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June 9, 2017

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Karen L. Smith, MD, MPH
Director and State Public Health Officer
California Department of Public Health
PO Box 997377, MS 0500
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Re: CCLHO Recommendations Regarding the Proposed Medical Cannabis Manufacturing Regulations

Dear Dr. Smith:

The California Conference of Local Health Officers (CCLHO) sincerely appreciates the opportunity to provide input on the proposed Medical Cannabis Manufacturing Regulations issued by the California Department of Public Health (CDPH). CCLHO was established in statute in 1947 to advise the California Department of Health Services (now the California Department of Public Health), other departments, boards, and commissions, as well as officials of federal, state and local agencies, the Legislature and other organizations on all matters affecting health. CCLHO membership consists of all legally appointed physician health officers in California's 61 city and county jurisdictions. On June 1, 2017, CCLHO held a meeting of local Health Officers from across the state to review and vote on recommendations regarding the draft medical cannabis manufacturing regulations.

With the recent legalization of adult-use cannabis and the continuing commercialization of medical cannabis, California is entering a new era which holds the potential for both benefit and harm. Cannabis already impacts communities throughout the state, and this impact will only increase in the coming years, with unknown net long term impacts. As such, it is incumbent on us, as policy makers, subject matter experts, and leaders to be deliberate and conscientious in designing the statutory and regulatory framework in order to both protect health and to ensure the success of the policies enacted by the legislature and approved by the voters.

CCLHO believes that great attention should be given to protecting public health and minimizing negative health impacts. In the interest of protecting the health of our citizens and communities, we urge CDPH to include the following considerations in the adopted regulations:

1. **Ensure product safety.** Cannabis is a rapidly evolving industry creating new and innovative products that have not been widely tested or used. It is critical that policies are put in place to maximize product safety. Regulation is needed to ensure the safe content of cannabis products and prevent product contamination by pesticides, solvents and other chemicals. Manufacturing should adhere to hygiene and sanitation standards. Edible products should be self-stable (non-potentially hazardous food products) and have clear, correct labels.
2. **Protect against overdose and accidental ingestion.** Products need to be immediately identifiable as cannabis products. The manufacture and sale of edible products should be kept entirely separate from food production and sale to prevent confusion or cross contamination. All products should have limits on the amount of active ingredients allowed per dose and per package. Product packaging and labeling should be designed to prevent accidental ingestion.

3. **Prevent youth use.** Available research demonstrates that cannabis may negatively impact the developing brain in individuals up to the age of 25. This is an important detail, for even though adult-use cannabis may be legal for persons 21 and older, this does not mean that chronic use in early adult life will have the same health effects as someone above the age of 25 and may indeed be more risky. In addition, regulations need to be designed to prevent youth use, with policies created to address product visibility, prevent the glamorization of product use and prevent advertising that targets youth. In addition, policies should prohibit the discounting of products to youth-friendly price points. CCLHO also recommends the enactment of policies to prevent the diversion of cannabis and cannabis products to youth who are restricted from accessing these products.
4. **Ensure compliance with regulations and provide adequate resources for enforcement.** The cannabis industry is entirely new to regulation; therefore, now is the critical time to establish and ensure adherence to policies and procedures as this will set the tone for the future. CCLHO strongly believes that the state must inspect commercial operations at least once per year. This inspection schedule is especially critical as the ability of different jurisdictions to oversee the cannabis industry will vary.
5. **Conduct ongoing epidemiology and measure impacts.** Current cannabis scholarship and research is scant. There is particular urgency in understanding more about the biologic effects; health, societal and cultural impacts; and changes in norms and behaviors over time. CCLHO recommends reporting requirements on metrics for both commercial cannabis operations and regulatory agencies, to facilitate the analysis of cannabis commercialization impacts and enable the state and local health departments to accurately evaluate and adjust policy as needed to protect the public's health.

CCLHO believes the Medical Cannabis Regulation and Safety Act (MCRSA) and the proposed regulations from CDPH provide a strong start to regulating this industry, and we applaud those who have worked diligently to build this framework. We have specific thoughts and recommendations, including specific areas where we recommend strengthening the proposed regulations. Please see the detailed attachment enclosed below.

Thank you again for this opportunity to provide input on this important public health issue. If you have any questions, please feel free to contact me via email at Ken.Cutler@co.nevada.ca.us or by phone at 530-265-7154.

Sincerely and on behalf of the CCLHO membership,

Original signed by Dr. Ken Cutler

Ken Cutler, MD, MPH
President, California Conference of Local Health Officers

Enclosure

cc: Lori Ajax, Chief, Bureau of Medical Cannabis Regulation
Amber Morris, Branch Chief, California Department of Food and Agriculture

The California Conference of Local Health Officers (CCLHO) has provided below our specific thoughts and recommendations regarding the draft manufacturing regulations from the California Department of Public Health (CDPH). The CCLHO recommendations are divided into categories, with our highest priorities highlighted in bold italics.

