Q1 First Name (Optional)

Philip

Q2 Last Name (Optional)

Anderson

Q3 Organization (Optional)

Sky Ranch Family Farms

Q4 Title (Optional)

Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

We are makers of a high end pre-roll with added oil. We are worried about the limitations with the 1000mg cap on manufactured products. We do not believe that that cap translates across all products. What's good for a edible or a soda or a lotion might is not suitable for a product meant to be smoked, especially a product that is 80-90% cannabis flower. We do not believe that the flower should be counted towards final mg count in a manufactured product such as ours or there should be a different cap for pre-rolls with added oil. If a consumer is allowed to purchase an ounce of flower at 25% thc level which is the equivalent of 7000mg of thc then we should be allowed to make a high-end pre-roll that isn't made to smoke in one sitting but rather multiple sittings or with friends at a party. We urge you to reconsider the 1000mg cap as it relates to products that contain cannabis flower.

Thank you.
Page 1

Q1 First Name (Optional)  
Respondent skipped this question

Q2 Last Name (Optional)  
Respondent skipped this question

Q3 Organization (Optional)  
Respondent skipped this question

Q4 Title (Optional)  
Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Please consider the following recommendations:

1. Allow tamper evident packaging (TEP) as opposed to child resistant packaging (CRP). TEP allows for resealable, no-tear notch packaging that protects young children especially when properly stored by parents. Children that have recently ingested cannabis (SF school) would be able to open CRP and thus would not have been "protected" by the CRP regulation. Requiring manufacturers to use CRP is cost prohibitive and wasteful. Other states like Oregon do not require CRP use by the manufacturer but do require CRP exit bags- this is a reasonable requirement and can be "applied" to several items at check-out with less overall cost and waste.

2. Increase the margin of error (MOE) test requirements for THC/CBD cannabinoids. The 10% margin is far too strict and should be increased to 20% similar to current FDA food standards. Further, current MOEs for edible testing at cannabis labs is up to 20% depending on the edible type. Without better testing methodology at the lab level, it is quite difficult to meet the 10% MOE regulations.
Q1 First Name (Optional)
Gina

Q2 Last Name (Optional)
Pippin

Q3 Organization (Optional)
QVI, Inc.

Q4 Title (Optional)
President

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee
I would like to encourage the subcommittee to approve a license type (S Type, I believe is what is being considered) that would allow multiple licensees to share space on one premises. This would allow the smaller ventures access to safe premises that meet the required regulations who otherwise could not afford a space of their own.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#4

COMPLETE

Collector: Web Link 1 (Web Link)
Started: Sunday, February 18, 2018 3:02:00 PM
Last Modified: Sunday, February 18, 2018 3:09:22 PM
Time Spent: 00:07:22
IP Address: 104.180.158.20

Page 1

Q1 First Name (Optional)
Kelly

Q2 Last Name (Optional)
McCormick

Q3 Organization (Optional)  Respondent skipped this question

Q4 Title (Optional)  Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.
Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Manufacturing facilities are damaging the neighborhoods in which they operate. Neighboring businesses don't have a say in the issue, yet are subjected to noxious fumes, fire danger, crime, and security issues. In San Diego, for example, there's an over-saturation in specific parts of the city, and the city is not enforcing basic construction permitting regulations that all other businesses are subjected to. Manufacturers cut holes in roofs, build (shoddy) ducts, etc. without proper permits.
Q1 First Name (Optional)

Arash

Q2 Last Name (Optional)

Merpour

Q3 Organization (Optional)

Delta 9

Q4 Title (Optional)

In-House Counsel, Compliance Officer

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Full Statute:

Article 3. Packaging
§40415. Packaging. A package used to contain a cannabis product shall adhere to the following requirements:
(a) The package shall protect the product from contamination and shall not expose the product to any toxic or harmful substance.
(b) The package shall be tamper-evident, which means that the product shall be packaged in packaging that is sealed so that the contents cannot be opened without obvious destruction of the seal.
(c) The package shall be child-resistant. A package shall be deemed child-resistant if it satisfies the standard for “special packaging” as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)) (Rev. December 1983), which is hereby incorporated by reference.
(d) The package shall not imitate any package used for products typically marketed to children.
(e) If the product is an edible product, the package shall be opaque.
(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is maintained throughout the life of the package.

Proposal: Clarify that §40415(c) “child-resistant” can be satisfied without the adult testing standards for “special packaging” as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)).

Issue: §40415 attempts to clarify the definition of “child-resistant.” §40415(c) incorporates the “special packaging” definition as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)). However, the statute requires child AND senior testing to be certified as “child-resistant.” After contacting a few federally recommended “child-resistant” testing facilities we learned that senior testing is more than twice as expensive as the child testing.

Conclusion:
In §40415, a package shall be deemed child-resistant if it satisfies the standard for “special packaging” as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)) through child testing only.

Or

§40415 (c) is amended to only require child testing to be deemed child resistant in satisfying the “special packaging” standard set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)).
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#6

Collector: Web Link 1 (Web Link)
Started: Tuesday, February 20, 2018 10:12:26 AM
Last Modified: Tuesday, February 20, 2018 10:17:05 AM
Time Spent: 00:04:39
IP Address: 209.77.204.154

Page 1

Q1 First Name (Optional)
marvin

Q2 Last Name (Optional)
moskowitz

Q3 Organization (Optional)
sonoma county environmental health

Q4 Title (Optional)
program manager

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

The emergency regulations clarified that certain cannabis products are not considered to be edibles, including capsules, tinctures, slaves, balms and topicals. Will there be any general sanitation requirements for the manufacture of these types of products?
#7

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## Page 1

**Q1 First Name (Optional)**

Chris

**Q2 Last Name (Optional)**

McG

**Q3 Organization (Optional)**

Respondent skipped this question

**Q4 Title (Optional)**

Business Exec/Investor

**Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.**

Manufacturers Subcommittee

**Q6 Feedback for Subcommittee**

Too many manufacturers being approved, please halt new permits til supply/demand equalize.
Page 1

Q1 First Name (Optional)
Christina

Q2 Last Name (Optional)
Gunn

Q3 Organization (Optional)
Brandmetta

Q4 Title (Optional)
CMO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Madams and Sirs,

I think the advertising regulations are a bit dated. If a site or online engine (such as Google and Facebook) can parse out where you can advertise, we should be able to do this considering we can target users over 21 and people within California. Right now, these services are so afraid, they are not even allowing advertising on their platforms because of the vagueness of what's allowed.

Cannabis advertising should follow the same path as alcohol advertising if you need some guidelines if this is the case. At least people in media already know what this means and what is allowable and works and what is not and doesn't. There are already proven test cases and court cases that can help steer decisions. We don't have to recreate the wheel. We simply need to adopt and adapt what works already.

The lack of this is causing a significant strain to the industry. Please help us. Thank you for your consideration.
Q1 First Name (Optional)
Bridget

Q2 Last Name (Optional)
May

Q3 Organization (Optional)
Little Green Bee

Q4 Title (Optional)
President

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.
Manufacturers Subcommittee

Q6 Feedback for Subcommittee
Hi, I own a small manufacturing business in San Francisco called Little Green Bee. Since January 1st I have ceased operations while I find a permissable space and get it up to speed. Needless to say, this is an extremely costly and difficult thing to do and I'm not there yet. There are some changes to the regulations that would help small businesses survive and help prevent black market from perpetuating while still protecting public safety. I have been working with a group to come to a concensus thus the use of "we".

Packaging: CCR § 40415

We are in full support of tamper-evident packaging. It's proven successful in preventing contaminated products getting into the hands of consumers across other well established industries.

Requiring child resistant packaging as stated in the proposed legislation is expensive and creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.
Requiring opaque packaging removes the consumer's ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product. We would like to see the removal of the requirement that edibles be in opaque packaging.

Only bottle and glassware should be re-sealable child resistant. All other packaging should be tamper proof. Retailers can bag in an opaque child-resistant carry-out bag.

Edible products should be tamper-evident (not Child Resistant Packaging) - not requiring special certification.

Products for topical application should have more lenient child-resistant packaging requirements as the danger of ingestion is low and are not for internal use.

Suggested Approach:

Alcohol isn’t required to be child-resistant.

Environmental impact of over-packaging/redundancy

Look to other states. Washington has not required CR packaging and have not seen safety issues as a result.

The consumer needs to take responsibility for keeping packaging out of hands of children.

Balance consumer and licensee responsibility.

Reconsider “child-resistant” packaging. Clarification. Sensible, airtight, vacuum-sealed packaging. One-time CR makes sense. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.”

Different labeling requirements for topicals: BPC § 26120(c)(1)(B)

Topical products should have different labeling requirements based on scientific evidence that make logical sense. Requiring this warning on the label on topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer. The lipid bilayer of the epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot impair judgement or reaction timing. Transdermal cannabis products should certainly contain the prescribed warning about impairment.

Proposed solution: Modify required language: “For external use only. Do not ingest.”

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2)

This limit is not appropriate for patients, who may require higher dosage. A 10mg limit per serving means some patients will have to eat several servings to get the full dose.
Keep the 10mg limit for Adult Use consumers, but allow flexibility for patients (medicinal cannabis consumers) to obtain single servings with higher dosages and packages with more than 100mg.

Suggested Comments:

The consumer should drive what the mg level is. No reason to cap.

Mandated language: Recommended serving size?

Larger per-package dosage is more cost-effective for consumers.

More environmentally friendly.

Keep 10mg/dose delineation but remove per-package cap. This allows novice consumers to responsibly consume, while offering additional options for those seeking a higher dose.

Single manufacturing license for A & M: CCR § 40115(c) and (d)

Is there actually a separate administrative process the agency must complete for each license type? If not, why not let manufacturers apply for both under a single fee and application? (vs. charging as if the inspection and administration occurs two times. The A&M application approval processes could be completed simultaneously by the agencies.)

This is an excessive and redundant cost for small businesses and the regulatory justification is unclear.

By splitting into two tracks, threatening medical market because licensees may prefer A market if the economics of parallel markets → forces a choice.

Extend timeframe under CCR 5029 (transition provisions) to allow licensees to conduct business with other licensees, irrespective of the M or A designation on their licenses. This will allow time for legislators to pursue statutory change to allow businesses to obtain a single state license to conduct M & A activities.

Designation A or M should occur at the retail level.

Preparation of non-cannabis products off site: CCR § 40175(a)

Shared spaces: CCR § 40190-40199

Allow shared manufacturing spaces as soon as possible. Keep licensing fees low. Clarify necessary separations/barriers. Equity incubators require shared space.

Small business friendly.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

The cost of space is a huge barrier to entry for small businesses, equity incubators,

Rely on existing food manufacturing, non-cannabis manufacturing styles of operation

Consideration of allowing shared equipment. Cost effective. For non-extraction related equipment.

No cap on square footage/No cap on number of employees sharing space

Shared storage areas.

Reporting ownership changes to DPH: CCR § 40178

Allow licensees 30 calendar days to notify the state.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e)
Sampling in final form: BPC § 26100(b) & CCR § 5705(b) and (c)

Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. The concern is that demo samples may not be safely in compliance with testing, so I propose samples be allowed, but be distributed to dispensaries through the same channels with the same testing requirements as sellable product. We feel that so long as the chain of custody is preserved under the proposed safety compliance channels, sampling is a safe and effective way to educate. Providers can work with distributors to increase the amount of product dropped off in preparation for a demo day.

We would like to see concessions added to allow sales samples to be given away to prospective buyers. No one is going to pick up a new product to put in their shelves if they can’t try it out. We should be able to still track and tracebut have a sensible allowance for sales samples like 4% of product may be allocated for sales samples for the purpose of B2B account establishment only.

Requiring a 2nd person for quality control:

Recommendation: Omit the section where each batch needs a verification signature different from the actual manufacturer of that batch.

Possible Solutions: Verification signature only needed at critical control points...covered in SOPs.

