

**DPH-17-010 Modified Text Explanation of Changes  
15-Day Public Comment Period #1**

The Department of Public Health is proposing modifications to the regulation text initially noticed on July 13, 2018.

**Section 40100(i)** is a technical, grammatical change.

**Section 40100(k)** adds “homogeneity” to the definition of “cannabis product quality.”

**Section 40100(dd)(2)(B)** is added to clarify that the processing of pre-rolls is not a manufacturing activity, and conforms with the Bureau of Cannabis Control’s draft regulations that allow the preparation of pre-rolls by a distributor.

**Section 40100(dd)(2)(E)** is added to clarify that the cannabinoid content labeling on the package of cannabis or cannabis products by the distributor is not a manufacturing activity. This addition is necessary to align with Section 40409, which has been added to allow distributors to label the cannabinoid content based on the Certificate of Analysis after the product has been tested. Currently, all cannabis products must be packaged and labeled by a manufacturer prior to testing.

**Section 40128(b)(3)** is a technical, grammatical change.

**Section 40128(b)(4)** is a technical, grammatical change.

**Section 40128(b)(5)** is added to align with AB 2799 (Chapter 971, Statutes of 2018) related to OSHA training requirements.

**Section 40129(a)(7)** is amended to add foreign limited liability companies to the list of business structures to be disclosed on the application, and makes a clarifying change.

**Sections 40129(a)(8) and (9)** are amended to clarify that all owners and financial interest holders need to be disclosed on the license application.

**Section 40129(a)(12)** is amended to include additional examples of business formation documents.

**Section 40130(a)(7)** is a technical, grammatical change.

**Section 40130 (a)(8)** is a technical change.

**Section 40130 (a)(9)** is added to require an owner to disclose ownership or financial interest in any other cannabis business licensed under the Act.

**Section 40137 (d)** is a technical, grammatical change.

**Section 40152(c)** is a technical, grammatical change.

**Section 40179** is added to specify what happens to a license in the event of an owner's death, incapacity, receivership, assignment for the benefit of creditors of a licensee, or other event rendering an owner incapable of performing the duties associated with the license. This section is necessary as it provides an owner's successor in interest the opportunity to transition the owner's operations and/or wind-down the licensed business' affairs prior to expiration of the license while ensuring the Department is aware of the situation and that licensing rules are being followed. Although the successor in interest may continue operations on the licensed business premises for a period of time, the successor in interest is not automatically guaranteed issuance of a state cannabis license. Requiring the successor in interest to submit a new application for licensure after a certain period enables the Department to determine a new owner's fitness for licensure as required by the Act. The requirements of this section duplicate requirements established by the Bureau of Cannabis Control.

**Section 40192(b)(1)** is a technical, grammatical change.

**Section 40192(b)(2)(A)** is a technical, grammatical change.

**Section 40205(e)** is amended to remove the requirement that monitoring equipment be stored in secure rooms or access-controlled environments.

**Section 40205(g)** is a technical, clarifying change.

**Section 40220(a)(3)** is changed to conform with Section 40223, which requires ethanol used for extraction and post extraction to be food-grade due to the residual amount of solvents that remain in the product. Residual amounts of CO<sub>2</sub> will remain in the product and therefore should be food-grade.

### **Articles 3 and 4: Good Manufacturing Practices (Restructured)**

The original proposal was heavily drawn from US Food and Drug Administration requirements for manufacturing of food, drugs, and dietary supplements. The modifications to the text do not substantively remove, nor add any additional regulatory requirements. Instead, the modified text has restructured and revised the Good Manufacturing Practices and Process and Procedures articles of this proposal. The revisions are intended to clarify the requirements, remove duplicative language, and be more conducive to a comprehensive understanding of good manufacturing practices and quality control operations, and their relationship to product adulteration or misbranding.

As such, the necessity and rationale presented in the Initial Statement of Reasons are still applicable.

**Section 40230** is amended as follows:

Subsection (a) is deleted. The term “actual yield” has been combined with the definition of “theoretical yield” and added to the definition of “yield” under subsection (y).

Subsection (b) is deleted. The term “adequate” has been removed from the proposed text.

*The remaining subsections in 40230 have been renumbered accordingly.*

Subsection (b) is amended to include raw materials in the definition of “component.”

Subsection (c) clarifies the definition of “contact surface.”

