State of California—Health and Human Services Agency
California Department of Public Health
Manufactured Cannabis Safety Branch

Draft Inspection Checklist

❖ A check off indicates a deficiency, violation or corrective action

DISCLAIMER

This checklist is intended to provide guidance only. This checklist does not replace or supersede relevant laws and regulations. The information contained in this checklist is based upon the laws and regulations in effect as of January 16, 2019.

§26038 – Unlicensed Activity

- ☐ A person engaging in commercial cannabis activity without a license required by this division shall be subject to civil penalties of up to three times the amount of the license fee for each violation

§26160 – Record Keeping

- ☐ (a) A licensee shall keep accurate records of commercial cannabis activity
- ☐ (b) All records related to commercial cannabis activity as defined by the licensing authorities shall be maintained for a minimum of seven (7) years
- ☐ (c) Licensing authorities may examine the records of a licensee and inspect the premises of a licensee as the licensing, state, or local authority, all inspections and examinations of records shall be conducted during standard business hours of the licensed facility or any other reasonable time, and licenses shall provide and deliver records to the licensing authority upon request
- ☐ (d) Licensees shall keep records identified by the licensing authorities on the premises of the location licensed. Licensing authorities may make any examination of the records of any licensee and provide and deliver copies of documents to the licensing authority upon request
- ☐ (e) A licensee, or its agent or employee, that refuses, impedes, obstructs, or interferes with an inspection of the premises or records of the licensee pursuant to this section, has engaged in a violation of this division
- ☐ (f) If a licensee, or an agent or employee of a licensee, fails to maintain or provide the records required, the licensee shall be subject to a citation and fine up to thirty thousand dollars ($30,000) per individual violation

§40200 – Security Plan: Every applicant and licensee shall develop and implement a written security plan

- ☐ (a) Prevent access to the premises by unauthorized personnel
  - ☐ (1) Establishing physical barriers to secure perimeter access of all points of entry
  - ☐ (2) Installing a security alarm system
  - ☐ (3) Establishing an identification sign-in/ sign-out for everyone
  - ☐ (4) Maintaining the premises such that visibility & security monitoring of the premises is possible; &
  - ☐ (5) Establishing procedures for investigation of suspicious activity
- ☐ (b) Prevent against theft or loss of all cannabis and products
  - ☐ (1) Establishing an inventory system for tracking cannabis & cannabis products & personnel responsible for processing it throughout manufacturing processes;
  - ☐ (2) Limiting access of personnel within the premises to those areas necessary to complete their job duties & time-frames specifically scheduled for completion of their job duties, including outside vendors, suppliers, contractors or other individuals that require access to the premises;
  - ☐ (3) Supervising tasks or processes with high potential for diversion, including loading/unloading product from cannabis transportation vehicles
  - ☐ (4) Providing areas to store & access personal items that are separate from manufacturing areas
- ☐ (c) Secure and back up electronic records that prevents unauthorized access & ensures records are maintained

§40205 – Video Surveillance

- (a) Licensed premises shall have a digital video surveillance system (1280 x 720 pixels) and be able to effectively and clearly record images of the area under surveillance
- (b) Installed in a manner that prevents obstruction, tampering, and disabling
- (c) Required recorded areas include the following:
  - (1) Cannabis and cannabis products are weighed, packed, stored, quarantined, loaded and unloaded for transportation, prepared, or moved within the premises
  - (2) Limited-access areas
  - (3) Security rooms
  - (4) Storage device areas
  - (5) Interior and exterior of all entrances and exits of the premises
- (d) Continuous for twenty-four (24) hours per day at a speed of fifteen (15) frames per second
- (e) Any on-site surveillance system storage devices shall be located in secure rooms or areas of the premises in an access-controlled environment
- (f) Recordings shall be kept for at least ninety (90) days
- (g) All video surveillance recordings shall be available on the licensed premises & are subject to inspection also be copied and sent to Department upon request
- (h) Shall display the current date and time of recorded events
- (i) If multiple licensed premises are contained within the same building, a single video surveillance covering the entire building may be used by all the licensees under the following conditions:
  - (1) Shall disclose on their premises diagram where the surveillance recordings are stored
  - (2) Shall include in their security operating procedures an explanation of how the video surveillance system will be shared, including who is responsible for monitoring the video footage and storing any video recordings
  - (3) Shall have immediate access to the surveillance recordings to produce them pursuant to the requirements of this section
  - (4) Shall be held responsible and subject to discipline for any violations of the video surveillance requirements

§40220 – Permissible Extractions

- (a) Except as provided in this subsection (b) Cannabis extraction shall be only conducted using:
  - (1) Mechanical
  - (2) Chemical extraction using a nonvolatile solvent such as a nonhydrocarbon-based or other solvent such as water, vegetable glycerin, vegetable oils, animal fats, or glycerin. Nonhydrocarbon-based solvents shall be food grade;
  - (3) Chemical extraction using a professional closed loop CO_2 gas extraction system and be food grade
  - (4) Chemical extraction using a volatile solvent, as defined in Section 40100(xx), using a professional closed loop extraction system; or
  - (5) Any other method authorized by the Department pursuant to subsection (b)
- (b) The applicant or licensee shall submit a detailed description of the extraction method including documentation that validates the method and safety procedures to the public and worker

§40222 – Volatile Solvent Extractions - Chemical extractions using volatile solvents:

- (a) Hydrocarbon-based solvents with at least 99% purity
- (b) Shall be performed in a closed loop extraction system (§40225); and
- (c) No volatile solvent extractions shall occur in area zoned (residential)

§40223 – Ethanol Extractions

- (a) Ethanol used for extractions or for post-extraction processing shall be food-grade
- (b) Operations shall be approved by the local fire code official and operated in accordance with applicable Division of Occupational Safety & Health (Cal/OSHA), state, and local regulation requirements

§40225 – Closed-Loop Extraction System Requirements

- (a) Chemical extractions using CO_2; a volatile solvent; or chlorofluorocarbon, hydrocarbon, or other fluorinated gas shall be conducted in a professional closed loop extraction system designed to recover the solvents. The system shall be commercially manufactured and permanently affixed and visible serial number, certified by a California-licensed engineer that the system is commercially manufactured, safe for intended use, and built to codes of good engineering practices
  - (1) The American Society of Mechanical Engineers (ASME)
  - (2) American national Standards Institute (ANSI)
  - (3) Underwriters Laboratories (UL)
  - (4) The American Society for Testing and Materials (ASTM)
- (b) Must be approved for use by the local fire code official and any code requirements related to processing, handling, and storage of the applicable solvent or gas
- (c) The certification document shall contain the signature and stamp of a California-licensed professional engineer and the serial number of the extraction unit being certified
- (d) The licensee shall establish and implement written procedures to document that the closed loop extraction system is maintained in accordance with the equipment manufacturer specifications and to ensure routine verification that the system is operating in accordance with specifications and continues to comply with fire, safety, and building code requirements
- (e) A licensee shall develop standard operating procedures, good manufacturing practices, and a training plan prior to producing extracts. Any personnel using solvents or gases in a closed loop system to create extracts must be trained on how to use the system, have direct access to applicable safety data sheets, and handle and store solvents and gases safely
- (f) The extraction operation shall be operated in an environment with proper ventilation, controlling all sources of ignition where a flammable atmosphere is or may be present, and shall be operated in accordance with applicable Division of Occupational Safety and Health (Cal/OSHA) regulations and any other state and local requirements
- (g) No closed loop extraction system operation shall occur in an area zoned as residential

