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CGA Comment on BCC Proposed Regulations – August 2018

On behalf of the California Growers Association, representing over 1,000 cannabis businesses in 46 counties, the below comments represent our perspective on the proposed regulations. Eight months into state permitting, the regulated cannabis market lags far behind expectations.

The official numbers, including Q2 state tax revenue at less than 50% of projections, underscore the consensus of our membership: that state and local regulation has been even more difficult to navigate than expected, that high costs and bottlenecks have created substantial barriers to compliance, and that competition with the unregulated market continues to be a major challenge.

Although statute prevents regulators from addressing several key issues, including over-taxation, there's many steps the BCC can take to improve things significantly. Given the serious challenges confronting the regulated market, the BCC should consider wide-ranging and ambitious reforms alongside smaller technical fixes.

A few themes run throughout our members' feedback on the proposed regulations. First, many well-intended regulations that are appropriate for large and/or urban businesses are major barriers from the perspective of small, cottage, or off-grid businesses. This is a special challenge in the BCC's regulations, which formally cover urban-leaning retailers and distributors, but which also have enormous implications for small and rural cultivators and manufacturers. For instance, one recurring theme in our comments is the inappropriate extension of urban security requirements to rural contexts where these requirements are both unnecessary and impractical. Despite challenges, it's important to note that most cultivators are still small businesses operating in rural areas: of the 1,273 individual businesses that held cultivation licenses on August 5, 65% were permitted for less than 10,000 square feet, and 92% were permitted for less than an acre.

Second, fulfilling the BCC's legislative mandate to protect the public means ensuring that regulated cannabis can compete with unregulated alternatives. As the regulated market struggles to compete with illicit competition, practical and financial costs of compliance are a major factor. If the regulated market fails, the state will not realize its goals for public safety, environmental sustainability, or tax collection.

Finally, of all the challenges that our members identified in surveys and discussions, testing issues stood out as the consistent top priority. Testing is currently costly, slow, and inconsistent, and affects every aspect of the regulated market. Accordingly, measures to increase testing

capacity and reliability, while protecting public safety, should be a top priority for the BCC. These comments contain several specific suggestions for amending testing requirements, including regulations to allow for "compositing," an amendment which our members identified as their top regulatory concern.

We appreciate your attention to these difficult issues, and we look forward to continuing to work with you to develop rules that promote the success of California's regulated marketplace, protect public health and safety, and reduce barriers to entry for the thousands of small and independent cannabis businesses throughout the state.

Respectfully,

HD Allen

Hezekiah D. Allen
Executive Director

Summary of Comments

1. Implement compositing regulations to manage the cost of testing.
2. Amend §5411(b)(1) to remove the requirement that a patient must have a county-issued ID card to qualify for compassionate use donations, as recommended unanimously by the Cannabis Advisory Committee.
3. Clarify rules regarding samples between businesses, as recommended by the Cannabis Advisory Committee.
4. Make distribution transport-only licenses accessible to small businesses by recognizing several key policy differences from full-service distribution, particularly the lack of rationale for regulation on the physical "licensed premises."

    4A. Amend §5315 to exempt all transport-only distributors - not just self-distributors - from premises-based security requirements in Article 5, as recommended by the Cannabis Advisory Committee.

    4B. Allow a transport-only premises to be shared with another licensed premises, or to be based in a home office.

    4C. Amend §5315(d) to clarify that transport-only distributors may transport products for non-certified testing.

    4D. Amend §5308 to reduce insurance requirements on small transport-only and self-distributors.

5. Support - new requirements in §5413 for child-resistant exit bags, with several amendments to encourage sustainability and preserve flexibility.

    5A. Packaging may be in either child-resistant exit bags or child-resistant product packaging.

    5B. By 2020 all exit bags should be required to be durable, intended for multiple uses, and made of compostable materials.

    5C. Customers may reuse their exit bags.

    5D. Retailer should be required to make exit bags available on request. Retailers may charge a fee for exit bags as part of a program to encourage reuse.

6. Ensure the microbusiness license serves its intended purpose to facilitate small cultivators, as recommended unanimously by the Cannabis Advisory Committee at their August meeting.

    6A. Exempt microbusinesses from security requirements in §5042-§5047 upon a positive finding from a local government that they are not necessary.