Subsection (d) has been added to clarify the Department’s definition of easily cleanable, for the ease of licensees to understand the requirements of this section. This definition is taken from Health and Safety Code §113767 of the California Retail Food Code.

Prior subsection (i) is deleted. The term is no longer used in the proposed text and therefore the definition is not needed.

New subsection (i) makes a technical change to align with further regulatory provisions.

Subsection (l) adds a definition of “potable” so that licensees understand the requirements for water used in the manufacturing operation. The definition of potable is taken from Health and Safety Code §113869 of the California Retail Food Code.

Subsection (m) makes a technical change to align with further regulatory provisions.

Subsection (t) deletes the term “adequately” and is a technical, clarifying change.

Subsection (u) adds a definition of “smooth” so that licensees can understand further regulatory requirements. The definition of smooth is taken from Health and Safety Code §113916 of the California Retail Food Code.

Subsection (v) is deleted. Actual and theoretical yield definitions have been merged into subsection (y).

New Subsection (v) adds a definition of “utensil” to clarify the Department’s use of the term for the ease of licensees to understand the requirements of this section.

Subsection (y) adds a definition of “yield” to clarify the Department’s use of the term for the ease of licensees to understand the requirements of this section.

**Sections 40232 and 40234** have been deleted and restructured into the new Quality Control Program sections.

**Section 40235** outlines the specific quality control elements that should be considered in order to reduce the potential for misbranding or adulteration of cannabis and cannabis products. The physical location, equipment and utensils, personnel, components used to create a cannabis product, and processes and procedures present opportunities for products to become contaminated if not appropriately addressed in a quality control program.

Subsection (a) requires each licensee to implement an overall quality control program, which includes the following:

Paragraphs (1) through (5) outline the specific areas in which the Department has determined provide opportunities for adulteration or contamination to take place. Therefore, the Department has identified these areas as requiring specific plans and policies be in place to prevent the possibility of adulteration or contamination and ensure product quality.

The restructured requirements take licensees step-by-step through the establishment of a basic quality control program, beginning outside of the facility and continuing through to the manufacturing procedures. The sections hereafter will focus on each one of these elements to ensure the regulated community has a clear understanding of requirements necessary to prevent products from becoming contaminated.

Subsection (b) includes the existing requirement that overall quality control be under the supervision of one or more qualified individuals assigned responsibility for the task.

Subsection (c) establishes that Health and Safety Code section requirements referenced in the text that use the term “food” shall be considered to include cannabis, cannabis products, components, and contact surfaces. This provision is necessary so that licensees understand the requirements apply to cannabis products even though the requirements refer to “food.”

**Sections 40236, 40238, and 40240** have been revised and reformatted into the revised Section 40240.

**Revised Section 40240** establishes the minimum requirements for the facility exterior, interior, and manufacturing premises.

Subsection (a) contains the minimum requirements for the exterior facility and grounds. Proper sanitation of the manufacturing process starts outside of the premises. The grounds and exterior of the building can contribute to pest infestation, drainage issues, and airborne or other contaminants impacting the manufacturing premises. The licensee must ensure the facility exterior and grounds meet the following minimum standards:

Paragraph (1): grounds under the licensee's control are equipped with draining areas in order to prevent pooled or standing water. This requirement was in prior Section 40234(c).

Paragraph (2): requires that, in order to minimize the potential for grounds under the licensee's control to constitute an attractant, breeding place, or harborage for pests, equipment must be stored, waste removed, and weeds and grass must be cut. This requirement was in prior Section 40234(a).

Paragraph (3): requires roads, yards and parking lots under a licensee's control to be maintained to prevent product contamination where cannabis products are handled and transported. This requirement was in prior Section 40234(b).

Paragraph (4): requires openings into buildings to be sealed in a manner that prevents pests from entering. This requirement was in prior Section 40236(j).

Paragraph (5): requires waste treatment and disposal systems to be provided and maintained to prevent product contamination in areas where cannabis products may be exposed to such wastes and waste-by-products. This requirement was in prior Section 40234(d).

Paragraph (6): specifies that a licensee shall exercise other precautions within its premises in order to eliminate pests, dirt, and filth that pose a source of cannabis product contamination when bordering grounds are outside of the licensee's control. This requirement was in prior Section 40234(e). This paragraph also adds the requirement that any use of insecticide, rodenticide, or other pesticide within the premises shall meet the requirements of Health and Safety Code §114254, which describes the requirements for use of these chemicals in food facilities. This provision is necessary to protect public health by preventing adulteration of cannabis products through the use of pest-controlling chemicals.

