

SUPPLEMENT TO THE INITIAL STATEMENT OF REASONS

In order to ensure public understanding of the proposed regulations, the California Department of Public Health (Department) is providing additional information regarding the rationale and necessity for certain regulatory provisions. This document is intended to supplement the Initial Statement of Reasons previously noticed on July 13, 2018. Changes to the initially noticed Initial Statement of Reasons are indicated in green text and strike-out/underline font. Regulatory provisions for which additional rationale and necessity are not included have been omitted from this document to provide for ease of reading. For rationale and necessity on omitted provisions, see the Initial Statement of Reasons.

This document only discusses the text as initially proposed. For information on the modified text, see the Explanation of Modified Text.

DETAILED DISCUSSION OF EACH REGULATION

Section 40100. Definitions. This section provides definitions for the terms used throughout the text. The adoption of these definitions is reasonably necessary to provide for uniform interpretation of the text, consistency in the terminology used in the proposed regulations, and to provide clarity to the regulated industry in order to effectuate the purposes of the enabling statute.

The emergency regulations contained all of the definitions in this section. As necessary definitions continued to be added, the definition section became increasingly lengthy and was not user-friendly. All of the definitions solely related to good manufacturing practices have been moved to the relevant subchapter to provide for greater ease of use.

Subsection (a): Adopt the term “A-license” to mean a license issued for commercial cannabis activities involving cannabis and cannabis products that are intended for individuals 21 years of age and older and who do not possess physician’s recommendations. This is a statutory definition (Business and Professions Code (BPC), § 26001(a)) and is in order to provide a comprehensive listing of definitions for terms used in further regulatory provisions. ~~included in order to provide clarity to the regulated industry.~~

Subsection (b): Adopt the term “Act” to mean the Medicinal and Adult-Use Cannabis Regulation and Safety Act, BPC §26000 et seq. This definition is included ~~in order to provide clarity to the regulated industry~~ to clarify the specific statute referred to in regulatory provisions.

Subsection (c): Adopt the term “adult-use market” to mean products intended for sale at ~~an A-licensed~~ retailer or microbusiness to individuals 21 years of age and older and who

do not possess physician's recommendations. This is needed to ensure that THC and other cannabinoid levels are within the acceptable parameters for adult use versus higher levels for medical use. ~~This definition is necessary in order to provide clarity to the regulated industry.~~

Subsection (d): Adopt the term "adulterated" or "adulteration" to mean a product that meets the conditions of §26131 of the Act. (BPC §26131). This definition is necessary in order to ~~provide clarity to the regulated industry~~ clearly define what constitutes adulteration of a product so the regulated industry can understand further regulatory requirements regarding adulterated products.

Subsection (e): Adopt the term "allergen" to mean a major food allergen including any of the following: (1) Milk, eggs, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans. (2) A food ingredient that contains protein derived from a food specified in (1), except the following: Any highly refined oil derived from a food specified in (1) and any ingredient derived from such highly refined oil. This definition is reasonably necessary to inform the regulated industry of what is meant by the term allergen in the context of these regulations. The Department has defined allergen in the same manner as the United States Food and Drug Association (USFDA) in Section 202 of the Food Allergen Labeling and Consumer Protection Act of 2004, as this is the general consumer understanding of what types of allergens will be indicated on a label. This ensures a consistent definition of allergen across the industry and sets a specific standard licensees may follow.

Subsection (f): Adopt the term "applicant" to mean the owner who is applying on behalf of a commercial cannabis business for a license to manufacture cannabis products. ~~This definition is consistent with statute and included for clarity. BPC §26001(c) defines applicant as an "owner applying for a state license." Because a business entity may have several owners, the Department has decided to further clarify the "applicant" is the designated owner who has submitted the license application on behalf of the business. This is necessary so it is clearly understood which person must follow certain application requirements, such as attesting to specific information.~~

Subsection (g): Adopt the term "batch" or "production batch" to mean (1) an amount of cannabis concentrate or extract produced in one production cycle using the same extraction methods and standard operating procedures; or (2) an amount of a type of cannabis product produced in one production cycle using the same formulation and standard operating procedures. ~~As further provisions of the regulations specify requirements for each product batch, this definition is necessary to provide clarity to the regulated industry. This is a statutory definition (BPC, § 26001(d)) and is duplicated in these regulations in order to provide a comprehensive listing of definitions for terms used in further regulatory provisions.~~

Subsection (h): Adopt the term “Bureau” to mean the Bureau of Cannabis Control in the Department of Consumer Affairs. ~~This definition is necessary to provide clarity to the regulated industry. This is a statutory definition (BPC, § 26001(e)) and is duplicated in these regulations in order to provide a comprehensive listing of definitions for terms used in further regulatory provisions.~~

Subsection (i): Adopt the term “cannabis concentrate” to mean cannabis that has undergone a process to concentrate one or more active cannabinoids, thereby increasing the product’s potency. ~~“Cannabis concentrate” includes, but is not limited to, the separated resinous trichomes of cannabis, whether crude or purified (including dab, wax, or shatter), tinctures, capsules, suppositories, extracts, and vape cartridges.~~ This definition further clarifies the types of products that the Department considers to be a “concentrate,” including tinctures, capsules, suppositories, vape cartridges, and inhaled products (such as shatter, dab, or wax). This provision is necessary to distinguish “concentrates” from “edibles” so that the public and the regulated industry can follow the appropriate requirements for each product. ~~These examples are included because they represent the products for which the Department has received the most frequent questions regarding classification.~~ This change has been made at the request of stakeholders for their ease of understanding.

Subsection (j): Adopt the term “cannabis product” to mean cannabis that has undergone a process whereby the plant material has been transformed into a concentrate, including, but not limited to, concentrated cannabis, or an edible or topical product containing cannabis or concentrated cannabis and other ingredients. This is a statutory definition (Health & Safety Code (HSC), § 11018.1) and is duplicated in these regulations in order to provide a comprehensive listing of definitions for terms used in further regulatory provisions. ~~necessary to provide clarity to the regulated industry.~~

Subsection (k): Adopt the term “cannabis product quality,” “quality cannabis product,” or “quality” to mean that the cannabis product consistently meets the Bureau established specifications for identity, cannabinoid concentration (as specified in Section 5724 of Title 16 of the California Code of Regulations), composition, and limits on contaminants (as specified in Section 5718 to 5723, inclusive, of Title 16 of the California Code of Regulations), and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration and misbranding. This provision is necessary to ensure the safety of cannabis products for public consumption and to ensure the regulated industry and consumers create and receive quality products. Further provisions of the regulations establish requirements for manufacturers to create processes that result in “quality cannabis products.” Because the universe of cannabis products is so broad, it is not possible for the Department to set defined procedures for businesses to follow. By establishing the goal of “cannabis product quality,” businesses can make the determination of the best and most appropriate method to achieve the goal. This definition is necessary for the regulated industry to understand what the Department considers to be a “quality product.”

Subsection (l): Adopt the term “cannabis waste” to mean waste that contains cannabis or cannabis products, but is not otherwise a hazardous waste. ~~This definition is included to provide clarity to the regulated industry. This definition has been developed in accordance with the other licensing agencies and is necessary so licensees understand what the Department considers cannabis waste in order to properly dispose of it. Hazardous waste is exempted from the definition of cannabis waste because anything classified as hazardous waste has separate handling requirements specified in the Public Resources Code.~~

Subsection (m): Adopt the term “CBD” to mean the compound cannabidiol. This definition is included ~~in order to provide clarity to the regulated industry so businesses can understand labeling requirements that mandate the listing of CBD content.~~

Subsection (n): Adopt the term “commercial-grade, non-residential door lock” to mean a lock manufactured for commercial use. Further provisions of the regulations contain specific requirements for security procedures including the use of commercial-grade, non-residential door locks. The definition is necessary ~~to provide clarity to the regulated industry so the regulated industry can further understand the security requirements~~

Subsection (o): Adopt the term “Department” to mean the State Department of Public Health. This definition necessary to provide clarity as to which licensing authority is being referred to in the proposed regulations.

Subsection (p): Adopt the term “distribution” to mean the procurement, sale, and transport of cannabis and cannabis products between licensees. This is a statutory definition (BPC, § 26001(r)) and is ~~included in order to provide clarity to the regulated industry.~~ included in order to provide clarity to the regulated industry.

Subsection (q): Adopt the term “edible cannabis product” to mean a cannabis product that resembles ~~conventional traditional~~ foods or beverages and cannabis products that dissolve or disintegrate in the mouth. This definition is necessary to provide clarity and to address products that could potentially be ambiguous as to whether they are considered an edible, such as mouth strips, ~~and~~ lozenges, ~~and tinctures~~. Requirements for edible products differ from other cannabis products; this definition is necessary for the regulated industry to understand which requirements apply to which products.

Subsection (r): Adopt the term “extraction” to mean the process by which cannabinoids are separated from cannabis plant material through chemical or physical means. This definition is necessary to make specific the provisions of the regulations and ~~to provide clarity to the regulated industry so businesses know for which license type to apply.~~

Subsection (s): Adopt the term “finished product” to mean a cannabis product in its final form to be sold at a retail premises. This definition is necessary ~~to provide clarity to the regulated industry in order for the regulated industry to understand and define what is needed for products to be saleable at retail.~~

Subsection (t): Adopt the term “harvest batch” to mean a specifically identified quantity of dried flower or trim, leaves, and other cannabis plant matter that is uniform in strain, harvested at the same time, and, if applicable, cultivated using the same pesticides and other agricultural chemicals. This is a statutory definition (BPC, § 26001(d)(1)) and is duplicated in these regulations in order to provide a comprehensive listing of definitions for terms used in further regulatory provisions. ~~included in order to provide clarity to the regulated industry.~~

Subsection (u): Adopt the term “informational panel” to mean any part of the cannabis product label that is not the primary panel and that contains required labeling information. Statutory requirements for label information are extensive enough that multiple areas of the product package will be used to contain the information. The Department has specified which requirements are required to be on which portion of the package so consumers can expect consistency between packages and know how to find information relevant to their interests. Further provisions of the regulations contain requirements for the informational panel. This definition is necessary to provide clarity to the regulated industry as to which part of the packaging label information must be located.

Subsection (v): Adopt the term “infusion” to mean a process by which cannabis, cannabinoids, or cannabis concentrates are directly incorporated into a product formulation to produce a cannabis product. The cannabis manufacturing process includes all aspects of the infusion process. This definition is necessary ~~to provide clarity to the regulated industry~~ so businesses know which type of license application to submit.

Subsection (w): Adopt the term “infused pre-roll” to mean a pre-roll into which cannabis concentrate or other ingredients have been incorporated. This definition is necessary to clarify the difference between a “pre-roll,” which is not considered a manufactured cannabis product, and an “infused pre-roll,” which is a manufactured product. Infusion, by definition, is a manufacturing activity as per BPC §26001(ah), and therefore an infused pre-roll is considered a manufactured product.

Subsection (x): Adopt the term “ingredient” to mean any substance that is used in the manufacture of a cannabis product and that is intended to be present in the product’s final form. Further provisions of the regulations contain specific requirements regarding the storage and handling of ingredients. The informational panel is required to include a list of all product ingredients in descending order of predominance by weight or volume. This definition is necessary to provide clarity to the regulated industry so labeling

requirements can be understood, and is modeled after the definition used by the USFDA in 21 C.F.R. §111.3.

Subsection (y): Adopt the term “kief” to mean the resinous trichomes of cannabis that have been separated from the cannabis plant. This definition corresponds to terminology used in the industry and definitions used by CalCannabis. It is necessary to provide clarity on terminology in the regulated industry.

Subsection (z): Adopt the term “labeling” to mean any label or other written, printed, or graphic matter upon a cannabis product, or upon its container or wrapper, or that accompanies any cannabis product. Further provisions of the regulations contain specific labeling requirements for cannabis products. This is a statutory definition (BPC §26001(w)) and is duplicated in these regulations in order to provide a comprehensive listing of definitions for terms used in further regulatory provisions.

Subsection (aa): Adopt the term “limited-access area” to mean an area in which cannabis or cannabis products are stored or held and is only accessible to a licensee and authorized personnel. Further provisions of the regulations contain specific requirements for limited-access areas. ~~This definition is necessary to provide clarity to the regulated industry.~~ The definition is necessary so the regulated industry understands the security requirements for the regulatory provisions.

Subsection (bb): Adopt the term “M-license” to mean a license issued for commercial cannabis activity involving medicinal cannabis. This is a statutory definition (BPC, § 26001(ae)) and is duplicated in these regulations in order to provide a comprehensive listing of definitions for terms used in further regulatory provisions.

Subsection (cc): Adopt the term “manufacturer licensee” or “licensee” to mean the holder of a manufacturer license issued pursuant to the Act and associated with a specific manufacturing premises. This is a statutory definition (BPC §26001(z)) and is duplicated in these regulations in order to provide a comprehensive listing of definitions for terms used in further regulatory provisions.