    6B. Remove the limits on qualifying microbusiness activities in §5500(a).

    6C. Amend §5014(c) to create additional microbusiness fee tiers for businesses under $2.5M.

6D. Allow microbusinesses that include outdoor cultivation to conduct manufacturing at a nearby but non-identical premises.

7. Consider skip-lot or process validation rules to address testing capacity issues.

8. Clarify that immature cannabis plants and seeds are not required to be sold in child-resistant packaging, consistent with legislative intent.
9. Amend §5303.1 to allow the net weight of flower to vary up to 5-10% greater than, but not less than, the labeled amount.
10. Amend §5303(b) to allow distributors to relabel manufactured products.
11. Remove §5407 to allow retailers to sell non-cannabis goods.
12. Amend §5050(d) to grant regulators discretion to allow normal commercial cannabis activity in the event of an extended METRC outage.
13. Remove the requirement in §5601(h)(11) that temporary event participants must specify a list of all employees involved in sales.
14. Amend §5718 to exempt topicals from residual solvent testing for ethanol, consistent with the BCC's ISOR.
15. Clarify the intent of §5303(a) to allow distributors to produce pre-rolls from dried flower.
16. Amend §5000 to clarify that "cannabis products" is a term of art referring to manufactured cannabis products.
17. Beta test METRC prior to release.
18. Amend §5014 to include an additional license tier for small events.
19. Support - clarification in §5307 that distributors may transfer product to other distributors after testing.
20. Support - current microbiological testing requirements in §5720.

21. Support - §5718(d)(2)(A), clarifying that tinctures will not fail testing due to ethanol content, and request that this clarification be extended to existing emergency regulations.
22. Support – efforts to reduce variance in testing through requiring labs to submit SOPs in §5711.
23. Support – amendment to §5305(c) decreasing the sampling video storage requirement to 90 days.

Comments on BCC Regulations

1. Implement compositing regulations to manage the cost of testing.

Regulations that allow for compositing were identified as our members' #1 regulatory priority in our internal survey. Compositing is a set of testing rules that allow multiple strains to be tested together for pesticides and other contaminants, so long as they were harvested at the same premises at the same time, and the consolidated batch falls under the total maximum batch size of fifty pounds. These rules have already been adopted in Oregon and are explained in detail on pages 2-4 of the OLCC's "Sampling and Testing Metrc Guide." (https://www.oregon.gov/olcc/marijuana/Documents/CTS/SamplingandTestingGuide.pdf)

Under the current system, a cultivator growing three strains – each of which produce fifteen pounds – must pass three independent tests for pesticides, solvents, microbial impurities, foreign material, mycotoxins, and heavy metals, even if all three strains were harvested from the same premises at the same time.

Adopting compositing rules would have major and positive impacts for both businesses and consumers. Based on current laboratory testing prices, we estimate compositing would decrease testing costs by 20-40% – between $1,000-$3,000 – for a small 3,000 square foot outdoor farm harvesting eight strains totaling three hundred pounds.

In addition to reducing costs for cultivators, compositing would reverse artificial incentives towards monoculture, encouraging the production of diverse cannabis strains and allowing for more medically-targeted strains and greater consumer choice in the regulated market. It would also decrease the overall burden on testing labs, alleviating the bottlenecks which affect everyone.

The Bureau has broad authority to implement regulations that manage testing costs. Sections 26100(b) and 26104(b)(2) of the Business and Professions Code direct the Bureau to "develop criteria to determine which batches shall be tested" and "specify how often licensees shall test cannabis and cannabis products," respectively. As the industry as a whole struggles under limited testing capacity and increasingly demanding Phase 2 testing requirements, we believe compositing is a commonsense way for the BCC to manage testing costs and bottlenecks without compromising consumer safety.

2. Amend §5411(b)(1) to remove the requirement that a patient must have a county-issued ID card to qualify for compassionate use donations, as recommended unanimously by the Cannabis Advisory Committee.

§5411(b)(1) of the Bureau's emergency regulations currently requires patients to possess a county-issued ID card in order to qualify to receive free cannabis product. The requirement to hold this ID card is a significantly higher standard than the general legal requirement, first established under Proposition 215, to receive a medical recommendation from a doctor in order to qualify as a medical cannabis patient. County ID cards were first established in 2003 under SB 420 as a purely voluntary program:

"(2) With respect to individuals, the identification system established pursuant to this act must be wholly voluntary, and a patient entitled to the protections of Section 11362.5 of the Health and Safety Code need not possess an identification card in order to claim the protections afforded by that section."