Subsection (b) establishes the requirements for construction, design, and maintenance of the interior of the manufacturing premises as follows.

Paragraph (1): specifies that walls, ceilings and floors shall be constructed of material that is smooth, nonporous, easily cleanable, corrosion-resistant and suitable to the activity to be conducted. This requirement was in prior Section 40236(d) and is necessary to prevent product adulteration. This paragraph also states that fixtures, ducts, and pipes shall not pose a source of drip or condensate that may contaminate products, packaging, or contact surfaces and was in prior Section 40236(e).

Paragraph (2): updates the requirements for lighting. It has also been updated to reference requirements for food facilities in the Health and Safety Code. The requirements for shatter-resistant bulbs and minimum lighting standards were included in prior Section 40236(g).

Paragraph (3): specifies the requirements for the plumbing system and fixtures.

Subparagraph (A) states that running water must be supplied as required by Health and Safety Code §114192 and that water that contacts cannabis, cannabis products, components, contact surfaces, or packaging materials shall be potable. These requirements were included in prior section 40240(a).

Subparagraph (B) updates the requirements for plumbing. It has also been updated to reference requirements for food facilities in the Health and Safety Code. The requirements for plumbing were included in prior Section 40240(b).

Subparagraph (C) specifies the requirements for sewage disposal. It has also been updated to reference requirements for food facilities in the Health and Safety Code. The requirements for sewage were included in prior Section 40240(c).

Subparagraph (D) specifies the requirements for toilet facilities. It has also been updated to reference requirements for food facilities in the Health and Safety Code. The requirements for toilet facilities were included in prior Section 40240(d).

Subparagraph (E) specifies the requirements for hand-washing facilities. It has also been updated to reference requirements for food facilities in the Health and Safety Code. The requirements for hand-washing facilities were included in prior Section 40240(e).

Subparagraph (F) specifies the requirements for waste disposal. It has also been updated to reference requirements for food facilities in the Health and Safety Code. The requirements for waste disposal were included in prior Section 40240(f).

Paragraph (4): specifies the requirements for ventilation. It has also been updated to reference requirements for food facilities in the Health and Safety Code. The requirements for ventilation were included in prior Section 40240(i).

Paragraph (5): specifies the requirements for cleaning and maintenance. It has also been updated to reference requirements for food facilities in the Health and Safety Code. This requirement was in prior Section 40238(a).

Subparagraph (A) establishes requirements for janitorial facilities. This is a new requirement.

Subparagraph (B) specifies the requirements for storage of cleaning equipment and supplies by referencing requirements for food facilities in the Health and Safety Code. This requirement was in prior section 40238.

Subparagraph (C) specifies the requirements for storage of toxic materials by referencing requirements for food facilities in the Health and Safety Code. This requirement was in prior section 40238(d).

**Section 40243** focuses on the importance of properly designed, cleaned, and maintained equipment and utensils, as these items can be a potential source of contamination to cannabis products. Equipment that is not properly installed can restrict cleaning, sanitizing, and maintenance. Improperly cleaned and sanitized equipment can be a source of microbiological contamination. Improperly maintained equipment can be a source of chemical or physical hazards, such as lubricants or metal shavings. Section 40243 requires a manufacturer to include written procedures, as well as a cleaning schedule, for the cleaning, sanitizing, and maintenance of equipment and utensils.

Subsection (a) specifies the standards for the design of equipment and utensils as those required by Health and Safety Code sections 114130.1, 114130.2, 114130.3, and 114130.4. The requirements are those previously included in prior Section 40242 (a), (b), (d), (e), (f), and (g).

Subsection (b) specifies the requirements for installation of equipment as required in prior Section 40242(c). This section also provides requirements for equipment that is not easily moveable currently required in food facilities under the Health and Safety Code; this requirement was not specifically included in the prior version of the regulations and is included here to clarify requirements to which licensees must adhere.

Subsection (c) requires the quality control program for cleaning, sanitizing, and maintenance of equipment and utensils to include the following elements, at minimum:

Paragraph (1): requires a detailed, written procedure for cleaning, sanitizing, and maintaining equipment and utensils. This requirement is necessary so that personnel know the proper procedures for cleaning, sanitizing, and maintaining equipment and utensils.

