emergency Rules Related to the
Colorado Retail Marijuana Code

R 100 Series – General Applicability

Basis and Purpose – R 102

The statutory authority for this rule is found at subsection 12-43.4-202(2)(b), C.R.S. The purpose of this rule is to clarify that each rule is independent of the others, so if one is found to be invalid, the remainder will stay in place. This will give the regulated community confidence in the rules even if one is challenged.

R 102 – Severability

If any portion of the rules adopted July 1, 2013 is found to be invalid, the remaining portion of the rules shall remain in force and effect.

Basis and Purpose – R 103

The statutory authority for this rule is found at subsection 12-43.4-202(2)(b), C.R.S. The purpose of this rule is to provide necessary definitions of terms used throughout the rules.

R 103 – Definitions

Definitions. The following definitions of terms, in addition to those set forth in section 12-43.4-103, C.R.S., shall apply to all rules and regulations promulgated pursuant to the Retail Code, unless the context requires otherwise:

- A. "Alarm Installation Company" means a Person engaged in the business of selling, providing, maintaining, servicing, repairing, altering, replacing, moving or installing a Security Alarm System in a Licensed Premises.
- B. "Applicant" means a Person that has submitted an application pursuant to these rules that was accepted by the Division but has not been approved or denied by the State Licensing Authority.
- C. "Batch Number" means any distinct group of numbers, letters, or symbols, or any combination thereof, assigned by a Retail Marijuana Cultivation Facility to a specific Batch of Retail Marijuana.
- D. "Batch" means a specifically identified quantity of processed Retail Marijuana that is uniform in strain and potency, cultivated utilizing the same herbicides, pesticides, and fungicides, and harvested during the same cultivation cycle.
- E. "Cannabinoid" means any of the chemical compounds that are the active principles of marijuana.
- F. "CBD" means cannabidiol.
- G. "CBDA" means cannabidiol-acid.

H. "CBG" means cannabigerol.

I. "CBN" means cannabiol.

J. "CHILD-RESISTANT PACKAGING" MEANS SPECIAL PACKAGING THAT IS

(1) OPAQUE SO THAT THE PRODUCT CANNOT BE SEEN WITHOUT OPENING THE PACKAGING MATERIAL, OR IS CONTAINED WITHIN AN OPAQUE PACKAGING SLEEVE;

(2) RECLOSABLE FOR ANY PRODUCT INTENDED TO BE EXPOSED OR REMOVED FROM THE PACKAGE AS PART OF NORMAL USE;

(3) LABELED PROPERLY AS REQUIRED BY RULE 1003(A)(7)(b) AND 1003(B)(7)(b); AND

(4) DESIGNED OR CONSTRUCTED TO BE SIGNIFICANTLY DIFFICULT FOR CHILDREN UNDER 5 YEARS OF AGE TO OPEN AND NOT DIFFICULT FOR NORMAL ADULTS TO USE PROPERLY AS DEFINED BY 16 C.F.R. § 1700.20 (2012) AND ASTM CLASSIFICATION STANDARD D3475-12.

A. [4][A] 16 C.F.R. § 1700.20 (2012) IS THE CONSUMER PRODUCT SAFETY COMMISSION CHILD RESISTANT PACKAGE TESTING STANDARD

B. [4][B] "ASTM CLASSIFICATION STANDARD D3475-12" IS THE CLASSIFICATION STANDARD FOR CHILD RESISTANT PACKAGING.

K. "Container" means the sealed package in which Retail Marijuana or a Retail Marijuana Product is placed for sale to a consumer and that has been labeled according to the requirements set forth in Rule R 1002 et. seq.

L. "Denied Applicant" means any Person whose application for licensure pursuant to the Retail Code has been denied.

M. "Department" means the Colorado Department of Revenue.

N. "Director" means the Director of the Marijuana Enforcement Division.

O. "Division" means the Marijuana Enforcement Division.

P. "Edible Retail Marijuana Product" means any Retail Marijuana Product which is intended to be consumed orally, including but not limited to, any type of food, drink, or pill.

