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CDPH Proposed Medical Cannabis Manufacturing Regulations

Comment Summary and Response (9/28/17)

The California Department of Public Health would like to extend its sincere thanks to everyone who submitted comments on the proposed regulations. The comments received will be extremely valuable to CDPH as the next round of regulations is developed.

The recently approved budget trailer bill, SB 94, merged the Medical Cannabis Regulation and Safety Act (MCRSA) and the Adult Use of Marijuana Act (AUMA) to create the Medicinal and Adult Use of Cannabis Regulation and Safety Act (MAUCRSA). The new law incorporates elements of both MCRSA and AUMA. Accordingly, CDPH will need to revise its proposed regulations to conform with statutory changes.

The following document provides an overview of the most common comments received by CDPH on the proposed medical cannabis regulations. Please be assured that even if not included in the summary below, all comments have been reviewed and will be considered for the final regulation text, if appropriate.

Maximum THC Content

A substantial number of comments expressed significant concern and disagreement with CDPH's proposal to limit the amount of THC in a medicinal edible product to 10 mg per serving and 100 mg per package. Most expressed that, while 10 mg may be the right policy for the adult use market, which is more likely to have novice cannabis users, it is insufficient for the needs of the medicinal use. Similarly, commenters also had concerns about the cap of 1,000 mg THC per package of other cannabis products.

Several alternatives were suggested to CDPH:

- Increase the caps, both per serving and per package (suggestions ranged from a cap of 25 to 200 mg per serving and from 500 mg to 2,000 mg per package).
- Eliminate THC caps for all medicinal products.
- Eliminate THC caps for certain medicinal products – such as capsules, tinctures, or topicals (items that are not edibles)



- Allow an exemption to the total THC per package, if the package used is a blister package (each individual serving must be removed from the package separately, similar to the way over-the-counter pharmaceuticals such as cold medicine are sold).

SB 94 imposed a restriction that all edible cannabis products be sold with a serving size of no more than 10 mg THC. CDPH has no authority to allow greater THC concentrations per serving in edible products, either for the medicinal or adult use market (SB 94 did not speak to limits on total THC per package).

CDPH will continue to review the comments and remains committed to protecting public health by minimizing accidental consumption and over-exposure.

Prohibited Products

CDPH received a range of comments regarding the prohibition on certain products (§40300).

1. Alcoholic beverages:

- Clarification was requested as to whether the prohibition would extend to a prohibition on tinctures. This prohibition is not intended to restrict the production of tinctures. CDPH will make clarifying changes to the text for the MAUCRSA regulations.
- Clarification was requested as to whether the prohibition was applicable to just infusion with THC or included CBD as well. CDPH will continue to review the issue.
- Requests were made to allow THC-infused alcoholic beverages. CDPH continues to have concerns regarding the combination of THC and alcohol, and we will continue to review the issue.

2. Caffeine as an additive:

- Clarification was requested regarding the prohibition on caffeine as an additive. This prohibition is not intended to restrict the manufacture and cannabinoid infusion of products with naturally-occurring caffeine, such as coffee, tea, and chocolate. CDPH will make clarifying changes to the text for the MAUCRSA regulations.
- Requests were made to allow caffeine, perhaps a capped amount, to be added to products. CDPH will review the comments provided and remains committed to protecting public health.

3. Potentially hazardous foods as products:

- A majority of commenters expressed concerns regarding the prohibition on the manufacture of any product considered a potentially hazardous food. The most common concerns cited included:
 - That the prohibition would eliminate a large segment of the existing industry,
 - Many manufacturers and patients would turn to the black market,
 - Patient needs and desires for these products would not be met.
- On the other side, local jurisdictions, public health organizations, and the California Medical Association expressed support for the prohibition, due to the decreased risk of foodborne illnesses. CDPH continues to have concerns about product safety. Because cannabis is still considered an adulterant under federal laws, the same food safety laws and levels of oversight are not applicable to cannabis products. CDPH will continue to review the issue to ensure public health concerns are addressed.

4. Potentially hazardous foods as ingredients:

- Clarification was requested as to whether this restriction would apply to ingredients used in manufacturing. The restriction on the use of potentially hazardous foods is not intended to apply to ingredients (such as milk, butter, eggs, or juice), as long as the final product does not need time temperature controls to maintain its quality and safety. CDPH will make clarifying changes to the text for the MAUCRSA regulations.
- Similarly, clarification was requested as to whether the prohibition on canned foods would prohibit the use of cans as a packaging option. The prohibition only intended to apply to low-acid canned products, the kind that pose a risk of botulism. CDPH will make clarifying changes to the text for the MAUCRSA regulations.

Shared Facilities

A request to allow for shared facilities or community kitchens (a shared facility is one in which multiple licensees share the same premises and equipment) was another common theme. Commenters expressed numerous potential benefits to shared facilities. However, because the

definition of “premises” added to MAUCRSA limits a premises to only one licensee, CDPH does not believe it has the authority to permit shared facilities and that a statutory change would be necessary in order to do so.

Definition of “Owner”

The definition of “owner” and which individuals are required to be included as an owner in the licensing application will be revised according to the statutory requirements in the MAUCRSA. Many commenters expressed concerns that the requirement for any person who participates in the “direction, control, or management” of the cannabis business be licensed as an owner is overly broad and will be cumbersome for businesses to comply with.

CDPH is continuing to review this requirement in an effort to balance the intent of the MAUCRSA to vet individuals who have ownership in cannabis businesses with the business needs of the licensee. To this end, CDPH is also revisiting how businesses can notify the Department of changes in ownership and what categories of ownership change will require a new license application. CDPH will continue to review the requirements in conjunction with the CA Department of Food and Agriculture (CDFA) and the Bureau of Cannabis Control (BCC).