Paragraph (2): requires a schedule for cleaning, sanitizing, and maintaining equipment and utensils. This requirement is necessary so that personnel can clean equipment and utensils as established by the schedule and so that the Department can verify during inspections that such activities have occurred.

Paragraph (3): specifies the requirements for a procedure and log for cleaning, sanitizing, and maintenance. This requirement was in prior section 40238(l).

Paragraph (4): specifies the requirements for a detailed, written procedure for storing cleaned and sanitized equipment. This requirement was in prior section 40232(a).

**Section 40246** focuses on the importance of proper hygienic practices for personnel in order to protect against allergen cross contact and contamination of cannabis products. Personnel known to be suffering from, or to be carriers of, certain diseases transmitted through food can spread those diseases through improper personal hygiene or improper hygienic practices during the manufacturing process. The Department included specific Health and Safety Code provisions to ensure manufacturers are aware of the types of illnesses that pose a reasonable threat of microbiological contamination to cannabis products, contact surfaces, or packaging materials, as well as prescribe methods of wound covering to prevent contamination. The revised section is substantively the same as prior Section 40232.

**Section 40248** focuses on the importance of preventing the incorporation of unsanitary components into cannabis products as these components can contribute to the adulteration of cannabis products. Components of a cannabis product, including cannabis, cannabis concentrate, and other ingredients, can contribute to product adulteration if they are not of sanitary quality or are not handled in a manner that protects against microbiological contamination. Section 40248 requires manufacturers to establish written policies and procedures to ensure components, including raw materials, follow minimum sanitary requirements. The requirements of this section are substantively the same as prior Section 40252.

**Section 40250** focuses on the importance of establishing processes and procedures that prevent opportunities for cannabis products to become adulterated or misbranded. This section has been re-formatted and re-named to the Manufacturing Processes and Procedures section. Section 40250 specifies that a quality control program shall include, as a mechanism for evaluating, implementing and maintaining its processes and procedures, a hazard analysis and preventative controls, a master manufacturing protocol, and batch production records.

**Section 40252** has been removed and re-formatted into the other manufacturing sections.

**Section 40253** focuses on the importance of creating a product quality plan. This is a reformatting of the previous hazard analysis section, which has been simplified and clarified for the ease of licensees to understand how to prevent adulteration and ensure quality of the cannabis products.

Subsection (a) requires the licensee to create and implement a written product quality plan. The product quality plan must address the hazards associated with the premises or the manufacturing process that, if not properly mitigated, could cause the product to be adulterated or misbranded, or could cause the product to fail laboratory or quality assurance testing.

Subsection (b) states that the licensee must conduct a comprehensive assessment of the overall manufacturing 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.

Subsection (c) specifies that the product quality plan must evaluate specific potential risks to cannabis product quality.

Paragraph (1): Biological hazards, including microbiological hazards. These hazards may be inherent in the ingredients comprising a product and can be introduced during handling and processing. They include a number of microbiological hazards known to cause major food-borne illnesses, such as *Salmonella* and *Clostridium botulinum*;

Paragraph (2): Chemical hazards, including radiological hazards, pesticide(s) contamination, solvent or other residue, natural toxins, decomposition, unapproved additives, or food allergens. Cannabis cultivation frequently uses pesticides and/or fertilizers. Such hazards may be compounded by the extraction process, which may concentrate various chemical compounds on the product and result in injury or illness if consumed. Additionally, the use of various solvents for extraction of cannabinoids from cannabis makes solvents a likely chemical contaminant for extract products. Natural toxins may thrive on product ingredients, and decomposition of product components may affect the chemical makeup of a product resulting in destabilization and harm if consumed.

Paragraph (3): Physical hazards, such as stone, glass, metal fragments, hair, or insects. The USFDA has identified the above materials and organisms as common physical hazards found in food products. Stones may be incorporated into products due to failed oversight in the harvest of agricultural material used as ingredients and may cause damage to teeth if consumed. Glass may be introduced during handling of input materials or equipment or light-fixture breakage during the manufacturing process and may result in laceration of the mouth, throat, and intestine if consumed. Metal fragments, including screws, if similarly introduced into the product may pose a choking hazard, as may sharp metal objects such as metal fragments. Additionally, hair and insects may be incorporated into products due to unsanitary conditions during handling or processing, and may become vectors for disease.

Paragraph (4): Process failures that may lead to product contamination, allergen cross-contact, packaging errors, labeling errors, or other errors affecting cannabis product quality.