§40235 – Quality Control Program

- (a) Each licensee is responsible for implementing a quality control program to ensure that cannabis products are not adulterated or misbranded. This program shall include quality control operations for all of the following:
  - (1) The grounds, building, and manufacturing premises (§40240)
  - (2) Equipment and utensils (§40243)
  - (3) Personnel (§40246)
  - (4) Cannabis product components (§40248)
  - (5) Manufacturing processes and procedures (§40250)
- (b) Shall be under the supervision of one or more qualified individuals assigned responsibility for this function
- (c) Use of the term “food” shall include cannabis, cannabis products, components, and contact surfaces

§40240 – Grounds, Building and Manufacturing Premises

- (a) Shall ensure the facility exterior and grounds under the licensee’s control meet the following standards:
  - (1) Grounds are equipped with draining areas in order to prevent pooled or standing water

- (2) Weeds, grass, and vegetation shall be cut within the immediate vicinity of the cannabis manufacturing premises, litter and waste shall be removed, and equipment shall be stored in order to minimize the potential of the grounds to constitute an attractant, breeding place, or harborage of pests
- (3) Roads, yards, and parking lots shall be maintained so that these areas do not constitute a source of contamination in areas where cannabis products are handled or transported
- (4) Openings into the building (windows, exhaust fans, ventilation ducts, or plumbing vent pipes) shall be screened, sealed, or otherwise protected to minimize potential for pests to enter the building
- (5) Waste treatment and disposal systems shall be provided and maintained so as to prevent contamination in areas where cannabis products may be exposed to such a system's waste by waste by-products
- (6) Shall implement precautions within the premises such as inspection or extermination if the premises is bordered by grounds outside the licensee's control in order to eliminate any pests, dirt, and filth that pose a source of cannabis product contamination

(b) Interior facility: Shall ensure construction, design, and maintenance of the interior of the premises as follows:

- (1) Walls, ceilings, and floors: Shall be constructed of material that in smooth, nonporous, easily cleanable, corrosion-resistant, and suitable to the activity that will be conducted. Fixtures, ducts, and pipes shall not pose a source of drip or condensate that may contaminate cannabis products, contact surfaces, or packaging material
- (2) Lighting. Interior facility lighting shall meet the requirements of subdivisions (a)(1) and (3), (b)(3) and (4), and (c) of section 114252 of the Health and Safety Code. Interior facility lighting shall also meet the requirements for shatter-resistant lighting in section 114252.1 of the Health and Safety Code. The requirements of Health and Safety Code section 114252.1, subdivision (a), shall also apply to all areas where glass breakage may result in the contamination of exposed cannabis, components or cannabis products at any step of preparation
- (3) Plumbing system and fixtures
  - (A) Water supply. Running water shall be supplied as required by Health and Safety Code section 114192 in all areas where required for the processing of cannabis products; in all areas used for the cleaning of equipment, utensils, and packaging materials; and for employee sanitary facilities. Any water that contacts cannabis, components, cannabis products, contact surfaces, or packaging materials shall be potable
  - (B) Plumbing. Plumbing systems shall meet the requirements of Health and Safety Code section 114190
  - (C) Sewage disposal. The sewage system shall be maintained and kept in good repair so that it does not pose a potential source of contamination to cannabis products, contact surfaces, or packaging materials
  - (D) Toilet facilities. Each manufacturing premises shall provide employees with access to toilet facilities that meet the requirements of Health and Safety Code section 114250. Toilet facilities shall be kept clean and shall not pose a potential source of contamination of cannabis, components, cannabis products, contact surfaces, or packaging materials
  - (E) Hand-washing facilities. Each manufacturing premises shall provide hand-washing facilities that meet the requirements of Health and Safety Code section 113953, subdivision (a) through (d)
  - (F) Waste disposal. The premises shall provide waste disposal in accordance with Health and Safety Code sections 114244(a), 114244(c), and 114245.1. Cannabis waste shall be disposed of in accordance with Section 40290 of these regulations
- (4) Ventilation. Ventilation systems shall meet the requirements of Health and Safety Code sections 114149 and 114149.3
- (5) Cleaning and maintenance. The premises, including any fixtures, and other physical facilities therein, shall be maintained in a clean and sanitary condition and kept in good repair so as to prevent cannabis products from becoming adulterated, and shall meet the requirements of Health and Safety Code section 114257.1

- (A) Shall have a janitorial facility that meets the requirements of Health and Safety Code section 114279(a)
- (B) Cleaning equipment and supplies shall be stored in a manner that meets the requirements of Health and Safety Code section 114281
- (C) Poisonous or toxic materials such as cleaning compounds, sanitizing agents, and pesticide chemicals that are necessary for premises and equipment maintenance and operation shall be handled and stored in a manner that meets the requirements of Health and Safety Code sections 114254.1, 114254.2 and 114254.3

§40243 – Equipment and Utensils: Licensee shall utilize equipment and utensils that meet the following requirements:

- (a) Design: Shall be used in accordance with their operating instructions to avoid the adulteration of cannabis products with lubricants, fuel, metal fragments, contaminated water, or any other contaminants
- (b) Installation: Equipment shall be installed so as to allow the cleaning and maintenance of the equipment and of adjacent spaces. Equipment that is not easily moveable shall meet the requirements of Health and Safety Code section 114169
- (c) Cleaning, sanitizing, and maintenance: The quality control program for cleaning, sanitizing, and maintenance of equipment and utensils shall include the following, at minimum:
  - (1) A detailed, written procedure for cleaning, sanitizing, and maintaining equipment and utensils
  - (2) A schedule for cleaning, sanitizing, and maintaining equipment and utensils
  - (3) A procedure, including a log, for documentation of the date and time of maintenance, cleaning, and sanitizing of equipment
  - (4) A detailed, written procedure for storing cleaned and sanitized equipment and utensils in a manner to protect the equipment and utensils from contamination

§40246 – Personnel

Licensees shall implement written procedures for personnel that include, at minimum:

- (a) Disease control: Any individual who by medical examination or supervisory observation is shown to have an illness or open lesion, and excluded from any manufacturing operations until their health condition is corrected
- (b) Cleanliness: All individuals working in direct contact with cannabis products, contact surfaces, and packaging materials shall maintain personal cleanliness in order to protect against allergen cross-contact and contamination of cannabis products while on duty. The methods include:
  - (1) Wearing clean outer clothing to protect against allergen cross-contact and contamination of cannabis products, contact surfaces, and packaging materials
  - (2) Washing hands thoroughly in a hand-washing facility (§40240) before starting work, after each absence from the work station, and at any time when the hands may have become soiled or contaminated
  - (3) Removing all unsecured jewelry and other objects that might fall into cannabis products, equipment, or containers. Hand jewelry that cannot be sanitized shall be removed during periods in which cannabis products are manipulated by hand. If jewelry cannot be removed, it shall be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the cannabis products, cannabis product-contact surfaces, or cannabis product-packaging materials
  - (4) Maintaining any gloves, in an intact, clean, and sanitary condition
  - (5) Wearing hair nets, caps, beard covers, or other hair restraints that are designed and worn to prevent hair contact with cannabis, cannabis product, contact surfaces, or cannabis product-packaging materials
  - (6) Storing clothing and personal belongings in areas separate from those where cannabis products are exposed or where equipment or utensils are washed