1. Premises:

- a. The Health Officers request clarification the portion of the definition of “Premise” in section 40100 which reads, “The premises must be a contiguous area and may only be occupied by one licensee.” As it is currently written it appears that if an individual holds more than one license, that person/operation could have more than one commercial activity occurring on the same premise. This could create enforcement issues in applying different regulations for different types of operations (i.e. dispensary, manufacturing) to the same location, as well as track and trace issues. In addition, this definition could create issues with potential product confusion if adult-use and medical-use are later allowed to be co-located.
- b. CCLHO also requests clarification as to what other activities may occur on manufacturing premises. ***We believe commercial premises should be limited to commercial operations only and not be permitted to have additional activities (i.e. parties) on-site, as this risks the safety and security of the manufactured cannabis product.***
- c. In addition, the premises of cannabis manufacturers should not be allowed to be used for food manufacturing. ***CCLHO recommends a clear prohibition on the production or sale of food products on site to prevent product contamination, product confusion and accidental ingestion of cannabis products.***

2. Manufacturing License Classifications: CCLHO supports the addition and definition of Type P and Type N manufacturing licenses as defined in section 40118.

3. Substantially Related Acts: The Health Officers support the inclusion of a violation of the California Food Sanitation Act that resulted in suspension or revocation of a license or any civil or criminal proceeding as a potential reason for denial of a license application (40159 and 40162).

4. Material Change Requests: We support the requirement that a manufacturer licensee must immediately notify CDPH of any change in information reported on the license application and of material changes in ownership or operations (40178).

5. Permissible Extractions: CCLHO supports the regulations on permissible extractions, particularly the requirement that non-hydrocarbon-based solvents must be food grade (40220).

6. Good Manufacturing Practices: The Health Officers support the good manufacturing practices requirements including:

- a. Procedures for personnel regarding disease control, cleanliness, garments and hygiene (40232).
- b. Written procedures and maintenance of premises and grounds to prevent contamination of components and products such as adequate draining and adequate waste treatment systems (40234).

- c. Facility construction and design that protects against allergen cross-contact and contamination or product by microorganisms, chemicals filth and other materials as well as construction requirements that ensure adequate lighting and safe movement (40236).
 - d. Sanitary operations that prevent product adulteration or contamination, ensure safe and adequate cleaning, and exclude pests (40238).
 - e. Facility controls to ensure adequate sanitary conditions such as clean water supply, plumbing, sewage disposal, and rubbish disposal (40240).
 - f. Equipment and utensil design and use that ensures they are adequately cleanable and protect against contamination and allergen cross-contact (40242).
7. Odor Control: ***The draft manufacturing regulations do not include requirements that manufacturers put processes and equipment in place to minimize odor and other chemicals from leaving the facility. CCLHO recommends the addition of this requirement to protect both the environment and the neighboring community.***
 8. Hazard Analysis: The Health Officers support the requirement that each licensee shall conduct a hazard analysis to identify or evaluate known or reasonably foreseeable hazards and then implement a plan for preventive control (40256).
 9. Master Manufacturing Protocols: CCLHO supports requirements that the licensee shall have a written manufacturing protocol for each unique formulation of the cannabis product and each batch, with details as to what needs to be included in the protocol (40262). We further support the record keeping requirements.
 10. Product Complaints: The Health Officers support the requirement that each licensee have a procedure for a “qualified individual” to evaluate all complaints, perform investigations, and recommend follow up actions (40266). We recommend further strengthening this section with a clear definition of what makes someone a “qualified individual.” In addition, ***we request a requirement that the licensee notify CDPH immediately if an investigation reveals any concern with the quality, safety, or packaging of product.*** This requirement will ensure that action is taken in a timely manner to recall a product and protect the public’s health.
 11. Track and Trace Requirements: CCLHO supports strong regulations regarding track and trace to prevent product diversion, as listed in section 40272.
 12. Training: CCLHO supports the requirement that all personnel who prepare, handle or package edible products complete a food handler course (40280). We believe this is an important protective measure to ensure product safety.
 13. Waste Management: CCLHO believes that it is critical to have strong regulations for cannabis waste management throughout the lifecycle of the cannabis product, from seed to manufactured product disposal. Section 40290 appears to be a good start and CCLHO recommends the consideration of further input via consultation with waste management experts, such as CalRecycle and the California Conference of Directors of Environmental Health (CCDEH).