Flexibility so that the second signer doesn’t have to be an employee of the company.

Testing
Testing at plant stage, extraction stage. SOPs should cover introduction of new heavy metals, pesticides. Periodic testing at each point, but SOPs already account for this. Testing in final form is redundant and doesn’t contribute to health and safety, but costs licensees.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

DPH has already checked protocols. Makes more sense for cultivators but not manufacturers.

Ex: vape cartridges. Results don’t change from source material to filled vape cartridge.

Pesticides should only be tested at cultivation or extraction level.

Proposed solution: Test only for microbiological pesticides at cultivation or extraction level. Test for concentration at final product stage. Spot check on finished goods.

Also good for consumer. Turnaround time is shorter, avoiding degradation to the product

We agree that all manufacturers should be able to provide full testing results for potency, residuals, pesticides, microbiologicals, and heavy metals for source materials (distillates, extracts, etc). However, we believe that our established SOP’s and CCP’s provide adequate protections for the integrity of our products and their manufacturing process. FDA guidelines rely on manufacturers’ processes and we believe that we should be held to the same standards.

We fully support periodic batch testing, but the requirement to analyze every single batch with any array of tests is untenable for small manufacturers.

thank you!
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#10

Collector: Web Link 1 (Web Link)
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Page 1

Q1 First Name (Optional)                          Respondent skipped this question
Q2 Last Name (Optional)                           Respondent skipped this question
Q3 Organization (Optional)                        Respondent skipped this question
Q4 Title (Optional)                               Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

The Overview document by BCC says “Retailer cannot package or label cannabis goods.” Based on the foregoing, please provide clarification as to the following:

1. Suppose business wants to purchase 5 ounces of dried cannabis flower and then package the cannabis into smaller amounts for sale. For example, divide the larger amount into smaller amounts, such as 1 gram packages, 2 gram packages, etc. What kind of license(s) would be required to conduct that activity?

2. Can a distributor do it if the sales are only to licensed retailers?

3. Is the process of dividing the larger amounts into smaller packages considered manufacturing?

3. Can a microbusiness do it, if approved for manufacturing, distribution, and retail?
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#11

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Time Spent: 00:01:09
IP Address: 69.181.70.4

Page 1

Q1 First Name (Optional)
Sharon

Q2 Last Name (Optional)
Krinsky

Q3 Organization (Optional)
Society Jane

Q4 Title (Optional)
CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regiment is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.
Q1 First Name (Optional)
Sharon

Q2 Last Name (Optional)
Krinsky

Q3 Organization (Optional)
Society Jane

Q4 Title (Optional)
CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

5411. Free Cannabis Goods

(a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers.

A retailer's ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase.

In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.
Q1 First Name (Optional)

Sharon

Q2 Last Name (Optional)

Krinsky

Q3 Organization (Optional)

Society Jane

Q4 Title (Optional)

CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e)

A licensee shall not give away any amount of cannabis or cannabis products, or any cannabis accessories, as part of a business promotion or other commercial activity

(a) A licensed dispensary shall not provide free samples of medical cannabis goods to any person.

Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely.

Recommendation: We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

(b) A licensed dispensary shall not allow representatives of other companies or organizations to provide free samples of medical cannabis goods to individuals on the licensed dispensary premises.

We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

Recommendation: We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale.

Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax for a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we have outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup
Page 1

Q1 First Name (Optional)
Menaka

Q2 Last Name (Optional)
Mahajan

Q3 Organization (Optional) Respondent skipped this question

Q4 Title (Optional) Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.
Manufacturers Subcommittee

Q6 Feedback for Subcommittee

I previously worked for a public agency (local level) on small business friendly policy/legislation and now work as a strategic and policy advisor within the cannabis industry. I have heard from many small businesses about the various provisions in the law that reduce their competitiveness against larger, better funded businesses and could put the smaller entrepreneurs out of business, as well as the challenges created for patients who are adapting to a different regulatory environment as they try to obtain their medicine. A large group of us have spent considerable time reviewing the regulations together and developing recommendations. Thank you very much for all your efforts to solicit feedback from the community and to develop regulations that are effective from a regulatory perspective, while keeping in mind the challenges of small operators who form the backbone of the cannabis industry. Please don't hesitate to reach out if I can be of service in crafting the formal regulations.

Packaging: CCR § 40415

A package used to contain a cannabis product shall adhere to the following requirements:

***
(b) The package shall be tamper-evident, which means that the product shall be packaged in packaging that is sealed so that the contents cannot be opened without obvious destruction of the seal.
(c) The package shall be child-resistant. A package shall be deemed child-resistant if it satisfies the standard for “special packaging” as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)) (Rev. December 1983), which is hereby incorporated by reference.

\( \textbf{***} \)

(e) If the product is an edible product, the package shall be opaque.

(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is maintained throughout the life of the package.

Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers. Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.”

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product. We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.

Primary Panel Labeling Requirements: CCR § 40405

It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

Recommendation: clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412

Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

Recommendation: amend required size of CA state universal symbol to .25 in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B)

(B) For cannabis products: “GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

(c) of cannabis products. GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS 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 CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION."

Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

Recommendation: For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) <-- DONE

(c) Edible cannabis products shall be:
(2) Produced and sold with a standardized concentration of cannabinoids not to exceed 10 milligrams tetrahydrocannabinol (THC) per serving.
A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

Recommendation: Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d)
(c) A M-license is required in order to manufacture cannabis products for sale in the medicinal-use market.
(d) An A-license is required in order to manufacture cannabis products for sale in the adult-use market.

This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

Recommendation: Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once.
The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029
Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199

We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry. We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e)

A licensee shall not give away any amount of cannabis or cannabis products, or any cannabis accessories, as part of a business promotion or other commercial activity

--

(a) A licensed dispensary shall not provide free samples of medical cannabis goods to any person.

Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely.

Recommendation: We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

(b) A licensed dispensary shall not allow representatives of other companies or organizations to provide free samples of medical cannabis goods to individuals on the licensed dispensary premises.

We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

Recommendation: We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this
state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

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(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale.

Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax of a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we have outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup

5411. Free Cannabis Goods

(a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers.

A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase.

In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c)

(b) The bureau shall develop criteria to determine which batches shall be tested. All testing of the samples shall be performed on the final form in which the cannabis or cannabis product will be consumed or used.

(b) The laboratory may obtain and analyze samples only from batches in final form as required by Business and Professions Code section 26100.

(c) The laboratory shall collect both a primary sample and a field duplicate sample from each batch. The primary sample and field duplicate sample shall be stored and analyzed separately.

Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.
On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologials, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regimen is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods
A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264

Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178

The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens

The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins,
and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044

Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7.
Q1 First Name (Optional)
Sharon

Q2 Last Name (Optional)
Krinsky

Q3 Organization (Optional)
Society Jane

Q4 Title (Optional)
CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.
Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Shared spaces: CCR § 40190-40199

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Q1 First Name (Optional)
Sharon

Q2 Last Name (Optional)
Krinsky

Q3 Organization (Optional)
Society Jane

Q4 Title (Optional)
CEO

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Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Single manufacturing license for A & M: CCR § 40115(c) and (d)

(c) A M-license is required in order to manufacture cannabis products for sale in the medicinal-use market.
(d) An A-license is required in order to manufacture cannabis products for sale in the adult-use market.

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Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

Recommendation: Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once.

The A & M designations may be logical at the retail level, but not for suppliers.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#17

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IP Address: 69.181.70.4

Page 1

Q1 First Name (Optional)
Sharon

Q2 Last Name (Optional)
Krinsky

Q3 Organization (Optional)
Society Jane

Q4 Title (Optional)
CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Different labeling requirements for topicals: BPC § 26120(c)(1)(B)

(B) For cannabis products: “GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS 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 CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.”

Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

Recommendation: For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) <-- DONE

(c) Edible cannabis products shall be:

(2) Produced and sold with a standardized concentration of cannabinoids not to exceed 10 milligrams tetrahydrocannabinol (THC) per serving.

A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

Recommendation: Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg
#18

Collector:  Web Link 1 (Web Link)

Started:  Wednesday, February 21, 2018 10:56:02 AM

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IP Address:  69.181.70.4

Page 1

Q1 First Name (Optional)

Sharon

Q2 Last Name (Optional)

Krinsky

Q3 Organization (Optional)

Society Jane

Q4 Title (Optional)

CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Universal Symbol: CCR § 40412

Many edible products are small and don't have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

Recommendation: amend required size of CA state universal symbol to .25in
Page 1

Q1 First Name (Optional)
Sharon

Q2 Last Name (Optional)
Krinsky

Q3 Organization (Optional)
Society Jane

Q4 Title (Optional)
CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Packaging: CCR § 40415

A package used to contain a cannabis product shall adhere to the following requirements:

***

(b) The package shall be tamper-evident, which means that the product shall be packaged in packaging that is sealed so that the contents cannot be opened without obvious destruction of the seal.

(c) The package shall be child-resistant. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)) (Rev. December 1983), which is hereby incorporated by reference.

***

(e) If the product is an edible product, the package shall be opaque.

(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is maintained throughout the life of the package.

Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers.

Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque tamper-evident carry-out bags at the point of sale.
Q1  First Name (Optional)

Stephani

Q2  Last Name (Optional)

Smith

Q3  Organization (Optional)  Respondent skipped this question

Q4  Title (Optional)  Respondent skipped this question

Q5  Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

To Whom It May Concern,

With the State's legalization of adult-use cannabis, numerous ancillary industries have arisen in response to new and pending regulations. I've recognized there is a lack of consideration for cannabis waste in particular. This is a concern of mine due to the increasing number of cultivation, manufacturing and retailer licenses being granted within the state without identified guidelines and/or regulations regarding safe disposal of cannabis byproduct and cannabis waste.

Cannabis waste is expansive and differs from cultivators, manufacturers, and retailers. As such, it would also be prudent to clarify streams of waste by industry vertical. For example, cannabis waste runs the gamut of post-extracted cannabis plants and flowers, failed lab tested materials, ancillary manufactured waste (for example, i.e., wax paper, gloves, beakers, etc.), retail display items, and returned/damaged retail items, and more. Currently, certain streams of cannabis waste are frequently mistaken with safe-to-consume products, posing a risk to children and disenfranchised individuals.

It is my recommendation that regulations reflect who is qualified to handle cannabis waste. A licensed cannabis waste handler ought to be contracted for each cannabis cultivator, manufacturer, and retail site to combat the negative repercussions cannabis waste has on human and environmental health. The inclusion of such a standard will complete the symbiotic relationship between key stakeholders—the environment, the public and the industry.
Page 1

Q1 First Name (Optional)  Respondent skipped this question
Q2 Last Name (Optional)  Respondent skipped this question
Q3 Organization (Optional)  Respondent skipped this question
Q4 Title (Optional)  Respondent skipped this question
Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee
How will waste be managed?
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#22

Collector: Web Link 1 (Web Link)
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Page 1

Q1 First Name (Optional) Respondent skipped this question
Q2 Last Name (Optional) Respondent skipped this question
Q3 Organization (Optional) Respondent skipped this question
Q4 Title (Optional) Respondent skipped this question
Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments. Manufacturers Subcommittee
Q6 Feedback for Subcommittee
How will waste be managed?
Page 1

Q1 First Name (Optional)
Rachel

Q2 Last Name (Optional)
O.

Q3 Organization (Optional)
Somatik

Q4 Title (Optional)
Sales

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Manufacturers Subcommittee 4

Packaging: CCR § 40415 4

Different labeling requirements for topicals: BPC § 26120(c)(1)(B) 5

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) <-- DONE 6

Single manufacturing license for A & M: CCR § 40115(c) and (d) 6

Shared spaces: CCR § 40190-40199 7

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Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e) 7

5411. Free Cannabis Goods 9

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c) 9

Testing Manufactured Goods 11

Batch Production Record & 2nd person for quality control: CCR § 40264 11

Reporting ownership changes to DPH: CCR § 40178
Q1 First Name (Optional)
Margot

Q2 Last Name (Optional)
Wampler

Q3 Organization (Optional)
Lifted Logistics

Q4 Title (Optional)
CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

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***
(e) If the product is an edible product, the package shall be opaque.
(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is
maintained throughout the life of the package.

Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers. Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.

Primary Panel Labeling Requirements: CCR § 40405

It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

Recommendation: clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412

Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

Recommendation: amend required size of CA state universal symbol to .25in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B)

(B) For cannabis products: “GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS 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 CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.”
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc., assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

Recommendation: For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) <-- DONE

(c) Edible cannabis products shall be:
(2) Produced and sold with a standardized concentration of cannabinoids not to exceed 10 milligrams tetrahydrocannabinol (THC) per serving.
A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

Recommendation: Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d)

(c) A M-license is required in order to manufacture cannabis products for sale in the medicinal-use market.
(d) An A-license is required in order to manufacture cannabis products for sale in the adult-use market.

This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

Recommendation: Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once.
The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029

Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e)

A licensee shall not give away any amount of cannabis or cannabis products, or any cannabis accessories, as part of a business promotion or other commercial activity

(a) A licensed dispensary shall not provide free samples of medical cannabis goods to any person.

Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely.

Recommendation: We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

(b) A licensed dispensary shall not allow representatives of other companies or organizations to provide free samples of medical cannabis goods to individuals on the licensed dispensary premises.

We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

Recommendation: We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retail units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

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(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the
purchaser at the time of sale.

Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax f a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we have outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup

5411. Free Cannabis Goods

(a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers.

A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase.

In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c)

(b) The bureau shall develop criteria to determine which batches shall be tested. All testing of the samples shall be performed on the final form in which the cannabis or cannabis product will be consumed or used.

(b) The laboratory may obtain and analyze samples only from batches in final form as required by Business and Professions Code section 26100.

(c) The laboratory shall collect both a primary sample and a field duplicate sample from each batch. The primary sample and field duplicate sample shall be stored and analyzed separately.

Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the small scale model will likely not be viable.
additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regimen is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods
A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264

Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178

The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens

The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.
Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7.
Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Manufacturers Subcommittee
3/1 subcommittee meeting topics:
a. Packaging Requirements
b. Child-Resistant Packaging
c. Products Attractive to Children
d. Employee Health and Safety
e. Dosage, Medicinal v. Adult-Use
f. Volatile vs. Nonvolatile Manufacturing (e.g., Purity levels for gas)
g. Waste Destruction
h. Labeling
Samples?

Packaging: CCR § 40415

A package used to contain a cannabis product shall adhere to the following requirements:

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(b) The package shall be tamper-evident, which means that the product shall be packaged in packaging that is sealed so that the contents cannot be opened without obvious destruction of the seal.
(c) The package shall be child-resistant. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as

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(e) If the product is an edible product, the package shall be opaque.

(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is maintained throughout the life of the package.

Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers.

Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.

Primary Panel Labeling Requirements: CCR § 40405

It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

Recommendation: clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412

Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

Recommendation: amend required size of CA state universal symbol to .25in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B)

(B) For cannabis products: “GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS PRODUCTS MAY ONLY BE POSSESSED OR
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Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

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Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c)

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Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

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On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

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Page 1

Q1 First Name (Optional)
Luna

Q2 Last Name (Optional) Respondent skipped this question

Q3 Organization (Optional) Respondent skipped this question

Q4 Title (Optional) Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments. Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be forced to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regiment is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods
A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264

Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#27

Collector: Web Link 1 (Web Link)
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Last Modified: Wednesday, February 21, 2018 1:15:26 PM
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Page 1

Q1 First Name (Optional) Respondent skipped this question

Q2 Last Name (Optional) Respondent skipped this question

Q3 Organization (Optional) Respondent skipped this question

Q4 Title (Optional) Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Security Systems: CCR § 5044

Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7.
Q1 First Name (Optional)  
Respondent skipped this question

Q2 Last Name (Optional)  
Respondent skipped this question

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Respondent skipped this question

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Page 1

Q1 First Name (Optional)
Blaine

Q2 Last Name (Optional)
Hatab

Q3 Organization (Optional)
Distru

Q4 Title (Optional)  Respondent skipped this question

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Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Manufacturers Subcommittee
3/1 subcommittee meeting topics:
a. Packaging Requirements
b. Child-Resistant Packaging
c. Products Attractive to Children
d. Employee Health and Safety
e. Dosage, Medicinal v. Adult-Use
f. Volatile vs. Nonvolatile Manufacturing (e.g., Purity levels for gas)
g. Waste Destruction
h. Labeling
Samples?

Packaging: CCR § 40415
A package used to contain a cannabis product shall adhere to the following requirements:

***

(b) The package shall be tamper-evident, which means that the product shall be packaged in packaging that is sealed so that the contents cannot be opened without obvious destruction of the seal.

(c) The package shall be child-resistant. A package shall be deemed child-resistant if it satisfies the standard for “special packaging” as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)) (Rev. December 1983), which is hereby incorporated by reference.

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(e) If the product is an edible product, the package shall be opaque.

(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is maintained throughout the life of the package.

[Issue] Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers.

Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.

Requiring opaque packaging removes the consumer's ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product. We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It's proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.

Primary Panel Labeling Requirements: CCR § 40405

[Issue] It's unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412

[Issue] Many edible products are small and don't have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25in
Different labeling requirements for topicals: BPC § 26120(c)(1)(B)

(B) For cannabis products: “GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS 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 CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.”

[Issue] Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot either impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) <-- DONE
(c) Edible cannabis products shall be:
(2) Produced and sold with a standardized concentration of cannabinoids not to exceed 10 milligrams tetrahydrocannabinol (THC) per serving.

[Issue] A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d)
(c) A M-license is required in order to manufacture cannabis products for sale in the medicinal-use market.
(d) An A-license is required in order to manufacture cannabis products for sale in the adult-use market.

[Issue] This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once.
The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029
Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199

We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.
We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.
Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e)

A licensee shall not give away any amount of cannabis or cannabis products, or any cannabis accessories, as part of a business promotion or other commercial activity

- A licensed dispensary shall not provide free samples of medical cannabis goods to any person.

[Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

(b) A licensed dispensary shall not allow representatives of other companies or organizations to provide free samples of medical cannabis goods to individuals on the licensed dispensary premises.

We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

Recommendation: We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

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(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale.

Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax for a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we have outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup

5411. Free Cannabis Goods

(a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers.

A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase.

In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c)

(b) The bureau shall develop criteria to determine which batches shall be tested. All testing of the samples shall be performed on the final form in which the cannabis or cannabis product will be consumed or used.

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(b) The laboratory may obtain and analyze samples only from batches in final form as required by Business and Professions Code section 26100.

(c) The laboratory shall collect both a primary sample and a field duplicate sample from each batch. The primary sample and field duplicate sample shall be stored and analyzed separately.

66 / 213
Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regiment is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods
A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264

Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178

The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens
The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044

Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7.
Q1 First Name (Optional)
Chris

Q2 Last Name (Optional)
Schroeder

Q3 Organization (Optional)
A Tribe Of Us

Q4 Title (Optional)
Founder

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Manufacturers Subcommittee

Q6 Feedback for Subcommittee

First thank you SO much for your time and effort on this subcommittee. It's a huge task and the general feeling amongst us operators is that you are doing a fantastic job listening to us and trying to create a great environment for the industry that's both safe for consumers and supportive of businesses. Below are some thoughts the San Francisco and Bay Area Manufacturers worked on with the hopes of illustrating some amendments to the regulations. We're committed to safety and quality, and also want to protect our business enough to ensure we can thrive in our huge new market. Thank you and I'll see you on the 1st!

Packaging: CCR § 40415
A package used to contain a cannabis product shall adhere to the following requirements:

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(b) The package shall be tamper-evident, which means that the product shall be packaged in packaging that is sealed so that the contents cannot be opened without obvious destruction of the seal.
(c) The package shall be child-resistant. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as

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(e) If the product is an edible product, the package shall be opaque.

(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is maintained throughout the life of the package.

[Issue] Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers.

Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product. We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendation] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.

Primary Panel Labeling Requirements: CCR § 40405

[issue] It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendation] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412

[issue] Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendation] Amend required size of CA state universal symbol to .25in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B)

(B) For cannabis products: “GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS 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 CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION."

[Issue] Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles.

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100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) <-- DONE
(c) Edible cannabis products shall be:
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[Issue] A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

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(c) A M-license is required in order to manufacture cannabis products for sale in the medicinal-use market.
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The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

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[Recommendation] We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e)
A licensee shall not give away any amount of cannabis or cannabis products, or any cannabis accessories, as part of a business promotion or other commercial activity

(a) A licensed dispensary shall not provide free samples of medical cannabis goods to any person.

[Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

(b) A licensed dispensary shall not allow representatives of other companies or organizations to provide free samples of medical cannabis goods to individuals on the licensed dispensary premises.

[Issue] We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

[Recommendation] We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser's liability for the cannabis
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

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(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale.

[Issue] Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax of a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

[Recommendation] Above, we have outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup

5411. Free Cannabis Goods
(a) A retailer shall not provide free cannabis goods to any person.

[Issue] Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers.

A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase.

In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

[Recommendation] Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c)

(b) The bureau shall develop criteria to determine which batches shall be tested. All testing of the samples shall be performed on the final form in which the cannabis or cannabis product will be consumed or used.

(b) The laboratory may obtain and analyze samples only from batches in final form as required by Business and Professions Code section 26100.
(c) The laboratory shall collect both a primary sample and a field duplicate sample from each batch. The primary sample and field duplicate sample shall be stored and analyzed separately.

[Issue] Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals,
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

pesticides, microorganisms, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale products. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be forced to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regimen is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

[Recomendation] We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods
A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264

Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178

The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens

The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.
Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044

Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#31

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Page 1

**Q1 First Name (Optional)**
Respondent skipped this question

**Q2 Last Name (Optional)**
Respondent skipped this question

**Q3 Organization (Optional)**
Respondent skipped this question

**Q4 Title (Optional)**
Respondent skipped this question

**Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.**

**Manufacturers Subcommittee**

**Q6 Feedback for Subcommittee**

Packaging: CCR § 40415

A package used to contain a cannabis product shall adhere to the following requirements:

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(b) The package shall be tamper-evident, which means that the product shall be packaged in packaging that is sealed so that the contents cannot be opened without obvious destruction of the seal.

(c) The package shall be child-resistant. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)) (Rev. December 1983), which is hereby incorporated by reference.

***

(e) If the product is an edible product, the package shall be opaque.

(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is maintained throughout the life of the package.

[Issue] Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers. Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.

Requiring opaque packaging removes the consumer's ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It's proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.

Primary Panel Labeling Requirements: CCR § 40405

[Issue] It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412

[Issue] Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B)

(B) For cannabis products: “GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS 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 CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.”

[Issue] Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) <-- DONE
(c) Edible cannabis products shall be:
(2) Produced and sold with a standardized concentration of cannabinoids not to exceed 10 milligrams tetrahydrocannabinol (THC) per serving.

[Issue] A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d)
(c) A M-license is required in order to manufacture cannabis products for sale in the medicinal-use market.
(d) An A-license is required in order to manufacture cannabis products for sale in the adult-use market.

[Issue] This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once.

The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029
Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199

We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.
We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e)

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Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

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Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c)

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Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

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Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

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[Recommendations] amend required size of CA state universal symbol to .25in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B)

(B) For cannabis products: “GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS 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 CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.”
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(c) Edible cannabis products shall be:
(2) Produced and sold with a standardized concentration of cannabinoids not to exceed 10 milligrams tetrahydrocannabinol (THC) per serving.

[Issue] A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d)
(c) A M-license is required in order to manufacture cannabis products for sale in the medicinal-use market.
(d) An A-license is required in order to manufacture cannabis products for sale in the adult-use market.