Despite Prop 215 and SB 420's intent, ID cards have moved from purely voluntary to near-mandatory under current regulations. This shift is extremely troubling given that the vast majority of California cannabis patients do not possess an ID card, and there are major costs to obtaining one. County ID cards are costly and can be held up by slow processing times and bureaucratic delay. Even more crucially, cannabis patients continue to face discrimination in employment, housing, eligibility for federal benefits, and gun ownership rights. As long as this discrimination remains, patients who formally register with state or county governments will be placing themselves at risk.

3. Clarify rules regarding samples between businesses, as recommended by the Cannabis Advisory Committee.

The ability for producers to provide samples to distributors and retailers is essential in any industry, and follows long-standing practice in the cannabis industry. Samples can help small producers gain a foothold in the marketplace and ensure that patients and customers have access to high-quality products.

Our understanding is that providing samples is technically allowed under current regulation so long as samples are not given away for free, as would be prohibited under Business and Professions Code Section 26153. CDTFA also provides guidance to distributors on B2B handling of cannabis samples on its website at http://www.cdtfa.ca.gov/industry/cannabis.htm#Distributors, under Sales of Samples or Promotional Items," and requires these items to be labeled as "not for resale."

That said, regulations currently don't provide clear guidance on how samples can be entered into track and trace or recorded if they are not intended for final sale to the consumer. Regulations clarifying that samples may be provided between businesses in compliance with B+P Section 26153, must be labeled as "not for resale," and may not be sold to a consumer, would help provide businesses with the clarity and confidence to use samples more consistently.

4. Make distribution transport-only licenses accessible to small businesses by recognizing several key policy differences from full-service distribution, particularly the lack of rationale for regulation on the physical "licensed premises."

Distribution transport-only licenses are crucial to ensure that small producers can transport their product to and from nurseries, cultivators, processors, manufacturers, and testing laboratories (for non-certified testing) without relying on full-service distributors. For the regulatory system to function smoothly, the Bureau's goal should be to make the transport-only license easily accessible to every licensee that wishes to obtain one.

Unlike other license types, transport-only licenses have no land use impact or premises requirements other than as a physical location for recordkeeping. §5315(f)(2) prohibits transport-only distributors from storing cannabis on-site in any situation. Transport-only distributors – whether licensed for self-distribution or for transport more broadly – are only permitted to transfer cannabis in a vehicle directly from one licensed premises to another. As a result, counties including Mendocino and Humboldt have granted transport-only authorization via a sub-$100 business license with no additional fees or regulations.

Despite the transport-only license's low impact, to this point it has not been accessible to small cultivators. As of August 14, only 44 transport-only licenses have been issued statewide. The result is a shortage of licensed transportation: full-service distributors are not scaled to engage in small-scale transportation from a nursery or cultivator or from a cultivator to a processor, leaving many farmers unable to move their product off-farm.

To increase the accessibility of the transport-only license, we support the following four amendments.

> **4A. Amend §5315 to exempt all transport-only distributors - not just self-distributors - from premises-based security requirements in Article 5, as recommended by the Cannabis Advisory Committee.**
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> We appreciate the addition of §5315(g) in the last round of emergency regulations, which exempts transport-only self-distributors from Article 5 security requirements, including video surveillance and alarm systems.
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> However, we think it's clear that this exemption should be expanded to all transport-only distributors, as formally recommended by the Cannabis Advisory Committee at their March meeting, and consistent with the transport-only license's total lack of land use impact. To be clear, we support security requirements on vehicles themselves under

§5311, and our requested change is limited to security requirements applied to the premises itself.

The current security exemption for self-distribution is not sufficient for rural communities which may have dozens of licensed cultivation sites located hours from a major roadway. In these cases, centralizing transport in a single licensee will often be more efficient than each business obtaining its own self-distribution transport-only license.

4B. Allow a transport-only premises to be shared with another licensed premises, or to be based in a home office.