- (7) Confining the following activities to areas separate from those where cannabis products may be exposed or where equipment and utensils are washed: Eating food, chewing gum, drinking beverages, and using tobacco

§40248 – Cannabis Product Components

- (a) Shall establish and implement written policies and procedures to ensure and maintain the quality of products
- (b) Components are subject to the following requirements:
  - (1) Raw materials and other ingredients shall be inspected upon intake – to ensure that they are clean and suitable for processing into cannabis products and shall be stored under conditions that protect against allergen cross-contact and contamination in such a way as to minimize deterioration
  - (2) Raw materials shall be washed or cleaned as necessary to remove soil and other visible contaminants. Water shall be potable for washing, rinsing, and conveying cannabis product ingredients
  - (3) Raw materials and other components shall contain levels of microorganisms that render the cannabis product injurious to human health or shall be pasteurized or treated during manufacturing so that they no longer contain levels of microorganisms that would cause the cannabis product to be adulterated
  - (4) Raw materials and other components susceptible to contamination with aflatoxin or other natural toxins, pests, or extraneous material shall not exceed limits by the U.S. Food and Drug Administration in the *Defect Levels Handbook,* before the raw materials or other ingredients are incorporated into finished cannabis products
  - (5) Raw materials and other components shall be held in containers designed and constructed to protect against allergen cross-contact or contamination and shall be held at such temperature and relative humidity to prevent the cannabis products from becoming adulterated
  - (6) Frozen raw materials and other components shall be kept frozen. If thawing is required before use, it shall be done in a manner that prevents the raw materials and other ingredients to become adulterated
  - (7) Raw materials and other ingredients that are food allergens shall be identified and held in a manner that prevents cross-contact with other raw materials or ingredients
  - (c) Holding and storage of raw materials and other components shall meet the requirements of section 114047, subdivisions (a) and (b), section 114049, and section 114051 of the Health and Safety Code

§40250 – Manufacturing Processes and Procedures

- (a) Shall implement and maintain manufacturing processes and procedures to ensure all cannabis quality (§40253)
- (b) Shall maintain written master manufacturing protocols (§40255), for each formulation of cannabis product manufactured to ensure only intended components are included and that the cannabis product is packaged and labeled
- (c) Shall maintain written batch product records (§40258), to document the production process and, if needed, to verify that the established processes and procedures, including the preventive measures and master manufacturing protocol were implemented correctly
- (d) All manufacturing records are subject to inspection by the Department, its inspectors, and agents

§40253 – Product Quality Plan

- (a) Shall create and implement a written product quality plan for each type of product manufactured at the premises and address the hazards associated with the premises or the process
- (b) Shall conduct a comprehensive assessment of the overall process, identifying each step from component intake through transfer of product from the premises, to determine the potential risks associated with each step, the preventive measures to mitigate the potential risks identified, the methods to evaluate and monitor the effectiveness of the preventive measures, and action to take if a preventive measure was unsuccessful
- (c) Shall evaluate the following potential risks to cannabis product quality:
  - (1) Biological hazards, including microbiological hazards

- (2) Chemical hazards, including radiological hazards, pesticide contamination, solvent or other residue, natural toxins, decomposition, or allergens
- (3) Physical hazards, such as stone, glass, metal fragments, hair, or insects
- (4) Process failures that may lead to product contamination, allergen cross-contact, packaging errors, labeling errors, or other errors affecting cannabis product quality

- (d) Shall identify the preventive measure that will be implemented to mitigate each potential risk that include:
  - (1) Cleaning and sanitizing of equipment and utensils to mitigate against risk of microbiological hazards
  - (2) Conducting in-house testing of raw cannabis to mitigate against the risk of pesticide contamination
  - (3) Establishing an allergen control program to ensure that allergen cross-contact does not occur between product types
  - (4) Implementing procedures to ensure proper homogeneity of cannabinoids into a cannabis product to mitigate against the risk of a not-homogeneous product
- (e) Shall identify methods to evaluate and monitor the effectiveness of the preventive measures in mitigating the potential risks identified in subsection (c). Methods for evaluation and monitoring of preventive measures include the following:
  - (1) Review of test results conducted to determine contamination such as pesticide residue
  - (2) Maintaining and reviewing cleaning, sanitizing, or maintenance logs to verify actions have been taken
  - (3) Conducting environmental testing to determine if equipment or utensils are contaminated with undesirable pathogens
  - (4) Monitoring the temperature of raw materials that need to be held below forty-one (41) degrees Fahrenheit to prevent microbial contamination
- (f) Shall identify actions to be taken if the evaluation and monitoring of the preventive measure indicates that the risk was not properly mitigated. The corrective action shall be specific to the type of product under evaluation and the specific risk to be mitigated. Examples are as follows:
  - (1) Destruction of product components or finished product
  - (2) Further processing of cannabis extract to remove impurities
  - (3) Reworking the unfinished product to further homogenize the cannabinoids
- (g) Licensee shall maintain the product quality plans and documentation of preventive measures, monitoring results, and corrective actions and make the records available to the Department upon request

§40255 – Master Manufacturing Protocol

- (a) Licensee shall establish and follow a written master manufacturing protocol for each unique formulation of cannabis product manufactured and for each batch size in order to mitigate against the potential for adulteration through incorporation of incorrect amounts of cannabinoids, unintended ingredients, or hazards identified in the product quality plan; against the potential for misbranding through incorporation of ingredients not identified on the label or the mislabeling of the product and to ensure uniformity in finished batches and across all batches produced
- (b) Shall include:
  - (1) The name and intended cannabinoid(s) concentration per serving of the cannabis product to be manufactured
  - (2) Component list of components used
  - (3) Weight or measure of each component to be used: The master manufacturing protocol for any given product may include the ability to adjust the amount or weight of cannabinoid-containing ingredients in order to account for the variability of cannabinoid content in harvest batches
  - (4) Identity & weight or measure of each ingredient that will be declared on the ingredients list of the cannabis product
  - (5) The expected yield of the finished product: Based on the quantity of components or packaging to be used in the absence of any loss or error in actual production and the maximum and minimum

percentages of expected yield beyond which a deviation investigation of a batch is necessary and material review is conducted and a decision on the disposition of the product is made
    - (6) Description of packaging and a representative label or cross-reference to the physical location of the actual or representative label
    - (7) Written instructions for each point, step, or stage in the manufacturing process
    - (8) Written instructions for any action mitigate an identified risk established in the product quality plan
- (c) Nothing in this chapter requires disclosure of the master protocol to any person other than the individuals conducting the activities