Subsection (dd): Adopt the term “manufacture” to mean to compound, blend, extract, infuse, or otherwise make or prepare a cannabis product. This is a statutory definition (BPC, § 26001(ag)) and is duplicated in these regulations in order to provide a comprehensive listing of definitions for terms used in further regulatory provisions. This definition further defines what is and is not included under the “manufacture” definition. Conversations with the other licensing agencies and stakeholders during the pre-regulatory process indicated that there was confusion around what would be considered a manufacturing activity, particularly in terms of the packaging and labeling of products. This provision is necessary to clarify that the Department shall consider any activity in which a cannabis product is processed or handled, outside of its packaging, to be a

manufacturing activity that requires a manufacturing license. Activities that are not considered to be “manufacture” are:

Paragraph (2), Subparagraph (A) – the repacking of cannabis products from a bulk shipping container by a distributor or retailer where the product’s original packaging and labeling is not otherwise altered. Although “packaging” is a manufacturing activity, it is not reasonable to interpret that any time a product is moved from one package to another – regardless of the circumstance – a manufacturing license is required. Packages of cannabis product will be sent in bulk to distributors and retailers, who will then be reasonably expected to break those products into smaller packages. As long as the product’s original packaging and labeling is not altered, there is no public safety threat and therefore no reason to prohibit this reasonable business activity.

Paragraph (2), Subparagraph (B) – the placing of cannabis products into opaque packaging for purposes of complying with BPC §26070.1 (requirements for exit packaging). Retailers are required to place cannabis products into exit package. This provision is necessary to clarify this is not a “manufacturing” activity.

Paragraph (2), Subparagraph (C) – the collection of resinous trichomes that are dislodged or sifted from the cannabis plant incident to cultivation activities. As cannabis plants are harvested and trimmed, the trichomes can be dislodged or stuck to cultivation implements. It has been long-standing industry practice for cultivators to collect the separated trichomes for sale. In consultation with the California Department of Food and Agriculture (CDFA or CalCannabis), the Department concluded it would be overly onerous to require this practice to be conducted under a manufacturing license. Provided the activity is done as part of cultivation activities under a licensed issued by CalCannabis, there is no public health threat.

Paragraph (2), Subparagraph (D) – the processing of “non-manufactured cannabis products” (as defined in Section 8000 of CalCannabis regulations) by a licensed cultivator. Under CalCannabis regulations, non-manufactured products include pre-rolls and packages of kief, shake, leaf, and trim. It has been long-standing industry practice for cultivators to create pre-rolls. In consultation with CalCannabis, the Department concluded it would be overly onerous to require this practice to be conducted under a manufacturing license. Provided the activity is done as part of cultivation activities under a licensed issued by CalCannabis, there is no public health threat.

Subsection (ee): Adopt the term “manufacturing” or “manufacturing operation” to mean all aspects of the extraction and/or infusion processes, including processing, preparing, holding, storing, packaging, or labeling of cannabis products. Manufacturing is further defined to mean any processing, preparing, holding, or storing of components and ingredients. This definition is in line with the statutory definition of “manufacture” described in these regulations and is included in this regulation to provide a comprehensive listing of definitions for terms used in further regulatory provisions.

~~Manufacturing does not include relabeling of cannabis products, the creations of pre-rolls, or the collection of kief incidental to cultivation activities. This definition is necessary to provide clarity to the regulated industry.~~

Subsection (ff): Adopt the term “MCLS” to mean the Manufactured Cannabis Licensing System, the online license applications system available on the Department’s website. Further provisions of the regulations provide for submission of applications and information through MCLS and this definition is necessary to clarify how to access the system.

Subsection (gg): Adopt the term “nonvolatile solvent” to mean any solvent used in the extraction process that is not a volatile solvent. For purposes of this chapter, a nonvolatile solvent includes carbon dioxide and ethanol used for extraction based on input from discussions with stakeholders, as these solvents are frequently used in the cannabis manufacturing industry. Further provisions of the regulations contain requirements for license Type 6, which involves the use of nonvolatile solvents. “Volatile solvents” shall have the same meaning as in paragraph (3) of subdivision (d) of Section 11362.3 of the Health and Safety Code (HSC). This definition is necessary to provide clarity to the regulated industry so individuals can determine what type of license application to submit.

Subsection (hh): Adopt the term “orally-consumed concentrate” to mean cannabis concentrates that are consumed by mouth and are not otherwise considered edibles. Orally consumed concentrates do not resemble conventional food products, but rather are more similar to traditional medicinal products (like a pill or capsule) or dietary supplements. These product formulations are not as attractive to children and are less likely to be unknowingly ingested by adults. Consequently, these products are not subject to the same strict limits as edible products. Further provisions of the regulations specify requirements for orally consumed concentrates; this definition is necessary to clarify the requirements to which products must adhere.

Subsection (ii): Adopt the term “package” or “packaging” to mean any container or wrapper that may be used for enclosing or containing any cannabis products. The term “package” does not include any shipping container or outer wrapping used solely for the transportation of cannabis products in bulk quantity to another licensee or licensed premises. Shipping container and outer wrappings are exempt from packaging rules as they are unseen by the consumer and therefore do not need to contain the information required on consumer-facing labels. Further provisions of the regulations contain requirements for packaging of cannabis products. This definition is necessary to provide clarity to the regulated industry so regulatory requirements can be followed.

Subsection (jj): Adopt the term “personnel” to mean any worker engaged in the performance or supervision of operations at a manufacturing facility, and includes full-time and part-time employees, temporary employees, contractors, and volunteers. As

applicable to training requirements, “personnel” also includes owner-operators. Further provisions of the regulations contain specific requirements for personnel at a manufacturing facility including training requirements. This definition is necessary to provide clarity to the regulated industry in order to clarify all individuals working on the licensed premises are subject to minimum training requirements.

Subsection (kk): Adopt the term “person” to mean any individual, firm, partnership, joint venture, association, corporation, limited liability company, estate, trust, business trust, receiver, syndicate, or any other group or combination acting as a unit, and the plural as well as the singular. This is a statutory definition (BPC, § 26001(an)) and is duplicated in these regulations in order to provide a comprehensive listing of definitions for terms used in further regulatory provisions. ~~included in order to provide clarity to the regulated industry.~~

Subsection (ll): Adopt the term “pre-roll” to mean any combination of flower, shake, leaf, or kief rolled in paper. Pre-rolls are a common and popular item sold, and is a term of art commonly used in the cannabis industry. However, it is necessary to distinguish pre-rolls that contain only parts of the cannabis plant from pre-rolls that are infused with concentrate or other ingredients. The Department developed this definition in conjunction with the Bureau and CalCannabis in order to ensure conformity of terminology in the regulated industry.

Subsection (mm): Adopt the term “premises” to mean the designated structure (s) and land specified in the application that is owned, leased, or otherwise held under the control of the applicant or licensee where the commercial cannabis activity will be or is conducted. This definition is included to provide clarity to the regulated industry by making specific what is meant by “premises” in the context of these regulations.

Subsection (nn): Adopt the term “primary panel” to mean the part of a cannabis product label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. This definition is necessary to clarify which portion of the label is the primary panel so that the regulated industry can properly understand and follow labeling requirements.

Subsection (oo): Adopt the term “product identity” or “identity of the product” to mean the generic, common, or usual name of the product by which it is most commonly known. The definition is necessary so the regulated industry understands the labeling requirements for the regulatory provisions.

Subsection (pp): Adopt the term “quarantine” to mean the storage or identification of a product to prevent distribution or transfer of the product. ~~This definition necessary to provide clarity to the regulated industry.~~ The definition is necessary so the regulated industry understands the storage requirements for products prohibited from going to retail.

Subsection (qq): Adopt the term “serving” to mean the designated amount of cannabis product established by the manufacturer to constitute a single unit. This definition is needed as the Department has set a maximum amount of cannabinoids per serving in edible products for both the medical and adult-use market. ~~This definition is necessary to provide clarity to the regulated industry.~~ The definition is necessary so the regulated industry understands the labeling requirements for the regulatory provisions.

Subsection (rr): Adopt the term “tablet” to mean a solid preparation containing a single serving of THC or other cannabinoid that is intended to be swallowed whole, and that is not formulated to be chewable, dispersible, effervescent, orally disintegrating, used as a suspension, or consumed in a manner other than swallowed whole, and that does not contain any added natural or artificial flavor or sweetener. This definition is necessary to provide clarity to the regulated industry and to differentiate between concentrates in tablet form meant to be swallowed whole and dissolving or flavored tablets, which are a greater risk of being mistaken for products that are attractive to children such as lozenges and mints and are therefore classified as edibles.

Subsection (ss): Adopt the term “THC” to mean the compound tetrahydrocannabinol and specifies that the use of the term “THC” in this chapter specifically refers to delta 9-tetrahydrocannabinol, which is the psychoactive variant of the compound. As it relates to consumer awareness, delta 9-THC is the cannabinoid content which consumers are most typically interested in knowing. This definition is necessary so that the regulated industry can properly follow labeling requirements to inform consumers of the amount of THC in a cannabis product.

Subsection (tt): Adopt the term “topical cannabis product” to mean a cannabis product intended to be applied to the skin rather than ingested or inhaled. This definition necessary ~~to provide clarity to the regulated industry so the regulated industry can understand the products that are considered topical products and can understand further regulatory requirements regarding topical products.~~

Subsection (uu): Adopt the term “track-and-trace system” to mean the program for reporting the movement of cannabis and cannabis products through the distribution chain established by CalCannabis in accordance with section 26067 of the Act.

The Act requires ~~the CDFA~~ CalCannabis, in consultation with the Bureau, to establish a track-and-trace program for reporting the movement of cannabis products throughout the distribution chain. Further provisions of the regulations include specific track-and-trace requirements for manufacturer licensees. ~~This definition necessary to provide clarity to the regulated industry.~~ This definition is necessary so licensees understand the system referred to in these regulations is the manner in which they are required to comply with reporting requirements of the Act.

Subsection (vv): Adopt the term “UID” to mean the unique identifier for use in the track-and-trace system established by the Department of Food and Agriculture in accordance with section 26069 of the Act. ~~This definition is included to provide clarity to the regulated industry. Although the term “unique identifier” is defined in the Act (BPC, § 26001(a)), the term primarily used in the track-and-trace system is “UID” instead. This definition is necessary to clarify the “UID” referred to in further regulatory provisions is the same as “unique identifier” defined in the Act.~~

Subsection (ww): Adopt the term “universal symbol” to mean the symbol established by the Department pursuant to paragraph (7) of subdivision (c) of section 26130 of the Act to indicate a product contains cannabinoids. Further provisions of the regulation require the use of the universal symbol. ~~The definition is necessary to provide clarity to the regulated industry.~~ The image is included in these regulations in Section 40412. This definition is necessary so licensees can understand labeling requirements.

Subsection (xx): Adopt the term “volatile solvent” to mean any solvent that is or produces a flammable gas or vapor that, when present in the air in sufficient quantities, will create explosive or ignitable mixtures, as defined in Health and Safety Code 11362.3(b)(3). Examples of volatile solvents include, but are not limited to, butane, hexane, or propane, which are frequently used in the cannabis manufacturing industry. The Act requires that the Department establish two manufacturer license types based on the type of solvent (volatile and non-volatile) used. This definition is necessary ~~to provide clarity to the regulated industry~~ so businesses understand which license type is applicable to their operations and know the appropriate license type for which to apply.

Section 40101. Applicability.

Subsection (a) clarifies that the regulations apply to the manufacturing of adult-use and medicinal cannabis products. BPC §26106 states standards for the production and labeling developed by the Department apply to manufacturers and microbusinesses. Although licenses can be issued for the manufacturing of either adult-use or medicinal cannabis products, the same regulatory requirements apply. This provision is necessary to provide clarity so licensees are clear the Department’s regulatory requirements apply regardless of the market for which products are manufactured.

Subsection (b) clarifies the specific regulatory sections that are applicable to microbusinesses. BPC §26106 states standards for the production and labeling developed by the Department apply to manufacturers and microbusinesses. Microbusinesses are licensed and regulated by the Bureau, under Title 17 Division 42 of the California Code of Regulations, sections 5000 through 5904. However, the Bureau has directed microbusinesses who engage in manufacturing and labeling, which fall under the purview of the Department, refer directly to the Department’s regulations for guidance on those activities. This provision is necessary to clarify which Department’s regulations licensees, ~~which are licensed by the Bureau,~~ must follow.

Section 40102. Owners and Financial Interest Holders. The Act establishes two levels of disclosure for individuals participating in the commercial cannabis industry. The highest level of disclosure is for “owners,” which is defined in BPC §26001(al), followed by “financial interest holders,” which are defined in this regulatory proposal. “Owners” are defined as:

- Any person that has an aggregate ownership interest, other than a security interest, lien, or encumbrance, in a commercial cannabis business of 20 percent or more;
- The chief executive officer of a commercial cannabis business;
- If a non-profit entity, each member of the Board of Directors;
- Any individual that will be participating in the direction, control, or management of the licensed commercial cannabis business.