Application Denials and Evidence of Rehabilitation

In addition to the reasons provided by statute for the denial of a license, CDPH specified several other reasons that a license may be denied. Comments on this section generally focused on whether the specified reasons were appropriate and sufficient. Suggestions included:

- Add additional factors to the list of criteria that could be used to deny a license application, such as whether the applicant has ever been denied a local license by any jurisdiction; or
- Clarification as to whether an applicant who currently holds a local license, but who was denied a local license in the past, can be denied a state license on those grounds.
- Publication of a specific list of criteria that CDPH will be using to evaluate applicants, such a list of prior convictions that would lead to denial or whether CDPH will be evaluating applicant’s industry experience and training.

It is CDPH’s interpretation that our statutory responsibility requires consideration of each applicant’s criminal history and evidence of rehabilitation on a case-by-case basis. There cannot be a list of prior convictions that would automatically result in denial of a license application. An applicant with prior convictions listed in the law is encouraged to include with the license application any information that shows evidence of rehabilitation.

Suggestions were also received to add additional information that could be presented as evidence of rehabilitation, for example the fact that the applicant holds a local license. CDPH will continue to review the suggestions for the next round of regulation text.

Labeling

The first category of comments recommended that CDPH strengthen the labeling requirements. This set of comments requested changes such as increased font size for the health warnings, additional warning statements (such as risk of dependence, cardiovascular disease, and cancer), minimum coverage area of the label with health warnings, and plain packaging requirements (no logos, colors, or branding).

The second category of comments requested readjustments to the labeling requirements, such as minor changes to the mandated warning statements or clarification as to what constitutes “attractive to individuals under age 21.” Because the mandated warning statements are specified in statute, CDPH has no ability to alter them. CDPH will review all of the suggestions received regarding further clarifications for changes to the next draft of the regulations.

Finally, several comments disagreed with the prohibition against any claims of health or physical benefits. Requests were made to allow reference to emotions and moods, allow the product’s therapeutic value to be included on a label if it can be substantiated by scientific or medical findings or patient testimony, or instead require disclaimers similar to those of dietary supplements (“This statement has not been evaluated by the FDA”). CDPH will review the comments provided and remains committed to protecting public health through accurate labeling of cannabis products.

Packaging

Comments on packaging requirements generally requested further clarification on certain elements, including:

- Whether all types of illustration are considered a “cartoon;”
- Whether the prohibition on the imitation of packaging of “products typically marketed to children” extends to items like juice boxes or soda cans;

CDPH will continue to review the suggestions for the next round of regulation text.

THC Product Symbol

Comments on the THC product symbol recommended changes to be made to the symbol (changes to the color, requests for a pictorial element such as a cannabis leaf). CDPH will be revisiting the specifications of the symbol.

License Type: Ethanol

Based upon comments received, CDPH will further clarify the use of ethanol in manufacturing. Ethanol extraction, if used in a manner that creates a risk of explosion or fire, such as high heat or pressure, would be classified as a Type 7 license. Other uses of ethanol, such as tinctures or “winterization” to refine extracts, would be considered Type 6.

Inventory Control

The requirement for a licensee to conduct inventory reconciliation on a daily basis was widely considered impracticable and overly onerous. CDPH will be revisiting this requirement to ensure that the requirements for manufacturer licensees are in line with CDFA and BCC licensees.

Master Manufacturing Protocol

Several requests were received to allow for multiple manufacturing protocols in order to account for different cannabis strains. CDPH understands the business needs behind this request and will revisit the issue in the text for the MAUCRA regulations.

Several requests were also received to eliminate the requirement that at least two individuals be involved in the manufacturing process, as this would effectively prohibit individual operators. CDPH understands the business needs behind this request and will revisit the issue in the text for the MAUCRA regulations.

Video Surveillance Requirements

Primary concerns included the retention time and some of the specifications the system needs to meet. CDPH will continue to review the video surveillance requirements in conjunction with CDFA and BCC.

Waste Management

Commenters requested clarification on many of the elements of the requirements for management of cannabis waste. CDPH will continue to review the requirements in conjunction with CDFA and BCC and will clarify that waste management should be done in accordance with existing state laws.

Fees

Comments on the fees primarily focused on the impact to smaller businesses. Many expressed concern that Tier I and II businesses would be overburdened by the proposed fee. A common suggestion was to charge a percentage of annual revenue, rather than a flat fee, or cap the percentage of revenue that would comprise the fee (such as, \$3,000 or no more than 2% of the gross annual revenue).

The law requires CDPH to (1) establish fees on a scaled basis, based on the size of the business; and (2) through fees, cover the cost of administering the program, but not to exceed the reasonable regulatory cost. CDPH has calculated the proposed fees based upon the number of anticipated licensees and the budgeted cost of the program. Assessing a percentage of gross revenue as the fee could be considered a tax. Further, capping the fee at a certain percentage of gross revenue would not be tied to the reasonable cost of the program.

CDPH would like to assure licensees that the fees are intended to cover the costs of administering the program and can be reassessed in the future when licensing data is collected.

Proprietary Information

CDPH is reviewing the requests to strengthen protections around trade secrets and proprietary information.

Inspections

This regulation package only included a general overview of CDPH's inspection authority. Many commenters inquired about additional specificity, such as the frequency of inspections and the fines and penalties for violations of the statute or regulations. The statute provides a basic enforcement framework providing authority for inspections, recalls and embargos, citations and fines, and license suspensions and revocations. CDPH will be promulgating regulations to address specific inspection and enforcement details as a separate package in the near future.

Local Authority

Many local jurisdictions requested that CDPH provide additional enforcement and inspection authority for the local jurisdiction. CDPH does not have statutory authority to enhance local government oversight by regulation, but local governments can adopt and enforce their own local ordinances.