

Date of Hearing: April 18, 2017

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Rudy Salas, Chair

AB 175 (Chau) – As Introduced January 17, 2017

***NOTE:** This bill is double referred, and if passed by this Committee, it will be referred to the Assembly Committee on Health.*

SUBJECT: Adult-use marijuana: marketing: packaging and labeling.

SUMMARY: This bill requires manufacturers of edible cannabis products to submit packaging for each product intended for sale in California to the Bureau of Medical Cannabis Regulation (Bureau) within the Department of Consumer Affairs (DCA) for review; and provides a 60 day review period for the Bureau to ensure that packaging meets the standards established in the division for child resistant packaging. This bill requires the Bureau to notify the manufacturer in writing and the manufacturer may pursue a reassessment of the packaging and labeling; any time a manufacturer makes a material change to the packaging or labeling of a product, it must resubmit it to the Bureau for evaluation. to cover the cost of the evaluation, the bill permits the Bureau to charge a fee to manufacturers.

EXISTING LAW:

- 1) Requires a manufacturer, prior to delivery or sale, to label and place marijuana products in a resealable, child resistant package. Packages and labels shall not be made to be attractive to children and must be labeled clearly as containing a marijuana product. (Business and Professions Code (BPC) Section 26120)
- 2) All marijuana and products must be labeled and must include the manufacture date and source, the appellation of origin (if any), list of pharmacologically active ingredients, a list of all ingredients and nutritional information, any solvents, nonorganic pesticides, or fertilizers, a warning if allergens are used in manufacturing, and one of the following statements: (BPC Section 26120)
 - For marijuana: GOVERNMENT WARNING: THIS PACKAGE CONTAINS MARIJUANA, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. MARIJUANA MAY ONLY BE POSSESSED OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER UNLESS THE PERSON IS A QUALIFIED PATIENT. MARIJUANA USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF MARIJUANA IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.”
 - For marijuana products: “GOVERNMENT WARNING: THIS PRODUCT CONTAINS MARIJUANA, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. MARIJUANA PRODUCTS MAY ONLY BE POSSESSED OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER UNLESS THE PERSON IS A QUALIFIED PATIENT. THE INTOXICATING EFFECTS

OF MARIJUANA PRODUCTS MAY BE DELAYED UP TO TWO HOURS. MARIJUANA USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF MARIJUANA PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.”

- 3) Requires that marijuana products shall:
 - Not be designed to appeal to children or be easily confused with commercially available candy or foods.
 - Have a standardized dosage up to 10 milligrams tetrahydrocannabinol (THC) per serving.
 - Be scored or easily broken up into standardized serving sizes if the product contains more than one serving and is in solid form.
 - Be homogenized to ensure uniform distribution of cannabinoids throughout the product.
 - Be manufactured and sold in sanitary conditions and provided to customers with sufficient information to enable informed consumption. (BPC Section 26130)
- 4) Prohibits the sale or transfer of marijuana products to minors and forbids the presence of anyone under the age of 21 on any licensed premises. (BPC Section 26140)

THIS BILL:

- 1) Requires manufacturers, before introducing an edible marijuana product to market in California, to submit the packaging and labeling to the Bureau to be evaluated for whether the packaging and labeling comply with the requirements set in law.
- 2) Requires the Bureau to complete its initial determination within 60 days and if there is a delay, must notify the manufacturer at which date the determination is expected to be made. Determinations must be made in writing.
- 3) Requires that if the Bureau determines that the packaging and labeling are not in compliance, then the manufacturer shall have 60 days to redesign and submit the packaging for reassessment. The Bureau must then make the determination within 30 days and notify the manufacturer in writing.
- 4) Requires that, if, after resubmission, the Bureau still does not approve the design, the manufacturer may request an administrative hearing within 30 days of the Bureau’s notice.
- 5) Requires that any time a manufacturer seeks to make a change to the packaging or labeling, the manufacturer must resubmit the packaging and labeling to the Bureau for reassessment.
- 6) Permits the Bureau may charge a fee to the manufacturer to cover the costs of administering the approval process.

