11. ***§ 5311. Requirements for the Transportation of Cannabis Goods***
12. ***§ 5413. Cannabis Goods Packaging and Exit Packaging***
13. ***§ 5417. Delivery Vehicle Requirements***
14. ***§ 5718. Residual Solvents and Processing Chemicals Testing***
15. ***§ 5722. Foreign Material Testing***
16. ***§ 5724. Cannabinoid Testing***
17. ***§ 5726. Certificate of Analysis (COA)***

§ 5032. Commercial Cannabis Activity

§ 5032(b) adds a new provision that would prohibit a licensee's ability to enter into contractual agreements with entities not in possession of a commercial cannabis license.

Concern*:* The blanket prohibition, as outlined in § 5032(b), represents a sweeping change that would prohibit licensees from packaging and labeling cannabis products developed by individuals and entities not currently in possession of a state license.

While CCIA recognizes the intent of existing law - to only permit licensees to conduct commercial cannabis activity with other licensee - this language would prohibit brand partners, that simply license intellectual property, from entering into contractual arrangements with licensed businesses to manufacture their cannabis products.

White labeling and co-packing is a common practice across many industries. Prohibiting this activity unnecessarily restricts individuals and entities with innovative new products from participating in the market with no measurable, positive impact on consumer and public safety.

With only 35 percent of local jurisdictions authorizing some form of commercial cannabis activity, having the ability to utilize licensed cannabis businesses to manufacture products developed by third party entities is essential. White labeling and co-packing:

- Provides a pathway for boutique and social equity operators to build their brands;
- Preserves legacy brands, that can no longer legally manufacture their products, by allowing them to remain in the legal marketplace;
- Provides additional capital for existing, licensed manufacturers to meet the rigorous regulatory standards and taxation requirements;
- Promotes economic growth in the legal market by offering more safe compliant products that correspond to consumer demands; and
- Provides a mechanism for existing cannabis manufacturers to mitigate IRS rule 280E, which prohibits the deduction of normal business expenses[1].

[1] Many legal cannabis businesses structure the companies, so that the "non-plant touching" activities of their businesses, including management services, administration, human relations, and intellectual property, are established as separate business entities. This allows them to take standard business deductions that would otherwise be disallowed, as IRS § 280E forbids "plant touching" cannabis businesses from deducting other ordinary business expenses.

Recommendation: We strongly oppose this change and recommend that § 5032(b) be removed to provide sufficient time for the Bureau and stakeholders to find a mutually agreeable solution. Such a solution should permit white labeling and co-packing activities, while ensuring that such contractual arrangements are properly disclosed. We equally believe that any solution must also address advertising to ensure that non-licensees with cannabis brands are subject to the same advertising restrictions as licensees.

§ 5003. Designation of Owner

Proposed changes to § 5003 significantly expand the definition of "Owner" for purposes of applying for a state license to include individuals that assume mid-level management responsibilities within a cannabis business, including, but not limited to individuals engaged in non-plant-touching portions of the business operation. Changes further define owners as all entities and individuals with a financial interest in the entity, including, but not limited to all entities in a multi-layer business structure, partners (whether managing or passing), trustees and all persons that have control of a trust, managing members and non-member managers of an entity.

Concern: The definition of cannabis business "Owner" was the subject of significant debate and discussion in the California State Legislature beginning in 2015 as the medicinal cannabis framework was being developed. After careful negotiations between the legislature and numerous stakeholders, consensus was finally reached in 2017 with the passage of SB 94, which enacted the Medicinal and Adult Use Cannabis Regulation and Safety Act. Under the statutory definition, an owner is defined as any of the following: 1) A person with an aggregate ownership interest of 20 percent or more in the person applying for a license or a licensee, unless the interest is solely a security, lien, or encumbrance; (2) The chief executive officer of a nonprofit or other entity; (3) A member of the board of directors of a nonprofit; or (4) An individual who will be participating in the direction, control, or management of the person applying for a license.

While CCIA recognizes the need to appropriately disclose owners and individuals with an aggregate interest of 20 percent or more and/or executives that have direct control over business operations, the new language is excessively broad and has the potential to inadvertently capture a significant number of mid-level employees who do not have a direct ownership and/or exercise any control of business, as well a individual and entities with no direct control over the business operation.

Recommendation: We recommend that the changes currently proposed be stricken and that the BCC adopt the language, as proposed in the original draft released in July.