“Owners” are required [by the Act \(BPC, § 26051.5\(a\)\(1\)\(A\)\)](#) to submit their fingerprints to the Department of Justice for purposes of a criminal history background check.

In contrast, “financial interest holders” are required to be disclosed on the application, but do not need to undergo a background investigation. BPC §26051.5(d) requires the applicant to “provide a complete list of every person with a financial interest in the person applying for the license,” and, among other exclusions, specifically excludes “persons whose only interest in a licensee is an interest in a diversified mutual fund, blind trust, or similar instrument.”

The proposed regulation [further](#) clarifies the [statutory](#) distinction between owners and financial interest holders, and is necessary to provide clarity to the regulated industry. In addition, the requirements of this section were developed in conjunction with the Bureau and CalCannabis so that all aspects of the commercial cannabis industry are subject to the same requirements.

Subsection (a) specifies an owner shall mean the following:

Paragraph (1): any person that has an aggregate ownership interest, other than a security interest, lien, or encumbrance, in a commercial cannabis business of 20 percent or more;

Subparagraph (A) clarifies that if the owner identified in subsection (a)(1) is an entity, then the chief executive officer and members of the board of directors of the entity shall be considered owners.

Paragraph (2): the chief executive officer of a cannabis business;

Paragraph (3): if a non-profit entity, each member of the Board of Directors; or

Paragraph (4): any individual participating in the direction, control, or management of

the commercial cannabis business, including:

Subparagraph (A): Each general partner of a commercial cannabis business that is organized as a partnership;

Subparagraph (B): Each non-member manager or managing member of a limited liability company for a commercial cannabis business that is organized as a limited liability company; and

Subparagraph (C) Each officer or director of a commercial cannabis business that is organized as a corporation.

Subparagraph (D) Any individual that assumes responsibility for the licensee.

Paragraph (5) The Trustee(s) and all persons that have control of the trust and/or the commercial cannabis business that is held in trust.

The Department has chosen these entities based on the requirements in BPC §26001(a). These entities have direction, control, and/or management of a cannabis business. These provisions are necessary so that the Department can fulfill its mandate to assess the background of cannabis business owners.

Subsection (b) specifies that persons that hold an ownership interest of less than 20 percent ([the definition of "owner" per BPC §26001\(a\)](#)) are considered financial interest holders that need to be disclosed on the application. This subsection also specifies that "financial interest" means an agreement to receive a portion of the profits of a commercial cannabis business, investment into a commercial cannabis business, a loan provided to a commercial cannabis business, or any other equity interest in a commercial cannabis business. This provision is necessary to [provide guidance to applicants that a financial industry is not just owning shares of the company but also receiving a financial benefit from the company and to](#) clarify for the regulated industry what responsibilities fall to owners and financial interest holders in cannabis businesses.

Subsection (c) clarifies that the following persons are not considered to be owners or financial interest holders:

Paragraph (1) A bank or financial institution whose interest constitutes a loan;

Paragraph (2) Persons whose only ownership interest in the commercial cannabis business is through an interest in a diversified mutual fund, blind trust, or similar instrument;

Paragraph (3) Persons whose only financial interest is a security interest, lien, or encumbrance on property that will be used by the commercial cannabis business; and

Paragraph (4) Persons who hold a share of stock that is less than 5 percent of the total shares in a publicly traded company. This threshold is modeled after the Security Exchange Commission ownership reporting threshold (Section 12 of the Securities and Exchange Act of 1934). Any individual whose interest is less than 5 percent of the total shares is not in a position to exercise any control over the business. Additionally, for publicly traded companies, those that hold shares at less than 5% may frequently turn over without knowledge of the Board of Directors. The Department has determined it does not serve a regulatory purpose to require disclosure of holders of such small interest.

The Department has determined that the persons specified in subsection (c) do not have sufficient holdings within a cannabis business to warrant the same scrutiny as an owner or investor, and therefore, they are not subject to the background investigation requirements, nor is an applicant required to disclose them on the annual license application.

Section 40105. Premises Diagram. This section specifies the information that must be included on the premises diagram required to be submitted as part of the licensing application.

Subsection (a) requires that the premises diagram required pursuant to BPC§26051.5(c) of the Act shall meet the following requirements:

Paragraph (1) The diagram shall be specific enough to enable ready determination of the bounds of the property and the proposed premises to be licensed. This is a statutory requirement (BPC, § 26051.5(c));

Paragraph (2) The diagram shall be to scale. A scaled diagram is necessary to properly ascertain and evaluate the proposed premises;

Paragraph (3) If the proposed premises consists of only a portion of a property, the diagram shall be labeled to indicate which part of the property is the proposed premises and identifying what the remaining property is used for. The neighboring portions of the property can impact the manufacturing operations. In order to properly assess the submitted application, including quality control procedures, the Department must be aware of what occurs at the remaining portions of the premises.

The Department has determined that these provisions are necessary in order to assess the proposed manufacturing premises and to maintain consistency with other regulatory agencies.

Subsection (b) states that the premises diagram shall include:

Paragraph (1) All boundaries, dimensions, entrances and exits, interior partitions, walls, rooms, windows, and doorways. This is a statutory requirement (BPC, § 26051.5(c));

Paragraph (2): The areas in which all commercial cannabis activities will be conducted. This is a statutory requirement (BPC, § 26051.5(c)). This provision further specifies the Commercial cannabis activities that shall be identified on the diagram include the following, as applicable to the business operations: infusion activities, extraction activities, packaging activities, labeling activities, and transportation activities such as loading and unloading of cannabis and cannabis products.

Paragraph (3): The limited-access areas, areas used for video surveillance monitoring and surveillance system storage devices, and all security camera locations. The Department must be able to ascertain these locations to properly evaluate whether the premises meets all legal requirements.

Paragraph (4): Areas used for disposal of cannabis waste. The Department must be able to determine the areas of the premises used for waste disposal to properly evaluate whether the premises meets all legal requirements.

The Department has determined that these provisions are necessary in order to assess the proposed manufacturing premises and to maintain consistency with other regulatory agencies.

Subsection (c) requires that if the proposed premises consists of only a portion of a property that will contain two or more licensed premises, the diagram shall clearly show any entrances and walls under the exclusive control of the applicant or licensee. The diagram shall also show all proposed common or shared areas of the property, including entryways, lobbies, bathrooms, hallways, and breakrooms. This subsection is necessary to include as space for manufacturing of cannabis products can be costly, and large manufacturing buildings are frequently shared by several licensed manufacturers.

Subsection (d) states that the diagram shall be used by the Department to determine whether the premises meets the requirements of the Act and this chapter. This is necessary in order to ensure all licensed manufacturing premises are in line with state and local ordinances, laws, and regulations.

Section 40115: No change to Statement of Reasons.

Section 40116: No change to Statement of Reasons.

Section 40118. Manufacturing License Types. The Act establishes two license types for manufacturers – Type 6 for manufacturers using nonvolatile solvents and Type 7 for manufacturers using volatile solvents (BPC §26050). BPC §26012 authorizes the

Department to create additional license types as needed. This section specifies additional license types created by the Department.

Subsection (a) specifies ~~that a manufacturing license may be issued for either the adult-use market or the medicinal-use market~~ the types of licenses described in the rest of the section are available from the Department. These types of licenses may be issued to either the adult-use or the medicinal use market.

Paragraph (1) implements the statutorily mandated Type 7 license for manufacturing conducting extractions with volatile solvents. This section further clarifies in subparagraphs (A)-(D) that Type 7 licensees can also conduct extractions with nonvolatile solvents, infusions (provided that the infusion operations and product types are noted on the application form), packaging and labeling manufacturing activities, and register and operate a premises as a shared-use facility. This provision is necessary to clarify that a single manufacturing license can cover multiple manufacturing activities and that a business does not need to get a separate license for each activity. Requiring a business to apply for multiple licenses on the same premises poses an undue burden on the industry and does not improve public health. Therefore, the Department has decided to allow for multiple activities to be done under one license. This decisions came about from stakeholder feedback in pre-regulatory hearings.

Paragraph (2): implements the statutorily mandated Type 6 license for manufacturers conducting extractions with nonvolatile solvents. This section further clarifies in subparagraphs (A)-(C) that Type 6 licensees can also conduct infusions, packaging and labeling manufacturing activities, and register and operate a premises as a shared-use facility. This provision is necessary to clarify that a single manufacturing license can cover multiple manufacturing activities and that a business does not need to get a separate license for each activity.

Paragraph (3): creates a new license category of “Type N” for manufacturers that produce cannabis products other than extracts or concentrates that are produced through extraction. This section further clarifies in subparagraphs A and B that Type N licensees can also conduct packaging and labeling manufacturing activities and register their licensed premises as shared-use facilities in accordance with Article 6 of Subchapter 2. Establishing a new license type for infusion-only is reasonably necessary for the Department to appropriately oversee licensing operations and to clarify that a single manufacturing license can cover multiple manufacturing activities and that a business does not need to get a separate license for each activity.

Paragraph (4): creates a new license category of “Type P” for manufacturers that only engage in the packaging and labeling of cannabis products. Packing operations offer numerous opportunities for contamination of a product if not conducted in accordance with GMPs. In order to mitigate the risk of contamination, it is necessary for packaging operations to be under the oversight of the Department. During the pre-regulatory

stakeholder meetings, the Department heard from numerous individuals who expressed an interest in only the packaging or labeling of products. This provision is necessary to for the Department to fulfill its mandate under the Act to license and regulate manufacturers.

Paragraph (5): creates a new license category of “Type S” for manufacturers that allows a Type S to conduct Type N or P manufacturing activities at a registered shared-use facility as outlined in Article 6, commencing with Section 40190. Due to safety concerns, the Department determined that shared-use facilities may not use volatile solvent extraction methods. During the pre-regulatory stakeholder meetings, the Department heard from numerous individuals who expressed a need, due to a lack of real estate in their area or for economic reasons, to conduct manufacturing activities in a shared-use space. This license is necessary to assist these manufacturers and address equity concerns raised during public workshops. This provision is reasonably necessary for the Department to fulfill its mandate to issue manufacturing licenses.

Section 40120. Additional Activities. This section clarifies that a licensee may also roll and package pre-rolls and package dried cannabis. It is a common industry practice for cultivators and distributors, as well as manufacturers, to create pre-rolls and packages of flower. The licensing authorities made a joint policy decision to allow these activities to be conducted under any license type as the Act (BPC §26000 et seq.) does not specifically limit them to any particular license type. Pre-rolls and cannabis flower are not considered manufactured products and the existing emergency regulations were not clear as to whether manufacturers could conduct such activities. This provision is necessary to clarify the activities that manufacturers are allowed to conduct under a manufacturing license.

Section 40126. Temporary Licenses. This section establishes a system for temporary licenses. Temporary license authority is provided to the Department in BPC §26050.1, along with the basic requirements. Due to the time constraints created by SB 94 (which became law on June 27, 2017), the Department would have been unable to meet its statutory mandate to issue licenses beginning January 1, 2018 if it needed to both promulgate complete regulations and review license applications before January 1, 2018. A temporary license process was thus necessary because it allowed the Department to issue licenses on an accelerated schedule, minimizing disruption in the medicinal cannabis market and allowing the adult-use cannabis market to begin as intended by California voters. This section adopts subsection (a)-(f) previously adopted via the emergency regulations of 2017, and the re-adoption of those subsections in May of 2018. The statute allows the Department to issue temporary licenses until January 1, 2019, but is silent as to what happens to licenses after that date. This section clarifies that any temporary license with an expiration date on or after January 1, 2019, will be valid for entire term of the license, but that such licenses will not be extended.

The following explanation was included in the Finding of Emergency for rulemaking

package DPH-17-010E, which implemented the requirements of this section. The explanation was inadvertently omitted from the Initial Statement of Reasons, and is therefore incorporated into this Addendum so the public can understand the Department's rationale for the requirements.

Subsection (a) states to request a temporary license, an applicant shall submit to the Department the following:

Paragraph (1) requires licensees fill out form CDPH 9041 (11/17), which is hereby incorporated by reference. This form is necessary as it contains all relevant information on the licensee for review by the MSCB licensing unit.

Paragraph (2) requires a copy of a local license, permit, or other authorization, issued by a local jurisdiction that enables the applicant to conduct commercial cannabis business at the location requested for the temporary license. Upon receipt of the application, the Department shall contact the applicable local jurisdiction to confirm the validity of the authorization. If the local jurisdiction does not respond within 10 calendar days, the Department shall consider the authorization valid. This 10 day period was established in connection with the other licensing agencies, with input from local jurisdictions, and was determined to be sufficient time to allow local jurisdictions to review requests without undue delay on application processing. This provision is necessary as it ensures the licensee is performing cannabis manufacturing in a city or jurisdiction that allows said manufacturing. Several cities and counties in California have opted not to allow manufacturing in their jurisdiction, this provision ensures licensees are not superseding local rules.