Subsection (d) requires the product quality plan to identify the preventive measures that will be used to mitigate potential hazards identified in the analysis.

Paragraphs (1) – (4) are examples of preventive measures that licensees may employ. These are provided solely as examples and are not meant to be an exhaustive list of

options. Licensees should determine the preventive measure based on the specific product and identified risk.

Subsection (e) requires the product quality plan to identify methods to evaluate and monitor the effectiveness of the preventive measures in mitigating the potential risks identified in subsection (c).

Paragraphs (1) – (4) are examples of methods to monitor and evaluate preventive measures that licensees may employ. These are provided solely as examples and are not meant to be an exhaustive list of options. Licensees should determine the monitoring and evaluation based on the specific preventive measure employed.

Subsection (f) requires the product quality plan to identify actions to be taken if the evaluation and monitoring show that the risk was not properly mitigated.

Paragraphs (1) – (3) are examples of potential actions. These are provided solely as examples and are not meant to be an exhaustive list of options. Licensees should determine the action based on the type of product under evaluation and the specific risk to be mitigated.

Subsection (g) requires the product quality plans and any documentation to be kept as records and requires these records to be made available to the Department upon request. This subsection also allows the product quality plan to be considered a trade secret.

**Section 40254** has been removed and redistributed into the other manufacturing sections.

**Section 40255** focuses on the importance of developing a master manufacturing protocol to ensure product uniformity and minimize the potential for product adulteration or misbranding. Section 402255 requires a manufacturer to establish a written manufacturing protocol for each unique formulation of cannabis product manufactured, including the intended cannabinoid concentration, components, and ingredients to be identified on the label. Manufacturers shall also include written instructions for each step of the manufacturing process and critical points in the hazard analysis and preventative measures needed.

**Section 40256** has been removed and redistributed into other manufacturing sections.

**Section 40258** includes the language previously in 40264, Batch Production Records, and makes the following modifications:

Subsection (b)(1) specifies that the UID(s) of the cannabis used shall be maintained as part of the record. This is a technical change to conform to track-and-trace system requirements.

Subsection (b)(6) makes a technical change to align with modified definitions.

Subsection (b)(13) clarifies that the Certificate of Analysis (COA) shall be added to the record after testing has been completed. There is no way for a manufacturer to add the COA to the batch production record during production, as the COA is issued after the batch has been tested. Section 40258 also contains other technical, clarifying changes.

Subsection (c)(4)(D) clarifies that the batch number also be included as part of the batch production record.

**Section 40275(a)(5)** is a technical change to conform this section with the restructured Good Manufacturing Practices.

**Section 40277(c)** is amended based on comments received by CalCannabis from the California Agricultural Commissioners and Sealers Association to clarify that a weighmaster certificate is not required when the cannabis or cannabis product is weighed for entry into the track-and-trace system.

**Section 40280** contains technical, grammatical changes.

Subsection (a)(2) clarifies that the training requirements regarding manufacturing processes apply to manufacturing and production personnel.

Subsection (a)(2)(C) makes a conforming change to match other changes in the modified text.

**Section 40290** makes several technical changes to clarify and conform to the requirements of the other licensing authorities.

Subsection (c) clarifies vape cartridges are not required to be emptied prior to disposal. Based on a number of comments received by the Department via its MCSB mailbox and during the 45-day comment period, there was confusion as to whether the prohibition on disposing of product in its packaging meant that vape cartridges had to be drained of cannabis oil prior to disposal. This clarification is needed to remove any such confusion. Products must be removed from the packaging in order to reduce the potential for diversion or theft. Draining a vape cartridge of oil prior to destroying the cartridge does not provide any additional public health or safety protection.

The remaining amendments to this section are made to conform the waste disposal requirements to those of CalCannabis.

**Section 40295** is renumbered from 40266 and makes a technical, grammatical change.

**Section 40297** is renumbered from 40268 and makes a clarifying change in subsection (e). Some types of cannabis products, such as vape cartridges, are recorded in the track-and-trace system by count in addition to weight.

**Section 40300(c)** is a technical, grammatical change.

**Section 40300(m)** is a technical, clarifying change.

**Section 40305** makes grammatical changes.

**Section 40308** is revised to clarify that the two (2) fluid ounces package size restriction applies to orally-consumed products containing ethanol, not topicals that use ethanol as an ingredient or non-ethanol based tinctures. During the 45-day comment period, the Department became aware that this section was not sufficiently clear. The intent of this section was to limit the size of a product consumed orally that contained ethanol as an ingredient.