Since the transportation-only license has no land use impact and does not authorize cannabis storage, it should be clarified that the license does not have any state land use requirements other than the requirement to have a premises of some sort. Requiring the designation of a separate structure for a transport-only license imposes significant costs on businesses for no regulatory benefit, especially when considering high real estate costs in urban areas and building code issues in rural areas.

The simplest solution for most licensees would be to allow a transport-only license to be issued at a premises already permitted for another activity by that licensee, and require records to be kept at this premises. This would follow established legal precedent in the original emergency regulations, which allowed multiple licenses to be issued at a single premises for adult-use and medicinal activity conducted by the same licensee.

4C. Amend §5315(d) to clarify that transport-only distributors may transport products for non-certified testing.

§5315(d), which understandably prohibits transport-only distributors from arranging for certified (final) testing, could be interpreted as prohibiting non-certified testing as well. Non-certified testing is essential for establishing liability and creating trust between cultivators, manufacturers, and distributors. We request that this section be clarified to allow for transport-only distributors to arrange for this type of testing.

4D. Amend §5308 to reduce insurance requirements on small transport-only and self-distributors.

§5308 currently requires all distributors to hold $2,000,000 in insurance regardless of their size. While state law requires distributors to be insured, it does not specify at what level. Current one-size-fits-all insurance requirements are a major burden on small

operators and are not appropriate for transport-only distributors and self-distributors carrying small amounts of product.

5. Support - new requirements in §5413 for child-resistant exit bags, with several amendments to encourage sustainability and preserve flexibility.

We support the BCC and DPH's new standards regarding child-resistant packaging (CRP), which would remove requirements for CRP on products, and instead require retailers to place all products in child-resistant and resealable exit bags. Requiring CRP on each product produces large amounts of waste and is significantly more expensive than CR exit bags. Current universal product-level CRP requirements are also clearly inappropriate for many products, such as flower, which are not accessible to children under five.

We also support several amendments to the proposed regulation:

5A. Packaging may be in either child-resistant exit bags or child-resistant product packaging.

Some producers have made large investments in developing and purchasing child-resistant packaging under current regulations and should have the flexibility to use this packaging rather than exit bags. Additionally, some producers may prefer to place CRP on the product itself and should be allowed to do so.

5B. By 2020 all exit bags should be required to be durable, intended for multiple uses, and made of compostable materials.

While most current CR exit bags contain mylar and are not environmentally sustainable, it's essential that sustainable exit bags be developed and adopted universally as soon as possible. Standardizing design in exit bags - rather than in thousands of different packages for individual products - provides an opportunity for sustainable design at scale. If the market does not provide this solution, the state should require it.

5C. Customers may re-use their exit bags.

Re-use, even more than recycling, is crucial to environmental sustainability. Single-use exit bags will produce enormous amounts of unnecessary waste.

5D. Retailers should be required to make exit bags available on request. Retailers may charge a fee for exit bags as part of a program to encourage reuse.

Customers should have the opportunity to request exit bags if they prefer. Additionally, the ability for retailers to charge a fee for exit bags is important to encourage customers to re-use exit bags.

6. Ensure the microbusiness license serves its intended purpose to facilitate small cultivators, as recommended unanimously by the Cannabis Advisory Committee at their August meeting.

In the run-up to the vote on Proposition 64, microbusinesses were frequently cited as a key provision protecting the competitiveness of small and independent businesses, and small craft cultivators in particular. To this point, however, it has achieved exactly the opposite effect: it has facilitated large dispensaries that want to grow their own product, while locking out small cultivators who want to sell at retail. .

In our view – consistent with Proposition 64's intent and the unanimous recommendation of the Cannabis Advisory Committee – the microbusiness should be an on-ramp to limited vertical integration for small urban and rural producers that seek direct retail access to consumers. It is not too late to make microbusiness licenses accessible to the businesses that they were created to help, but achieving this goal will require several significant regulatory changes.

6A. Exempt microbusinesses from security requirements in §5042-§5047 upon a positive finding from a local government that they are not necessary.

Expansive security requirements are specific to the Bureau's regulatory scheme, which largely covers businesses located in dense urban areas, and are not reflected in CDFA regulations, which have been geared more towards rural businesses. In particular, §5044 (video surveillance), §5045 (security personnel), and §5047 (alarm systems) are generally not appropriate for rural and home-based microbusinesses, and can be costly or impossible to comply with for remote and off-grid licensees.

