



KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

PROPOSED MEDICAL CANNABIS MANUFACTURING REGULATIONS

- *License Types.* In addition to Type 6 (non-volatile solvent and/or mechanical extractions) and Type 7 (volatile solvent extractions), CDPH is proposing two additional types of manufacturing licenses: a Type P license for businesses that will only package and/or label another manufacturer's products; and a Type N license for businesses that only conduct infusions (e.g. create edibles, topicals, or other products using extracts from another manufacturer) and/or packaging and labeling their own products. A facility will receive a single license based on the activities it is conducting.
 - Type 6 and Type 7 licensees can conduct extractions, infusions, and can package and label their own products;
 - Type N licensees can conduct infusions and can package and label their own products;
 - Type P can do only packaging and labeling for other licensed cannabis manufacturers.
- *Definition of Owner.* For publicly traded companies, the CEO and any person or entity with ownership interest of 5% or more is defined as an owner. For all other entity structures, any person or entity with ownership interest of 20% or more, or any person that participates in the direction, control, or management of the cannabis business is considered to be an owner. All owners must disclose their spouse (or any other person who has a community property interest), including identifying information. In order to prevent circumvention of the denial, the spouse of the denied applicant will be prohibited from applying for the same license type for a specified timeframe.
- *Substantially-related offenses.* CDPH is clarifying that offenses related to the adulteration or misbranding of food, drugs, or dietary supplements will be considered substantially-related and can be used as a basis for denial of an application. Furthermore, except for specified convictions related to use of or sale to minors, prior controlled substances convictions will not be considered substantially related offenses.
- *Good Manufacturing Practices.* CDPH will be requiring good manufacturing practices that are substantively similar to the Sherman Food and Drug Act and FDA requirements.
- *Operational Requirements.* The proposal specifies the operational requirements licensees must comply with, including: security and surveillance measures, record-keeping, employee training, inventory control, and cannabis waste disposal.
- *Product Standards.* Products cannot be infused with nicotine, added caffeine, or alcohol. Products can only be made into non-potentially hazardous foods (e.g. nothing that requires temperature controls, nothing canned, no meat or seafood products, and only shelf-stable products).

- *THC Limits.* CDPH is proposing to limit edible products to no more than 10 mg of THC per serving and 100 mg of THC per package. CDPH is also proposing to limit other products (tinctures, capsules, topicals, etc.) to no more than 1,000 mg of THC per package.
- *Packaging.* In addition to the statutory requirements (not attractive to children and tamper-proof), CDPH is proposing to (1) prohibit packaging from resembling traditionally available food packages; (2) require packaging to be resealable if it includes more than one serving; and (3) require edible products to be packaged in opaque packages. CDPH is also proposing to require all manufactured products to be packaged in their final form prior to release to a distributor.
- *Labeling.* In addition to the statutory requirements (not attractive to individuals under age 21, mandated warning statements, THC content) CDPH is proposing each label include: (1) a listing of all ingredients in descending order; (2) the amount of sugar, sodium, and fat per serving; and (3) a cannabis product symbol. The proposal will prohibit labels from making any claims of health or other physical benefit. CDPH is also proposing to clarify what is considered “attractive to individuals under age 21” – no cartoons, no images popularly used to advertise to individuals under age 21, no imitations of candy packaging or labeling.
- *Fees*
 - One time license application processing fee of \$1,000
 - *Annual License Fee* that will be scaled according to the gross annual revenue of the licensed premises:

▪ Tier I (gross annual revenue below \$100,000)	\$2,000
▪ Tier II (gross annual revenue of \$100,001 - \$500,000)	\$7,500
▪ Tier III (gross annual revenue of \$500,001 - \$2 million)	\$15,000
▪ Tier IV (gross annual revenue of \$2 million – \$5 million)	\$35,000
▪ Tier V (gross annual revenue over \$5 million)	\$50,000

The fees are intended to cover operational costs, database development, track-and-trace program, and repayments to the General Fund.