§ 5004. Financial Interest in a Commercial Cannabis Business

Proposed changes in this section significantly expand which persons and/or entities must be disclosed as part of the license application to include employees with an equity interest in the cannabis business,

salespeople who earn commissions, as well as consultants, attorneys and other contractors who provide services for a share of the profits.

***Concern**:* CCIA questions the need for this level of disclosure, which we believe is excessive and unnecessary. As we discussed in our comments relative to § 5003 above, financial disclosure was the subject of careful legislative negotiations that aimed to strike the appropriate balance between ensuring appropriate financial disclosure of individuals and entities while ensuring that access to capital was not hindered as a result of excessive and burdensome disclosure requirements that stifle investment.

Without considerable revisions, we believe the new language as proposed in draft two of the regulations will result in substantial expense to those compliant businesses, who will likely be forced to disclose, on a potentially weekly basis, changes concerning individuals with and equity interest in the business and/or shareholders in publicly traded companies. We further believe that such disclosure will be equally burdensome on the Bureau, which will be inundated with inquiries concerning who and what entities should be disclosed, as well as processing notifications of changes in a cannabis business's financial interests.

Recommendation: We recommend that changes proposed be stricken and that the BCC adopt the language, as proposed in the original draft released in July. Should the Bureau feel additional financial disclosure is still necessary, we recommend that other options be considered, including, but not limited to, increasing the threshold for financial interest holders in a publicly traded company and excluding from disclosure the financial interest of a person or entity holding less than five percent of a financial interest in a cannabis business.

§ 5014. Fees

§ 5014 adjusts the scaling and tiering of the licensing fees to reflect the sizes and types of the business entities seeking licensure. As described in the Bureau's notice of modification, the changes to the licensing fees are now based on estimated gross revenue for the 12-month license period.

Concern: While CCIA appreciates the Bureaus efforts to provide more tiers, which will inevitably reduce licensing fees for many cannabis businesses, the testing lab fees are significantly higher than the proposed licensing fees for distribution, retail or microbusiness with similar gross revenues. For instance, a lab with gross revenues of $1.5 million must pay $32,000 compared to distributors who would pay $6000, retailers who pay $11,000 and microbusiness who would pay $12,000. This is a substantial burden on what is already considered the bottleneck in a newly regulated industry. The fact that the fees are based on gross revenue is noteworthy because testing labs must usually deploy large amounts of capital expenses on instrumentation when certain thresholds (based on instrument load and revenue) are met.

Furthermore, laboratories service the only statutorily mandated part of the supply chain. All cannabis products, regardless of type, must be tested by a licensed testing facility, which means laboratories often handle large work loads.

Recommendation: We recommend that the testing lab fee schedule be re-evaulated to reflect the essential role of labs in ensuring consumer health and safety. This would include consideration of the excessive operating expenses encumbered by labs that far exceed those of other licensed entities.

§ 5015. Payment of Fees

This section specifies the manner is which licensing fees must be paid to the Bureau, and outlines grounds for disciplinary action when it is determined that the license holder paid less than the appropriate amount.

***Concern*:** CCIA recognizes that this section did not change since draft one of the proposed regulations were released in July and that our comments may, therefore, not be considered. However, we would argue that the modifications to the fee schedule contained in § 5014 may require a reconsideration of the 50 percent penalty fee. While we understand that the imposition of the 50 percent penalty is at the discretion of the Bureau and that it may not be imposed, we believe is equally important to note the 50 percent penalty was developed when there were less tiers and the threshold within each tier reduced the chances that a licensed cannabis business would underestimate its appropriate licensing fee.

Recommendation: In light of the significant modifications to the fee schedule contained in § 5014, we recommend that the penalty fee of 50 percent of the appropriate licensing fee be reduced in a manner that is more commensurate with the scaling and tiering of the licensing fees, or include an option to refund a portion of the licensing fee if gross receipts are less than projected.

§ 5040.1. Marketing Cannabis Goods as Alcoholic Products

This section prohibits licensees from selling or transporting cannabis goods that are labeled as beer, wine, liquor, spirits, or any other term that may create a misleading impression that the product is an alcoholic beverage.

Concern: While we appreciate the intent of the of this section, we are concerned that what is and is not permissible will be subjective and lead to differing interpretations by cannabis distributors and retailers.