FISCAL EFFECT: Unknown. This bill is keyed fiscal by legislative counsel.

COMMENTS:

Purpose. This bill is sponsored by the **National Union of American Physicians and Dentists** as well as the **American Federation of State, County and Municipal Employees (AFSCME) AFL-CIO**. According to the author, “As it pertains to marijuana legalization in California, children must come first. In a recent newspaper article, Colorado Governor John Hickenlooper was adamant that his state “didn’t regulate edibles strongly enough at first.” As a result, Colorado experienced a spike in emergency room visits by children who had consumed marijuana products, and one instance of an underage individual dying after ingesting marijuana. In an attempt to curb the potential for unsafe packaging and marketing of edible marijuana products to children, Washington requires their State Liquor and Cannabis Board to approve the labeling and packaging for all marijuana infused products, prior to offering these items for sale in retail stores. With edibles growing in popularity as an alternative form for consuming marijuana, it is important that we establish a packaging and labeling approval process to ensure that these products are child resistant, and not made in a way that is specifically attractive to children.”

Background. This bill seeks to protect minors from cannabis products by requiring cannabis product manufacturers to submit labeling and packaging for any new cannabis product to the Bureau for evaluation of conformance with statute.

The bill also places strict prohibitions on the collection and use of data from underage users, explicitly stating that personally identifiable information may not be collected in the course of advertising or seeking to advertise marijuana or related products and services.

History of Legal Cannabis in California - In 1996, California voters passed Proposition 215, legalizing the use of medical cannabis (MC) in the state. In October 2015, nearly 20 years after the authorization of the use of MC, Governor Jerry Brown signed into law a trio of bills [AB 243 (Wood), Chapter 688, Statutes of 2015, AB 266 (Bonta, Cooley, Jones-Sawyer, Lackey, and Wood), Chapter 689, Statutes of 2015, and SB 643 (McGuire), Chapter 719, Statutes of 2015] collectively known as the Medical Cannabis Regulation and Safety Act (MCRSA). MCRSA established the state's first regulatory framework for MC. In 2016, the voters of California passed Proposition 64, the Adult Use of Marijuana Act (AUMA), to legalize the recreational use of cannabis in the state by 2018.

As of 2016, 28 states, the District of Columbia, and Guam allow MC programs. Even though California was the first to authorize the medical use of cannabis, it was the only state that allowed cannabis-use without a robust state regulatory framework until passage of MCRSA. States with MC laws generally have a form of patient registry, which may provide some protection against arrest for possession up to a certain amount of cannabis for personal medicinal use. A limited number of states restrict MC usage to products with low to zero THC and high CBD concentrations, in an effort to more strictly limit the use of THC due to its known psychoactive effects. To date, eight states, Alaska, Colorado, Oregon, Washington, California, Nevada, Massachusetts, Maine, and the District of Columbia have legalized recreational cannabis.

The authors of AUMA sought to make use of much of the regulatory structure and authorities set out by MCRSA while making a few notable changes to the structure being implemented. In addition, the AUMA approved by the voters adopted the January 1, 2018 deadline for state

implementation of recreational cannabis in addition to the regulations required in MCRSA that are scheduled to take effect on the same date. The same agencies as under MCRSA remain responsible for implementing regulations for adult use.

Under AUMA, the Department of Consumer Affairs (DCA), continues to serve as the lead regulatory agency for all cannabis, both medical and non-medical, and renames the existing Bureau of Medical Cannabis Regulation as the Bureau of Marijuana Control. AUMA includes 19 different license types compared to the 17 in MCRSA and authorizes DCA (and the Bureau) the exclusive authority to create and regulate a license for transportation of cannabis.

While the language of AUMA allows for modifications to the law by majority vote of the legislature, any legislative changes inconsistent with the original intent of the law may require voter approval. If the state and its various agencies of jurisdiction have not finalized regulations, hired staff, and created technology solutions by January 1, 2018, it is unclear how wide-sweeping and detrimental the consequences may be.