§40258 – Batch Production Record

- (a) Licensee shall prepare a written batch production record every time a batch of a cannabis product is manufactured and shall accurately follow the appropriate master manufacturing protocol and each step shall be performed in the production of the batch
- (b) Shall document complete information relating to the production and control of each batch, including:
    - (1) UID and the batch or lot number of the finished batch of cannabis product and the UIDs of all cannabis or cannabis products used in the batch
    - (2) Equipment and processing lines used in producing the batch
    - (3) Date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or records (equipment logs)
    - (4) Identification number assigned to each component, packaging, or labeling used
    - (5) Identity, weight or measure to each component
    - (6) Statement of the actual yield and the percentage of expected yield at the appropriate phases of processing
    - (7) Actual results during monitoring process
    - (8) Testing / examination performed during the batch production
    - (9) Documentation at the time of performance
        - (A) Date on which the step of the master manufacturing protocol was performed
        - (B) Initials of the person performing each step that includes:
            - (i) Weighing or measuring each component used in the batch
            - (ii) Verifying the weight or measure for each component used in the batch
            - (iii) Adding component to the batch
            - (iv) Verifying the addition of components to the batch
    - (10) Packaging and labeling documentation at the time of performance, including:
        - (A) Representative label or cross-reference to the physical location of the actual label
        - (B) Expected number of packaging and labels to be used
        - (C) The results of any tests or examinations conducted on packaged and labeled cannabis products or cross-reference to the physical location of the results
    - (11) Documentation at the time of the performance
        - (A) Reviewed the batch production record
        - (B) Required monitoring operations
        - (C) The results of all tests / examinations for finished batches of cannabis product
        - (D) Either approved and released or rejected batch distribution
        - (E) All finished cannabis products
    - (12) Required material review and disposition decision
    - (13) The Certificate of Analysis issued for the batch by the licensed testing lab, which shall be added to the record after regulatory compliance testing has been completed
- (c) The batch production record shall:
    - (1) Contain the actual values, observations and monitoring during verification activities

- (2) Be accurate, indelible and legible
- (3) Created concurrently with performance of the activity documented
- (4) Detailed as necessary to provide history of work performed
  - (A) Including the identity of any associated manufacturing facility
  - (B) Date and time of activity documented
  - (C) Signature or initials of the person performing the activity
  - (D) The Identity of the product, the UID, and the batch or lot number

§40270 – Juice Processing

- (b) Manufacturers of cannabis juice or cannabis-infused juice or beverages shall prepare and implement a written juice hazard analysis and critical control plan in accordance with the requirements of 21 CFR, Part 120, subpart A, section 120.8, and subpart B, section 120.24, (Rev. January 2001)

§40272 - Dried Meat Processing.

- Manufacturing of cannabis-infused dried meat products shall be conducted in accordance with the United States Department of Agriculture FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments: 2014 Compliance Guideline (Rev. 2014), which is hereby incorporated by reference. Meat for processing into dried meat products shall be acquired from a commercially-available source

§40275 – Standard Operating Procedures

- (a) Licensee shall establish and maintain written standard operating procedures that are easily accessible to onsite personnel. This includes:
  - (1) Any policies or procedures developed in accordance with the security plan (§40200)
  - (2) Emergency response procedures including safety data sheets for any chemicals on-site
  - (3) Under (§40225)
  - (4) Article 3 (Good Manufacturing Practices)
  - (5) Track-and-trace requirements
  - (6) Inventory (§40282)
  - (7) Cannabis waste management procedures (§40290)
- (b) Procedures shall be written in English, but may be made available in other languages, as necessary for the licensee's personnel

§40277 – Weights and Measures

- (a) Licensee shall be approved, tested, and sealed in accordance with §12500 and §12240. Approved and registered devices shall be used whenever:
  - (1) Cannabis or cannabis product is bought or sold
  - (2) Packaged for sale
  - (3) Entered in track-and-trace system
  - (4) Weighing device is used for commercial purposes
- (b) "Count" means numerical count of the individual cannabis product units
- (c) Whenever the licensee is determining the weight, measure or count of cannabis and cannabis products, this shall be determined by a licensed weighmaster. The weighmaster certificate required under section 12711 of the Business and Professions Code shall not be required when cannabis or cannabis products are weighed for entry into the track-and-trace system

§40280 – Training Program

- (a) Licensee shall implement a training program to ensure that all personnel present at the premises are provided information and training that covers the following topics:
  - (1) Within thirty (30) days of the start of employment
    - (A) Health and safety hazards
    - (B) Hazards presented by all solvents or chemicals used at the premises
    - (C) Emergency procedures
    - (D) Security procedures
    - (E) Record keeping requirements
    - (F) Training requirements
  - (2) Manufacturing and production personnel, prior to independently engaging in any cannabis manufacturing process:
    - (A) Overview of the standard operating procedures
    - (B) Quality control procedures
    - (C) The product quality plans developed in accordance with §40253
    - (D) Proper and safe usage of equipment / machinery
    - (E) Safe work practices applicable to an employee's job tasks
    - (F) Cleaning and maintenance requirements
    - (G) Emergency operations including shutdown
    - (H) Additional programs related to the employees job duties
  - (3) Complete a California food handler certificate course from any ANSI within 90 days of employment
  - (4) Licensee shall ensure that all personnel receive annual refresher training to cover, at minimum, the topics listed below and must be completed within 12 months of the previous training completion date
- (b) Licensee shall maintain a record of training which contains at minimum:
  - (1) A list of all personnel at the premises including at minimum name and job duties
  - (2) Documentation of training topics and dates of training completion including refresher training for all personnel
  - (3) The signature of the individual personnel and the licensee verifying receipt and understanding of each training or refresher training completed
  - (4) Any official documentation attesting to the successful completion
- (c) Licensee may assign responsibility for the training of individual personnel to supervisory personnel. Assigned supervisory personnel must have the education, training, or experience (or a combination thereof) necessary to ensure the production of quality cannabis products by all personnel. The assigned training personnel shall sign and date a document on an annual basis attesting that he or she has received and understands all information that will be provided to individual personnel in the training program. This documentation shall be maintained as part of the record requirements
- (d) Personnel shall receive required training no later than ninety (90) days after the effective date of the annual license

§40282 – Inventory Control – Cannabis and Cannabis Products

- (a) Licensee shall establish and implement a written inventory control plan capable of tracking the location and disposition of all cannabis and products at the premises
- (b) Reconcile the on-hand inventory of cannabis and products with the records in the track-and-trace database least once every thirty (30) days
- (c) Discrepancy between the on-hand inventory and the track-and-trace database licensee shall conduct an audit
- (d) Notify the Department within 24 hours of completion of the audit or inventory if it is more than 5%

§40290 – Waste Management

- (a) Licensee shall have a written cannabis waste management plan and shall dispose of all waste, including cannabis waste, in accordance with applicable state and local laws and regulations including laws regulating "organic waste". It is the responsibility of the licensee to properly evaluate waste to determine if it should designated and handled as a hazardous waste
- (b) Dispose of any cannabis waste in a secured waste receptacle or area on the premises
- (c) No cannabis product shall be disposed of in its packaging and shall be unrecognizable and unusable at the time of disposal
- (d) Shall be entered into the track-and trace system (§40512)
- (e) Cannabis waste may be collected from a licensee in conjunction with a regular organic waste collection route used by the local agency, waste hauler franchised or private waste hauler contracted by the local agency
    - (1) Provide the Department with the name, address, contact person, and contact phone number of the entity hauling the waste
    - (2) Obtain documentation from the entity hauling that evidences subscription to a waste collection service
- (f) If a licensee is self-hauling cannabis waste as allowed by the local jurisdiction, the licensee shall be subject to all of the requirements:
    - (1) Shall only be transported by the licensee or its employees
    - (2) Shall only be transported to the following:
        - (A) A manned fully permitted solid waste landfill or transformation facility
        - (B) A manned fully permitted composting facility or manned composting operation
        - (C) A manned fully permitted in-vessel digestion facility or manned in-vessel digestion operation
        - (D) A manned fully permitted transfer/processing facility or manned transfer/processing operation
    - (3) The licensee or its employee who transports the waste shall obtain for each delivery of cannabis waste a copy of a certified weight ticket or receipt from the solid waste facility