**Section 40330** is revised to allow edible products that fail laboratory testing because they exceed the per package limit of THC (100 mg) to be repackaged as a form of remediation. Under the current emergency regulations, edible products that contain more than 100 mg of THC per package must be destroyed. In some instances, however, repackaging the product to meet the requirements would pose no public health risk. The following limitations on repackaging failed product batches are established below ensure the integrity of the product:

Subsection (f), paragraph (1): requires that the Department approve the remediation plan. This provision is necessary to ensure the Department maintains oversight authority to ensure the product is not adulterated.

Paragraph (2): requires the product to be returned to the manufacturer that packaged the product. The manufacturer that packaged the product should have the capability to repackage the product without adulterating it.

Paragraph (3): states that the product itself cannot be altered in any way. Altering the product, such as cutting pieces off or pouring out part of a beverage, could introduce contamination or could impact the accuracy of the way the consumer determines a single serving.

Paragraph (4): requires the product to be labeled to accurately state the contents. This is a standard requirement for all products, and is reiterated here to clarify that the package must be relabeled and cannot simply rely on the prior labeling.

This section also makes other technical, grammatical changes, including amendments to conform to terminology used by the Bureau of Cannabis Control.

**Section 40401** is revised to conform the definition of “final form” with other modifications to the text. Currently, a manufactured product must be in its final form, including packaged and labeled, prior to being released to a distributor. This modification to the text is necessary to align this section with post-testing labeling requirements prescribed in Section 40409 and with the requirements of child-resistant packaging in Section 40417.

**Section 40403** is amended to clarify what information is needed on the label of a container that is separable from the package to conform to the allowance of post-testing labeling.

**Sections 40404 and 40405** are amended to clarify labeling requirements to account for post-testing labeling of cannabinoid content.

**Section 40408** make several technical, grammatical changes, as well as the following: Subsection (a)(5)(C) is added to exempt ingredients used for flavoring from being disclosed in the ingredients list. This change was made based on comments received during the public comment period. The Food and Drug Administration considers flavoring added to products to be proprietary information. The Department concurs that there is no public health risk in conforming to FDA requirements in this matter.

Subsection (c) is amended to clarify that the unique identifier (UID) and batch number cannot be placed on supplemental labeling. The UID and batch number are critical information in cases of recall and should not be separated from the product container.

Subsections (d) and (e) are amended to conform to post-testing cannabinoid labeling prescribed in Section 40409.

**Section 40409** is modified to allow the labeling of packages containing cannabis, pre-rolls, and cannabis products to be labeled with the cannabinoid content after testing has been conducted. The Department received numerous comments during the 45-day comment period and via the MCSB email box from manufacturers related to products failing label claim review for cannabinoids. As a result, products have been required to be remediated or destroyed, costing manufacturers significant time and money. Labeling cannabis and cannabis products after testing allows consumers to make more informed choices when purchasing cannabis and cannabis products.

Subsection (a) states that labeling of cannabinoid content may be done either at the manufacturing premises prior to release to distributor or at the distribution premises after regulatory compliance testing is done.

Paragraphs (1) – (4) are the same requirements for labeling cannabinoid content of cannabis and cannabis products proposed in the initial text.

Subsection (b) clarifies the manner in which the cannabis or cannabis product must be labeled with cannabinoid content if done prior to release to distributor.

Subsection (c) establishes the requirements for labeling cannabinoid content if the labeling is done at the distribution premises after regulatory compliance testing is complete.

Paragraph (1) requires THC and CBD content as listed on the Certificate of Analysis, as well as any cannabinoid that is 5 percent or greater of the total cannabinoid content. The level of 5 percent was selected to conform to the Bureau's testing requirements. Cannabinoid levels can vary greatly between plants. However, after the testing has been conducted, the cannabinoid levels are known and can therefore be provided to consumers.

Paragraph (2) requires the manufacturer to identify a location for the cannabinoid content labeling on the outermost packaging. Manufacturers remain responsible for proper labeling; in order to ensure that the cannabinoid content does not obscure other required information, the manufacturer must ensure sufficient space to place the information.

Paragraph (3) specifies that the cannabinoid content labeling cannot obscure other required information and that it shall be placed in the identified location.