We understand that eliminating some or all of §5042-§5047 is likely not practical given that local governments, especially in urban areas, have relied on BCC regulations to ensure the security of local microbusiness dispensaries. Instead, the Bureau should stipulate that §5042-§5047 do not apply to microbusinesses in jurisdictions where the local government has made an affirmative finding that they are not necessary to ensure security. Mendocino County has signaled that it would favor a solution along these lines, and other rural counties would be likely to follow. This "opt-out" clause would allow each local government to strike the appropriate balance between accessibility and security for their local conditions.

6B. Remove the limits on qualifying microbusiness activities in §5500(a).

§5500(a) is a new regulation that would limit qualifying microbusiness activities to licenses created by statute, and exclude licenses created through regulation.

First, we substantively oppose further restriction on qualifying microbusiness activities. The proposed regulation compounds other regulatory decisions that paradoxically increase barriers to entry for small businesses to obtain a microbusiness license, while privileging well-capitalized businesses seeking an on-ramp to vertical integration. Licenses created in regulation are lower-cost and lower-barrier licenses, and §5500(a) would essentially require microbusinesses to engage in capital-intensive activities in order to qualify.

Second, if this regulation stays in place, it should be clarified to specify which licenses are included and excluded. For instance, a Type N license clearly falls under the "Type 6" license contemplated under MAUCRSA, but has been subsequently separated out by DPH to allow for greater specificity. In some way, all licenses "created in regulation" are just further specifications of licenses created by statute.

Finally, the proposed regulation appears to be in violation of statute. B+P 26070(A)(3) requires the BCC to issue microbusiness licenses to businesses acting as small cultivators, Level 1 manufacturers, distributors, and retailers. There is no statutory authority to further limit the availability of these licenses.

6C. Amend §5014(c) to create additional microbusiness fee tiers for businesses under $2.5M.

Current microbusiness fee tiers are extremely broad, and inconsistent with the intent of the license to promote small business. All licensees under $750,000 are charged the same $10,000 fee, and all licensees between $750,000-$2,500,000 are charged the same $30,000 fee. Additional license tiers under $750,000 and in the $750,000-$1.5M range will help tier fees according to business' ability to pay.

6D. Allow microbusinesses that include outdoor cultivation to conduct manufacturing at a nearby but non-identical premises.

Zoning constraints in rural areas have been major barrier to the microbusiness license for small rural farmers. Properties zoned for cultivation, manufacturing, distribution, and retail are most often found in industrial areas in cities, and are not typical in rural areas. By allowing outdoor-only cultivators to utilize a nearby premises, the BCC can make the microbusiness license accessible to rural businesses while preventing abuse by larger urban businesses engaged in indoor cultivation.

7. Consider skip-lot or process validation rules to address testing capacity issues.

Oregon and Colorado have addressed testing capacity issues using process validation and skip-lot rules that exempt licensees with a track record of positive tests from some testing requirements. The Bureau also previously adopted this approach in §5716(b) of its November 2017 emergency regulations, which specified that edible batches must be tested for homogeneity only once every six months following an initial "pass" result. So far, however, the Bureau has not exercised this authority in any other context.

Expanding this rule to other tests would be a sensible measure to manage testing costs for cultivators. Oregon's temporary rules, which temporarily required only 33% of harvest batches to be tested while laboratory capacity caught up with demand, would be a more extreme approach, but possibly warranted if testing capacity continues to lag far behind demand. This policy maintained quality assurance by including a rule that, if any given batch failed testing, all subsequent batches were required to be tested.

A more managed approach would be to create skip-lot procedures for some or all tests identified in §5715(c) and (d), which the Bureau has already identified as lower-priority and waived testing entirely for the first six to twelve months. While we defer to the Bureau's judgment on which tests should be prioritized to protect public health and safety, we believe there are strong reasons to identify lower-priority tests and create policies that treat them as such: once full testing rules are phased in, all tests will be treated as the same, when in reality the majority of concerns stem from a few contaminants that have been systematically identified in cannabis products.

8. Clarify that immature cannabis plants and seeds are not required to be sold in child-resistant packaging, consistent with legislative intent.