Subsection (b) states a temporary license shall be valid for 120 days from the effective date. This is a statutory requirement from BPC §26050.1(b)(1). No temporary license shall be issued on or after January 1, 2019. After January 1, 2019, all licenses will be annual, and temporary licenses will be phased out.

Subsection (c) states a temporary license may be extended by the Department for additional 90-day periods if the holder of a temporary license submits a complete application for annual licensure to the Department pursuant to Section 40128 prior to the initial expiration date of the temporary license. This is a statutory requirement from BPC §26050.1(b)(1). Any temporary license issued or extended that has an expiration date after December 31, 2018, will be valid until it expires, but shall not be extended beyond the expiration date. This provision is necessary in order to give licensees the ability to apply for annual licenses before their temporary license expires, and gives leeway as the Department moves into annual-only licensing in January of 2019.

Subsection (d) states a temporary license is a conditional license and authorizes the holder thereof to engage in commercial cannabis activity as would be permitted under the privileges of the license for which the applicant may submit an application to the

licensing authority. This provision clarifies a temporary license gives the licensee the ability to engage in cannabis manufacturing activities.

Subsection (e) clarifies a refusal by the Department to issue or extend a temporary license shall not entitle the applicant to a hearing or appeal of the decision. BPC Chapter 2 (commencing with §480) of Division 1.5 and Chapter 4 (commencing with §26040) shall not apply to temporary licenses. This provision is necessary to clarify what rights a temporary licensee has in appealing rejections from the Department.

Subsection (f) clarifies a temporary license does not obligate the Department to issue an annual license to the temporary license holder, nor does the temporary license create a vested right in the holder to either an extension of the temporary license or to the granting of a subsequent annual license. Licensees must meet standards for good manufacturing practices, business activities, and other requirements in order to qualify for an extension of a temporary license or the receipt of an annual license.

Section 40128 Annual License Application Requirements. This section specifies the information and documentation that an applicant for an annual manufacturing license must submit to the Department. This section is reasonably necessary in order for the Department to establish the specific rules and regulations needed to provide for the proper licensing of manufacturers in accordance with its authority under the Act.

Subsection (a) establishes the information that an applicant must submit on behalf of the commercial cannabis business in order to apply for a license, as follows:

Paragraph (1) a complete licensing application form prescribed by the Department, or through MCLS. A complete application is necessary so that the Department may ensure that applicants are qualified for the type of license sought and so that it may maintain proper oversight of licensing activities in its capacity as a licensing authority. For the purpose of this chapter, a complete licensing application is one which includes all of the following information:

Subparagraph (A) The business information specified in Section 40129;

Subparagraph (B) The owner information specified in Section 40130;

Subparagraph (C) Manufacturing premises and operations information as specified in Section 40131.

Paragraph (2): a non-refundable application processing fee with the application package. BPC §26180 authorizes the Department to establish an application fee.

Paragraph (3): Evidence of compliance with or exemption from the California Environmental Quality Act.

Paragraph (4): The limited waiver of sovereign immunity, if required.

Subsection (b) requires the applicant to sign the application form under penalty of perjury that the information provided in and submitted with the application is complete, true, and accurate, as mandated by BPC §26051.5(a)(4) and to the following attestations:

Paragraph (1) the applicant is authorized to act on behalf of the commercial cannabis business. The Department has a regulatory interest in assuring that he applicant has the authority to act on behalf of the business.

Paragraph (2) if the applicant entity has 20 or more employees, the applicant entity will enter into and abide by a labor peace agreement as soon as reasonably practicable, as required by BPC §26051.5(a)(5)(A). The applicant shall also provide the Department with a copy of the page of the labor peace agreement that contains the signatures of the union representatives and the applicant or applicant entity. This clarification is necessary because it highlights the importance of a labor peace agreement for applicants that have never dealt with labor issues. The subsection also requires a copy of the page of the labor peace agreement containing the signatures as evidence of the agreement. Further, it protects the employees of the applicant by ensuring that once licensed the licensee does not forgo or put off its responsibility to enter into such an agreement. This provision is necessary to comply with the statutory requirement.

Paragraph (3) the commercial cannabis business is operating in compliance with all local ordinances, as required by Business and Profession Code section 26055. Cannabis businesses are required to abide by any applicable local ordinances. Requiring applicants to attest that they are operating in compliance with local ordinances will ensure that applicants are aware of this requirement.

Paragraph (4) the proposed premises is not within a 600-foot radius of a perimeter of a school, day care, or youth center, unless a different radius is otherwise specified by local ordinance. This is a statutory requirement (BPC §26054(b)).

Subsection (c) allows the Department to request additional information as necessary to determine the applicant's qualification. This provision is necessary so that the Department can fulfill its statutory mandate to only issue licenses to qualified applicants.

Section 40129. Annual License Application Requirements—Business Information. This section outlines the information that must be submitted to the Department in order to apply for a commercial cannabis license.

Subsection (a) requires the following information to be submitted in order for the Department to meet its statutory obligation to issue licenses only to qualified applicants:

Paragraph (1) Legal business name. This item is necessary to identify the applicant's legal business identity and to know in which name to issue the license;

Paragraph (2) the federal tax identification number. This item is necessary in order to provide a unique identification number for a business in cases of similar names;

Paragraph (3) the name(s) under which the business will operate if applicable. This information is necessary so the Department may maintain accurate records in accordance with its role as a licensing authority;

Paragraph (4) the business's mailing address which will serve as the address of record. This information is necessary so the Department can comply with requirements to send information by mail, such as notices of denial, notices of violations, appeals hearings, and other administrative notices;

Paragraph (5) the name, title, phone number and email address of the primary contact person for the commercial cannabis business. This provision is necessary to ensure that the Department can contact the business if needed;

Paragraph (6) the seller's permit number issued by the California Department of Tax and Fee Administration or notification from same that the business is not required to have a seller's permit, or an attestation the applicant is currently applying for a seller's permit if they have not yet received one. This provision is necessary to comply with the statutory requirement that licenses only be issued if the applicant has a seller's permit;

Paragraph (7) the business structure of the commercial cannabis business as filed with California Secretary of State (e.g. limited liability company, partnership, corporation). A commercial cannabis business that is a foreign corporation shall include in its application the certificate of qualification issued by the Secretary of State of California. This provision is necessary to allow the Department to verify that the appropriate owners, specifically those defined as owner submit their finger prints and/or meet the definition of owner in section 40102, have submitted owner applications;

Paragraph (8) a list of the owners, as defined in Section 40102 of these regulations. This provision is necessary so that the Department may verify that the owners have submitted their owner applications;

Paragraph (9) a list of financial interest holders, as defined in Section 40102. This includes disclosure requirements for financial interest holders who are individuals (subparagraph A) and those who are entities (paragraph B). Disclosure of financial interest holders is required by statute;

Paragraph (10) proof of having obtained a surety bond in the amount of \$5,000, payable

to the State as oblige. BPC §26051.5(a)(10) requires all applicants to provide proof of a bond to cover the costs of destruction of cannabis or cannabis products if necessitated by a violation of licensing requirements. Discussions with other states indicated that cannabis businesses had difficulty obtained surety bonds, and that if the requirement was set any higher than \$5,000, businesses would not be able to comply. All three of the regulatory agencies in California have set the bond minimum at \$5,000, which is considered a sufficient amount to cover costs of destruction while still being low enough to be obtained by licensees

Paragraph (11) the license type applied for and whether the application is for medicinal or adult-use manufacturing, or both. This information is required for proper processing of the application and to ensure that the applicant is applying for a license type that is allowed within their local jurisdiction;

Paragraph (12) business formations documents, including, but not limited to, articles of incorporation, operating agreements, partnership agreements, fictitious business name statements, and copies of trust documentation if the company is held in trust. This information is necessary to the Department to clarify owners and financial interest holders.

Paragraph (13) requires that all documents filed with the California Secretary of State are also included with the application. The section is necessary for the Department to ensure that cannabis businesses are registered with the State.

Subsection (b) establishes the process by which the Department will confirm the validity of a local license, permit, or other authorization voluntarily submitted by an applicant in accordance with BPC §26055(e). The statute permits the Department to presume that an applicant that voluntarily submits a local license, permit, or other authorization is in compliance with local ordinances. However, local jurisdictions expressed concerns to the Department that invalid authorizations may be submitted and requested the opportunity to confirm the document's validity. In order to accommodate the request, the Department added a process for confirmation that parallels the confirmation process for temporary licenses. Upon receipt of the application, the Department shall contact the applicable local jurisdiction to confirm the validity of the authorization. If the local jurisdiction does not respond within 10 calendar days, the Department shall consider the authorization valid. The Department has chosen 10 days in order to maintain consistency with the temporary license requirements. This provision is necessary as it ensures the licensee is performing cannabis manufacturing in a city or jurisdiction that allows said manufacturing.

Section 40130. Owner Applications. This section specifies the information and documentation that each owner must submit to the Department as part of the application process. This provision is reasonably necessary so that the Department may provide for the proper licensing of manufacturers in accordance with its enabling statute

and so that it may provide clarity to the regulated public.

Subsection (a) specifies each owner shall submit the following:

Paragraphs (1)-(6) contact and identifying information, including name, title or position held, phone number, mailing and email address, date of birth, and social security number or individual tax payer identification number. This information is required for proper record keeping and so the Department can contact the owner if needed. An owner's social security number or tax payer identification number is required in order to match applicants with the results from the Department of Justice criminal history background check.

Paragraph (7) a copy of Department of Justice form BCIA 8016 that was used to submit the applicant's fingerprint images for purposes of a background check. The form contains important information that will enable the Department to contact the Department of Justice about a specific owner's background record if necessary (i.e., if results do not get properly transmitted to the Department).

Paragraph (8) requires disclosure of any of the following specified conditions, including a description of the circumstances if applicable. BPC §26057(b)(4) requires the Department to conduct a thorough review of the circumstances of the conviction and any evidence of rehabilitation of the applicant or owner. This provision is necessary in order to provide the applicant a method by which they can describe the circumstances of his or her conviction.

Subparagraph (A) requires the applicant to disclose any criminal conviction. BPC §26057 allows, but does not require, the Department to deny a license application if an owner has been convicted of specified offenses or any offense substantially related to the qualifications, duties, or functions of a manufacturer. This provision is reasonably necessary for the Department to implement BPC §26057(b)(4).

Subparagraph (B) requires the applicant to disclose any civil proceedings, administrative citations, or penalty or license sanction that is substantially related to the qualifications of a manufacturer as identified in Section 40162 of these regulations. This is a statutory requirement under BPC §26057(b)(4).

Subparagraph (C) requires the applicant to disclose any fines or penalties for cultivation or production of a controlled substance on public or private land. This is a statutory requirement under BPC §26057(b)(6).

Subparagraph (D) requires the applicant to disclose any sanctions by a licensing authority, or a city or county, for unlicensed commercial cannabis activity within the three (3) years preceding the date of the application. This is a statutory requirement under BPC §26057(b)(7).

Subparagraph (E) requires the applicant to disclose any suspension or revocation of a cannabis license by a licensing authority or a local jurisdiction within the 3 years preceding the date of the application. This is a statutory requirement under BPC §26057(b)(7).

Subparagraph (F) requires the application to disclose any administrative orders or civil judgements for violations of labor standards within the three years immediately preceding the date of the application, per BPC §26057(b)(7). Labor violations within the three years preceding the application for licensure are sufficiently close in time to be relevant to an owner's current qualification for licensure and ability to maintain a safe and compliant premises. Stakeholders expressed concern regarding labor violations such as wage theft and occupational safety hazards in the cannabis market pre-regulation. The Department determined that said issues were relevant to an applicant's qualifications for licensure and has therefore included the requirement to disclose an owner's labor violations with the application for licensure. ~~Labor violations within the three years preceding the application for licensure are sufficiently close in time to be relevant to an owner's current qualification for licensure and ability to maintain a safe and compliant premises.~~ The Department is also requesting disclosure of such sanctions that may have been assessed against the owner individually or against a business in which the owner was an officer or owner because such sanctions may have been taken against the business entities rather than the individual.

Subsection (b) requires the owner application form be signed by the owner under penalty of perjury that the information provided in and submitted with the application is complete, true, and accurate. This section is necessary to ensure all information provided in applications is true and attested to be true and is required under BPC §26051.5(a)(4).