§40295 – Product Complaints: The licensee shall establish and implement written procedures:

- (a) The licensee shall establish and implement written procedures to ensure that:
- (1) A qualified individual shall review and investigate all product complaints to determine whether such complaints involve a possible failure of a cannabis product to meet any of its specifications
- (2) Quality control personnel shall review and approve decisions determining whether to investigate a product complaint and shall review and approve the findings and follow up action(s) of any investigation performed
- (3) Pursuant to subsections (a) and (b) in this section, any review or investigative activities by qualified individuals and quality control personnel shall extend to all relevant batches and records
- (4) Quality control personnel shall maintain written records for every product complaint and subsequent investigation, if any. The records shall include:
    - (1) Name and description of the cannabis product
    - (2) Batch number or UID of the cannabis product, if available
    - (3) Date the complaint was received and the name, address, and telephone number of the complainant, if available
    - (4) Nature of the complaint including, if known, how the product was used
    - (5) Reply to the complainant, if any
    - (6) Findings of the investigation or follow-up action taken when an investigation is performed; and
    - (7) Basis of any determination not to conduct an investigation
- (b) For purposes of this section, "product complaint" means any written, electronic, or oral communication that contains any allegation expressing concern, for any reason, with the quality of a cannabis product that could be related to the manufacturing practices. Examples of product complaints may include but not limited to: foul odor, off taste, illness or injury, disintegration time, color variation, foreign material in a cannabis product container, improper packaging, mislabeling, cannabis products that contain incorrect concentration of cannabinoids, or

cannabis products that contain an identified ingredient, or any form of contamination

§40297 – Recalls:

- (a) A licensee shall establish and implement written procedures for recalling cannabis products manufactured by the licensee that are determined to be misbranded or adulterated. These procedures shall include:
- (1) Factors which necessitate a recall
- (2) Personnel responsible for implementing the recall procedures; and
- (3) Notification protocols, including:
  - (A) Mechanism to notify all customers that have, could have, or obtained the product including outreach
  - (B) Mechanism to notify any licensees that supplied or received the recalled product
  - (C) Instructions to the general public and other licensees for the return or destruction of the product
- (4) Procedures for the collection and destruction of any recalled product. Shall meet the following requirements:
  - (A) All recalled products that are intended to be destroyed shall be quarantined for a minimum of seventy-two (72) hours. The licensee shall affix to the recalled products any bills of lading, shipping manifests, or other similar documents with product information and weight and the product held in quarantine shall be subject to auditing by the Department
  - (B) Following the quarantine period, the licensee shall render the recalled cannabis product unusable and unrecognizable and dispose of it in accordance with Section §40290, and do so on video surveillance in accordance with §40205
- (b) A licensee shall use the track-and-trace database (§40512) and on-site documentation to ensure that recalled cannabis products intended for destruction are identified, weighed, and tracked while on the licensed premises and when disposed. For recalled cannabis products, the licensee shall enter the following details into the track and trace database: the weight and count of the product, reason for destruction, and the date the quarantine period will begin
- (c) The licensee shall notify the Department of any recall within 24 hours of initiating the recall

§40300 – Prohibited Products: The following types of products shall not be sold as edible cannabis products:

- (a) Alcoholic beverages (§23004)
- (b) Nicotine and caffeine (except coffee, tea, and chocolate)
- (c) Cream / custard-filled pies, pies / pastries which consists of milk or milk products
- (d) Low-acid cannabis products
- (e) Acidified cannabis products
- (f) Any juice that is not shelf-stable or that is not processed in accordance with §40270
- (g) Dairy products of any kind except that butter purchased from a licensed milk products plant or retail location that is subsequently infused or mixed with cannabis may be sold as a cannabis product
- (h) Meat products except dried meat products (§40272)
- (i) Any seafood products
- (j) Any product that is manufactured by application of cannabinoid concentrate or extract to commercially available candy or snack food items without further processing of the product. Commercially available candy or snack food items may be used as ingredients in a cannabis product, provided that they are used in a way that renders them unrecognizable as the commercially available items and the label, including the ingredient list, does not note that the final cannabis product contains the commercially available item
- (k) Attractive to children (§40410)
- (l) The Department determines is easily confused with commercially available foods that do not contain cannabis
- (m) Products that are shaped of a human being, animal, insect, or fruit

§40305 – Requirements for Edible Cannabis Products

- (a) No product ingredient or component shall be used in the manufacture of an edible cannabis product except cannabis, cannabis concentrate, terpene, unless that ingredient or component is permitted by the USFDA as specified in *Substances Added to Food in the United States*
- (b) Edible cannabis products that consist of more than a single serving shall be either:
  - (1) Scored or delineated to indicate one serving, if it is in solid form
  - (2) If not in solid form, packaged in a manner such that a single serving is readily identifiable or easily measureable
- (c) Consisting of multiple servings shall be homogenized so that each serving contains the same concentration of THC

§40306 – Requirements for Topical Cannabis Products, Concentrates, and Other Cannabis Products

- Except for cannabis, cannabis concentrate, or terpenes, topical cannabis products shall only contain ingredients permitted for cosmetic manufacturing in accordance with Title 21, Code of Federal Regulations, Part 700, subpart B (section 700.11 et seq.) (Rev. March 2016)

§40308 – Orally-Consumed Products Containing Alcohol

- Any orally-consumed product that contains more than 0.5% alcohol by volume, and is not an alcoholic beverage shall not be sold in a package larger than two (2) fluid ounces and shall include a calibrated dropper or other similar measuring device

§40315 - THC Concentration Limits

- (a) An edible cannabis product shall not contain more than:
- (1) 10 milligrams THC per serving; and
- (2) 100 milligrams THC per package
- (b) Notwithstanding subsection (a), a package containing an edible product that is an orally-dissolving product, such as sublingual lozenges or mouth strips, may contain up to 500 milligrams THC per package, if:
- (1) The cannabis product consists of discrete servings of no more than 10 milligrams THC per piece
- (2) The cannabis product is labeled "FOR MEDICAL USE ONLY;" and
- (3) The cannabis product is only available for sale to a medicinal-use customer
- (c) A topical cannabis product or a cannabis concentrate shall not contain more than 1,000 milligrams THC per package
- (d) Notwithstanding subsection (c), a topical cannabis product or a cannabis concentrate may contain more than 1,000 milligrams THC per package, but not more than 2,000 milligrams THC per package, if the product is labeled "FOR MEDICAL USE ONLY" and is only available for sale to a medicinal-use customer