[Issue] This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once.

The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029
Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199

We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly
as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e)

A licensee shall not give away any amount of cannabis or cannabis products, or any cannabis accessories, as part of a business promotion or other commercial activity

(a) A licensed dispensary shall not provide free samples of medical cannabis goods to any person.

[Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

(b) A licensed dispensary shall not allow representatives of other companies or organizations to provide free samples of medical cannabis goods to individuals on the licensed dispensary premises.

We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

Recommendation: We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retail units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

***

(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale.
Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax of a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we have outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup.

5411. Free Cannabis Goods

(a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers.

A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase.

In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c)

(b) The bureau shall develop criteria to determine which batches shall be tested. All testing of the samples shall be performed on the final form in which the cannabis or cannabis product will be consumed or used.

(b) The laboratory may obtain and analyze samples only from batches in final form as required by Business and Professions Code section 26100.

(c) The laboratory shall collect both a primary sample and a field duplicate sample from each batch. The primary sample and field duplicate sample shall be stored and analyzed separately.

Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.
For manufacturers and established manufacturing processes, this testing regimen is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods
A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264

Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178

The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens

The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044
Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7.
Q1 First Name (Optional)
Jane

Q2 Last Name (Optional)
Eisner

Q3 Organization (Optional) Respondent skipped this question

Q4 Title (Optional)
Co-Founder/CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments. Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Packaging: CCR § 40415

[Issue] Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers. Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat”.

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product. We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#34

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Page 1

Q1 First Name (Optional)
Ryan

Q2 Last Name (Optional)
Armistead

Q3 Organization (Optional) Respondent skipped this question

Q4 Title (Optional)
Co-Founder/COO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.
Manufacturers Subcommittee
Q6 Feedback for Subcommittee

We are a small beverage business. We’d like to see the formal regulations reflect the following suggestions. Packaging: CCR § 40415

[Issue] Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers. Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

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Page 1

Q1 First Name (Optional)
Jane

Q2 Last Name (Optional)
Eisner

Q3 Organization (Optional)
Wildflower Press

Q4 Title (Optional)
Co-Founder/CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Primary Panel Labeling Requirements: CCR § 40405

[Issue] It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.
Q1 First Name (Optional)

Ryan

Q2 Last Name (Optional)

Armistead

Q3 Organization (Optional)

Wildflower Press

Q4 Title (Optional)

Co-Founder/COO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

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[Recommendations] clarify primary panel may also be inclusive of the lid to a product.
Q1 First Name (Optional)

Todd

Q2 Last Name (Optional)

Respondent skipped this question

Q3 Organization (Optional)

Respondent skipped this question

Q4 Title (Optional)

Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Thank you for all of the hard work that has gone into making our industry what it is today, I hope that you will consider the following recommendations as you continue to refine the regulations.

1. Requiring opaque packaging removes the consumer's ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product. We would like to see the removal of the requirement that edibles be in opaque packaging.

2. We are in full support of tamper-evident packaging. It's proven successful in preventing contaminated products getting into the hands of consumers across other well established industries.

3. For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about "intoxicating effects." We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer "For external use only. Do not ingest."

4. Please remove the 100mg limit per package on adult use edibles. There are many people who require larger doses for a variety of reasons. These people are being unnecessarily burdened with the extra costs that are associated with having to buy a greater number of edibles to meet their dose requirements.
5. Please reevaluate whether there is an administrative need to have two license types for suppliers.

6. It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

7. We request you to consider allowing shared equipment for non-extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry. We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety. Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

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(b) A licensed dispensary shall not allow representatives of other companies or organizations to provide free samples of medical cannabis goods to individuals on the licensed dispensary premises.

We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

Recommendation: We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

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***

(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale.

Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax of a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we have outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples be non-taxable items to match other industries.

9. Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.
On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

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We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

10. Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Thank you.
Q1 First Name (Optional)
Jane

Q2 Last Name (Optional)
Eisner

Q3 Organization (Optional)
Wildflower Press

Q4 Title (Optional)
Co-Founder/CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

We are a small beverage business and wish to see the following reflected in the new regulations.

Universal Symbol: CCR § 40412

[Issue] Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25in
Q1 First Name (Optional)
Ryan

Q2 Last Name (Optional)
Armistead

Q3 Organization (Optional)
Wildflower Press

Q4 Title (Optional)
Co-Founder/COO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee
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[Recommendations] amend required size of CA state universal symbol to .25in
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

Page 1

**Q1 First Name (Optional)**

Jane

**Q2 Last Name (Optional)**

Eisner

**Q3 Organization (Optional)**

Wildflower Press

**Q4 Title (Optional)**

Co-Founder/CEO

**Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.**

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Different labeling requirements for topicals: BPC § 26120(c)(1)(B)
My small beverage business wishes to have the following reflected in the regulations.

[Issue] Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.
#41

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IP Address: 76.102.106.134

Page 1

Q1 First Name (Optional)
Ryan

Q2 Last Name (Optional)
Armistead

Q3 Organization (Optional)
Wildflower Press

Q4 Title (Optional)
Co-Founder/COO

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Manufacturers Subcommittee
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

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Page 1

Q1 First Name (Optional)

Jane

Q2 Last Name (Optional)

Eisner

Q3 Organization (Optional)

Wildflower Press

Q4 Title (Optional)

Co-Founder/CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2)

We are a small business and wish to have the following reflected in the new regulations.

[Issue] A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg.
Page 1

Q1 First Name (Optional)
Ashley

Q2 Last Name (Optional)
Manta

Q3 Organization (Optional)
CannaSexual

Q4 Title (Optional)
Owner

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

"Packaging: CCR § 40415 [Issue]: Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy: Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers. Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product. We would like to see the removal of the requirement that edibles be in opaque packaging.
[Recommendations] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.

Primary Panel Labeling Requirements: CCR § 40405: [Issue] It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412 [Issue]: Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25 in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B) [Issue]: Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) : [Issue] --- A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d); [Issue] --- This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once. The A & M designations may be logical at the retail level, but not for suppliers.
Extend time to conduct business irrespective of M & A designation: CCR § 5029: Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199: We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e): [Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely. We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

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(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale. Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax f a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as
well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup.

5411. Free Cannabis Goods: (a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers. A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase. In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c): (ISSUE): Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologials, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regimen is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods : ISSUE - A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264 : Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to
perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178: The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens: The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044: Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7."

Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings
Q1 First Name (Optional)

Ryan

Q2 Last Name (Optional)

Armistead

Q3 Organization (Optional)

Wildflower Press

Q4 Title (Optional)

Co-Founder/COO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2)

We are a small business and wish to have the following reflected in the new regulations.

[Issue] A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

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Manufacturers Subcommittee

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We are small business who wish the following to be reflected in the regulations.

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[Issue] This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended
that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once.

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[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

(b) A licensed dispensary shall not allow representatives of other companies or organizations to provide free samples of medical cannabis goods to individuals on the licensed dispensary premises.

We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

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On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

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Security Systems: CCR § 5044

Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

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Thank you.
Q1 First Name (Optional)
Michelle

Q2 Last Name (Optional)
Dizitser

Q3 Organization (Optional)
Kannibox

Q4 Title (Optional)
Founder and CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

KANNIBOX IS A SOCIALLY RESPONSIBLE COMPANY PROVIDING AN EASY WAY FOR PEOPLE TO DISCOVER DIFFERENT TYPES OF CANNABIS AND TRY PRODUCTS THROUGH A PERSONALIZED SAMPLE SUBSCRIPTION BOX

OUR GOAL AT IS TO HELP SMALL BUSINESS THRIVE BY PROVIDING THEM A PLATFORM AND A CHANNEL TO MARKET. WE WANT TO SEE THE ILLICIT CANNABIS MARKET DISAPPEAR BY GIVING OPPORTUNITIES FOR SMALL BUSINESS TO HAVE A VOICE AND REACH THEIR TARGET CONSUMERS.

WE FEEL THAT SOME OF THE HURDLES THAT HAVE BEEN CREATED BY THE CURRENT REGULATIONS, HAVE HAMPERED THE POTENTIAL SUCCESS OF SMALL BUSINESSES BY NOT GIVING THEM A REASONABLE PATH TO GET TO LEGALIZATION, AND THUSLY HAS POSITIONED THE ILLICIT MARKET TO THRIVE.

KANNIBOX AIMS TO EDUCATE CONSUMERS ABOUT ALL DIFFERENT TYPES OF CONSUMPTION METHODS, DOSING, AND WHAT WORKS BEST FOR THEM AS INDIVIDUALS. HEALTH AND SAFETY IS A NUMBER ONE PRIORITY. IF WE HAVE
EDUCATED CONSUMERS WHO UNDERSTAND WHAT THEY ARE CONSUMING, WE WILL HAVE A STRONGER AND MORE COMPASSIONATE MARKET.

WE ARE APPLYING FOR A BOTH MEDICAL AND ADULT USE MICROBUSINESS LICENSES.

Packaging: CCR § 40415

A package used to contain a cannabis product shall adhere to the following requirements:
***
(b) The package shall be tamper-evident, which means that the product shall be packaged in packaging that is sealed so that the contents cannot be opened without obvious destruction of the seal.
(c) The package shall be child-resistant. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)) (Rev. December 1983), which is hereby incorporated by reference.
***
(e) If the product is an edible product, the package shall be opaque.
(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is maintained throughout the life of the package.

[Issue] Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers.
Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat”.

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product. We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.

Primary Panel Labeling Requirements: CCR § 40405

[Issue] It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

Universal Symbol: CCR § 40412

[Issue] Many edible products are small and don't have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B)

(B) For cannabis products: “GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS 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 CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.”

[Issue] Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) <-- DONE

c) Edible cannabis products shall be:
(2) Produced and sold with a standardized concentration of cannabinoids not to exceed 10 milligrams tetrahydrocannabinol (THC) per serving.

[Issue] A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d)

c) A M-license is required in order to manufacture cannabis products for sale in the medicinal-use market.

(d) An A-license is required in order to manufacture cannabis products for sale in the adult-use market.

[Issue] This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to
completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once.

The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029
Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199

We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e)

A licensee shall not give away any amount of cannabis or cannabis products, or any cannabis accessories, as part of a business promotion or other commercial activity

--

(a) A licensed dispensary shall not provide free samples of medical cannabis goods to any person.

[Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

(b) A licensed dispensary shall not allow representatives of other companies or organizations to provide free samples of medical cannabis goods to individuals on the licensed dispensary premises.
We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

Recommendation: We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

***

(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale.

Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax f a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we have outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup

5411. Free Cannabis Goods

(a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers.

A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase.

In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c)
(b) The bureau shall develop criteria to determine which batches shall be tested. All testing of the samples shall be performed on the final form in which the cannabis or cannabis product will be consumed or used.

(b) The laboratory may obtain and analyze samples only from batches in final form as required by Business and Professions Code section 26100.

c) The laboratory shall collect both a primary sample and a field duplicate sample from each batch. The primary sample and field duplicate sample shall be stored and analyzed separately.

Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regiment is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods
A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264

Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178

The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may...
and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens

The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044

Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7.
Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

We are small business who wish the following to be reflected in the regulations.

Single manufacturing license for A & M: CCR § 40115(c) and (d)

[Issue] This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

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Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once.

The A & M designations may be logical at the retail level, but not for suppliers.

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Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

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Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

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Thank you.
Page 1

Q1 First Name (Optional)

Alisha

Q2 Last Name (Optional)

M

Q3 Organization (Optional)

Respondent skipped this question

Q4 Title (Optional)

Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

Packaging: CCR § 40415 [Issue]: Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy: Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers. Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.”