Child-Resistant Marijuana Packaging – The regulation of cannabis has been subdivided between three state agencies: 1) the California Department of Food and Agriculture (CDFA) will regulate the cultivation of cannabis, 2) the Department of Public Health (DPH) will regulate cannabis products, including edibles, and 3) the Bureau under the direction of DCA will regulate commerce and handle the largest segment of enforcement. Agencies are in the process of creating regulations in accordance with MCRSA and are expected to release the initial regulations in April of 2017.

Current law requires marijuana products to be labeled and packaged in a resealable, child-resistant package and stipulates that packages and labels shall not be made attractive to children. The law does not state by which standards packaging would be determined to be child resistant or what constitutes labeling that is unattractive to children. There are a number of such vague prescriptions in current law that will be clarified by regulation when it is implemented. Most relevant to this bill will be the regulations issued by DPH regarding edibles and their manufacture and sale. These regulations have been broadly outlined, including the likely restriction on anything other than “shelf-stable” products and an emphasis on preventing the diversion and accidental consumption of cannabis products by minors, however it is not clear how these regulations would tackle the issues raised in this bill.

The cannabis industry, regulators, and lawmakers are concerned about the accidental consumption of cannabis and cannabis products by children. In response to these concerns, the California Cannabis Industry Association (CCIA) released a white paper on October 26, 2016 outlining its position on this issue. Specifically, the paper highlights concerns that child resistant packaging is only intended to prevent access by children five years of age or younger and that child resistant packaging fails to prevent teens from accessing cannabis. This issue is bolstered by data from the Washington Poison Center, which indicates that in 2015 it received 272 calls for exposure to cannabis products, of which, 46 percent, 126 calls, were regarding children. Of those 126 calls, most involved teens, nearly 25 percent of all cannabis related poison center calls statewide. (Washington Poison Center Toxic Trends Report: 2015 Annual Cannabis Report)

Pediatric Cannabis Exposure - In September 2016, the American Medical Association published a study comparing the incidence of exposure to cannabis before and after the legalization of

recreational cannabis and found that Colorado saw more cases of unintentional pediatric exposure to cannabis than the rest of the United States. Specifically the study found that the mean rate of exposure increased from 1.2 per 100,000 population two years prior to legalization to 2.3 per 100,000 population two years after legalization. (Wang, Le Lait, Deakyne, et al. “Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015” *JAMA Pediatrics*.) While Colorado’s increase of 34 percent per year of exposure is higher than other states, it is notable that pediatric cannabis exposure is on the rise generally in the United States, increasing 19 percent over the same time period. The study found that when the source of the exposure was known, 48 percent included cannabis edibles and 40 percent of scenarios were attributed to poor-child supervision or product storage. For 9 percent of cases, the product was not in a child resistant container.

Similar Statewide Labeling Approvals – As recently as 2015, beer makers in the state were required to submit labels to the California Department of Alcohol Beverage Control (ABC) in a similar effort to protect the health, safety and welfare of the people of the state. This practice was ceased by the passage of AB 893 (Stone, Chapter 410, Statutes of 2015) as the growth of the craft beer industry had led to a large backlog of label approvals at ABC, creating a bottleneck in the industry that prevented inventory from getting to shelves in a timely fashion and created economic harm to brewers. The bill placed the responsibility for compliance on brewers and granted full authorization to ABC to enforce noncompliance.

Current Related Legislation. AB 350 (Salas) requires that marijuana products shall not be manufactured in the shape of a person, animal, insect, fruit, or any other shape normally associated with candy. *STATUS: This bill has been referred to the Assembly Committee on Health*

AB 389 (Salas) requires the Bureau to establish and make available a guide for consumers to educate the public on the regulation of medical and nonmedical marijuana. *STATUS: This bill has been referred to the Assembly Committee on Business and Professions*

AB 64 (Bonta, Cooley, Jones-Sawyer, Lackey, Wood) seeks to reconcile a number of differences between MCRSA and AUMA to provide clarity in regulation and enforcement of both medical and recreational cannabis. *STATUS: This bill has been referred to the Assembly Committee on Business and Professions and will be heard on April 18, 2017*

Prior Related Legislation. AB 266 (Bonta, Cooley, Jones-Sawyer, Lackey, Wood) part of the legislative package that became known as MCRSA, and required the regulation of medical cannabis products, including edibles.