Recommendation: The Bureau may wish to issue further guidance on this section to minimize the number of inquiries it will likely receive concerning what is permissible and what is not.

§ 5050. Loss of Access

This provision stipulates that if a licensee loses access to the track-and-trace system—through no fault of its own—it must cease delivering any cannabis goods until such time as access is restored.

Concern: When METRC goes live, it will have had no prior beta or field testing. This means loss of access is, at some point, an inevitability. Under the proposed language, a METRC outage of as little as a week could cause massive financial damage to cannabis businesses and the state alike, costing millions of dollars in lost sales and potential tax revenue. Furthermore, the requirement that businesses must have files back online within three days is difficult, especially in cases of extended METRC outages.

Additionally, the proposed language change from "business" days to "calendar" days is problematic. It is not only inconsistent with operating hours of other regulated industries, but is inconsistent with the hours the regulators themselves operate during. This definition also effectively denies cannabis businesses the holidays that other industries are granted.

Recommendation: We request that the BCC eliminate § 5050(b) which requires licensees to stop deliveries and transport during an outage, and instead simply require licensees to:

1. Maintain paper records during any outage per § 5050(a), and
2. Enter activity that occurred during the loss of access into the track-and-trace system within 3 days of access being restored per § 5050(c)(1) and (2).

We would also request that the BCC revert back to business days rather than calendar days.

§ 5301(b) - Distributor Storage Services

Concern: New proposed language in § 5301(b) suggesting that licensed distributors may only provide storage services for cannabis goods "packaged as they will be sold at retail" is problematic. Storage services of (holding custody but not title to) bulk flower or bulk oil on behalf of another party is a common and necessary business model, whereby a distributor providing storage services can provide a safe, secure location for the goods to be held while the owner of the goods identifies a buyer, or whereby the storage distributor may also facilitate the co-packing of flower from bulk to packaged as part of a supply chain service to make the goods marketable to a buyer. These aggregation centers are common and facilitate a need to individual producers who may not have the proper facilities to aggregate and package, but who want to maintain ownership of their product and dictate to whom the end product will be sold.

Recommendation: We recommend that changes in draft two be stricken and that the Bureau adopt the language, as proposed in the original draft released in July.

§ 5303(b) - Distributors rolling pre-rolls

Concern: New proposed language in § 5303(b) allowing distributors to roll pre-rolls "that consist exclusively of any combination of flower, shake, leaf, or kief" is a positive clarification. Further defining that, "Pre-rolls shall be rolled prior to regulatory compliance testing" is understandable.

Recommendation: To avoid massive batches of mixed pre-roll contents, the regulations should further clarify that all pre-rolls be treated as cannabis for the purposes of the batch sampling requirements, whereby a fifty-pound batch is the maximum batch size for pre-rolls versus 150,000 units, the maximum batch size for manufactured products.

§ 5303(c) - Distributors labeling and relabeling manufactured cannabis goods

Concern: New proposed language in § 5303(c) clarifying that distributors may label and re-label manufactured cannabis goods with amounts of cannabinoids and terpenes is a positive improvement and clarification.

Recommendation: Clarification is needed to make certain that distributors may also re-label for further compliance. For example, if a label is missing certain labeling requirements, or new regulatory guidance requires additional label information, businesses should have the ability to correctly re-label batches, thus allowing them to remain compliant and retail-ready.

§ 5311. Requirements for the Transportation of Cannabis Goods

This provision added the requirement that the cannabis goods in distribution vehicles must be in a fully enclosed box and no portion of the enclosed box, container, or cage shall be comprised of any part of the body of the vehicle or trailer.

Concern: § 5311 is problematic as it would prohibit the use of the body of the vehicle as a portion of the required enclosed box, container, or cage. This has a heavier impact on distribution, because a cage would not require a full six sides that are not the vehicle walls, including the floor and roof, rather than just partitioning the vehicle into the driver area and the storage area.

We fail to understand the justification for this change which would impose significant challenges including additional costs, while providing no additional protections on secure vehicles that are held to the highest safety and security standards.

Recommendation: We recommend that changes in § 5311 (f) be stricken and that the Bureau adopt the language as proposed in the original draft released in July.

§ 5413. Cannabis Goods Packaging and Exit Packaging

Concern: CCIA spent hundreds of hours discussing the nuances of child resistant packaging, exit bags, liability, and public perception. Every angle was reviewed and debated, and every outcome was weighed. Our committees, committee chairs, and board of directors came to consensus in support of the original text of § 5413, and continue to stand behind child resistant packaging being met by exit bags.