§40330 – Failed Product Batches

- (a) A finished cannabis product batch that fails any regulatory compliance laboratory testing requirement (§26100) shall be destroyed unless:
  - (1) The cannabis product batch can be remediated by relabeling pursuant to subsection (d); or
  - (2) A corrective action plan for remediation or reprocessing is approved by the Department pursuant to subsection (e)
- (b) Remediation or reprocessing of a failed product batch or the use of a harvest batch that has failed any regulatory test shall comply with the requirements and procedures established by the Bureau in Section 5727 of Title 16 of the California Code of Regulations, in addition to the requirements of this article
- (c) Except as provided in subsections (d) and (f), edible cannabis products that fail testing shall not be remediated or reprocessed and shall be destroyed. If any edible cannabis product that has failed testing is remediated, reprocessed, or otherwise mixed with another batch of cannabis product, shall render the final cannabis product adulterated, regardless of the defect level of the final cannabis product

- (d) A cannabis product batch that fails testing for cannabinoid or terpenoid content may be remediated by relabeling the product with the correct information from the laboratory certificate of analysis, provided that the THC limits in §40315 are met. In addition:
  - (1) The manufacturer licensee shall notify the Department within three (3) business days of notification by a distributor that a the product failed cannabinoid content testing and is required to be relabeled
  - (2) Notification shall be given to the Department by email and shall include a copy of the certificate of analysis for the batch and the name and license number of the licensee relabeling the product
- (e) Shall not be remediated or reprocessed unless the Department has approved a corrective action plan submitted by the manufacturer licensee. The corrective action plan shall include, at minimum, a description of how the product or harvest batch will be remediated so that the product or harvest batch, or any product produced, and will meet all regulatory compliance laboratory testing and quality assurance requirements
- (f) Edible cannabis products that fail testing because the package limit of THC has been exceeded, may be remediated by repackaging under the following conditions:
  - (1) The Department has approved a remediation plan for repackaging the product
  - (2) The product batch is returned to the manufacturer that packaged the product
  - (3) The product itself is not altered in any way
  - (4) The product is labeled to accurately state the contents
- (g) All remediation of harvest or product batches shall be documented in the batch production records

§40401 – Release to Distributor as Finished Product

- (a) Prior to release of a cannabis product to a distributor, a licensee shall ensure that the product is in finished form and is labeled and packaged in its final form for sale
- (b) Does not include:
  - (1) Labeling of cannabinoid content if the cannabinoid content is to be added to the label at the distribution premises after issuance of the Certificate of Analysis (§40409); or
  - (2) Placing the cannabis or cannabis product into child-resistant packaging as prescribed in Section 40417. This provision shall expire on December 31, 2019

§40403 – General Provisions

- (a) Any information required to be listed on a label shall be in English
- (b) Label shall be unobstructed and conspicuous so that it can be read by the consumer
- (c) All required label information shall be located on the outside container or wrapper of the finished product to be sold at a retailer. If the product container is separable from the outer-most packaging (e.g., a container placed inside of a box), the product container shall also include the following:
  - (1) For edible cannabis products, topical cannabis products, suppositories, or orally-consumed concentrates, all of the information specified in §40405 and §40406
  - (2) For inhaled products (e.g., as dab, shatter, and wax), the universal symbol as prescribed in §40412

§40404 – Labeling Requirements: Pre-Rolls and Packaged Flower

- (a) Shall include a primary panel that includes the following information in a type size no less than six (6) point font and in relation to the size of the primary panel and container:
  - (1) Identity of the product
  - (2) The net weight of cannabis in the package, listed in both metric and U.S. customary units; and
  - (3) Universal symbol
- (b) Shall include an informational label that includes the following information in a type size no less than six (6) point font and in relation to the size of the informational panel and container:
  - (1) The UID
  - (2) The licensed cultivator or licensee packaging the product and its contact number or website address

- (3) The date of packaging for retail sale
- (4) The following statement in bold print: "GOVERNMENT WARNING: THIS PACKAGE CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS MAY ONLY BE POSSESSED OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER UNLESS THE PERSON IS A QUALIFIED PATIENT. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION."

- (c) Nothing in this section prohibits the inclusion of additional information on the label, provided that the label does not violate the requirements of §40410
- (d) The cannabinoid content for a package of pre-rolls or packaged flower shall be labeled as specified in §40409

§40405 – Primary Panel Labeling Requirements: Manufactured Products

- (a) The label for a manufactured cannabis product shall include a primary panel that includes the following information in a type size no less than six (6) point font and in relation to the size of the primary panel and container:
  - (1) Identity of the product, in a text size related to the most prominent printed matter on the panel
  - (2) Universal symbol (§40412); and
  - (3) The net weight or volume of the contents of the package, listed in both metric and U.S customary units
- (b) Cannabinoid content may be included on the primary panel and manufactured cannabis products shall be labeled (§40409)
- (c) Nothing in this section prohibits the inclusion of additional information on the primary panel provided that the label does not violate the requirements of §40410

§40406 – Additional Primary Panel Labeling Requirements: Edible Products

- In addition to the requirements of §40405, the primary panel of an edible cannabis product shall include the words "cannabis-infused" immediately above the identity of the product in bold type and a text size larger than the text size used for the identity of the product

§40408 – Informational Panel Labeling Requirements

- (a) The label for a manufactured cannabis product shall include an informational panel that includes the following:
  - (1) Licensed manufacturer name (legal business name or registered name under which business operates on license certificate) and its contact number or website
  - (2) Date of the cannabis product's manufacture and packaging
  - (3) Following statement in bold print: "GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS PRODUCTS MAY ONLY BE PROCESSED OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER UNLESS THE PERSON IS A QUALIFIED PATIENT. THE INTOCICATING EFFECTS OF CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODCUTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION." (§26120)
  - (4) The statement "FOR MEDICAL USE ONLY" if:
    - (A) The cannabis product is intended by the manufacturer only for sale to medicinal-use customers
    - (B) The product is an orally-dissolving edible product containing more than one-hundred (100) milligrams THC per package (§40315b)

- (C) The product is a topical cannabis product or an orally-consumed concentrate containing more than one-thousand (1,000) milligrams THC per package (§40315d)
- (5) A list of all product ingredients in descending order of predominance by weight or volume. If any product ingredient contains sub-ingredients, the list shall either:
  - (A) Include the common name of the ingredient followed by a parenthetical listing of all ingredients in descending order by weight or volume; or
  - (B) List all sub-ingredients as individual ingredients in descending order of predominance
  - (C) This paragraph shall not apply to flavoring, which shall instead be compliant with the requirement of 21 C.F.R. 101.22 (Rev. Jan 2009)
- (6) If the cannabis product contains an ingredient, flavoring, coloring, or an incidental additive that bears or contains a major food allergen, the word "contains" followed by a list of the applicable major food allergens
- (7) The names of any artificial colorings contained in the product
- (8) If an edible cannabis product, the amount in grams or milligrams of sodium, sugar, carbohydrates, and total fat per serving
- (9) Instructions for use such as the method of consumption or application and any preparation necessary prior to use
- (10) Product expiration date, "use by" date, or "best by" date
- (11) The UID and batch or lot number; and
- (12) If the cannabis product is perishable or is perishable after opening, the statement, "KEEP REFRIGERATED" or "REFRIGERATE AFTER OPENING," as applicable