Q. "Exit Package" means a sealed Container or package provided at the retail point of sale, in which any Retail Marijuana or Retail Marijuana Products already within a Container are placed. An Exit Package must be designed to ensure that the contents are secure and child-resistant AS DEFINED IN RULE R103(J).

R. "Good Cause" for purposes of denial or discipline of a license or permit means:

1. The Licensee or Applicant has violated, does not meet, or has failed to comply with any of the terms, conditions, or provisions of the Retail Code, any rules promulgated pursuant to the Retail Code, or any supplemental relevant state or local law, rule, or regulation;
2. The Licensee or Applicant has failed to comply with any special terms or conditions that were placed upon the license pursuant to an order of the State Licensing Authority or the relevant local jurisdiction; or

3. The Licensee's Licensed Premises have been operated in a manner that adversely affects the public health or welfare or the safety of the immediate neighborhood in which the establishment is located.
- S. "Good Moral Character" means an individual with a personal history demonstrating honesty, fairness, and respect for the rights of others and for the law.
- T. "Identity Statement" means the name of the business as it is commonly known and used in any advertising or marketing materials.
- U. "Label" or "Labeling" means all labels and other written, printed, or graphic matter upon a Container holding Retail Marijuana or a Retail Marijuana Product.
- V. "Licensed Premises" means the premises specified in an application for a license pursuant to the Retail Code that are owned or in possession of the Licensee and within which the Licensee is authorized to cultivate, manufacture, distribute, sell, or test Retail Marijuana in accordance with the provisions of the Retail Code and these rules.
- W. "Licensee" means any Person licensed pursuant to the Retail Code.
- X. "Limited Access Area" means a building, room, or other contiguous area upon the licensed premises where Retail Marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under control of the Licensee.
- Y. "Medical Code" means the Colorado Medical Marijuana Code found at sections 12-43.3-101 et. seq., C.R.S.
- Z. "Medical Marijuana Business" means a Medical Marijuana Center, a Medical Marijuana-Infused Products Manufacturing Business, or an Optional Premises Cultivation Operation.
- AA. "Medical Marijuana Center" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-402, C.R.S., and sells medical marijuana to registered patients or primary caregivers as defined in Article XVIII, Section 14 of the Colorado Constitution, but is not a primary caregiver.
- AA. "Medical Marijuana-Infused Products Manufacturing Business" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-404, C.R.S.
- BB. "Monitoring Company" means a Person in the business of providing Monitoring services for a Retail Marijuana Establishment Licensed Premises.
- CC. "Monitoring" means the continuous and uninterrupted attention to potential alarm signals that could be transmitted from a Security Alarm System located at a Retail Marijuana Establishment Licensed Premises, for the purpose of summoning a law enforcement officer to the premises during alarm conditions.
- DD. "Notice of Denial" means a written statement from the State Licensing Authority, articulating the reasons or basis for denial of a license application.

- EE. "Optional Premises Cultivation Operation" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-403, C.R.S.
- FF. "Order to Show Cause" means a document from the State Licensing Authority alleging the grounds for imposing discipline against a Licensee's license.
- GG. "Owner" means the Person or Persons whose beneficial interest in the license is such that they bear risk of loss other than as an insurer, and have an opportunity to gain profit from the operation or sale of the establishment.
- HH. "Person" means a natural person, partnership, association, company, corporation, limited liability company, or organization; except that "Person" does not include any governmental organization.
- II. "Retail Code" means the Colorado Retail Marijuana Code found at sections 12-43.4-101 et. seq., C.R.S.
- JJ. "Retail Marijuana" means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including marijuana concentrate that is cultivated, manufactured, distributed, or sold by a licensed Retail Marijuana Establishment. "Retail Marijuana" does not include industrial hemp, nor does it include fiber produced from stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant which is incapable of germination, or the weight of any other ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other product.
- KK. "Retail Marijuana Cultivation Facility" means an entity licensed to cultivate, prepare, and package Retail Marijuana and sell Retail Marijuana to Retail Marijuana Stores, to Retail Marijuana Product Manufacturing Facilities, and to other Retail Marijuana Cultivation Facilities, but not to consumers, as described in section 12-43.4-403, C.R.S.
- LL. "Retail Marijuana Establishment" means a Retail Marijuana Store, a Retail Marijuana Cultivation Facility, a Retail Marijuana Products Manufacturing Facility, or a Retail Marijuana Testing Facility.
- MM. "Retail Marijuana Products Manufacturing Facility" means an entity licensed to pursuant to these rules to operate a business as described in section 12-43.4-404, C.R.S.
- NN. "Retail Marijuana Product" means concentrated Retail Marijuana Products and Retail Marijuana Products that are comprised of Retail Marijuana and other ingredients and are intended for use or consumption, such as, but not limited to, edible products, ointments, and tinctures.
- OO. "Retail Marijuana Store" means an entity licensed to pursuant to these rules to operate a business as described in section 12-43.4-402, C.R.S.