Subsection (d) allows the content of other cannabinoids or terpenes to be provided on the label, provided the information is verified by the Certificate of Analysis. This subsection is clarifying in nature and is included so that licensees understand the labeling requirements.

**Section 40410(g)** is added to state that cannabis product labeling must adhere to the requirements of the Bureau of Cannabis Control in Section 5040.1 of Division 42 of Chapter 16 of the California Code of Regulations. This provision is necessary so that manufacturer licensees understand that distributors and retailers are prohibited from transporting or selling cannabis products labeled to give a misleading impression that the product is an alcoholic beverage so that manufacturer licensees can act accordingly.

**Section 40415** is amended to conform to the requirements of child-resistant packaging specified in 40417.

**Section 40417** establishes requirements for child-resistant packaging.

Subsection (a) establishes that, beginning January 1, 2020, a package of cannabis or cannabis product for retail sale must meet the following requirements for child-resistant packaging:

Paragraph (1): edible products, orally-consumed concentrates, and suppositories must be in child-resistant packaging for the life of the product. This provision is necessary to protect public health, specifically to reduce the opportunity for children to be able to access the types of products more likely to be attractive to children. This paragraph also states that if a product with multiple servings is packaged so that each serving is in individually child-resistant packages, the outermost box does not need to also be child-resistant. This type of packaging can be thought of the way many over-the-counter cold medicines are packaged – innermost child-resistant blister pack containing each serving, placed inside a non-child-resistant package. This provision is intended to clarify that it is not necessary for both the innermost container and the outermost packaging to be child-resistant.

Paragraph (2): clarifies that topical products and inhaled products may utilize packaging that is child-resistant only until first opened. These types of products are less likely to appeal to children, so it is reasonable to require these products to meet the minimum statutory requirements, rather than subject them to higher protective standards. Additionally, topical products are commonly used by medicinal customers who may have difficulty with child-resistant packaging. In this proposal, the Department is attempting to meet the needs of medicinal consumers while still protecting public health and safety. This provision further requires that packaging that is no longer child-resistant after opening be labeled as such. It is a matter of public health and safety to properly inform consumers if the packaging is not child-resistant.

Subsection (b) establishes the types of packaging that are considered child-resistant:

Paragraph (1): any packaging that has been certified as child-resistant under the requirements of the federal Poison Prevention Packaging Act of 1970 Regulations. The federal regulations establish a comprehensive set of testing requirements in order to certify packaging as child-resistant. Rather than recreate these requirements, it is reasonable for the Department to incorporate the requirements by reference.

Paragraph (2): a bottle with a pry-off metal crown (similar to a beer bottle) provided the bottle contains only a single serving. Bottle caps that require a tool to open provide sufficient child-resistance. However, the bottle cannot meet the requirement of being resealable, so in order to meet the statutory requirement, the bottle must only contain a single serving.

Paragraph (3): plastic packaging that is at least 4 mils thick and is heat-sealed without an easy-open tab, corner or flap, provided that the package contains a product that is only a single serving. Plastic packaging that meets this requirement cannot be opened by hand and will require scissors to open. This provision is modeled after a similar provision in Washington.

Subsection (c) clarifies that until the provisions of subsection (a) become effective, the statutory requirement for child-resistant packaging (BPC §26120) can be met through

the use of child-resistant exit packaging at retail. This provision is necessary to provide licensees a sufficient opportunity to acquire child-resistant packages and to clarify the manner in which licensees may meet statutory requirements until that time.

**Section 40510** is modified to conform to requirements for the track-and-trace system made by CalCannabis, which has authority over the system. Throughout this section, timelines have been modified from business days to calendar days. Business days may vary depending on the company or organization. Changing to calendar days provides a more reliable reporting system.

Subsection (c)(9) is added to clarify that licensees must notify the Department of any loss of access to track-and-trace that exceeds 72 hours. This provision is necessary to conform to the requirements of CalCannabis.

**Section 40517** is amended to modify business days to calendar days, as described in Section 40510.

**Section 40550(b)** is amended to clarify that the Department may inspect any area of a premises where manufacturing activities are occurring. This provision is necessary to conform to the Department's authority to oversee manufacturing activities.

**Section 40550(g) and (h)** are added to clarify the Department's authority to collect evidence and make copies of materials for purposes of investigations and enforcement proceedings.

**Section 40551(c)** is modified to change calendar days to business days to better correspond to current Department practice.