- (b) Informational panel text shall be in a text size of no less than six (6) point font and in relation to the size of the primary panel and container
- (c) Except for the information required by paragraph (a)(11), the requirements of subsection (a) may be fulfilled through the use of supplemental labeling, which may include, but is not limited to, a package insert, fold-out or booklet label, or a hanging tag
- (d) Cannabinoid content may be included on the informational panel and for manufactured cannabis products shall be labeled as specified in §40409
- (e) Nothing in this section prohibits the inclusion of additional information on the informational panel provided that the label does not violate the requirements of §40410

§40409 – Cannabinoid Content Labeling

- (a) Each package for retail sale of cannabis product, cannabis, or pre-rolls shall be labeled with the cannabinoid content on either the primary panel or an informational panel. This may be included on the product label at the manufacturing premises prior to release to a distributor or it may be added to the product at the distribution premises after issuance of the regulatory compliance testing Certificate of Analysis for the batch. Cannabinoid content labeling shall include the following:
  - (1) For an edible product, and a cannabis concentrate for which the manufacturer has established serving designations, THC and CBD content, expressed in milligrams per serving and milligrams per package
  - (2) For a topical cannabis product and a cannabis concentrate without serving designations, THC and CBD content, expressed in milligrams per package
  - (3) Packages of pre-rolls or cannabis flower that do not include cannabinoids other than that naturally occurring in the plant material are not required to list cannabinoid content in milligrams. Instead, such packages may be labeled with the cannabinoid content expressed as a percentage
  - (4) Packages of infused pre-rolls shall be labeled with either:
    - (A) The cannabinoid content in milligrams; or
    - (B) The cannabinoid content of the dried flower expressed as a percentage and the added cannabinoid content in milligrams

- (b) A manufacturer that includes the cannabinoid content on the product label prior to release to a distributor, shall label products as appropriate to the product. For THC or CBD concentration that is less than two (2) milligrams per serving or per package, the THC or CBD may be labeled as "<2.0 mg per serving" or "<2.0 mg per package".
- (c) A manufacturer may arrange for cannabinoid content labeling at the distribution premises after issuance of the Certificate of Analysis in accordance with the following:
  - (1) Each package of cannabis product in the batch shall be labeled with the cannabinoid content as specified that is indicated on the Certificate of Analysis, as well as any other cannabinoid that is five (5) percent or greater of the total cannabinoid content
  - (2) The manufacturer shall identify a location for the cannabinoid content label on the outer packaging of the product. The location shall be sufficient in size for the required cannabinoid content to be printed in at least six (6) point font
  - (3) The cannabinoid content label shall be affixed to the identified location on the outer packaging of the product and shall not obscure any other label information
- (d) Nothing in this section precludes the labeling of terpenes or additional cannabinoid content on the product, provided that the information is verified by the Certificate of Analysis

§40410 – Labeling Restrictions

Cannabis product labeling shall not contain any of the following:

- (a) The name of a California county, including any similar name that is likely to mislead consumers as to the origin of the product, unless 100% of the cannabis used in the product was grown in that county
- (b) Content that is, or is designed to be, attractive to individuals under the age of twenty-one (21), including but not limited to:
  - (1) Cartoons
  - (2) Any likeness to images, characters, or phrases that are popularly used to advertise to children
  - (3) Any imitation of candy packaging, labeling
  - (4) The terms "candy" or "candies" or variants in spelling such as "kandy" or "kandeez"
- (c) Any information that is false or misleading
- (d) Any health-related statement that is untrue or misleading
- (e) If the product is an edible product, a picture of the product contained therein
- (f) False or misleading information includes any indication that the cannabis or cannabis product is organic that authorizes organic designation and certification for cannabis and the cannabis or cannabis product meeting the requirements for such designation and certification. This includes use of the word "organic" on the labeling or variants in spelling such as "organix"
- (g) Any labeling in violation of Section 5040.1 of Division 42 of Title 16 of the California Code of Regulations

§40411 – Statement of Characteristic Anticipated Effects

- A cannabis product may include information on the characteristic anticipated effects of the cannabis product if the manufacturer has substantiation that the information is truthful and not misleading. Information may be located on the informational panel of the label or as an insert included in the cannabis product package

§40412 – Universal Symbol:

- (a) The primary panel of a cannabis product shall be marked, stamped, or imprinted with the universal symbol.
- (b) The symbol shall replicate (

) in form.
- (c) The symbol shall be black in color. For packaging that is dark in color, the symbol may be made conspicuous by printing the symbol on, or outlining the symbol with, a contrasting color

- (d) The symbol shall be no smaller in size than one half (.5) inch by one half (.5) inch and shall be printed legibly and conspicuously
- (e) The symbol shall not be altered or cropped in any way other than to adjust the sizing for placement on the primary panel

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

- (a) Shall protect the product from contamination and shall not expose the product to any toxic or harmful substance
- (b) Tamper-evident (sealed so its contents cannot be opened without obvious destruction of the seal)
- (c) If the product has multiple uses, the package shall be resealable
- (d) Not imitate any package used for products typically marketed to children
- (e) If it is an edible product the package shall be opaque. Amber bottles shall be considered opaque for purposes of this section
- (f) Notwithstanding subsection (e), opaque bottles used to contain a cannabis beverage product may utilize a single, vertical, clear strip of no wider than 0.25 inches for the purpose of determining serving amounts
- (g) Shall be child-resistant (§40417)

§40417 – Child-Resistant Packaging Requirements

- (a) A package containing cannabis or cannabis products transferred to a distributor for retail sale shall be child-resistant, as follows: *(Beginning on January 1, 2020)*
  - (1) An edible product, an orally-consumed concentrate, or a suppository shall be child-resistant for the life of the product. A package that contains more than a single serving is not required to be child-resistant if each individual serving is packaged in child-resistant packaging
  - (2) Cannabis or a cannabis product intended to be inhaled or a cannabis product that is applied topically may utilize packaging that is child-resistant only until first opened, if the package is labeled with the statement "This package is not child-resistant after opening."
- (b) The following packages are considered child-resistant:
  - (1) Any package that has been certified as child-resistant
  - (2) A bottle sealed with a pry-off metal crown cork style bottle cap, provided that the bottle contains only a single serving
  - (3) Plastic packaging that is at least four (4) mils thick and heat-sealed without an easy-open tab, dimple, corner, or flap, provided that the package contains a cannabis product or is a cannabis product that is only a single serving
- (c) Until the date specified in subsection (a), the child-resistant package requirement specified in section 26120 of the Act may be met through the use of a child-resistant exit package at retail sale

§40500 – Record Keeping Requirements

- (a) Licensee shall maintain the following documents on the premises at all times and shall make the documents available to the Department upon request:
  - (1) Valid state license issued by the Department
  - (2) Any other valid license issued by a state cannabis licensing agency
  - (3) Valid license, permit or other approval issued by the local jurisdiction
  - (4) Premises diagram (§40105)
  - (5) Current standard operating procedures (§40275)
  - (6) Shipping manifests
  - (7) Personnel records including evidence of personnel qualifications and training procedures and records (§40280)

- (8) Contracts with other licensees regarding commercial cannabis activity;
- (9) Financial records related to the commercial cannabis activity including, but not limited to, bank statements, and tax records;
- (10) Sales invoices and receipts as described in section 26161 of the Act and Section 40505 of these regulations; and
- (11) Any other record or documentation required to be kept pursuant to this Chapter or the Act