Currently, no regulation clearly specifies that immature cannabis plants and seeds must be sold in child-resistant packaging (CRP). Despite this, we understand that regulators have at times suggested that CRP is required for these items, and some retailers refuse to carry immature plants and seeds based on that impression.

The reasons for excluding these items from CRP requirements are straightforward. Live plants will die in CRP packaging; immature cannabis plants and seeds are not psychoactive or dangerous to children; and Prop 64's intent can't be carried out unless consumers have the ability to access the base materials for personal cultivation.

Business and Professions Code 26110(a) exempts immature plants and seeds from quality assurance and testing, and several BCC regulations – notably §5301(c) and §5315(a) – further

underscore that live plants are exempt from quality assurance. In this context, an exemption from CRP for these items is consistent with legislative intent, existing regulation, and common sense.

9. Amend §5303.1 to allow the net weight of flower to vary up to 5-10% greater than, but not less than, the labeled amount.

§5303.1 as proposed would require the labeled net weight of flower to vary by no more than 2.5% from the actual weight, in either direction. Instead, we propose there should be no tolerance for variance that would "short" the consumer (e.g. labeling at 3.5g when the flower's actual weight is 3.4g), but that there should be greater tolerance for weight that exceeds the labeled content by up to 5-10% (e.g. labeling at 3.5g when the flower's actual weight is 3.6g).

A 2.5% allowable variance will be very difficult to meet consistently, especially for packages or pre-rolls weighted in gram increments: in this case, an allowable variance of 2.5% would be just .025g. There is a need for greater allowable variances, but those variances shouldn't allow businesses to short-change consumers. Allowing the label to underestimate, but not overestimate, the net weight of the product by a reasonable margin can deal with both concerns. Allowable variances of 5% would be more appropriate for small-increment packages, while a 10% variance would be more appropriate for large-increment packages.

10. Amend §5303(b) to allow distributors to relabel manufactured products.

§5303(b) prohibits distributors from repackaging or relabeling manufactured products, with a limited exception for relabeling potency after testing and for certain distributors who also hold manufacturing licenses.

The BCC is likely aware of widespread confusion regarding labeling requirements and the high frequency of small mistakes and oversights. In this light, it is unreasonable for distributors to send products back to manufacturers simply to correct minor issues in labeling. While the limited exemption for potency is helpful, the BCC should go further to allow relabeling in general for manufactured products. The key reasons for this change are contained in the BCC's ISOR itself:

"The ability of a distributor to package and label cannabis goods will allow for more efficient and streamlined movement of cannabis goods through the distribution chain, which is necessary to minimize the disruption to the commercial cannabis enterprise. Disruptions to the movement of cannabis goods through the supply chain will increase risks of diversion, as the cannabis goods will be exposed to a larger number of entities and persons before ultimately reaching the retailer and end-user. This section ensures that the risk of diversion is decreased, while also ensuring the risk of cannabis goods being contaminated after laboratory testing is decreased by limiting the ability to go back through the supply chain for relabeling."

While Business and Professions Code §26121(a)(1) prohibits packaging by a distributor, statute does not prevent relabeling by a distributor.

11. Remove §5407 to allow retailers to sell non-cannabis goods.

The proposed changes to §5407 are concerning given that previous regulations explicitly affirmed the ability of retailers to sell non-cannabis goods, and many retailers developed business models under these rules. We view diverse and creative retail business models as beneficial to everyone, including producers, retailers, and consumers. At the minimum, goods such as books, educational materials, clothing, artwork, and industrial hemp-derived products are clearly appropriate for many retail stores, and retailers with on-site consumption should have the ability to explore options such as coffee shops and yoga studios. For comparison, alcohol retailers, tobacco retailers, and pharmacies are authorized to sell products that are not their primary business, such as magazines, candy, and beverages.

From the perspective of small cultivators and manufacturers, appealing and creative retail spaces are important to underscore California's cannabis culture, to emphasize that cannabis is not simply a commodity product, and to contextualize cannabis' uses within a holistic perspective. For smaller retailers, more creative business models are an alternative to competing with larger retailers on volume alone. The proposed regulation also threatens to increase retail prices by limiting the ability to retailers to deduct non-cannabis expenses under IRS 280E, undermining all players in the regulated market.