- PP. "Retail Marijuana Testing Facility" means an entity licensed to pursuant to these rules to operate a business as described in section 12-43.4-405, C.R.S.
- QQ. "Security Alarm System" means a device or series of devices, intended to summon law enforcement personnel during, or as a result of, an alarm condition. Devices may include hard-wired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audible, visual, or electronic signal; motion detectors, pressure switches, duress alarms (a silent system signal generated by the entry of a designated code into the arming station to indicate that the user is disarming under duress); panic alarms (an audible system signal to indicate an emergency situation); and hold-up alarms (a silent system signal to indicate that a robbery is in progress).
- RR. "Shipping Container" means any container or wrapping used solely for the transportation of Retail Marijuana or Retail Marijuana Products in bulk, or in a quantity for other Retail Marijuana Establishments.
- SS. "Standardized Graphic Symbol" means a graphic image or small design adopted by a Licensee to identify its business.
- TT. "State Licensing Authority" means the authority created for the purpose of regulating and controlling the licensing of the cultivation, manufacture, distribution, and sale of medical and Retail Marijuana in this state, pursuant to section 12-43.3-201, C.R.S. UU. "THC" means tetrahydrocannabinol.
- VV. "THCA" means tetrahydrocannabinolic acid.
- WW. "Universal Symbol" means the image established and made available to Licensees by the Division indicating Retail Marijuana or a Retail Marijuana product is within a Container.

R 1000 Series – Labeling, Packaging, and Products Safety

Basis and Purpose – R 1001

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b) and 12-43.3-202(3)(c)(III), C.R.S. Extensive Labeling and secure packaging of Retail Marijuana and Retail Marijuana Products is of statewide concern. A purpose of this rule, and the rules in this series, is to ensure that all Retail Marijuana and Retail Marijuana Products are sold and delivered to lawful consumers in packaging that is not easily opened by children. This rule also clarifies packaging and Labeling terms that will be used throughout this rule and rules in the same series to ensure that Coloradoans are adequately informed. Other graphic identifies will ensure that the Colorado Retail Marijuana and Retail Marijuana Products are easily and readily detectable if they are diverted out of state, and easily tracked back to the retailer, grower or manufacture.

R 1001 – Packaging Requirements: General Requirements

A. Retail Marijuana – General Packaging Requirement for Child- -RESISTANT Packaging. The sale of retail marijuana is prohibited unless previously placed within a Container by a Retail Marijuana

Store. If a Licensee does not place the Container within an Exit Package, the Container must be designed to ensure that the contents are secure and child-resistant, AS DEFINED IN RULE R103(J).

B. Retail Marijuana Product – General Packaging Requirement for Child— -RESISTANT Packaging. The sale of a retail marijuana product is prohibited unless previously placed within a Container by a Retail Marijuana Products Manufacturing Facility. The Container must be designed to ensure that the contents are secure and child-resistant, AS DEFINED IN RULE R103(J).