Recommendation: We recommend that changes in draft two be stricken and that the Bureau adopt the language, as proposed in the original draft released in July.

§ 5417. Delivery Vehicle Requirements

Concern: § 5417 (d) states that the history of all locations traveled to by a delivery employee while engaging in delivery shall be maintained by the licensee for a minimum of 90 days. This seems like an excessive amount of time for these records to be kept. This could result in higher operating costs for delivery operators. It's unclear if these records need to be kept in hard copy form.

***Recommendation**:* We request clarification detailing that such records can be kept electronically, rather than in a hard-copy form. Furthermore, we request that the proposed timeline for maintaining these files be reduced to 30 days, rather than 90 days.

§ 5718. Residual Solvents and Processing Chemicals Testing

Concern: § 5718 was amended to include action levels for Category 1 residual solvents rather than minimum LOQ levels. The justification for this change states that "The Bureau received numerous comments that the proposed language is arbitrary and that it increases variability in testing results from one laboratory to the next. Numerous commenters specifically requested the Bureau to establish specific action levels for Category 1 solvents, rather than allowing laboratories to establish a LOQ on their own." The same justification ought to be applied to the category 1 Pesticides.

Recommendation: Category 1 pesticides should have action levels rather than minimum LOQ requirements to stay consistent with Category 1 solvents.

§ 5722. Foreign Material Testing

§ 5722 (e)(2) states that the sample can pass foreign material testing if the presence of the foreign material does not exceed "1/4 of the sample area covered by mold".

Concern: This would mean that a 50lb batch could have 12lb of mold and still pass compliance. The mold issue is a significant public health risk and should be lowered to no visible mold. Once mold is visible, it is present in sufficiently large concentrations to cause adverse health risks. Because of the narrow testing standards for mold, several types of common molds in cannabis like Botrytis and Powdery Mildew can be visibly present and still pass compliance testing.

Recommendation: We recommend striking "¼ of the sample area covered by mold" and replace with "any visible signs of mold."

§ 5724. Cannabinoid Testing

§ 5724 added restrictive language that now interprets non-medical manufactured edibles fail testing when the package contains any THC variance above 100mg, and fails when the per serving dose exceeds 10mg of THC.

Concern: An effect of this new language is that most manufacturers that aim for 10mg per serving or 100mg package will effectively lose the top 10% variance that is currently allowed. Manufacturers that aim for 100 mg and test at 100.1mg would now fail cannabinoid testing. The target concentrations would have to be lowered to accommodate this amendment. This means substantial changes in SOP and processes for manufacturers at significant expense.

The 100mg per package limit was a threshold determined by the CDPH in the ***regulatory*** process, and was determined in their first draft of emergency regs. Setting a cap of 100mg per package was not dictated by Prop 64, AUMA, MAUCRSA, or in BPC.

Recommendation: We believe a 10% variance should be acceptable as is used in the pharmaceutical industry.

Add "plus 10%" to the end of sections (d)(1)(2)(3), to read:

(d) The sample shall be deemed to have passed the cannabinoid testing if the following conditions are met:

(1)For all edible cannabis products, the milligrams per serving for THC does not exceed 10 milligrams per serving plus 10%

(2)For edible cannabis products that are not orally-dissolving products labeled "FOR MEDICAL USE ONLY", the milligrams per package for THC does not exceed 100 milligrams per package plus 10%

(3)For edible cannabis products that are orally-dissolving products labeled "FOR MEDICAL USE ONLY," the milligrams per package for THC does not exceed 500 milligrams per package plus 10%

§ 5726. Certificate of Analysis (COA)

Concern: § 5726 included changes on the certificate of analysis and § 5732 included several forms that would be included with the data package. One necessary and practical addition to these sections would be a COA amendment form. There is currently no process for making changes or amendments to COA. While testing labs do have QC programs and processes in place, typographical and human errors will occur and some of these errors may not be identified until after the COA is generated. Testing labs have to deal with tremendous pressure of delivering results in a very short amount of time. This, in combination with the fact that many of the testing methods are newly developed and unique to the cannabis industry, necessitates a process by which COA can be amended with appropriate documentation.

Recommendation: A COA amendment form that can be submitted along with supporting data to the BCC before a COA change is made.