Subsection (c) requires an owner disclosing any criminal convictions or other penalties or sanctions pursuant to subsection (a) paragraphs (8)(A) and (B) shall submit evidence of rehabilitation for consideration by the Department. The statement of rehabilitation shall be written by the owner, contain evidence for the Department's consideration on fitness for licensure, and supporting evidence if desired. ~~This section is necessary to assure applicants that a previous conviction for certain crimes is not prohibitive to receiving a license. This provision is necessary in order for the Department to determine an individual's suitability to hold a license. Previous convictions do not automatically disqualify an individual from holding a license, but in order to determine whether an individual is qualified for licensure, the individual must demonstrate he or she has been rehabilitated and does not pose a threat to public safety. This is required by statute under BPC §26057(b)(4).~~

Section 40131. Annual License Application Requirements—Manufacturing Premises and Operations Information. This section specifies the information applicants must submit in regards to their manufacturing premises and operation

information when applying for an annual license. It outlines all the information that must be included in the application as indicated in the subsections below.

Subsection (a) requires the physical address of the manufacturing premises. This section is reasonably necessary as the premises is where the manufacturing activities is licensed and enforced.

Subsection (b) requires the applicant to indicate whether the premises manufactures medicinal-use, adult-use, or both cannabis products. This section is reasonably necessary since a manufacturer may choose to make one or both cannabis product types.

Subsection (c) requires the type of activity conducted on the premises. This section is reasonably necessary so the Department is aware of what activities are being conducted (i.e., extractions, infusions, packaging and labeling) for enforcement purposes.

Subsection (d) requires the types of products that will be manufactured, packaged, or labeled, including a product list. This section is reasonably necessary for enforcement purposes for the Department to review the application. Without a list of products manufactured at the site, the Department cannot evaluate the applicant's premises or operating procedures.

Subsection (e) requires the name, title, email address, and phone number of the on-site individual who manages the operation of the premises. This section is reasonably necessary to ensure the Department has the contact information of the appropriate contact person at the premises in order to ensure access for compliance and inspections.

Subsection (f) requires the name, title, email address, and phone number of an alternate contact person for the premises, if applicable. This section is reasonably necessary to ensure that if the premises has a second contact person, the Department has the relevant contact information.

Subsection (g) requires the number of employees at the premises. This section is necessary so the Department can determine whether the applicant is required to have a labor peace agreement, which is required in order to meet the requirements of Business and Professions Code section by BPC §26051.5(a)(5)(A), which requires a licensee with 20 or more employees to enter into a labor peace agreement.

Subsection (h) requires the gross annual revenue from products manufactured at the premises. Section 40150 establishes licensing fees based on a licensee's gross annual revenue. This section is reasonably necessary to provide clarity to the regulated industry so the Department can evaluate whether the proper licensing fee has been

[paid.](#)

Subsection (i) requires a premises diagram as specified in Section 40105. BPC §26051.5 (c) requires an applicant to submit a premises diagram [as part of the application. The requirement is duplicated here to provide a comprehensive list of application requirements.](#)

Subsection (j) requires the following:

Paragraph (1) the applicant to submit a description of inventory control procedures that is sufficient to demonstrate how the applicant will comply with the requirements of Section 40282 of these regulations. This provision is reasonably necessary in order for the Department to fulfill its mandate under BPC §26051.5(b)(4), and to comply with the intent of the Cole Memo (U.S. Department of Justice, August 29, 2013, Guidance memorandum regarding Marijuana Enforcement for all U.S. Attorneys, written by James A. Cole, Deputy Attorney General). While rescinded, the Department has chosen to work under the guidelines of the Cole memo for the purposes of this regulation. One of the priorities outlined in the Cole Memo is preventing diversion. This provision furthers the intent of preventing diversion through inventory control. [Without proper inventory control, a licensee will not be able to assess whether the any cannabis or cannabis product has been diverted or stolen.](#)

Paragraph (2) the applicant to submit a description [or a copy](#) of quality control procedures sufficient to demonstrate how the applicant will comply with the requirements of Sections 40232-40268 of these regulations. This provision is reasonably necessary in order for the Department to fulfill its mandate under BPC §26051.5(b)(5).

Paragraph (3) the applicant to submit a description [or a copy](#) of the transportation process to be used by the applicant. This provision is reasonably necessary in order for the Department to fulfill its mandate under BPC §26051.5(b)(3).

Paragraph (4) the applicant to submit a description [or a copy](#) of security procedures sufficient to demonstrate how the applicant will comply with the requirements of Section 40200 of these regulations. This provision is reasonably necessary in order for the Department to fulfill its mandate under BPC §26051.5 (b)6) and to comply with the Cole Memo. One of the priorities outlined in the Cole Memo is preventing diversion. This provision furthers the intent of preventing diversion by mitigating opportunities for theft.

Paragraph (5) a [description of](#) the cannabis waste disposal procedures that comply with Section 40290, or a copy of the standard operating procedure addressing cannabis waste management. This provision is reasonably necessary to ensure licensees follow state and local waste management laws.

Subsection (k) requires a written statement signed by the owner of the property or their agent, identifying the physical location of the property and acknowledging and consenting to the manufacture of cannabis products on the property. This must also include the name, address, and contact phone number for the owner or owner's agent. This section ensures that owners are aware of and responsible for the risks associated with cannabis manufacturing, and is necessary in order for the Department to contact the licensee as needed.

Subsection (l) requires a copy of the signed closed-loop system certification and a document evidencing approval of the extraction operation by the local fire code official, if required pursuant to Sections 40223 or 40225. Local fire code officials and certified engineers have the expertise required to determine that closed-loop systems are designed and installed in a manner that protects public safety. This section is necessary to ensure public safety in the case of volatile solvent use.

Subsection (m) states any manufacturer submitting operating procedures and protocols to the Department pursuant to the Act may claim such information as a trade secret or confidential by clearly identifying such information as "confidential" on the document at the time of submission. Any claim of confidentiality by a manufacturer must be based on the manufacturer's good faith belief that the information marked as confidential constitutes a trade secret as defined in Civil Code section 3426.1(d), or is otherwise exempt from public disclosure under the California Public Records Act in Government Code section 6250 et seq. This section is necessary to differentiate public information from confidential business data.

Section 40132: No change to Initial Statement of Reasons.

Section 40133: No change to Initial Statement of Reasons.

Section 40135. Incomplete and Abandoned Applications. This section will implement and make specific the rules and regulations adopted by the Department in order to properly license manufacturers in accordance with the Act. (BPC §§26012 (a)(3) and 26013(a))

Subsection (a) specifies that an incomplete application will not be processed, and the Department shall issue a written notice to the applicant informing them of any information missing from the application. This provision is reasonably necessary so that the Department may comply with BPC §26055(a) mandating that licensing authorities only issue licenses to qualified applicants, and in order to provide clarity to the regulated industry.

Subsection (b) provides that applications that remain incomplete 180 days after the Department has provided notice to the affected applicant(s) will be deemed abandoned, and application fees will not be returned. This provision is necessary in order to provide

clarity to the regulated industry and to provide applicants with a reasonable amount of time in which to review the application requirements, correct any deficiencies in their application, and provide the Department with any additional documents necessary in order to complete the application. This section is also necessary as staff costs remain in processing applications even if they are withdrawn or abandoned.

Subsection (c) states that an applicant may reapply at any time following an abandoned application, but that a new application and application fee are required. This is due to the requirement for staff time to review the new applications, and ensure the information on the application is not out-of-date. This section is necessary in order to provide clarity to an applicant regarding reapplying for a license.

Section 40137. Application Withdrawal.

Subsection (a) states that an applicant may withdraw an application for annual licensure at any time prior to the issuance or denial of the license. Requests to withdraw an application shall be submitted in writing to the Department or through MCLS.

Documents must be submitted in writing or online in order for the Department to keep accurate records. This section is necessary to allow applicants to withdraw their applications if they are incomplete or unable to meet the requirements for licensure.

Subsection (b) states that an applicant may reapply for annual licensure at any time subsequent to the withdrawal of an application. This section allows applicants who have withdrawn time to correct any errors on applications or other reasons for withdrawing an application and reapply when specified corrections are completed.

Subsection (c) states that withdrawal of an application shall not deprive the Department of its authority to institute or continue a proceeding against the applicant for the denial of the license upon any ground provided by law or to enter an order denying the license upon any such ground. This section is necessary in order for the Department to keep records of denials and to keep track of applicants who have a history of withdrawn applications, which may indicate unfitness for licensure for all of the licensing authorities.

Subsection (d) states that application fees paid for a withdrawn application shall not be refunded. This section is necessary as license and application fees pay for the staff time needed to review and investigate applications.

Section 40150. Fees. As previously mentioned, the Department is mandated to charge a fee to cover its costs and to scale the fee based on the size of the business. (BPC §26180(c))

Subsection (a) establishes a nonrefundable application fee for manufacturer applications.

Paragraph 1 establishes a fee of \$1,000 for Type 7, Type 6, Type N and Type P licenses and Paragraph 2 establishes a fee of \$500 for Type S licenses.

This provision is reasonably necessary so that the Department may cover its costs in accordance with the Act.

As a new program with a newly regulated industry, the Department has no historical data on which to base its estimated workload assessments. Using information from various licensing programs within the Department, the Department has estimated the cost of processing and reviewing each application for licensure. Application reviews will be conducted by a licensing unit that has both administrative and scientific staff. Staff will review the application for completeness and will process and review all submitted documents.

The Department estimates that it will take an average of 28 hours to fully process and review an application package, with the majority of the work performed by an Associate Governmental Program Analyst and an Environmental Scientist. Multiplying the annual classification salary by the number of hours needed per classification, the total annual salary cost for licensing manufacturers is estimated to be \$3,338,520. Dividing this number by the 3,000 licenses anticipated by the [Standard Regulatory Impact Assessment \(SRIA\)](#) to be issued under the proposed regulations results in a per license application cost of \$1,113, which has been rounded down to \$1,000.

Type S applicants are only subject to a \$500 application processing fee, rather than the \$1,000 fee applicable to other applicants. Type S applications will have a reduced review workload to Department staff as many of the elements will have already been reviewed during the assessment of the primary licensee's application.

Application fees will be nonrefundable. This is necessary because the Department's cost for processing and reviewing the application remains regardless of the outcome of the application.

Subsection (b) establishes the annual license fee previously discussed in section 40128. The fee is based on the gross annual revenue of the licensed premises and is tiered accordingly. The tiers were determined by the research conducted by HIIMR as part of the SRIA. The fees are as follows:

Paragraph (1) For a licensed premises with an annual gross revenue of up to \$100,000 (Tier I), the fee shall be \$2,000;

Paragraph (2) For a licensed premises with an annual gross revenue of \$100,001 to \$500,000 (Tier II), the fee shall be \$7,500;

Paragraph (3): For a licensed premises with an annual gross revenue of \$500,001 to \$1,500,000 (Tier III), the fee shall be \$15,000;

Paragraph (4): For a licensed premises with an annual gross revenue of \$1,500,001 to \$3,000,000 (Tier IV), the fee shall be \$25,000;

Paragraph (5): For a licensed premises with an annual gross revenue of \$3,000,001 to \$5,000,000 (Tier V), the fee shall be \$35,000;

Paragraph (6): For a licensed premises with an annual gross revenue of \$5,000,001 to \$10,000,000 (Tier VI), the fee shall be \$50,000;

Paragraph (7): For a licensed premises with an annual gross revenue of over \$10,000,000 (Tier VII), the fee shall be \$75,000.

These license fees were determined by accounting for the cost of administering the manufactured cannabis safety program. These costs include, but are not limited to: operational staff, Department administrative staff, IT system for licensing, and the Track and Trace Fees required by BPC §26067. The Department used the estimated market share of each tier to estimate the number of businesses that would be included in each tier. The fees were then set at an amount sufficient to fund the Department's costs as described above.

Funding for the MCSB program for FY 2017-18 (when the fees were established) is \$13.5 million, appropriated from the Cannabis Control Fund 3288, which has 63 positions.

Subsection (c) states that any fee paid is nonrefundable. Department administrative costs and licensee track-and-trace system fees are derived from license fees. These costs remain even if a licensee surrenders or abandons operations.

Section 40152. Gross Annual Revenue Calculation. This section clarifies for applicants the Department's expectation for calculation of gross annual revenue. During the effective period of the emergency regulations, the Department received numerous questions regarding the process for calculating gross annual revenue if the business was essentially providing a service for other businesses, rather than manufacturing their own products. This provision is modeled after Sherman Food and Drug Act (HSC, §§ 111550 and 111635) provisions for food processing firms to calculate revenue.

Applicants are required to calculate the gross annual revenue for the licensed premises based on the annual gross sales of cannabis products and, if applicable, the annual revenue received from manufacturing, packaging, labeling or otherwise handling cannabis or cannabis products for other licensees, in the twelve months preceding the

date of application (subsection (a)). For new license applicants, the gross annual revenue shall be based on the gross sales and revenue expected during the 12 months following licensure (subsection (b)).