14. Prohibited Cannabis Products: CCLHO strongly supports Section 40300. In addition:
 - a. **CCLHO strongly supports the prohibition on infused alcoholic beverages.**
 - b. **We further support the restriction that no cannabis product shall contain any non-cannabinoid additive that would increase potency, toxicity or addictive potential, or that would create an unsafe combination with other psychoactive substances. Prohibited additives include, but are not limited to, nicotine and caffeine.** The full impacts of legalized, commercialized cannabis are yet to be measured and any substance which would potentially make a product more harmful to health should be prohibited.
 - c. **In addition, CCLHO views as critically important the prohibition against producing any cannabis product that would otherwise classify as a potentially hazardous food infused with cannabis.** As this is a new industry without experience in following regulations, and as enforcement mechanisms are just being put in place, there is great concern about the ability to ensure edible products are safe for human consumption. Products that require time-temperature controls to prevent the growth of pathogenic microorganisms or the production of toxins would require substantial regulatory oversight over the manufacturing, transport, distribution, and storage/sale that does not exist at this time.
 - d. CCLHO also supports the prohibition on manufacturing cannabis products by applying cannabinoid concentrate or extract to commercially available candy or snack food items.
15. Edible Product Serving Size: CCLHO supports the maximum THC content of 10 mg per edible product serving and not more than 100mg per package (40305). The health officers also recommend the inclusion of imprinted stamps on each individual serving of an edible cannabis product to ensure that when the product is removed from its packaging, it is still identifiable as a cannabis product with a certain THC content.
16. Maximum THC Contents: We further support the requirement that manufactured cannabis that is not an edible product be limited to no more than 1000mg THC per package of product (40306).
17. Uniform Distribution: CCLHO supports the requirement to homogenize edible cannabis products to ensure uniform disbursement of cannabinoids throughout the product (40307).
18. Labeling Requirements: CCLHO supports detailed packaging and labeling requirements to prevent youth access and use, prevent accidental consumption, and ensure users have information on product contents and safety. We support labeling requirements that include the clear identification that the product contains cannabis, the amount of all active ingredients, the amount per serving and the number of servings, the listing of other ingredients and allergens, and unique identifiers.
 - a. **We support the requirement for warning statements on labels** (40408) and, based on available data, request two adjustments:
 - i. The statement that “cannabis use while pregnant or breastfeeding may be harmful” is insufficient. **The warning should be changed to clearly state that cannabis “should not be used by those who are pregnant, breastfeeding or planning to become pregnant.”**

- ii. ***An additional statement should be added to reflect the clear evidence indicating impact on the developing brain recommending against use by individuals under 25 years of age.*** CCLHO recommends including this warning in regulations for adult-use products, especially as they are available to individuals over 21 years of age.
 - b. The Health Officers support restrictions on labeling (40410) that prohibit the product from being attractive to individuals under the age of 21.
 - c. CCLHO supports utilizing a cannabis product symbol (40412) on all labels to indicate there is THC in the product and to prevent accidental ingestion. However, we believe the current symbol proposed may not be clearly identifiable to the lay individual, and recommend the consideration of another symbol, such as a cannabis leaf.
19. Packaging: CCLHO supports the packaging requirements of section 40415, including the requirements that the product be tamper-evident, child-resistant, not imitate other products typically marketed to children, be opaque if an edible, and re-sealable if it contains more than one serving.
20. Inspections and Enforcement: CCLHO strongly supports the ability of CDPH to conduct inspections (40500). ***Further, as manufacturing is the key point of production that influences product safety, CCLHO recommends that regulations require on-site inspections at least once per year to ensure permit compliance.*** CDPH should also report annually the number of violations in each jurisdiction.
21. Giveaways and Sales: The draft manufacturing regulations do not address whether a manufacturer may give away samples or sell directly to the public or other non-licensed entity. Although this is partially addressed under the Adult Use Medical Act and in the proposed Trailer Bill, it is not addressed in the Medical Cannabis Regulatory and Safety Act. The Health Officers believe the restrictions proposed for adult-use should apply for medical use. Specifically, ***manufacturers should be prohibited from providing free samples, selling or distributing cannabis products directly to the public. In addition, regulations should also prohibit manufacturers from issuing coupons, buy-one-get-one deals, and other forms of discounting as these activities encourage extra product purchasing and create youth/younger adult-friendly price points.*** This would include a prohibition on manufacturers donating product to promotional events; such as donations to a non-profit fundraiser.
22. Local Control: CCLHO believes that ensuring compliance to these regulations is critical not only for the success of the industry but also for protection of public health. This raises the concern that while cannabis regulations authorize state and local jurisdiction authority, Health Officers act in an intermediary function where most of us serve both the unincorporated county and the cities within the county. Many cities do not have a health expert who can act in situations that require a rapid local response and pose an acute threat and thereby rely on their County Health Officer. Given this industry will be new to regulation and failure to adhere to regulations or emerging situations could severely threaten public health, ***CCLHO believes that there should be clear authority for Health Officers to take action to protect health within both the unincorporated county area and the cities should an imminent threat exist. This is not intended to supplant the State's responsibility to ensure licensees adhere to regulations nor is it intended to incur a cost to a County for on-going permit enforcement within a City.*** However, authorizing a Health Officer

to act at his or her discretion to enforce issues which threaten human health and safety not only is a necessary protection for our residents, but is an existing expectation that many of our residents have. Therefore, both code and regulations should be clear and not preclude Health Officers from taking actions within a city that they would otherwise do for non-cannabis related issues.

In conclusion, the Health Officers appreciate the opportunity to comment on the draft manufacturing regulations. We recognize the months of hard work that went into crafting these provisions, which are clearly aimed at establishing a well-run industry while protecting public health. We hope our comments, which come from a population-based disease and injury prevention perspective, are helpful in furthering your aim to protect public health.