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product. We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#49

Collector: Web Link 1 (Web Link)
Started: Wednesday, February 21, 2018 2:58:37 PM
Last Modified: Wednesday, February 21, 2018 2:59:55 PM
Time Spent: 00:01:17
IP Address: 24.130.189.4

Page 1

Q1 First Name (Optional)
Alisha

Q2 Last Name (Optional)
M

Q3 Organization (Optional) Respondent skipped this question

Q4 Title (Optional) Respondent skipped this question

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Page 1

Q1 First Name (Optional)
Deborah

Q2 Last Name (Optional)
Sadler

Q3 Organization (Optional)
CBCB Berkeley

Q4 Title (Optional)
General Manager

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Primary Panel Labeling Requirements: CCR § 40405: [Issue] It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412 [Issue]: Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25 in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B) [Issue]: Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) : [Issue] --- A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d): [Issue] --- This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is
only completed once. The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029: Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199: We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non-extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e): [Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However, samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely. We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale. Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax f a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as
well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxed on the sample rate they were sold at instead of based on the standard markup.

5411. Free Cannabis Goods: (a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers. A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase. In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c): (ISSUE): Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regimen is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods : ISSUE - A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264: Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to
Perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178: The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens: The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044: Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7."
Page 1

Q1 First Name (Optional)
Alisha

Q2 Last Name (Optional)
M

Q3 Organization (Optional)
Respondent skipped this question

Q4 Title (Optional)
Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.
Manufacturers Subcommittee
**Q6** Feedback for Subcommittee

5411. Free Cannabis Goods: (a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers. A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase. In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#52

Collector: Web Link 1 (Web Link)
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Time Spent: 00:03:56
IP Address: 98.210.217.247

Page 1

Q1 First Name (Optional)
Paul

Q2 Last Name (Optional)
Roethle

Q3 Organization (Optional)
Peridot Labs // Chemistry // SG Scientific

Q4 Title (Optional)
CEO, CSO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Manufacturers Subcommittee
3/1 subcommittee meeting topics:
a. Packaging Requirements
b. Child-Resistant Packaging
c. Products Attractive to Children
d. Employee Health and Safety
e. Dosage, Medicinal v. Adult-Use
f. Volatile vs. Nonvolatile Manufacturing (e.g., Purity levels for gas)
g. Waste Destruction
h. Labeling
Samples?

Packaging: CCR § 40415
A package used to contain a cannabis product shall adhere to the following requirements:

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(b) The package shall be tamper-evident, which means that the product shall be packaged in packaging that is sealed so that the contents cannot be opened without obvious destruction of the seal.

(c) The package shall be child-resistant. A package shall be deemed child-resistant if it satisfies the standard for “special packaging” as set forth in the Poison Prevention Packaging Act of 1970 Regulations (16 C.F.R. §1700.1(b)(4)) (Rev. December 1983), which is hereby incorporated by reference.

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(e) If the product is an edible product, the package shall be opaque.

(f) If the package contains more than one serving of cannabis product, the package shall be re-sealable so that child-resistance is maintained throughout the life of the package.

[Issue] Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers.

Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat”.

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product. We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.

Primary Panel Labeling Requirements: CCR § 40405

[Issue] It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412

[Issue] Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.
Different labeling requirements for topicals: BPC § 26120(c)(1)(B)

(B) For cannabis products: "GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS 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 CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION."

[Issue] Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) <-- DONE

(c) Edible cannabis products shall be:
(2) Produced and sold with a standardized concentration of cannabinoids not to exceed 10 milligrams tetrahydrocannabinol (THC) per serving.

[Issue] A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d)

(c) A M-license is required in order to manufacture cannabis products for sale in the medicinal-use market.
(d) An A-license is required in order to manufacture cannabis products for sale in the adult-use market.

[Issue] This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is
only completed once.

The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029
Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199

We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.
We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.
Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e)

A licensee shall not give away any amount of cannabis or cannabis products, or any cannabis accessories, as part of a business promotion or other commercial activity

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(a) A licensed dispensary shall not provide free samples of medical cannabis goods to any person.

[Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

(b) A licensed dispensary shall not allow representatives of other companies or organizations to provide free samples of medical cannabis goods to individuals on the licensed dispensary premises.

We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

Recommendation: We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B
function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

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(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale.

Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax of a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we have outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup

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The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c)

(b) The bureau shall develop criteria to determine which batches shall be tested. All testing of the samples shall be performed on the final form in which the cannabis or cannabis product will be consumed or used.

(b) The laboratory may obtain and analyze samples only from batches in final form as required by Business and Professions Code section 26100.
Supply-chain regulations.

Accurate results into cannabis. Recommend:

Testing Batch.

Allowing batch control: CCR § 40264

Testing Manufactured Goods
A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264

Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178

The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair product burdens...
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Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044

Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7.
Q1 First Name (Optional)  
Respondent skipped this question

Q2 Last Name (Optional)  
Respondent skipped this question

Q3 Organization (Optional)  
Respondent skipped this question

Q4 Title (Optional)  
Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Constance Therapeutics is a medicinal cannabis company producing standardized, science-based whole-plant cannabis extracts. These extracts fill the gap between traditional pharmaceuticals and commonplace cannabis products, providing much needed additional treatment options for physicians and their patients. Since 2008, the company has employed stringent, science-based processes and standards to ensure the highest quality and consistency. Headquartered in San Francisco, CA, Constance Therapeutics’ cannabis extracts have historically been available exclusively for therapeutic use by registered California patients under Proposition 215 and California Senate Bill 420, without a single recreational user.

Comments:

Packaging: CCR § 40415
Packaging Requirements:

This is expensive and creates significant waste. Only bottle and glassware should be re-sealable child resistant. All other packaging should be tamper proof. Products for topical application should have more lenient child-resistant packaging requirements as the danger of ingestion is low and are not for internal use. Over packaging creates significant waste and is redundant and has a large, negative environmental impact. Other states, such as Washington, have not required Child Resistant packaging and have not seen safety issues. In addition to licensee responsibility, the consumer has a responsibility for keeping packaging out of hands of children.

Sensible, airtight, vacuum-sealed packaging. One-time CR makes sense. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do
not eat.”

60% of medicinal cannabis users are seniors and many take it for pain--nothing is more harmful to senior end users than multiple child proof obstacles on single packages.

§40306. Requirements for Topical Cannabis Products, Concentrates, and Other Cannabis Products

This limit is not appropriate for patients, who require substantially higher doses for “out of option” conditions.. A 2000mg limit per Package means some patients will receive protocols in tens of bottles instead of one to get the full protocol. This creates an issue for patients carrying several small bottles in addition to the environmental impact of extra waste. Our patients are coached before purchasing our products.

Keep the 1000mg limit for Adult Use consumers, which allows novice consumers to responsibly consume. Allow flexibility for patients (medicinal cannabis consumers) to obtain packages that match their medicinal dosing requirements and physician recommendations. Single manufacturing license for A & M: CCR § 40115(c) and (d)

Is there actually a separate administrative process the agency must complete for each license type? If not, why not let manufacturers apply for both under a single fee and application? Inspection does not occur two times so there isn't a duplicate cost associated with a M and A license. This is an excessive and redundant cost for small businesses and the regulatory justification is unclear. By splitting into two tracks, the medicinal market is threatened because licensees may prefer being in the A market because of economic reasons. If a licensee has been approved for the M market they have also been approved for the A market as the process is the same.

Extend timeframe under CCR 5029 (transition provisions) to allow licensees to conduct business with other licensees, irrespective of the M or A designation on their licenses. This will allow time for legislators to pursue statutory change to allow businesses to obtain a single state license to conduct M & A activities.

Shared spaces: CCR § 40190-40199

Allow shared manufacturing spaces as soon as possible. Clarify necessary separations/barriers to facilitate this. Allowing shared space is small business friendly as the cost of space is a huge barrier to entry for small businesses and equity incubators

Equity incubators require shared space.

Small businesses and equity incubators rely on existing food manufacturing, non-cannabis manufacturing.

Consideration of allowing shared equipment. Cost effective. No cap on square footage? No cap on number of employees sharing space? Shared storage?

Reporting ownership changes to DPH: CCR § 40178

Allow licensees 30 calendar days to notify the state
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#54

**Collector:** Web Link 1 (Web Link)

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**Time Spent:** 01:08:47

**IP Address:** 173.254.252.155

Page 1

**Q1 First Name (Optional)**

Daniel

**Q2 Last Name (Optional)**

Kosmal

**Q3 Organization (Optional)**

Doc Greens Healing Collective

**Q4 Title (Optional)**

President

**Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.**

*Manufacturers Subcommittee*
Q6 Feedback for Subcommittee

Greetings Manufacturing Subcommittee.

The requirement for Topical Cannabis products to be in continuous child resistant packaging is unnecessary, wasteful, costly, and most importantly, makes the products unusable for many elderly Californians with weak or arthritic hands.

Doc Greens Therapeutic Healing Cream was one of the early, if not the first, labeled topical cannabis products in California in 2009. Topical Cannabis products generally have no psychoactive effects, and there is little to no danger of children ingesting topical products, as they are not palatable.

Furthermore, a great number of topical cannabis users are elderly Californians, many of whom suffer with arthritis in their hands. We have received numerous requests over the years from elderly patients that find great pain relief from using our topical products, requesting easier access packaging, as they were frustrated trying to open a simple push button cap top and squeeze a bottle to dispense the infused lotion. Adding the complexity of a “child resistant” packaging feature (usually with tabs to depress or force to be applied) will simply make it impossible for many elderly Californians that would benefit most from topical cannabis products from using them.

We therefore recommend the following modifications to cannabis regulations:

Remove “Topical Cannabis Products” under 120mg/oz from the classification as a Cannabis product. Let’s follow Washington State’s example and have non-psychoactive Topical Cannabis products available to everyone, without packaging restrictions.
Exempt “Topical Cannabis” products from the requirement of having child resistant packaging.
If child resistant packaging is insisted on, please provide that topical products are only required to have child resistant outer packaging, but are exempt from child proofing the dispensing container.

Thank you for your consideration, and efforts in helping us get non-psychoactive, pain relieving topical cannabis products to Californians with pain.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#55

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Page 1

Q1 First Name (Optional)
Andrew

Q2 Last Name (Optional)
Hopkins

Q3 Organization (Optional)
The Werc Shop

Q4 Title (Optional)
Director, Compliance & Logistics

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Licensees need to be permitted to transfer in process/research samples between licenses without the use of a distributor. Small quantities of unfinished goods that are required for product development testing or quality assurance testing should not require a distributor for transportation.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

Q1 First Name (Optional)
Andrew

Q2 Last Name (Optional)
Hopkins

Q3 Organization (Optional)
The Werc Shop

Q4 Title (Optional)
Director, Compliance & Logistics

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee
Distributors need the ability to pay cultivation tax on behalf of manufacturers at the time of raw material purchase. Manufacturers would prefer to pay the cultivation tax before the cannabis goods are manufactured.
Q1 First Name (Optional)
Andrew

Q2 Last Name (Optional)
Hopkins

Q3 Organization (Optional)
The Werc Shop

Q4 Title (Optional)
Director, Compliance & Logistics

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

What is acceptable language to describe the instructions for use of shatter and wax concentrates? There is no dosing system and multiple methods to consume the concentrate.
#58

Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

Page 1

Q1 First Name (Optional)

Megumi

Q2 Last Name (Optional)

Reagan

Q3 Organization (Optional)  Respondent skipped this question

Q4 Title (Optional)  Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

To Whom It May Concern:

I’d like to give the following recommendations to the Subcommittee:

1. Define and clarify the difference between “cannabis byproduct” and “cannabis waste.”

“Cannabis byproduct” and “cannabis waste” are used interchangeably within the regulations. By definition in the current regulations, cannabis waste is cannabis product that has been rendered unrecognizable and unusable. Unrendered waste is still cannabis product/byproduct. Therefore, regulations in regard to cannabis waste management, should refer to byproduct and product as such and should require a cannabis distribution and processing license for a hauler to transport cannabis away for waste management service purposes.

2. Define and clarify how different types of “cannabis byproduct” should be handled.

Cannabis byproduct varies vastly between cultivation and manufacturing.