Subsections (c) and (d) provide the method by which a licensee that holds multiple licenses can determine the gross annual revenue from the manufacturing operations. The language is modeled after the requirements of the Revenue and Taxation Code [Section 25120 to 2539, inclusive](#).

Section 40155: No changes to the Statement of Reasons.

Section 40156. Priority License Issuance. This section is intended to implement the statutory provision of priority license issuance to businesses operating in compliance with the Compassionate Use Act as of September 1, 2016.

Subsection (a) reiterates the statutory provision of priority license issuance. Although a statutory requirement, the provision is included in this regulation to provide clarity and ease of understanding for the regulated public.

Subsection (b) provides the documentation that may be used to demonstrate eligibility for priority license issuance. The Department has determined that the specified documents, dated prior to September 1, 2016, reasonably demonstrate that a business was in operation as of the date required by statute. The acceptable documents include:

Paragraph (1) a local license, permit, or other [form-of-written](#) authorization;

Paragraph (2) a collective or cooperative membership agreement;

Paragraph (3) tax or business forms submitted to the Board of Equalization or Franchise Tax Board;

Paragraph (4) incorporation documents;

Paragraph (5) any other business documents that demonstrate operation prior to September 1, 2016.

Subsection (c) reiterates the statutory provision that local jurisdictions may identify businesses eligible for priority review (BPC §26054.2(b)). The provision is included in this regulation to provide clarity and ease of understanding.

Subsection (d) states that the Department may request additional documentation to verify the applicant's date of commencement of operations. This provision is necessary to clarify that the Department retains the authority to request additional information during its review [in order to issue a license](#).

Subsection (e) adopts the statutory sunset date of 12/31/19. This is necessary for clarity and ease of understanding of the eligibility for priority review.

Section 40159. Denial of License. Adopt this section to clarify and set forth grounds for denial of a manufacturing license for the purposed of the Act. ~~The Department may deny an application if the applicant has a record of performing actions that are grounds for disciplinary action.~~

Subsection (a) specifies that an application may be denied for any reason specified in BPC §26057(b) of the Act. Further, the Department may deny a new a renewal license application for any of the following reasons:

Paragraph (1) an application may be denied when the applicant, owner, or licensee has made a material misrepresentation in their application for licensure. This provision is reasonably necessary so that the Department may comply with the denial criteria in Division 1.5 of the BPC, commencing with §480 and is included here for the clarity of the regulated industry.

Paragraph (2) an application may be denied when an owner has been convicted of a crime or has committed a violation of law substantially related to the qualifications, functions or duties of a manufacturer as identified in Section 40162 of these regulations. BPC §26057(b)(4) identifies offenses that are substantially related to the qualifications for licensure for all applicants under the Act, and which may serve as grounds for license denial. The Department has identified additional acts, as specified in Section 40162 of these regulations, which are specifically related to the qualifications of a manufacturer and which the Department believes are appropriate reasons for denial of a manufacturing license. This provision is reasonably necessary so that the Department may establish and enforce the criteria for the denial of licensing applications in accordance with the intent of its governing statute.

Paragraph (3) an application may be denied when the ~~applicantowner,~~ or licensee has been denied a license, ~~permit, or other authorization~~ to engage in commercial cannabis activity by a state ~~or local~~ licensing authority. This provision is reasonably necessary to comply with BPC §26055(d), which requires a licensee to possess both a state and local authorization in order to engage in commercial cannabis activity.

Paragraph (4) an application may be denied when the applicant, owner, or licensee has denied the Department access to the manufacturing premises. BPC §26160(e) specifies that a licensee who refuses an inspection of the premises has committed a violation of the Act. Violations of the Act are grounds for disciplinary actions, license revocation, or license denial. (BPC §26030.) This provision is necessary to clarify and make specific that the Department's authority under the Act.

Paragraph (5) an application may be denied if the licensee has engaged in conduct that

is grounds for disciplinary action. BPC §26030 establishes the grounds for disciplinary action. This provision is reasonably necessary to ensure licensees are aware they may be denied a license in the future if they violate any of the provisions in §26030.

Subsection (b) specifies that an application shall be denied if the proposed manufacturing operation or premises would violate the applicable local ordinance. This is a statutory requirement per BPC §26055(d) and is included here for the clarity of the regulated industry.

Subsection (c) is adopted to clarify the meaning of the word “conviction.” This definition is in accordance with the definition of conviction contained in Division 1.5 of the Business and Professions Code section 480(a)(1). [Understanding what constitutes a conviction may be difficult for lay people, and this definition](#) is necessary in order to clarify what constitutes a conviction under the Act.

Subsection (d) clarifies the Department, prior to the denial of a license, shall consider any evidence of rehabilitation as provided in Section 40165. This is a statutory requirement per BPC §26057(b)(4) and is included here for clarity of the regulated industry.

Section 40162. Substantially Related Acts. This section is intended to clarify and set forth the criteria the Department shall use in order to determine the denial of a manufacturing license based upon “substantially related acts.” BPC §26057 authorizes the Department to deny a license if the applicant has been convicted of an offense “substantially related to the qualifications, function, or duties of the business or profession for which the application is made.” This section establishes the convictions and violations that the Department considers to be “substantially related:”

Subsections (a) – (e) identifies the specific felony convictions for which a person may be denied a license. These convictions correspond to BPC §26057.

Subsection (f) identifies violations for adulteration and misbranding related to both food and drugs. These are provisions of [Article 2 of the Sherman Food, Drug, and Cosmetic Law, specifically HSC §§ 111250-111325](#), making it unlawful to manufacture and sell adulterated or misbranded food and drugs.

Subsection (g) identifies violations governing Wholesale Food Processors, which includes the CA Food Sanitation Act ([HSC, §§ 111950-112055](#)). Because of the way the wholesale food provisions are structured, it is very difficult to only choose certain provisions as violations, thus the Department is citing the entire chapter.

Subsection (h) identifies a conviction under sections 382 and 383 of the Penal Code and is reasonably necessary as it specifies food and drug adulteration violations.

The above mentioned subsections (f)-(h) define the specific California food and drug safety laws whose violation may result in a denial of licensure. Because the Department will license the manufacturers of products intended for human consumption, the Department has further determined that it is reasonably necessary for the Department to include consideration of an applicant's violation of other relevant food and drug safety laws when determining whether to deny a license application on the grounds of a substantially related act.

Subsection (i) specifies a violation of law identified in subsections (f) or (g) committed by a business entity in which an owner was an officer or had an ownership interest is considered a violation that is substantially related to the owner's qualifications for licensure.

Section 40165. Criteria for Evidence of Rehabilitation. BPC §26057(b)(4) requires the Department to consider evidence of the applicant's rehabilitation prior to a license denial due to an applicant's prior conviction of a substantially related offense.

Subsection (a) specifies the information that the Department will accept in order to conduct the statutory-required evaluation of evidence of rehabilitation. The criteria in Paragraphs (1) – (8) were developed in accordance with the other licensing agencies, and are reasonably necessary for the Department to conduct this evaluation. Although each owner's criminal history and evidence of rehabilitation will be considered on a case-by-case basis, the following information will provide a standardized measurement for applicants so they may better understand the factors the Department will consider in evaluating the application.

Paragraph (1) the nature and severity of the act or offense, including the actual or potential harm to the public. Criminal acts that have caused harm to the public are more likely to be indicative that the applicant poses a risk to public safety if licensed. Further, the nature and severity of the offense may provide some indication of whether the offense will be repeated. Due to the Department's statutory mandate to place protection of the public as its highest priority (BPC §26011.5), the Department has determined that individuals who have a high risk of repeating their past severe criminal acts should not be licensed;

Paragraph (2) the owner's criminal record as a whole. The owner's criminal record as a whole may provide some insight as to whether prior offenses will be repeated;

Paragraph (3) evidence of any act committed subsequent to the act or offense under consideration that could be considered grounds for denial, suspension, or revocation of a manufacturing license. An individual's subsequent act may provide some indication of whether the offense will be repeated. If an individual has an extensive history of criminal acts, there may be a high risk of repeating criminal acts.

Paragraph (4) the time elapsed since commission of the act or offense listed in Section 40162, or in section 26057(b)(4) of the Act. The time elapsed since commission of the act may provide some indication of whether the offense is likely to be repeated. A lapse of a large amount of time since the offense was committed may be evidence that the individual is unlikely to recommit the offense;

Paragraph (5) the extent to which the owner has complied with any terms of parole, probation, restitution, or any other sanctions lawfully imposed against ~~the owner or licensee~~ the individual. Compliance with the terms of parole, probation, restitution, and any other sanctions may demonstrate the individual will be less likely to repeat prior criminal acts;

Paragraph (6) if applicable, evidence of dismissal under Penal Code section 1203.4, 1203.4a, 1203.41, or a similar law in another state. This is an important factor in determining whether an individual is fit for licensure because a court has determined the offense should no longer be considered part of the individual's criminal history;

Paragraph (7) if applicable, a certificate of rehabilitation obtained under Penal Code section 4852.01 or a similar law in another state. This is an important factor in determining whether an individual is fit for licensure because a court has determined the individual should be considered to be rehabilitated; and

Paragraph (8) other evidence of rehabilitation submitted by the owner. This provision is necessary to allow the Department to consider as much evidence as possible and to consider any information the individual thinks is relevant before determining the individual's fitness for licensure.

Section 40167. Appeal of License Denial. This section establishes the process by which an applicant may appeal a denial of a license.

Subsection (a) specifies the notification requirements the Department must issue upon denial of an application for license as a manufacturer. This is a statutory requirement under BPC §26058, which requires licensing authorities to notify an applicant of a denial in writing. This provision is necessary in order to comply with statutory requirements and to provide clarity to the regulated industry.

Subsection (b) sets forth the process by which the applicant may appeal the denial of the application. Specifically, this section requires an applicant who elects to petition the Department to file the written petition within 30 days of the date of denial as required by statute in BPC §26058. The request for a hearing must be postmarked within a 30-day period or the applicant's right to a hearing is waived. This provision is necessary to implement and make specific BPC §26058 and to provide clarity to the regulated industry.

Subsection (c) provides that the Department shall schedule a hearing date upon receipt of the petition request. This provision further specifies that the hearing will be conducted in accordance with the formal hearing provisions of the Administrative Procedure Act. This provision is a statutory requirement under BPC 26058 and is reasonably necessary in order to provide clarity to the regulated industry.

Section 40175. License Constraints. This section is added to clarify the licensing constraints to which a licensee must adhere.

Subsection (a) states that a manufacturer licensee shall not manufacture, prepare, package, or label any products other than cannabis products at the licensed premises. For the purposes of this section, the term “cannabis products” also includes packaged cannabis, pre-rolls, and products that do not contain cannabis, but are otherwise identical to the cannabis-containing product, and are intended for use as samples. This provision is reasonably necessary to protect public health and safety in accordance with BPC §26011.5 by ensuring that there is no possibility of cross-contamination between cannabis products and other types of products, and to ensure that non-cannabis products subject to regulation under other state and/or federal requirements are not manufactured at a premises licensed to manufacture cannabis products. This subsection further provides that the prohibition does not apply to products that are identical to cannabis products (except for the addition of cannabis) and are intended to be used for samples. The Department understands that it is a fairly common practice in the industry to manufacture “zero milligram THC” versions of products if needed. Because such products will remain within the cannabis market and will not be sold in the traditional food market, the Department agrees that such a practice is a reasonable business practice.

Subsection (b) prohibits a licensee from employing or retaining an individual under age 21 years of age. BPC §26140 restricts an A-licensee from employing or retaining a person under 21 years of age. The Department, in consultation with the other licensing authorities, has extended this prohibition to M-licensees as well. The statutory prohibition is intended to protect minors (the title of the relevant chapter is “Protection of Minors”). It is therefore reasonable to prohibit minors from similarly working in medicinal cannabis businesses.

Subsections (c) specifies that a manufacturer shall only use cannabinoid concentrates and extracts that are manufactured or processed from cannabis obtained from a licensed cannabis cultivator. This subsection is intended to ensure that unregulated or black market cannabis is not being used in the regulated market.

Subsection (d) specifies that a manufacturer licensee shall not manufacture, prepare, package or label cannabis products in a location that is operating as a retail food establishment or as a processed food registrant. This subsection is necessary to prevent the cross-contamination of food and beverages that are not cannabis products.

Subsection (e) specifies a manufacturer licensee shall not manufacture, prepare, package, or label cannabis products in a location that is licensed by the Department of Alcoholic Beverage Control (ABC) pursuant to Division 9 (commencing with section 23000) of the BPC. BPC §26200(g)(3) prohibits the sale or consumption of alcohol at a manufacturing premises. This provision is intended to provide clarity to the regulated industry that cannabis manufacturing activities are prohibited from being conducted at the same premises licensed by ABC.

Section 40177. Change in Licensed Operations. This section is intended to allow licensees to change the operations performed on a licensed premises, provided that the licensee informs the Department what forms of manufacturing will now take place, and that manufacturing standards are met.