ARGUMENTS IN SUPPORT:

Union of American Physicians and Dentists “AB 175 is ultimately about keeping California children safe and healthy during their formative years, which we believe to be of utmost importance.”

Community Action Service Advocacy for Safe & Healthy Neighborhoods “[We are] pleased to support AB 175 because it puts child safety first, and aims to make sure that marijuana commercialization is implemented in a safe responsible way.”

Gatekeeper Innovation Inc. “AB 175 is a good step towards putting child safety first, and aims to make sure that marijuana legalization is implemented in a safe and responsible way. We hope that the legislature will continue to push for the safe storage of medical marijuana products, and for those reasons we are pleased to support your bill.”

Saving Lives Camarillo “[We are] pleased to support AB 175 because it puts child safety first, and aims to make sure that marijuana commercialization is implemented in a safe, responsible way.”

Youth Forward “We appreciate your efforts through AB 175 to create a more robust review process of marijuana packaging and labeling to insure that marijuana products are not designed to appeal to kids and are labeled appropriately.”

Nurse Family Partnership “[We are] pleased to support AB 175 because it puts child safety first, and aims to make sure that marijuana legalization is implemented in a safe, responsible way.”

Consumer Federation of California “AB 175 provides important oversight for marijuana-infused edible products and protections against marketing practices that may appeal to children.”

American Federation of State, County, and Municipal Employees (AFSCME), AFL-CIO “California has a responsibility to protect the health and wellbeing of its residents, especially youth. As such, AFSCME strongly urges legislative approval for this measure in order to appropriately address public health concerns.”

California Chapter of the American College of Emergency Physicians “AB 175 is an important injury prevention measure that amends the Control, Regulate, and Tax Adult Use of Marijuana Act (AUMA).”

Common Sense Kids Action “AB 175 puts kids first by ensuring that as California legalizes the adult use of marijuana, children are protected from the potential for unsafe packaging and targeted marketing for edible marijuana products.”

California Police Chiefs Association Inc. “As the Legislature works to develop one system for cannabis regulation, we urge you to monitor any shifts in regulatory jurisdiction to assure that AB 175 works seamlessly with the broader effort to reconcile the Medical Cannabis Regulation and Safety Act and the Adult Use of Marijuana Act.”

National Association of Social Workers “(NASW-CA) supports AB 175 (Chau), which would require manufacturers of adult use marijuana to receive approval from the Bureau of Marijuana Control before releasing edible products, to ensure that the products are in compliance with child safety and marketing provisions specified under Proposition 64.”

California Association of Highway Patrolmen “We thank you for authoring this legislation and we look forward to its successful passage.”

California Children’s Hospital Association “AB 175 will ensure that manufacturers package their edible marijuana-infused products in compliance with these provisions, helping to protect children from inadvertent and potentially toxic exposure.”

California State PTA “California State PTA strongly supports these requirements for the protection of all children and youth and again asks for your aye vote to set strong standards for marijuana edible regulations in advance of the act taking effect on January 1, 2018”

ARGUMENTS IN OPPOSITION:

California Cannabis Industry Association “CCIA fully supports the need to curb the potential for unsafe packaging and marketing of edible cannabis products to children. That is why we have been proactively working with the California Department of Public Health, which is tasked with developing regulations governing cannabis manufacturers and standards for the manufacturing and labeling of all manufactured cannabis products, including edibles.

CCIA’s work also includes the development of a website promoting safe and responsible cannabis use, as well as several white papers on child resistant packing, safe manufacturing practices, and a code of conduct for responsible cannabis advertising and marketing.