Cultivation byproduct includes stalks, stems, leaves, flowers, soil, and root balls. Current regulations address composting on-site as a cannabis waste management procedure, but do not address composting standards i.e. having oversight by a licensed third-party. Without third-party verification, there is no way to confirm that on-site composting has been completed correctly and the cultivation waste has been properly documented. Additionally, composting off-site must require a cannabis licensed hauling company, who must obtain a cannabis distribution license. A random hauling company that is licensed to haul cannot service cannabis byproduct, if it has not yet been rendered unrecognizable and unusable. They must also have a cannabis distribution license as they are hauling cannabis product.

Manufactured byproduct is a high-profile stream of waste. As such, regulations must be adjusted accordingly and should not be the same as the regulations set forth for cultivation. Since manufactured waste is more hazardous than cultivation waste, my recommendation is to create more stringent standards that require a cannabis licensed hauling company to manage the waste.

Thank you.
**Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings**

#59

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**Q1 First Name (Optional)**  
Jason

**Q2 Last Name (Optional)**  
Rosenberg

**Q3 Organization (Optional)**  
Respondent skipped this question

**Q4 Title (Optional)**  
Respondent skipped this question

**Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.**  
Manufacturers Subcommittee

**Q6 Feedback for Subcommittee**

"Packaging: CCR § 40415 [Issue]: Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy: Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers. Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language "for external use only. Do not eat."

Requiring opaque packaging removes the consumer's ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It's proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale."
Primary Panel Labeling Requirements: CCR § 40405: [Issue] It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412 [Issue]: Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25 in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B) [Issue]: Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) : [Issue] --- A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d): [Issue] --- This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once. The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029: Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

Of a designation on their license. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199: We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e): [Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely. We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

***

(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale. Sales and promotional samples shall be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax for a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup

5411. Free Cannabis Goods: (a) A retailer shall not provide free cannabis goods to any person.
Moreover, industry sources has demonstrated the situation to be even worse due to the ever increasing regulations. As a result, cannabis businesses are forced to invest heavily in raw materials and remain within the strict guidelines set forth by the Department of Health and Human Services (DHHS) and the California Health and Safety Code (HSC) & the California Code of Regulations (CCR). Compliance with these regulations is complex and costly, often requiring significant investments in new equipment, facilities, and personnel training. Despite these efforts, the industry still faces challenges in ensuring that products meet the highest standards.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will result in a significant burden, with costs averaging $1000 per batch. Small manufacturers will thus be asked to spend a large portion of their capital for testing and will be forced to invest heavily in raw materials without having the ability to create revenue, or will be forced to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG's and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regiment is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP's) and critical control points (CCP's) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods: ISSUE - A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264: Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178: The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens: The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044: Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7."

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FOR "Delivery/Retail Subcommittee:"

"5411. Free Cannabis Goods: (a) "A retailer shall not provide free cannabis goods to any person." -- (ISSUE) Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers.

A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase. In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers. The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e): ISSUE: Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults. It’s reasonable
to assume sampling on-site can be done safely.

Recommendation: We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

(b) A licensed dispensary shall not allow representatives of other companies or organizations to provide free samples of medical cannabis goods to individuals on the licensed dispensary premises. ( ISSUE ) - Suppliers need to be able to offer sales samples to dispensary buyers. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

Recommendation: We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retail units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer: ISSUE -- Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax of a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA. It also helps ensure that small suppliers can compete, facilitating the diversity of products offered to consumers.

Recommendation: We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup.

5417. Methods of Delivery: (a) A retailer’s delivery employee, carrying cannabis goods for delivery, shall only travel in an enclosed motor vehicle operated by a delivery employee of the licensee. ( ISSUE ) -- The last thing a busy municipality needs is more cars on their streets. Allowing deliveries to be conducted by delivery employees via scooter, motorcycle, bicycle or even on foot would help alleviate congested roadways, ensure faster, safer deliveries and cut down on harmful emissions to the environment. Cannabis storage in an enclosed and secured compartment is still possible in an unenclosed vehicle. In addition, prohibiting delivery vehicles from carrying no more than $3,000 worth of inventory is counterproductive to public safety. This cap, which forces delivery drivers to make more frequent trips to and from the retailer, increases the likelihood that the driver will be a target of theft and other dangers. This is also less environmentally sound.

Recommendation: Method of delivery may be more appropriately regulated at the local level, given different population density and geography. Remove the cap on inventory to allow a dynamic delivery model. Do not require printed manifest for delivery. Drivers should be able to get TNC (Transportation Network Company) numbers to share insurance and use the driver’s personal vehicles. Lyft and Uber use this model successfully.

5420. Delivery Request Receipt: "A retailer shall prepare a delivery request receipt for each delivery of cannabis goods." ( ISSUE ) -- Type 9-Non-Storefront Retailers are prohibited from allowing public access to their premises. Requiring that the delivery request receipt include the address of the non-storefront retailer presents unnecessary and unsafe exposure for the non-storefront retailer. Not only does calling out the address invite criminal entities to the premises, it also signals to the consumer that their presence is allowed and encouraged.

Recommendation: Use the retailer’s license number rather than address on the receipt. Tracking is still possible, but this method reduces security risks.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

* Related: Address of Type 9-Non-Storefront Retailers should not be listed on the BCC website for the same reasons listed above.

Expand allowable event locations: BPC § 26200(e) ISSUE: -- Offer the ability to host an event with the option to purchase single use permits or a repeating event permit. Allowable locations should be broadened beyond county fairs and district agricultural associations. Event licensing should not eliminate existing (pre-MAUCRSA) small businesses, many of which have served patients for years and are an important part of the community. Regulators are concerned about educating new consumers. Dinner parties, yoga classes, and small gatherings provide safe and legal consumption experiences. They are excellent opportunities for direct education, perhaps more impactful than a flyer or pamphlet because they are interesting and interactive. Tourists will be able to select a supervised/guided experience, rather than purchasing and consuming on the street (and receiving a citation) or in a hotel room alone. Such events also contribute to the normalization of cannabis. There is a substantial therapeutic benefit in combining cannabis with wellness activities.

In terms of criminal justice, the scarcity of consumption locations and opportunities for consumers to enjoy cannabis creates a new form of criminalization. Existing consumption opportunities are incredibly limited and cannot accommodate demand. The law encourages consumers to consume in violation of the law, by having legal ways to purchase without sufficient legal ways to consume. This is an equity issue, as consumption in public housing is not allowed. Those consumers will have limited legal options to consume compared to a person of greater means who owns their property and cannot be restricted from consuming in their home."

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FOR "Distribution Subcommittee":

"Taxation: The existing tax structure pushes small and medium sized businesses out. Recommendation: Shift cultivation tax to one percentage-based number at the point of sale. Shift excise tax liability to retailer, rather than having retailer pay distributor in advance before collecting the tax from the consumer.

Create greater efficiency and clarity in the tax. Makes it more transparent for consumers, who should understand the taxes they are paying.

Medical patients shouldn't have to pay the excise tax, which is essentially a 'sin tax.' Requiring this is like charging an excise tax on prescription medications.

Commercial vehicle ownership: Recommendation: Allow employees to incorporate and own their vehicles. This is more cost-effective. Follow the TNC model (Lyft/Uber).

Relabeling by distributors: CCR § 5303: A manufacturer places test results on label. Distributors can't relabel after test results, even if testing shows different values; they can relabel THC but not CBD, terpenes. There is also a related issue of different testing results from labs using different methodologies that should be corrected through standardization. Suppliers need to be able to tell the distributors which labs have protocols that are effective for the product type. Please clarify acceptable variance and whether products need to be relabeled if test results are within that margin.

Recommendation: Allow distributors to relabel for CBD and terpenes; standardize testing methodologies or allow suppliers to specify labs that utilize compatible methodologies; allow a 20% margin for different testing labs' results."

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For "Equity Subcommittee":

"Shared spaces: CCR § 40190-40199: We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s
and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Extend time to conduct business irrespective of M & A designation: CCR § 5029: Licensees may ‘cross over’ between A and M until 6/30/18. The requirement of 2 separate licenses, when cannabis and products are subject to nearly identical quality control and public health requirements, creates an equity issue.

Recommendation: Thank you for including the 6 month transition period! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Please reevaluate whether this policy serves a critical public health and safety function or if another solutions would achieve that aim, with a lower administrative and cost burden to small businesses, which is especially acute for equity businesses."

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FOR "Cultivation Subcommittee":

"Eliminate or moderate the Trim Tax: This substantially increases the expense for suppliers and consumers. Compassionate Use:

Recommendation: Create policy that allows for and encourages donations to compassion programs. Associated tax and administrative provisions should not penalize suppliers who provide free goods to such programs.

Extend time to conduct business irrespective of M & A designation: CCR § 5029: Cultivators must designate a plant on the A or M track early on. Licensees may ‘cross over’ between A and M until 6/30/18.

Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Please reevaluate whether this policy serves a critical public health and safety function or if another solutions would achieve that aim, with a lower administrative and cost burden to small businesses."

THANKS FOR SHARING! <3 We need ALL OF YOU TO HELP to ensure we have a fair, equitable industry that allows all business types & sizes to thrive!
Page 1

Q1 First Name (Optional)
Andrew

Q2 Last Name (Optional)
Hopkins

Q3 Organization (Optional)
The Werc Shop

Q4 Title (Optional)
Director, Compliance & Logistics

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee
Brands require specific detection limits or action levels to be set for these compounds or labs will purchase insensitive equipment to purposefully make the pesticide residues difficult to detect.

§ 5719. Residual Pesticides Testing
(b) The laboratory shall report the result of the residual pesticides testing in unit micrograms per gram (µg/g) on the COA and indicate "pass" or "fail" on the COA.
Page 1

Q1 First Name (Optional)
Andrew

Q2 Last Name (Optional)
Hopkins

Q3 Organization (Optional)
The Werc Shop

Q4 Title (Optional)
Director, Compliance & Logistics

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Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Laboratories will have enough product to test multiple times using only the primary sample. This will cut the volume of holding samples to a more manageable level, and still provide for keeping a retained sample in the event of any questions about the sample outcome.
Q1 First Name (Optional)
Andrew

Q2 Last Name (Optional)
Hopkins

Q3 Organization (Optional)
The Werc Shop

Q4 Title (Optional)
Director, Compliance & Logistics

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee
We suggest 15 days storage. Not 45.

§ 5728. Post Testing Sample Retention
(a) The laboratory shall retain the reserve sample, consisting of any portion of a sample that was not used in the testing process. The reserve sample shall be kept, at minimum, for 15 business days after the analyses, after which time it may be destroyed and denatured to the point the material is rendered unrecognizable.
Page 1

Q1 First Name (Optional)
Andrew

Q2 Last Name (Optional)
Hopkins

Q3 Organization (Optional)
The Werc Shop

Q4 Title (Optional)
Director, Compliance & Logistics

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee
Please clarify how many tests need to be run per sample.

Article 3. Sampling Cannabis and Cannabis Products

§ 5705. General Sampling Requirements
Q1 First Name (Optional)
Andrew

Q2 Last Name (Optional)
Hopkins

Q3 Organization (Optional)
The Werc Shop

Q4 Title (Optional)
Director, Compliance & Logistics

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.  
Manufacturers Subcommittee

Q6 Feedback for Subcommittee
What is the difference? This sounds very similar if not completely the same.