Subsection (a) clarifies that at any time during the license period, a licensee may request to change the manufacturing operations conducted at the licensed premises. This section has been added to allow licensees to modify their manufacturing as needed to meet market demand or accommodate changes in business practice. The following changes require pre-approval from the Department as they rise to higher level of review by the Department due to the potential impact to public health and safety:

Paragraph (1) the addition of any extraction method subject to the requirements of Section 40225. The Department must ensure the public safety protection requirements, such as a closed-loop extraction system and approval from the fire code official, have been adhered to;

Paragraph (2) the addition of any other extraction method that necessitates a substantial of material change to the premises. Material changes to the premises are required by statute (BPC, § 26055(c)) to have preapproval by the Department;

Paragraph (3) the addition of infusion operations if no infusion activity is listed on the current license application filed with the Department;

Paragraph (4) any substantial or material alteration of the licensed premises from the diagram currently filed with the Department. This is required by BPC §26055(c) and is added for clarity for the regulated industry.

Subsection (b) for the purposes of this section, “substantial or material alterations” include: the removal, creation, or relocation of an entryway, doorway, wall, or interior partition; a change in the type of activity conducted in, or the use of, an area identified in the premises diagram; or remodeling the premises or portion of a premises in which manufacturing activities are conducted. These are the elements that are required to be noted on the premises diagram when submitted, therefore alteration to these elements

must be reported to and approved by the Department pursuant to BPC §26055(c). This section has been added to clarify what alterations must be reported by the licensee.

Subsection (c) States that in order to request approval for any change listed in subsection (a), a licensee shall submit the following:

Paragraph (1) the information required under Section 40131, and

Paragraph (2) a non-refundable \$700 application processing fee to review all documents. This paragraph is necessary in order to offset staff time needed to review all applications. The Department will need to review almost all of the same documentation as submitted for the initial license application in order to ensure that all of the requirements have been met. The only documentation that will not be reviewed is the Department of Justice criminal history information. This fee is necessary to cover staff time needed to review the application documentation, and is therefore non-refundable.

Subsection (d) states that the request for a change in licensing operations shall be evaluated on a case-by-case basis by the Department, and upon approval, the licensee may begin conducting the additional manufacturing operation. The existing license shall be amended to reflect the change in operations, but the date of expiration shall not change. This is intended to ensure changes in operations are not used to circumvent application for, and fees paid associated with, a new license. This subsection is necessary as county and city rules for allowable operations is likely to evolve and shift in the future, and the Department will need to ensure that the licensee is operating under local laws and regulations.

Subsection (e) states that licensees that choose to cease operation of any activity shall notify the Department within 10 days of cessation of the activity. The Department determined 10 days was a reasonable amount of time for licensees share this information, and keep Department records up-to-date for consistent compliance and enforcement. License fees shall not be pro-rated or refunded upon cessation of any activity. This paragraph is necessary to include for the clarity of the regulated market.

Subsection (f) states a licensee shall notify the Department through MCLS of any changes to the product list on file with the Department and provide a new list within 10 business days of making any change. The Department determined 10 days was a reasonable amount of time for licensees share this information, and keep Department records up-to-date for consistent compliance and enforcement. This is reasonably necessary for clarity to the regulated industry, and should field inspectors go out to a premises, the product list is consistent with what is being manufactured at the premises.

Section 40178. Add or Remove Owner(s). This section requires the licensee to submit to the Department any changes to the ownership of a licensed cannabis manufacturing

business. This section is necessary in order for the Department to determine if the proposed owner meets the qualifications for denial as previously described. This provision is reasonably necessary in order to provide clarity to the regulated industry.

Subsection (a) requires a licensee to notify the Department of any addition or removal of an owner within ten (10) calendar days through MCLS. The Department determined 10 days was a reasonable amount of time for licensees share this information, and keep Department records up-to-date for consistent compliance and enforcement. This section is necessary in order for the Department to determine if the proposed owner meets the qualifications for denial as previously described.

Subsection (b) requires that any new owner shall submit the information required under Section 40130 to the Department through MCLS or on a prescribed form. The form contains only the elements listed in the regulation, and is given as an option for submittal of relevant information for those who do not have internet access. The Department shall review the qualifications of the owner in accordance with the Act and the regulations to determine whether the change would constitute grounds for denial of the license. The Department may approve the addition of the owner, deny the addition of the owner, or condition the license as appropriate, to be determined on a case-by-case basis. This provision is reasonably necessary to provide clarity to the regulated industry that each owner is required to meet the requirements of the Act and the Department's regulations.

Subsection (c) requires an owner to notify the Department through MCLS of any change in their owner information submitted pursuant to Section 40130 within 10 calendar days of the change. This provision is necessary to ensure the Department's files are kept up to date. Ten days is sufficiently soon to meet the Department's purposes without being overly onerous on the business. ~~This provision is reasonably necessary to provide clarity to the regulated industry.~~

Subsection (d) also requires a licensee to notify the Department through MCLS of any change in the list of financial interest holders within 10 calendar days. This provision is reasonably necessary to provide clarity to the regulated industry and ensure that the Department has an up-to-date list of all parties with a financial interest in the licensed business. Ten days is sufficiently soon to meet the Department's purposes without being overly onerous on the business.

Section 40180. License Renewal. The purpose of this section is to establish the annual license renewal process in order to make specific the Department's obligation under BPC §26180 to establish a licensing scheme with an annual renewal fee.

Subsection (a) establishes that to apply for a license renewal, the licensee shall submit any changes to their current license application information on a form prescribed by the Department, or through MCLS, sign the renewal application under penalty of perjury

and submit the annual license fee as specified in subsection (b) of Section 40150. Forms are supplied in order for applicants and licensees without access to internet to be able to submit relevant information. This subsection is added for the clarity of the regulated industry. This subsection further requires the licensee to submit documentation of their gross annual revenue ~~for the preceding year~~ pursuant to Section 40152, such as tax returns filed with the California Department of Tax and Fee Administration. In order to properly assess the applicant's annual license fee, which is based on gross annual revenue, it is necessary that the Department be provided with documentation.

Subsection (b) establishes that a complete application for renewal of a manufacturing license shall be submitted to the Department no later than 5:00 pm on the last business day prior to the expiration date of the current license, but not more than 60 calendar days prior to the expiration date of the currently license. Online submissions will be accepted until midnight on the last business day prior to the expiration date of the current license. This discrepancy is due to the office hours of the Department, ensuring a paper application marked as received by the end of the business day. However, online submissions are time stamped, and therefore may be received up to midnight and still be considered same-day. A complete renewal application includes submission of all changes to the information required by Section 40128 and payment of all fees. This subsection is necessary to clarify date ranges acceptable to renew applications for the regulated industry.

Subsection (c) This subsection provides that if a licensee has not submitted a renewal application, no commercial cannabis activity can be conducted after the expiration of the license. Under statute (BPC §26053), commercial cannabis activity cannot be conducted without a valid license. This provision is necessary to clarify this statutory restriction.

Subsection (d) provides that a late fee of \$500 will be applied to a renewal application that is not submitted by the expiration date of the current license. The imposition of a late fee is reasonably necessary to provide deterrence from untimely submission of renewal applications, which impedes the Department's processing of applications. A licensed manufacturer that fails to submit a renewal application within 30 days after the expiration of their license is no longer eligible to renew the existing license and must instead apply for a new license. Thirty days is considered by the Department to be a reasonable amount of time for licensees to renew a license that will last for one year, while also giving them flexibility in completed the renewal paperwork. Commercial cannabis activity can only occur between holders of a valid license. It is reasonable to establish a date by which an expired license is no longer valid and therefore not eligible for renewal. Between the time the licensee is eligible to submit the renewal application and the time provided after the expiration date, the licensee will have 90 days to submit a renewal application, a sufficient amount of time to provide the information the Department is requesting.

The \$500 late fee is established in accordance with the Department's authority under BPC §26180 to set licensing and renewal fees. Late fees are a reasonably implicit aspect of licensing fees. Late submission of renewal applications can impact both the Department staff and other licensees, as staff time is diverted to quickly process the late application. If a licensee submits the renewal application on time, the only fee to be paid is the annual license fee – renewal applications are not subject to the \$1,000 application processing fee. CalCannabis and the Bureau have established their late renewal fee at 50% of the application fee. Similarly, the Department has established a late fee that is 50% of the regular application fee, which is equal to \$500.

Subsection (e) states that any changes to owner and financial interest holder information shall be made in accordance with Section 40178. That section is reasonably necessary to clarify that owners are still subject to the requirements of 40178 for license renewals.

Subsection (f) states that the Department shall notify the applicant upon approval of the renewal application through email or MCLS. The Department shall notify an applicant of the denial of an application in accordance with Section 40167. This section is necessary for the clarity of the regulated industry.

Section 40182. Disaster Relief. This section allows the Department to waive certain regulatory licensing requirements during a disaster and is necessary to ensure that licensees who have been impacted by a disaster are not deemed to have surrendered, abandoned, or quit their licenses, due to the impacts of the disaster, if their intent is to continue as a licensee. Additionally, as the Act places public safety as the top priority for licensing authorities (BPC §26011.5), the provisions allowing a licensee to move product to a location different than the original location approved by the Department is critical to public safety to ensure that cannabis and cannabis products are secured and unable to be accessed by the general public.

The Department has determined that in certain circumstances a licensee may be relieved from regulatory provisions. Additionally, Government Code section 8571 provides that during a state of emergency the Governor may suspend any regulatory statute, or statute prescribing the procedure for conduct of state business, or orders, rules, or regulations of any state agency, where the Governor determines and declares that strict compliance with any statute, order, rule, or regulation would in any way prevent, hinder, or delay the mitigation of the effects of the emergency. This section would allow licensees that have been impacted by a disaster to be relieved from rules, orders and regulations that would otherwise delay mitigation of the effects of the disaster and the ability to keep cannabis and cannabis products secured to prevent diversion in the illegal market and prevent minors from accessing cannabis or cannabis products. This section is also necessary to ensure that licensees are provided an opportunity to exercise the privileges of their license, when otherwise prohibited from

doing so by forces and circumstances beyond their control, that have made compliance with the regulations so onerous that the operation under their license is not worthy of being carried out in practice.

Subsection (a) states that if a licensee is unable to comply with any licensing requirement due to a disaster, the licensee may notify the Department of its inability to comply and request relief from the specific licensing requirement. Licensees may be tempted to walk away from a business or choose not to adhere to the law when a disaster occurs. This provision is reasonably necessary to ensure businesses have an opportunity to recover and remain compliant.

Subsection (b) allows the Department to exercise its discretion to provide temporary relief from specific regulatory requirements in this chapter and from other licensing requirements when allowed by law. It is likely that some licensees will request disaster relief, but will not meet the threshold established by the Department. Licensee's requests for disaster relief will be reviewed by the Department on a case-by-case basis. This provision is reasonably necessary as it provides clarity to the regulated industry, and provides the Department flexibility in determining whether a licensee should be exempted from the licensing requirements.

Subsection (c) states temporary relief from specific licensing requirements shall be issued for a reasonable amount of time in order to allow the licensee to recover from the disaster. Licensee's requests for relief from licensing requirements will be reviewed by the Department on a case-by-case basis. This provision is reasonably necessary to allow a business time to recover without being subject to licensing requirements that may be incapable of being met during a disaster.

Subsection (d) specifies the Department may require that certain conditions be followed in order for a licensee to receive temporary relief from specific licensing requirements. Temporary relief of licensing requirements is not intended to suspend all statutory and regulatory requirements. Therefore, it is reasonably necessary for the Department to request a licensee to meet certain conditions in order to receive temporary relief.

Subsection (e) states a licensee shall not be subject to an enforcement action for a violation of a licensing requirement in which the licensee has received temporary relief. This provision is reasonably necessary to provide clarity to the regulated industry.

Subsection (f) defines "disaster." The definition of disaster is consistent with the definition of a state or local jurisdictions declaration of an emergency in accordance with Government Code sections 8558 and 8625, or for which a local governing body has proclaimed a local emergency in accordance with Government Code sections 8558 and 8630. This term is necessary to ensure licensees who have been impacted by a disaster are aware of the specific situations in which they may be allowed to be relieved

of certain regulatory obligations. This provision is reasonably necessary to provide clarity to the regulated industry on what constitutes a disaster.