Specifically, we must oppose your bill for the following reasons:

- AB 175 is premature. The California Department of Public Health is expected to release its draft regulations later this month. Therefore, it is premature to be imposing additional requirements in advance of those regulations.
- AB 175 will slow down the implementation of the new regulatory system for cannabis. Requiring that the state create a system for approving all packaging on top of the work the licensing entities are already having to do is not practical at this time.
- AB 175 creates possible liability for the state. Requiring that a state regulator be the deciding factor in determining what packaging is attractive to children and what isn’t, opens the state up to potential liability.”

POLICY ISSUES FOR CONSIDERATION: The prevention of accidental ingestion of cannabis and cannabis products by not only minors, but any unintentional consumer, is of paramount importance to the Legislature and regulators. However, it is unclear if the provisions contained in this legislation will be effective at doing so. There are a number of packaging solutions that are already available to the industry that may achieve the goal of preventing children from consuming cannabis products. It is unclear if the pending regulations from DPH will be sufficient to prevent accidental consumption. Further, in the 2016 American Medical Association study, only 9 percent of cases of accidental exposure involved cannabis or cannabis products that were not in child-resistant packaging.

Additionally, while the aforementioned report from the Washington Poison Center demonstrates an uptick in cannabis related calls from 2014 to 2015, the vast majority of these cases involved teenage children who would likely not be deterred by child resistant packaging. The most

common clinical effects displayed were drowsiness/lethargy and tachycardia. To ensure that diversion and exposure are prevented to populations over the age at which children learn how to operate child resistant packaging, other solutions outside of packaging and labeling should be considered.

It is unclear if the Bureau will be able to recoup its costs through fee collection, most of which would likely be cash since the cannabis industry is largely unbanked. As packaging review program is not currently active, it is difficult to know what the scope of agency involvement would be and how many additional staff would be necessary to implement the bill effectively should it be enacted. Also, since DPH is the regulating agency for the manufacture and regulation of cannabis edibles, it is unclear how much institutional knowledge is present at the Bureau within DCA to carry out this work.

While the emphasis of the state is and should be placed on consumer protection rather than industry convenience, it is unclear whether extended timelines for approval of edible packaging and labeling would lead to diversion of products to the black market or circumvention of the review process all together. The initial time period for review of 60 days, followed by possible extensions of 30 days, an appeal of 60 days, another review period of 30 days, and a potential extension of an additional 30 days for an administrative hearing, could extend the overall process for nearly six months, tying up potential inventory and risking legal action from manufacturers or diversion.

The author should consider working with the Bureau and stakeholders to determine whether further action should be taken to prevent exposure to cannabis products by teens and to evaluate whether the Bureau is equipped and capable of fulfilling its mandate under this legislation.

IMPLEMENTATION ISSUES:

The existing text is that the bill references the division generally, without citing which part of statute must be complied with. This ambiguity may cause confusion for manufacturers and the enforcement staff alike, especially in light of pending regulations. Further, creating additional review processes in addition to the compliance already required in statute may cause a delay in the implementation of regulations. While the timeline in the bill provides accommodations to both the Bureau and industry to accommodate logistical challenges and possible delays, the extended time period could cause temptation for manufacturers or employees to engage in product diversion or could result in economic harm.

REGISTERED SUPPORT:

Union of American Physicians and Dentists
Community Action Service Advocacy for Safe & Healthy Neighborhoods
Saving Lives Camarillo
Gatekeeper Innovation Inc.
Youth Forward
Nurse Family Partnership
Consumer Federation of California
American Federation of State, County, and Municipal Employees (AFSCME), AFL-CIO
California Chapter of the American College of Emergency Physicians

Common Sense Kids Action
California Police Chiefs Association Inc.
National Association of Social Workers
California Association of Highway Patrolmen
California Children's Hospital Association
California State PTA

REGISTERED OPPOSITION:

California Cannabis Industry Association

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