The BCC's ISOR does not clearly justify a change of this magnitude, claiming that the restriction on non-cannabis goods is necessary to prevent contamination, a concern addressed by packaging and quality assurance regulations. If there are particular business models that are of concern to the BCC, not mentioned in the ISOR, we hope that the BCC will address these business models specifically and not enforce a blanket ban on all non-cannabis retail.

12. Amend §5050(d) to grant regulators discretion to allow normal commercial cannabis activity in the event of an extended METRC outage.

§5050(d) currently forbids any commercial transport or transfer of cannabis if a licensee loses access to the track-and-trace system. While we understand the intent of the regulation, we think it should be amended considering the potential for an extended server-side METRC outage, such as the one that impacted Maryland just last month. The current regulation is acceptable in most cases, but regulators should leave themselves discretion to allow normal commercial cannabis activity if necessary to prevent an extended market-wide shutdown, so long as licensees track their activity on paper.

13. Remove the requirement in §5601(h)(11) that temporary event participants must specify a list of all employees involved in sales.

The requirement to identify all employees is a major burden, especially since it must be submitted sixty days in advance and must be coordinated and submitted by the event organizer. We do not see a benefit of this requirement that justifies such a high level of scrutiny. Licensees are not required to submit a list of employees to the state in any other context.

14. Amend §5718 to exempt topicals from residual solvent testing for ethanol, consistent with the BCC's ISOR.

The proposed regulations sensibly create an exemption from ethanol testing for tinctures, recognizing that ethanol is a core ingredient - rather than an unwanted "residual solvent" - in certain product classes.

The ISOR, referring to §5718's testing exemption for tinctures, suggests that topicals should be exempted from ethanol testing as well:

> *"Proposed subsection (d)(2)(A) specifies that notwithstanding subsection (d)(2) the limit for ethanol does not apply to cannabis goods that intended for tinctures. This provision is necessary to clarify that* ***a laboratory may find test results exceeding the action levels for ethanol in such cannabis products intended for transdermal use, dermal use, or tinctures and that these products are essentially exempt from ethanol and isopropyl alcohol."***

Many cannabis topicals contain ethanol as an essential ingredient, either as a solvent to dissolve active ingredients into a homogenous product, or to hasten evaporation from the skin's surface. Ethanol is also a common ingredient in non-cannabis topicals, such as Purell and cosmetics.

15. Clarify §5303(a) to allow distributors to produce pre-rolls from dried flower.

§5303(a) states that a distributor may "package, re-package, label, and re-label" pre-rolls for retail sale. Our understanding, however, is that this wording may not allow distributors to produce pre-rolls from flower. This interpretation would create significant problems for small cultivators.

Many cultivators are not able to produce their own pre-rolls for a variety of reasons. Processing on-site frequently triggers expensive local code compliance requirements, and there is a shortage of independent processing facilities with capacity to produce pre-rolls. Even if that shortage were addressed, there is no reason to require cultivators to go through an additional supply chain step prior to distribution to make pre-rolls.

Creating pre-rolls at the distributor level has other benefits. When distributors weigh, portion, and package bulk flower, a substantial amount of loose dried cannabis collects in the process. This loose flower account for up to 5%-10% of each cultivation batch and will be wasted – at cost to the cultivator – if it cannot be converted into pre-rolls.

Currently, distributors may package dried flower. "Rolling" is no different than "Packaging," and there is no public safety or other reason to create a distinction. There is physically, practically and functionally no difference between the act of "rolling" a preroll [rolling dried cannabis in paper] and "packaging" [placing cannabis goods into "any container or wrapper that may be used for enclosing or containing any cannabis goods for final retail sale]."

16. Amend §5000 to clarify that "cannabis products" is a term of art referring to manufactured cannabis products.

While both state law and DPH regulation define "cannabis products" as manufactured products, BCC's regulations do not include a clear definition of "cannabis products." Without clarification, this is likely to cause confusion for non-attorneys and make regulatory compliance more difficult for businesses. Adding a definition of "cannabis products" consistent with state law will help to avoid confusion.

17. Beta test METRC prior to release.

Our members have several concerns about METRC, including its technical usability, its suitability for outdoor cultivation, and the potential that METRC will introduce informal "shadow regulations" that create additional constraints outside the stakeholder-driven regulatory process. Beta testing METRC is a commonsense way to check for bugs or errors before it goes into widespread use.