§ 5730. Laboratory Quality Control (LQC) Samples

Continuing calibration verification (CCV) for chemical analysis Percent recovery between 80% to 120%
Reference material and certified reference material for chemical analysis Percent recovery 80% - 120%
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

#65

Collector: Web Link 1 (Web Link)
Started: Wednesday, February 21, 2018 4:08:21 PM
Last Modified: Wednesday, February 21, 2018 4:12:09 PM
Time Spent: 00:03:47
IP Address: 172.10.166.97

Page 1

Q1 First Name (Optional)  Respondent skipped this question

Q2 Last Name (Optional)  Respondent skipped this question

Q3 Organization (Optional)  Respondent skipped this question

Q4 Title (Optional)  Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

FOR MANUFACTURING SUB-COMMITTEE:

"Packaging: CCR § 40415 [Issue]: Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy: Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers.
Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.
Requiring opaque packaging removes the consumer's ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It's proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.
Primary Panel Labeling Requirements: CCR § 40405: [Issue] It's unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412 [Issue]: Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25 in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B) [Issue]: Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) : [Issue] --- A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d): [Issue] --- This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once. The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029: Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M
or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199: We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e): [Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it's reasonable to assume sampling on-site can be done safely. We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

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(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale. Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax f a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

5411. Free Cannabis Goods: (a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers. A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase. In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c): (ISSUE): Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regimen is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods : ISSUE - A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264: Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178: The licensee shall notify the Department of the addition or removal of an owner

173 / 213
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens: The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044: Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7."
Q1 First Name (Optional)  Respondent skipped this question

Q2 Last Name (Optional)  Respondent skipped this question

Q3 Organization (Optional)  Respondent skipped this question

Q4 Title (Optional)  Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy.

Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers.

Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat”.

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product. We would like to see the removal of the requirement that edibles be in opaque packaging.
Page 1

Q1 First Name (Optional)

Jerry

Q2 Last Name (Optional)  
Respondent skipped this question

Q3 Organization (Optional)  
Respondent skipped this question

Q4 Title (Optional)  
Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

Q6 Feedback for Subcommittee

Hi. Thank you for all of your hard work. Please consider the following recommendations in regards to manufacturing and testing.

Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG's and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regimen is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.
Q1 First Name (Optional)  Respondent skipped this question

Q2 Last Name (Optional)  Respondent skipped this question

Q3 Organization (Optional)  Respondent skipped this question

Q4 Title (Optional)  Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

A licensee shall not give away any amount of cannabis or cannabis products, or any cannabis accessories, as part of a business promotion or other commercial activity

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(a) A licensed dispensary shall not provide free samples of medical cannabis goods to any person.

[Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.
Q1 First Name (Optional)
Tony

Q2 Last Name (Optional)
Bowles

Q3 Organization (Optional)
Americans for Safe Access

Q4 Title (Optional)
Chair of SF Chaper

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

FOR MANUFACTURING SUB-COMMITTEE:

"Packaging: CCR § 40415 [Issue]: Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy: Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers.

Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

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Requiring opaque packaging removes the consumer's ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It's proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.

Primary Panel Labeling Requirements: CCR § 40405: [Issue] It's unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412 [Issue]: Many edible products are small and don't have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25 in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B) [Issue]: Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) : [Issue] --- A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d); [Issue] --- This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once. The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029: Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199: We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry. We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety. Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e): [Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely. We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

***

(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale. Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax f a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to
more quickly compete in the market.

Recommendation: Above, we outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup.

5411. Free Cannabis Goods: (a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers. A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based on their specific and unique reactions prior to purchase. In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c): (ISSUE): Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regimen is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods : ISSUE - A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

Batch Production Record & 2nd person for quality control: CCR § 40264: Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178: The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens: The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweights the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044: Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7."
Q1 First Name (Optional)
Sarah

Q2 Last Name (Optional)
Clark

Q3 Organization (Optional) Respondent skipped this question

Q4 Title (Optional) Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.
Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Packaging: CCR § 40415 [Issue]: Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy: Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers. Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language "for external use only. Do not eat."

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.
Primary Panel Labeling Requirements: CCR § 40405: [Issue] It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412 [Issue]: Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25 in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B) [Issue]: Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc., assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

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[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once. The A & M designations may be logical at the retail level, but not for suppliers.

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Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

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We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

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We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

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Q1 First Name (Optional)
Adam

Q2 Last Name (Optional)
Swift

Q3 Organization (Optional)
Phytologie Oakland

Q4 Title (Optional)
Concentrates Manager

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

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Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

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Extend time to conduct business irrespective of M & A designation: CCR § 5029: Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199: We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e): [Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely. We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales sampling, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

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(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale. Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax for a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.

Recommendation: Above, we outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as
well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup.

5411. Free Cannabis Goods: (a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers. A retailer’s ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, strength, quality, taste, smell and personal preference. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based their specific and unique reactions prior to purchase. In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has a demonstrated commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c): (ISSUE): Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regimen is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods : ISSUE - A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264: Recommendation: Allow flexible options for licensees to perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to
perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178: The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens: The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044: Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7."

Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings
Q1 First Name (Optional)
Amanda

Q2 Last Name (Optional)
Respondent skipped this question

Q3 Organization (Optional)
Respondent skipped this question

Q4 Title (Optional)
Respondent skipped this question

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Q5 Manufacturers Subcommittee

Q6 Feedback for Subcommittee

"Packaging: CCR § 40415 [Issue]: Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy: Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers. Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language *for external use only. Do not eat. Requiring opaque packaging removes the consumer's ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product We would like to see the removal of the requirement that edibles be in opaque packaging.

[Recommendations] We are in full support of tamper-evident packaging. It's proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.
Primary Panel Labeling Requirements: CCR § 40405: [Issue] It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412 [Issue]: Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25 in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B) [Issue]: Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) : [Issue] --- A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d): [Issue] --- This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once. The A & M designations may be logical at the retail level, but not for suppliers.

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Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

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We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

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Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

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Q1 First Name (Optional)
Jewel

Q2 Last Name (Optional)
Zimmer

Q3 Organization (Optional)
Cocoa Collection LLC

Q4 Title (Optional)
owner

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Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

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#74

Collector: Web Link 1 (Web Link)
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Page 1

Q1 First Name (Optional)
David

Q2 Last Name (Optional)
Hua

Q3 Organization (Optional)
Meadow

Q4 Title (Optional)
CEO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

Packaging: CCR § 40415 [Issue]: Requiring child resistant packaging as stated in the proposed legislation creates significant waste. We urge you to consider the environmental impact from excessive packaging and redundancy: Requiring child resistant packaging is also expensive. The certification process is time consuming and costly. Sourcing certified child resistant packaging is equally cost prohibitive for small manufacturers.

Washington state does not require child resistant packaging and have not seen safety issues as a result, and the consumer needs to take responsibility for keeping packaging out of hands of children. We believe there should be a balance regarding responsibility consumer and licensee responsibility.

Products for topical application should have more less child-resistant packaging requirements because the danger of ingestion for topicals is low. Topicals should be easy enough to open for those with arthritis. Topicals should not be required to be in child resistant packaging. Instead, should include language “for external use only. Do not eat.

Requiring opaque packaging removes the consumer’s ability to interact with a product before purchasing. With proper labeling the consumer is informed of the contents of the product We would like to see the removal of the requirement that edibles be in opaque
[Recommendations] We are in full support of tamper-evident packaging. It’s proven successful in preventing contaminated products getting into the hands of consumers across other well established industries. We support retailers using opaque child-resistant carry-out bags at the point of sale.

Primary Panel Labeling Requirements: CCR § 40405: [Issue] It’s unclear whether primary panel includes the lid for items like beverages. This is one of the most visible part of the product to alert consumers the product contains THC, and would give us more flexibility in where we can alert the consumer. For example a beverage should be able to put the universal warning symbol on the primary label OR lid.

[Recommendations] clarify primary panel may also be inclusive of the lid to a product.

Universal Symbol: CCR § 40412 [Issue]: Many edible products are small and don’t have enough space for all of the requirements including a .5 in graphic. We believe that allowing the universal THC symbol to be .25 in would still be adequate to alert consumers and be more closely aligned with the symbol requirements from other legalized states, while allowing the rest of the required information to have room.

[Recommendations] amend required size of CA state universal symbol to .25 in

Different labeling requirements for topicals: BPC § 26120(c)(1)(B) [Issue]: Topical products should have different labeling requirements based on scientific evidence. Requiring a warning on the label of topical products that states that the product will impair the ability to drive etc, assumes that all cannabis topicals are formulated with a permeation enhancer as one would find in a transdermal product. The epidermis and dermis block migration of cannabinoids into the bloodstream. Without an efficacious delivery of cannabinoids into the circulatory or lymphatic systems, topical cannabis products cannot neither impair judgement or reaction timing, nor induce psychoactive effects. Transdermal cannabis products should certainly contain the prescribed warning about impairment as all other edibles.

[Recommendation] For transdermal products, we recommend maintaining the same warning and packaging guidelines as edibles. For all other topical products, we recommend eliminating the language about “intoxicating effects.” We further recommend that topicals be exempted from the child-resistant packaging requirements but that they include the disclaimer “For external use only. Do not ingest.” This disclaimer would conform to norms in the cosmetics industry.

100 mg limit for packages/10 mg limit for servings: BPC § 26130(c)(2) : [Issue] --- A 10mg limit per serving a great way to help ensure new patients have a safe experience, and keeps California’s regulations in parity with other legalized states. However, a 100mg per package limit is not appropriate for users who may require higher dosage, and patients will slowly learn their own tolerance and be able to set a sensible dose. Much of the cost of goods is burdened by labor, and packaging, so allowing an increased per package limit will help reduce costs of medicine for medical patients, and decrease overall environmental impact.

[Recommendation] Keep a 10mg limit for Adult Use consumers as well as the requirement to delineate or score, but increase the per package limit to 500mg or 1000mg

Single manufacturing license for A & M: CCR § 40115(c) and (d): [Issue] --- This seems to be a redundant cost for applicants seeking both license types, and one that is cost prohibitive for small businesses. Furthermore, dividing the market into two distinct tracks threatens the medicinal cannabis market. Businesses generally see the adult use market as more promising for growth potential and if forced to choose for economic or administrative reasons, they may choose adult use, leaving patients without sufficient products or retailers. For example a small business would need to maintain to completely separate supply chains from seed to sale losing out on economies of scale, and doubling a manufacturer’s up front cost to service both markets.

[Recommendation] Please reevaluate whether there is an administrative need to have two license types for suppliers. If an applicant applies for both A&M licenses, is the state agency processing each application separately from start to finish? If not, it is recommended
that the state allow a single application for both license types rather than charging to recover costs for two reviews when the process is only completed once. The A & M designations may be logical at the retail level, but not for suppliers.

Extend time to conduct business irrespective of M & A designation: CCR § 5029: Recommendation: Thank you for including this! It would be helpful if you could extend the time frame in which licensees may conduct business with other licensees irrespective of the M or A designation on their licenses. Businesses need more time to comply with regulations and this extension will allow legislators to pursue statutory change for a single state A&M license.

Shared spaces: CCR § 40190-40199: We are in full support and excited about shared manufacturing spaces! We urge you to define and communicate this legislation quickly as the lack of this legislation negatively impacts our equity partners/incubators and small manufacturers. Licensing fees have become a barrier to entry for small businesses and equity incubators. By allowing shared spaces, small businesses can afford to obtain zoning-compliant spaces and enter the regulated market.

Recommendation: We request you to consider allowing shared equipment for non extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

Finally, please allow licensees in shared spaces to have shared storage. This will help small businesses to afford the costs of compliance. Shared locked cages for product are economically practical and guidelines may be specified to ensure each licensee’s products remain separate within the cage.

Promotional Samples: BPC § 26153, CCR § 5411(a) and (b), RTC § 34011(a)(1) and (e): [Issue] Sampling is the most effective way for patients to discover the treatment methods that work best for them through firsthand experience. Medical cannabis products can be high-priced, and patients may be reluctant to spend money to find the best method of intake for them. However samples can be both properly tested, and distributed through the track and trace system to safely allow patients to experience new products. Cannabis has been deemed by the state to be safe for recreational use by adults, and dispensaries can only admit consenting adults it’s reasonable to assume sampling on-site can be done safely. We need to be able to offer sales samples to dispensary buyers. In order to grow our business effectively we need to be able to open up new accounts. The only way a dispensary will consider adding products to their menu is when they are able to sample the retail unit that they would purchase for patients and consumers.