C. EXCEPTIONS TO PACKAGING REQUIREMENTS – THE SALE OF RETAIL MARIJUANA OR A RETAIL MARIJUANA PRODUCT TO ELDERLY OR PERSONS WITH DISABILITIES WHO ARE UNABLE TO OPEN SPECIAL CHILD-RESISTANT PACKAGING MAY BE PROVIDED IN NONCOMPLYING PACKAGING OF A SINGLE SIZE THAT IS:

- (1) SUPPLIED BY THE INDIVIDUAL, AND
- (2) CONSPICUOUSLY LABELED TO INDICATE THAT THE PRODUCT IS “INTENDED FOR USE BY ADULTS 21 YEARS AND OLDER. NOT FOR USE IN HOUSEHOLDS WHERE YOUNG CHILDREN ARE PRESENT.”

D. REUSABLE PACKAGING – REUSABLE PACKAGING PRODUCTS, SPECIFICALLY DESIGNED FOR MULTIPLE TRIPS AND EXTENDED LIFE, MAY BE USED FOR CONTAINERS AND EXIT PACKAGES IF THE PRODUCTS COMPLY WITH RULE 103(J).

E. Additional Regulation Likely: The State Licensing Authority anticipates that it will further develop these packaging rules, after consultation with the Colorado Department of Public Health and Environment and other interested stakeholders to ensure that the public health and safety is protected.

Basis and Purpose – R 1002

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b) and 12-43.4-202(3)(a)(VII), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of this rule is to ensure that the Labeling on each Container of Retail Marijuana or a Retail Marijuana Product includes necessary and relevant information for consumers does not include health and physical benefit claims, is easily accessible to consumers, and is clear and noticeable.

R 1002 – Labeling Requirements: General Requirements

- A. Labeling Required. All Retail Marijuana and Retail Marijuana Products sold, transferred, or otherwise provided to a consumer must be in a Container that is Labeled with all required information, see Rules R 1003 – Labeling Requirements: Specific Requirements, Retail Marijuana and Retail Marijuana Products and R 1004 – Labeling Requirements: Specific Requirements, Edible Retail Marijuana Products, and that specifically excludes certain text. For compliance with this rule, it is insufficient to affix required Labeling to an Exit Package.
- B. Health and Benefit Claims. Labeling text on a Container may not make any false or misleading statements regarding health or physical benefits to the consumer.
- C. Font Size. Labeling text on a Container must be no smaller than 1/16 of an inch.
- D. Use of English Language. Labeling text on a Container must be clearly written or printed and in the English language.

- E. Unobstructed and Conspicuous. Labeling text on a Container must be unobstructed and conspicuous. A Licensee may affix multiple Labels to a Container, provided that none of the information required by these rules is completely obstructed.
- F. Additional Regulation Likely. The State Licensing Authority anticipates that it will further develop these Labeling rules, after consultation with the Colorado Department of Public Health and Environment and other interested stakeholders to ensure that the public health and safety is protected.

Basis and Purpose – R 1003

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b) and 12-43.4-202(3)(a)(VII), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of this rule is to ensure that each Container of Retail Marijuana includes necessary and relevant Labeling information for consumers.

R 1003 – Labeling Requirements: Specific Requirements, Retail Marijuana and Retail Marijuana Products

- A. Retail Marijuana Container Labeling Must Include the Following Information:
 - 1. The license number of the Retail Marijuana Cultivation Facility or Retail Marijuana Cultivation Facilities where the Retail Marijuana within the Container was grown.
 - 2. The license number of the Retail Marijuana Store that sold the Retail Marijuana to the consumer.
 - 3. The Identity Statement and Standardized Graphic Symbol of the Retail Marijuana Store that sold the Retail Marijuana to the consumer. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request.
 - 4. The Batch Number or numbers assigned by the Retail Marijuana Cultivation Facility to the marijuana plant or plants from which the Retail Marijuana contained within the Container was harvested.
 - 5. The date of sale to the consumer.
 - 6. The net weight, in grams, of the Retail Marijuana prior to its placement in the Container.
 - 7. The following warning statements:
 - a. “There may be health risks associated with the consumption of this product.”
 - b. “This product is intended for use by adults 21 years and older. Keep out of the reach of children.”
 - c. “This product is unlawful outside the State of Colorado.”
 - 8. A Universal Symbol, indicating that the Container holds marijuana, which must be no smaller than 1/4 of an inch by 1/4 of an inch.
 - 9. A Cannabinoid potency profile that must list, at minimum, the concentration of THC, THCA, CBD, CBDA, CBN, and CBG as a percentage of the total weight of the product.
 - 10. The amount, in milligrams, of THC in each gram of the Retail Marijuana.
 - 11. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Retail marijuana contained within the Container.