18. Amend §5014 to include additional license tiers for small events.
§5014 currently assesses a $5,000 annual fee for any event organizer who sponsors less than ten events per year. In addition to the $1,000 application fee, this sets a $6,000 floor for any cannabis event. The current standard of less than ten events per year does not track with either an organizer's ability to pay, or the BCC's costs of regulation: an organizer sponsoring nine events is much different from an organizer sponsoring two events, and large events with thousands of attendees are not comparable to small events with hundreds of attendees. §5014 could be amended to support small events by creating a lower licensing tier for event organizers that hold only a few events per year, or who hold events with less than 500 attendees.

19. Support - clarification in §5307 that distributors may transfer product to other distributors after testing.

We strongly support this clarification. Requiring distributors to transfer products directly to retail after testing will prevent major bottlenecks in the supply chain, and will allow distributors to more efficiently transport cannabis goods by specializing in statewide, regional, or local transportation. Products that have been tested and remain in final packaged form are not vulnerable to contamination and may be transferred between distributors without threatening consumer safety.

20. Support - current microbiological testing requirements in §5720.

We support the BCC's current microbiological testing standards, which test for specific identified pathogens, and strongly oppose changes that would involve generalized tests such as those for Total Yeast and Mold Count (TYMC) or Total Aerobic Plate Count (APC).

Current testing regulations reflect the findings of scientific publications that speak most directly to cannabis-related safety issues. The Cannabis Safety Institute's white paper on "Microbiological Safety Testing of Cannabis," for instance, concludes by recommending that "there is no need to test Cannabis for total yeast and mold."

"Total yeast and mold tests detect only a small fraction of the fungal species in the environment, and do not correlate with the presence of pathogenic species. The only pathogenic mold species on Cannabis are types of Aspergillus that must be tested for separately in any case. Molds can potentially be a cause of allergic hypersensitivity reactions, but there is no evidence that these are mediated by smoking. Molds can also be a source of plant spoilage, but these processes can be monitored appropriately by testing for water activity levels, and by visual or microscopic inspection."

Similarly, while the AHP's Cannabis Inflorescence Monograph suggests that TYMC tests can be useful information as part of a cultivator or manufacturer's quality control program, it strongly cautions against using TYMC as pass-or-fail criteria.

Microbes are a natural part of all botanical products, and most that occur on cannabis – and on plant material in general – are not human pathogens. Additionally, certain beneficial microorganisms such as *bacillus* and *beauveria bassiana* that would trigger failures under generalized plate count testing are specifically recommended by DPR for use on cannabis. While it's essential that the BCC require testing for specific pathogenic species of bacteria and fungi, such as *Aspergillus*, *Salmonella* and *E.Coli*, which have been demonstrated to harm human health, more generalized tests will result in high rates of false positives and fail to detect the specific pathogens that pose actual threats to public safety.

21. Support - §5718(d)(2)(A), clarifying that tinctures will not fail testing due to ethanol content, and request that this clarification be extended to existing emergency regulations.

This clarification is essential to allow tinctures to be sold consistent with DPH regulations. The requirement that tinctures cannot be an "alcohol beverage," along with DPH packaging and calibration requirements in §40308, will ensure that tinctures are consumed as intended and not as alcoholic products.

We also request that this clarification be expanded to the existing emergency regulations, which are ambiguous as to whether ethanol is a "residual solvent" in the context of a DPH-regulated tincture. Clarifying that ethanol is not a "residual solvent" for testing purposes under current regulation will clarify that tinctures can be sold for the next several months and keep manufacturing businesses operational.

22. Support – efforts to reduce variance in testing through requiring labs to submit SOPs in §5711.

Variance in testing results within and between labs is a major recurring concern for our members. We support the BCC's efforts to ensure the integrity of the testing system by scrutinizing laboratory testing procedures for accuracy and precision.

23. Support – amendment to §5305(c) decreasing the sampling video storage requirement to 90 days.
Lowering the requirement from 180 to 90 days is a reasonable amount of time to ensure sampling procedures were accurately followed, and cutting back on unnecessary requirements and will reduce the costs of getting products to market.