- (b) The records shall be maintained for a period of seven (7) years. Outdated standard operating procedures shall be maintained such that onsite employees cannot mistakenly access outdated information.
- (c) All documentation shall be maintained in English (§26160). However, nothing in this subsection prohibits the maintenance of documents in languages in addition to English as needed by the licensee

§40505 - Sales Invoices and Receipts

- (a) The licensee shall prepare a sales invoice or sales receipt for every sale, transport, or transfer of cannabis products to another licensee. Sales invoices and receipts may be maintained electronically, but shall be readily accessible for examination by the Department and its inspectors and agents
- (b) Each sales invoice or receipt shall include the following information:
- (1) Name, address, and license number of the seller
- (2) Name, address, and license number of the purchaser
- (3) Date of sale, transport, or transfer
- (4) Invoice or receipt number
- (5) Kind, quantity, size, and capacity of packages of cannabis or cannabis product sold, transported, or transferred; and
- (6) Cost to the purchaser for the cannabis or cannabis product, including any discount or trade allowance applied to the price, which shall be recorded on the invoice
- (c) For purposes of this section, “discount or trade allowance” means any price reduction or allowance of any kind, whether stated or unstated, and includes, without limitation, any price reduction applied to a licensee’s price list. The discounts may be for prompt payment, payment in cash, bulk purchases, related-party transaction, or “preferred-customer” status
- (d) Invoices and receipts for the sale, transport, or transfer of cannabis or cannabis products shall not be comingled with invoices covering other commodities

§40510 – Track-and-Trace System General Requirements

- (a) Each applicant or licensee shall identify an owner of the commercial cannabis business to be in the track-and-trace system account manager. The account manager shall register for track-and-trace system training within ten (10) business calendar days of receiving notice from the Department of Public Health that their application for licensure has been received
- (b) Applicants approved for an annual license shall not have access to the track-and-trace system until the account manager has completed the track-and-trace training and proof of completion has been validated
- (c) The licensee’s track -and-trace system account manager shall be responsible for all the following:
  - (1) Complete track-and-trace system training. If the account manager did not complete the track-and-trace system training prior to the licensee receiving their annual license, the account manager will be required to register for the track-and-trace system training within five (5) calendar days of license issuance
  - (2) Designate track-and-trace system users, as needed, and require the designated users to be trained in the proper and lawful use of the track-and-trace system before the users are permitted to access the track-and-trace system
  - (3) Maintain an accurate and complete list of all track-and-trace system designated users and update the list immediately when changes occur
  - (4) Cancel any track-and-trace designated users from the licensee’s track-and-trace system account if that individual is no longer authorized to represent the licensee

- (5) Correct any data that is entered into the track-and-trace system in error within three (3) calendar days of discovery of the error
- (6) Obtain UID tags from CDFA, or its designee, and ensure that a sufficient supply of UIDs is available at all times
- (7) Ensure that all inventory is tagged and entered in the track-and-trace system (§40512 & §40517)
- (8) Monitor all notifications from the track-and-trace system and resolve all issues identified in the notification. This shall not be dismissed by an account manager until the issue(s) identified in the notification has been resolved; and
- (9) Notify the Department of any loss of access to the track-and-trace system that exceeds seventy-two (72) hours

- (d) The applicant or licensee is responsible for notifying the Department in writing of any change to the designated track and trace system account manager within forty-eight (48) hours
- (e) The licensee is responsible for all actions its owners or employees take while logged into the track-and-trace system, or otherwise performing the track-and-trace activities
- (f) No person shall intentionally misrepresent or falsify information entered into the track-and-trace system. The track-and-trace system shall be the system of record. The licensee is responsible for the accuracy and completeness of all data and information entered into the track-and-trace system. Information entered into the track-and-trace system shall be assumed to be accurate and may be used to take enforcement action against the licensee if incorrect information is not corrected

§40512 - Track-and-Trace System Reporting Requirements

- (a) A system account manager or designated user shall record all of the following activities in the track-and-trace system within 24 hours of the activity:
- (1) Receipt of cannabis material
- (2) The transfer to or receipt of cannabis products for further manufacturing from another licensed manufacturer; and
- (3) All changes in the disposition of cannabis or cannabis products. A change in disposition includes, but is not limited to:
- (A) Processing of the cannabis or further processing of the cannabis product; and
- (B) Packaging and labeling of the cannabis or cannabis products or repackaging or relabeling of the cannabis or cannabis products
- (4) Use of cannabis or cannabis product for internal quality control testing or product research and development
- (5) Transfer of cannabis products to a distributor
- (b) The following information shall be recorded for each activity entered into the track-and-trace system:
- (1) The licensed entity from which the cannabis material or cannabis product is received, including that entity's license number, and the licensed entity to which the cannabis product is transferred, including that entity's license number
- (2) The name and license number of the distributor that transported the cannabis material or cannabis product
- (3) The type of cannabis material or cannabis product received, processed, manufactured, packaged, or transferred
- (4) The weight or count of the cannabis material or cannabis product received, processed, manufactured, packaged, or transferred
- (5) The date and time of receipt, processing, manufacturing, packaging, or transfer
- (6) The UID assigned to the cannabis material or cannabis product
- (7) Any other information required by other relevant licensing authorities

§40513 - Track-and-Trace System – Loss of Access

- (a) If a licensee loses access to the track-and-trace system for any reason, the licensee shall prepare and maintain comprehensive records detailing all required inventory tracking activities conducted during the loss of access
- (b) Upon restoration of access to the track-and-trace system, all inventory tracking activities that occurred during the loss of access shall be entered into the track-and-trace system within three (3) business days.
- (c) A licensee shall document the date and time when access to the track-and-trace system was lost, when it was restored, and the cause for each loss of access
- (d) A licensee shall not transfer cannabis products to another licensee or receive cannabis or cannabis products from another licensee until such time as access to the track-and-trace system is restored and all information is recorded into the track-and-trace system

§40515 - Track-and-Trace System – Temporary Licenses

- (a) A licensee operating under a temporary license issued pursuant to Section 40126 is not required to record commercial cannabis activity in the track-and-trace system as otherwise required by this article. Temporary licensees shall track all commercial cannabis activities on a paper sales receipt or invoice that includes the following information:
- (1) Name, address, and license number of the seller
- (2) Name, address, and license number of the purchaser
- (3) Date of sale or transfer and invoice number
- (4) Description or type of cannabis or cannabis product
- (5) Weight or count of the cannabis or cannabis product sold or transferred
- (6) Cost to the purchaser of the cannabis or cannabis product
- (b) After issuance of an annual license, the licensee may continue to conduct commercial cannabis activities with temporary licensees in accordance with subsection (a). Any commercial cannabis activity conducted between annual license holders shall be recorded in the track-and-trace system
- (c) The provisions of this section shall expire on July 1, 2019

§40517 – Track-and-Trace System – UID Tag Order

- (a) A licensee shall order UID tags within five (5) calendar days of receiving access to the track-and-trace system. The receipt of the UID tags by the licensee shall be recorded in the track-and-trace system within three (3) calendar days of receipt
- (b) Any licensee in operation at the time access to the track-and-trace system is granted shall input all inventory into the track-and-trace system no later than thirty (30) calendar days after receipt of the UID tags. After UID tags have been received, all commercial cannabis activity shall be recorded in the track-and-trace system by the licensee