12. A complete list of solvents and chemicals used in the creation of any Retail Marijuana concentrate.

B. Retail Marijuana Products Container Labeling Must Include the Following Information:

1. The license number of the Retail Marijuana Cultivation Facility or Retail Marijuana Cultivation Facilities where the Retail Marijuana used to manufacture the Retail Marijuana Product within the Container was grown;
2. The license number of the Retail Marijuana Store that sold the Retail Marijuana Product to the consumer;
3. The license number of the Retail Marijuana Products manufacturer that manufactured the Retail Marijuana Product;
4. The Identity Statement and Standardized Graphic Symbol of the Retail Marijuana Store that sold the Retail Marijuana Product to the consumer. A Licensee may elect to have its Identity Statement also serve as its Standardized Graphic Symbol for purposes of complying with this rule. The Licensee shall maintain a record of its Identity Statement and Standardized Graphic Symbol and make such information available to the State Licensing Authority upon request;
5. The Batch Number or numbers assigned by the Retail Marijuana Cultivation Facility to the marijuana plant or plants from which the Retail Marijuana used to manufacture the Retail Marijuana Product contained within the Container was harvested;
6. The date of sale to the consumer;
7. The following warning statements:
 - a. "There may be health risks associated with the consumption of this product."
 - b. "This product is intended for use by adults 21 years and older. Keep out of the reach of children."
 - c. "This product is unlawful outside the State of Colorado."
 - d. "This product is infused with Retail Marijuana."
 - e. "This product was produced without regulatory oversight for health, safety, or efficacy."
 - f. "The intoxicating effects of this product may be delayed by two or more hours."
8. A Universal Symbol, indicating that the Container holds marijuana, which must be no smaller than 1/4 of an inch by 1/4 of an inch;
9. A clear set of instructions for proper usage;
10. A Cannabinoid potency profile that must list, at minimum, the concentration of THC, THCA, CBD, CBDA, CBN, and CBG as a percentage of the total weight of the product;
11. The amount, in milligrams, of THC in each gram of the Retail Marijuana used in the Retail Marijuana Product;
12. A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Retail Marijuana contained within the Container; and
13. A complete list of solvents and chemicals used in the creation of any Retail Marijuana concentrate used in the manufacture of the Retail Marijuana Product.

Basis and Purpose – R 1004

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b) and 12-43.4-202(3)(a)(VII), 12-43.4-202(3)(c)(V) and 12-43.4-202(3)(c)(VI), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VI). The purpose of this rule is to ensure that each Container of an Edible Retail Marijuana Product includes necessary and relevant information for consumers.

R 1004 – Labeling Requirements: Specific Requirements, Edible Retail Marijuana Products

- A. THC Information Statement. The following consumer information statement: “The standardized serving size amount for this product that does not contain more than ten milligrams of active THC. This Container includes ___ servings.”
- B. Ingredient List. A list of all ingredients used to manufacture the Edible Retail Marijuana Product; which may include a list of any potential allergens contained within, or used in the manufacture of, the Retail Marijuana Product.
- C. Statement Regarding Refrigeration. A statement that the Retail Marijuana Product, if perishable, must be refrigerated.
- D. Statement of Expiration Date. A product expiration date, for perishable Retail Marijuana Products, upon which the product will no longer be fit for consumption, or a use-by-date, upon which the product will no longer be optimally fresh. Once a Label with a use-by or expiration date has been affixed to a Container of a Retail Marijuana Product, a Licensee shall not alter that date or affix a new Label with a later use-by or expiration date.
- E. Label May Be Affixed. A Licensee may, but is not required to, affix a Label to each Container of an Edible Retail Marijuana Product that provides the following information:
 - 1. A statement regarding the Retail Marijuana Product’s compatibility with dietary restrictions; and
 - 2. A nutritional fact panel that, if included, must be based on the number of THC servings within the Container.