[Recommendation] We propose samples be allowed for the purpose of patient education, and that they be distributed through licensed distributors using the same testing requirements as retail product. The chain of custody is preserved under the proposed safety compliance channels, ensuring sampling is a safe and effective way to educate.

We would like to see concessions that allow sales samples to be given away to prospective buyers as a B2B function. All retain units will go through the track and trace system, but a sensible allowance of 4% of product may be allocated for sales samples strictly for the purpose of B2B account establishment. We also recommend that for the purpose of B2B non-commercial sales prospecting, samples should be allowed to be delivered by type II distributors, as these products will not be for sale.

(a) (1) Effective January 1, 2018, a cannabis excise tax shall be imposed upon purchasers of cannabis or cannabis products sold in this state at the rate of 15 percent of the average market price of any retail sale by a cannabis retailer. A purchaser’s liability for the cannabis excise tax is not extinguished until the cannabis excise tax has been paid to this state except that an invoice, receipt, or other document from a cannabis retailer given to the purchaser pursuant to this subdivision is sufficient to relieve the purchaser from further liability for the tax to which the invoice, receipt, or other document refers.

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(e) Cannabis or cannabis products shall not be sold to a purchaser unless the excise tax required by law has been paid by the purchaser at the time of sale. Sales and promotional samples should be exempt from excise tax, and these are B2B tools for business development, and not for commercial use. It’s unreasonable to burden a sales sample with the full tax f a sellable product, and this will lead to more delays to getting product into the market which will ultimately drive more tax revenue for CA, and allow manufacturers to more quickly compete in the market.
Recommendation: Above, we outlined ways that we think manufacturers and distributors should be allowed to provide B2B samples, as well as consumer samples. We recommend that samples either be non-taxable items to match other industries, or, that they be taxes on the sample rate they were sold at instead of based on the standard markup.

5411. Free Cannabis Goods: (a) A retailer shall not provide free cannabis goods to any person.

Despite the fact that cannabis has been legally available to qualified medical patients in California since 1996, there exists a huge knowledge gap among cannabis consumers, particularly new or returning adult-use consumers. A retailer's ability to offer free samples will go a long way in closing that knowledge gap, helping to educate consumers regarding efficacy, dosage, consumption methods, and more. Cannabis is not a one-size-fits-all product. Every body processes cannabis differently, and sampling will enable consumers to evaluate products based on their specific and unique reactions prior to purchase. In addition, allowing manufacturers to offer samples to retailers will serve to educate retail staff who are often the first (and sometimes only) source of information for consumers.

The ability to give out free samples is especially important when considering cannabis compassion programs and the fact that the industry has demonstrated a commitment to helping those in need.

Recommendation: Adopt policy similar to the pharmaceutical industry where manufacturers are allowed to offer free samples to physicians who may then pass on the products to their patients. Mark sample products clearly as “not for sale” and limit the quantity/size of sample to a single serving/dose.

Sampling (for testing) in final form: BPC § 26100(b) & CCR § 5705(b) and (c): (ISSUE): Requiring the full battery of laboratory tests on every batch of final-form product is both economically onerous and scientifically unsound.

On the economic front, this will be a nearly insurmountable cost for small manufacturers. Testing each batch for potency, residuals, pesticides, microbiologicals, and heavy metals will end up costing many hundreds of dollars and likely result in delayed terms of payment for wholesale product. Small manufacturers will thus be asked to front thousands of dollars of capital for testing and will be forced to invest heavily in raw materials without being able to create revenue, or will be force to create batches much larger than their sales volume, and edible products do have a shelf life. And even if a small manufacturer can afford all of the capital outlays, the additional cost will greatly burden their COG’s and force them to pass along those costs to adult use consumers and medical patients.

For manufacturers and established manufacturing processes, this testing regiment is scientifically unsound. For a manufacturer our raw cannabis materials are tested before we incorporate them into our finished products. Our DPH-approved standard operating procedures (SOP’s) and critical control points (CCP’s) are designed in compliance with FDA and good manufacturing practices guidelines to ensure accurate potency and sanitary and safe manufacturing processes. Furthermore, the incorporation of other, non-cannabis raw materials into a finished product is no different than in many other regulated industries, such as food, beverages, and cosmetics, and it does not seem logical to hold us to higher laboratory testing requirements than those industries. We believe that the standards already laid out by the FDA and the CDPH protect public health and safety with regard to manufactured goods.

We would recommend requiring manufacturers to obtain full testing results for all cannabis raw materials (ingredients) and keep those results on file for an adequate period of time. Non-cannabis raw materials and other ingredients can be regulated in parity with FDA regulations as outlined in 21 CFR 117 Subpart G, which details the FDA verification process that ensures the safety of the ingredient supply-chain. And as for the final form product, we would recommend periodic testing once the previous two requirements are met.

Testing Manufactured Goods: ISSUE - A 10% MOE for edible cannabinoid testing is far too strict.

Recommendation: Allow a 20% margin - similar to current FDA food standards - especially in light of the current MOEs that most labs carry specific to edible products.

Batch Production Record & 2nd person for quality control: CCR § 40264: Recommendation: Allow flexible options for licensees to
perform the verification. Please do not require that the person verifying be a formal employee of the licensee, as this will create a huge additional cost for licensees that can conduct most operations with a single operator, but can retain services from a qualified individual to perform the verification steps. Allow the SOPs to define the critical control points at which such verification is necessary and effective.

Reporting ownership changes to DPH: CCR § 40178: The licensee shall notify the Department of the addition or removal of an owner occurring any time between issuance of a license and submission of an application to renew the license within 10 calendar days of the change. The new owner shall submit the information required under Section 40130 to the Department. The Department shall review the qualifications of the owner in accordance with the Act and these regulations and determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis.

Recommendation: Allow licensees 30 calendar days to notify the state.

Local taxation, and fair market burdens: The legalization of cannabis was meant to provide customers and patients with safe access to cannabis as well as provide the state with additional revenue. However many local jurisdictions have also imposed gross receipts tax on cannabis businesses that far outweighs the taxation on any other industry. Combined with state excise tax, and the complexity of the supply chain, this results in lower margins, and can make small businesses non-competitive with the larger market solely based on where they operate.

Recommendation: In order to give the entire industry a level playing field no matter where they operate, and to control the overall tax burden of a new industry, we propose capping county and municipal level local gross receipts taxes on manufacturers at 2%. Please also clarify tax collection as it relates to manufacturers.

Security Systems: CCR § 5044: Security systems are another barrier to entry for small businesses but there are a wide range of affordable systems which are extremely modern and up to date for those affordable cloud based services offer a maximum of 60 days of footage and record 5 minutes clips based on motion rather than 24-hour continuous recording. 24 hour continuous recording is more than any other industry and requires costly custom installations with large external storage systems. We love the idea of a cloud based system and it makes sense to set the regulations to match the standard met by the best modern security systems.

Recommendation: allow operators to capture 60 days of footage instead of 90, and allow footage to be captured when motion is detected rather than 24/7.
Page 1

Q1 First Name (Optional)
Daniel

Q2 Last Name (Optional)
Kosmal

Q3 Organization (Optional)
Doc Greens Healing Collective

Q4 Title (Optional)
President

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee

We are a Manufacturer licence holder, and we would like to provide the service of processing cannabis (extraction and refinement) to other Manufacturer and Packaging Licensing holders. A common transaction would be to receive cannabis flower and trim from the other licensed entity, and process it into oil for cartridges or other products for them. Assuming the flower tax has already been collected by the first manufacturer, we would only be providing a service, should not be required to collect flower taxes, or perform redundant testing.

Recommendation: Please define a clear process for Manufacturers to provide cannabis processing service for other permitted licence holders (ie Manufacturers and Packaging) without redundant testing or taxes.

Thank You
Q1 First Name (Optional)
Diana

Q2 Last Name (Optional)
Ciuca

Q3 Organization (Optional)
Steep Hill

Q4 Title (Optional)
Customer Experience Specialist

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee

Q6 Feedback for Subcommittee
I would like to add that any licensee is allowed to transport samples as long as it is for testing purposes only. Right now, only Distributors have that privilege -- forcing Licensees to pursue a Distribution license or partner up with a Distributor in order to ensure product quality testing. Cultivators and Manufacturers should have the ability to test their product by taking the sample to the lab without having to put extra pressure on testing labs to create a network of sample pick-ups across the state. Process analytics demands cannot be met by distributors alone.
Q1 First Name (Optional)

Ramona

Q2 Last Name (Optional)

Rubin

Q3 Organization (Optional)

Doc Green's Healing Collective

Q4 Title (Optional)

Founder/CIO

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

At Doc Green’s Healing Collective we have been producing topical cannabis products since 2010. We have seen a great number of people with diverse conditions benefit from these products without any risk associated with the cannabis.

I have two suggestions for the committee regarding topicals.

1. Topical Cannabis products of less than 120mg/ounce concentration pose no greater risk to children than the comparable product without cannabis. The risk for illegitimate use is negligible. Such products should be removed from classification as a cannabis product and not subject to further regulation. They should be permitted to be sold by any licensed California business, and purchased by anyone 18 or over as in Washington State.

2. The requirement for Topical Cannabis products to be in continuous child resistant packaging is: unnecessary, wasteful and costly, and makes the products less accessible to the elderly Californians or infirm.

Exempt unpalatable “Topical Cannabis” products of less than 500mg/ounce from the requirement of having child resistant packaging.
Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

Page 1

Q1 First Name (Optional)
heidi

Q2 Last Name (Optional)  
Respondent skipped this question

Q3 Organization (Optional)  
Respondent skipped this question

Q4 Title (Optional)  
Respondent skipped this question

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Manufacturers Subcommittee

Q6 Feedback for Subcommittee

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Recommendation: We request you to consider allowing shared equipment for non-extraction related equipment. With the proper GMP’s and SOP’s in place there should be little to no risk of cross contamination. This is similar for mobile bottlers in the alcohol industry or co-packers in the traditional food industry.

We urge you to avoid any language defining or capping square footage, number of employees or businesses per premise. There are significant safety measures put in place by the Fire Department as well as the Department of Public Health to address any concerns regarding limitations to shared food processing and building safety.

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Cannabis Advisory Committee: Subcommittee Input Survey for March 1 Meetings

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Page 1

Q1 First Name (Optional)
Charlie

Q2 Last Name (Optional)
Rutherford

Q3 Organization (Optional)
Boveda, Inc

Q4 Title (Optional)
Business Development Director

Q5 Please choose the one subcommittee to which you would like your feedback to be sent. Note: You may submit feedback to as many subcommittees as you wish. Simply click on the link again to submit additional comments.

Manufacturers Subcommittee
Q6 Feedback for Subcommittee

As a representative of Boveda, Inc., a manufacturer of humidity control technology designed for cannabis flower, I am writing to comment on the proposed emergency regulations. In section §5717, a maximum acceptable limit for Moisture Content (MC) at 13%, and Water Activity (AW) at 0.65 for cannabis has been set, which ensures the safety of the cannabis from microbial growth. But there is no set minimum limit, thus not defining “dry-weight ounce,” and this absence can introduce unwanted variance in the manufacturing process. Cannabis in flower form is subject to fluctuations depending on environmental and storage conditions, as well as intentional manipulation. Tax calculation, potency testing, and accuracy in labeling, are based on flower weight as if it is a static measurement. However, our research and secret shopping efforts have shown dramatic variation in flower moisture content and measured weight by the time it is sold at the retail level, to the tune of as much as 25% lower weight than labeled.

In order to maintain consistency in product throughout the manufacturing process, we urge this subcommittee to recommend the regulating agencies work together and set a legal definition for dry-weight ounce, including minimum values for both MC and AW. My colleagues and I are available to discuss the importance of these recommendations. Please contact me at (952) 745-2905 or charles.rutherford@bovedainc.com if you have any questions regarding my comments.