Subsection (g) provides that, if a licensee needs to move cannabis or cannabis products stored on the premises to another location immediately to prevent loss, theft, or degradation of the cannabis or cannabis products from the disaster, the licensee may move the cannabis or cannabis products without obtaining prior approval from the Department if the following conditions are met:

Paragraph (1) the cannabis or cannabis products are moved to a secure location where access to the cannabis or cannabis products can be restricted to the licensees, its employees, and its contractors. This provision is reasonably necessary to reduce the potential for diversion;

Paragraph (2) the licensee notifies the Department in writing that the cannabis or cannabis products have been moved and that the licensee is requesting relief from complying with the specific licensing requirements pursuant to subsection (a) of this section within 24 hours of moving the cannabis or cannabis products. The Department has determined that 24 hours is sufficient time for the licensee to immediately secure cannabis or cannabis products while providing prompt notice of the change in location to the Department;

Paragraph (3) the licensee agrees to grant the Department access to the location where the cannabis or cannabis products have been moved. BPC §26160 (e) specifies that a licensee who refuses an inspection of the premises has committed a violation of the Act. This provision is reasonably necessary to ensure the Department can inspect the location where the cannabis product is being held;

Paragraph (4) the licensee submits in writing to the Department within 10 days of moving the cannabis or cannabis products, a request for temporary relief that clearly indicates what statutory and regulatory sections relief is requested from, the time period for which the relief is requested, and the reasons relief is needed for the specified amount of time. The Department has determined that 10 business days is the appropriate time to allow a licensee to provide the Department with a request for relief as it allows the licensee time to address the immediate effects of the disaster on the licensee's business while not allowing too much time to elapse before the Department can evaluate the proposed plan.

Section 40184. Notification of Criminal Acts, Civil Judgments, and Revocation of a Local License, Permit, or Other Authorization after Licensure. This section clarifies a licensee's responsibilities in notifying the Department of any convictions or judgments made against them. This section has been added in order for the Department to fulfill its mandate under BPC §26055, which requires the licensure of

only qualified applicants. It further clarifies for the regulated industry that illegal activities may cause a license to be denied or revoked.

Subsection (a) requires that a licensee shall notify the Department in writing of a criminal conviction of any owner, either by mail or electronic mail, within 48 hours of the conviction. It is reasonably necessary to require the licensee to provide this information within 48 hours in order for the Department to assess whether the reason for the revocation rises to a level that should result in an immediate revocation as it poses significant public health and safety concerns. The written notification to the Department shall include the date of conviction, the court case number, the name of the court in which the owner was convicted, and the specific offense(s) for which the owner was convicted. This section is reasonably necessary in order for the Department to implement BPC §26057(b)(4).

Subsection (b) requires that a licensee shall notify the Department in writing of a civil penalty or judgment rendered against the licensee or any owner in their individual capacity, either by mail or electronic mail, within 48 hours of delivery of the verdict or entry of judgment, whichever is sooner. It is reasonably necessary to require the licensee to provide this information within 48 hours in order for the Department to assess whether the reason for the revocation rises to a level that should result in an immediate revocation as it poses significant public health and safety concerns. The written notification to the Department shall include the date of verdict or entry of judgment, the court case number, the name of the court in which the matter was adjudicated, and a description of the civil penalty or judgement rendered against the licensee or owner. This information is required in order for the Department to review the specific circumstances to determine whether the individual is still qualified to hold a license. This section is reasonably necessary in order for the Department to implement BPC §26057(b)(4).

Subsection (c) states that a licensee shall notify the Department in writing of the revocation of a local license, permit, or other authorization, either by mail or electronic mail, within 48 hours of receiving notice of the revocation. The written notification shall include the name of the local agency involved, a written explanation of the proceeding or enforcement action, and the specific violation(s) that led to revocation. Section 26200 (c) establishes a notification process for a local jurisdiction that revokes a licensee's authorization to conduct business. However, it only establishes that the local jurisdiction has to notify the state, but does not include a timeframe in which the notification has to occur. It is reasonably necessary to require the licensee to provide this information within 48 hours in order for the Department to assess whether the reason for the revocation rises to a level that should result in an immediate revocation as it poses significant public health and safety concerns.

Subsection (d) states that a licensee shall notify the Department in writing of an administrative order to violations of labor standard against the licensee of any owner in

their individual capacity, either by mail or electronic mail, within 48 hours of delivery of the order. The written notification shall include the date of the order, the name of the agency issuing the order, and a description of the administrative penalty or judgement against the licensee. Stakeholders expressed concern regarding the prevalence of wage theft and other labor violations in the cannabis market pre-regulation. The Department determined that said concerns were valid and has therefore included this section in order to ensure compliance with labor codes by applicants and licensees prior to renewal of a license. In addition, labor violations may serve as a basis for discipline pursuant to section 26030 of the Act.

Section 40190. Definitions. This section establishes definitions for Shared-Use Facilities, as follows:

Subsection (a) defines “common-use area” as any area of the manufacturer’s registered shared-use facility that is available for use by more than one licensee, including equipment. “Common-use area” is needed in order to ensure that all parties – primary licensee, Type S licensee, and the Department – understand which areas of the manufacturing premises the Type S licensee is authorized to use. It is also necessary to ensure only one licensee shall occupy a premises at once, as required by statute (BPC, § 26000(ap)).

Subsection (b) defines “designated area” as the area of the registered shared-use manufacturing facility that is designated by the primary licensee for the sole and exclusive use by a specific Type S licensee. “Designated area” is needed to ensure that all parties understand which areas of the manufacturing premises are for sole use by a specific Type S licensee, as to distinguish it from the common-use area as outlined in – subsection (a). Furthermore, the designated area in conjunction with the common-use area will constitute the Type S licensee’s “premises” during periods of use.

Subsection (c) defines “primary licensee” as the Type 7, Type 6, or Type N licensee that has been approved to operate a shared-use facility. The primary licensee is given specific responsibilities in further provisions of this proposal. The definition is needed to clarify who is the primary licensee.

Subsection (d) defines “shared-use facility” as a manufacturing facility operated by a Type 7, Type 6, or Type N licensee in which Type S licensees are authorized to conduct manufacturing operations. This definition is necessary to clarify further provisions of the proposal.

Subsection (e) defines “use agreement” as a written agreement between a primary licensee and a Type S applicant or licensee that specifies the designated area of the Type S licensee, the days and/or hours in which the Type S licensee is assigned to use the common-use area(s), any allocation of responsibility for compliance pursuant to Section 40196, and an acknowledgement that the Type S licensee has sole and

exclusive use of the common-use area(s) during the Type S licensee's assigned days and/or hours. This definition is necessary to clarify further provisions of the proposal.

Section 40191. Type S License.

Subsection (a) establishes the requirements for applications for a Type S license. Each user of a designated Type S shared space must hold a Type S license, and only one licensee may use the premises at a time.

Paragraph (1) requires that applications be made in accordance with Section 40128. Section 40128 provides the application process for all applicants;

Paragraph (2) requires the application to identify the registered shared-use facility the applicant will use. As part of its statutory mandate to ensure that manufacturing activities take place only in licensed locations, the Department needs to ensure that that the Type S licensee is operating in an approved facility;

Paragraph (3) requires the applicant to include a copy of the use agreement signed by both the applicant and the primary licensee. The Department will need the use agreement for oversight and enforcement activities. ~~This paragraph also specifies that the use agreement shall be considered the landlord approval required pursuant to section 26051.5(a)(2) of the Act. Because the use agreement requires signature of the primary licensee, it is reasonable to consider it as the landlord approval;~~

Paragraph (4) requires the applicant to include a premises diagram of the designated area to be used by the applicant pursuant to Section 40131(i). Only one licensee may use the shared space premises at a time, pursuant to BPC §2600(ap). All applicants are required by statute to submit a premises diagram, which the Department will use in its evaluation of the applicant's procedures to ensure the protection of public health.

Subsection (b) limits the availability of a Type S license to applicants with a gross annual revenue of less than \$1 million calculated pursuant to section 40152, during the preceding license term. The intent of the Type S license is to provide a means by which smaller businesses can enter the regulated market. As the business grows in size, it can reasonably be expected to operate its own facility. The emergency regulations limited Type S licenses to businesses with no more than \$500,000 in gross annual revenue. Feedback from the regulated industry indicated that this threshold was too low, given the limitations cannabis businesses face in terms of availability of locations, and requested the Department raise the threshold to \$1 million. The Department reconsidered its decision and raised the threshold to the requested \$1 million.

Subsection (c) specifies the operational activities a Type S licensee may conduct. The Department has determined that the following activities present lower public safety risk and can therefore be performed safely in a shared facility:

Paragraph (1) infusions, as defined in Section 40100(v);

Paragraph (2) packaging and labeling of cannabis products, and;

Paragraph (3) extraction operations using butter or food-grade oil, provided that resulting extract or concentrate is used solely in the manufacture of the Type S licensee's infused product, and is not sold to any other licensee. Extraction activities present a greater public safety risk than infusion activities because of risk of explosion. However, the Department is aware that many infused products are made by incorporating infused butter or other oil into a recipe formulation. Extractions with butter or food-grade oil do not present the same public safety risk as other types of extractions. The Department determined that the practice was a reasonable business practice to accommodate.

Section 40192. Registration to Operate a Shared-Use Facility.

Subsection (a) states that a licensee may not operate as a shared-use facility without prior approval by the Department. This provision is necessary so that the Department can fulfill its mandate to oversee manufacturing activities.

Subsection (b) provides that a Type 7, Type 6, or Type N licensee can request approval to operate as a shared-use facility by submitting to the Department through MCLS:

Paragraph (1) a copy of the local license, permit, or other authorization from the local jurisdiction explicitly authorizing operation of a shared-use facility. Local jurisdictions maintain ultimate authority over the type of cannabis activities that are conducted in their locality. Upon receipt of the application, the Department shall contact the applicable local jurisdiction to confirm the validity of the authorization. If the local jurisdiction does not respond within 10 calendar days, the Department shall consider the authorization valid. This 10 day period was established in connection with the other licensing agencies, with input from local jurisdictions, and was determined to be sufficient time to allow local jurisdictions to review requests without undue delay on application processing. This provision is necessary as it ensures the licensee is performing cannabis manufacturing in a city or jurisdiction that allows said manufacturing. This provision is necessary to ensure that local jurisdictions are aware and in support of shared-use facilities;

Paragraph (2) a registration form prescribed by the Department with the following information:

Subparagraph (A) the proposed occupancy schedule that the common-use area will be available for use by Type S licensees and when the common-use area will be used by the primary licensee. The occupancy schedule shall allow for adequate maintenance and sanitizing between use by individual licensees. In order to properly oversee manufacturing operations, the Department must have a record of the operating

schedule. This allows the Department to accurately inspect shared spaces, as maintenance of equipment and cleaning can be tracked to a specific Type S licensee. It also shows that enough time is set for each licensee to clean and sanitize before another licensee uses the shared-use space.

Subparagraph (B) a diagram indicating the below:

Clause (i) each designated area for a Type S licensee. This provision is necessary to differentiate designated areas for shared-use from other manufacturing areas. This section is necessary as statute requires only one licensee use the premises at any given time.

Clause (ii) the common-use area(s), including identification of any shared equipment. This provision is necessary to clarify which areas and/or equipment can be used by a Type S licensee. This provision is necessary in order for the Department to ensure shared equipment is being cleaned and maintained in a way that prevents cross contamination of any cannabis products.

Subsection (c) requires that the Department shall notify the Type 7, Type 6, or Type N licensee upon approval of the registration to operate as a shared-use facility. Notification shall be made through MCLS. This provision ensures that primary licensees are informed in a timely manner and may begin to allow shared-use manufacturing on their premises.

Subsection (d) specifies that at least one business day prior to a Type S licensee commencing manufacturing operations at a registered shared-use facility, the primary licensee shall provide written notification to the Department. The notification to the Department shall include the Type S licensee's business name, contact person, contact phone number, and license number. The primary licensee shall also provide an updated occupancy schedule to include the Type S licensee and an updated diagram indicating the designated area of the Type S licensee. Notification may be provided by email or through MCLS. One business day is the minimum amount of time needed for the Department to be aware of a new manufacturing facility commencing activity. This provision is necessary to ensure accurate documentation of operating licensees and to ensure the Department's ability to oversee and inspect the use of shared facilities.

Subsection (e) states that a primary licensee that wishes to discontinue operation as a shared-use facility may cancel its registration by providing at least 30 calendar days written notice to the Department and each Type S licensee authorized to use the shared-use facility prior to the effective date of the cancellation. This provision allows time both for the Department to update the Department's records and for Type S licensees using the shared facility to have time to potentially find a new operating space and to safely remove anything from their storage space at the shared-use facility.

Section 40194. Shared-Use Facility Conditions for Operation.

Subsection (a) establishes the conditions of operation that a primary licensee must ensure. The below subsections are necessary to set out the minimum requirements a primary licensee must demonstrate to operate a shared-use facility.

Subsection (b) requires each Type S licensee to be assigned a “designated area” that, at minimum:

Paragraph (1): is for exclusive use by the Type S licensee.

Paragraph (2): includes secure, locked storage for exclusive use by, and accessible only to, the Type S licensee for storage of that Type S licensee’s cannabis, cannabis concentrates, and cannabis products. The regulations referred to in paragraphs (1) and (2) are needed to require the primary licensee to provide a designated area and storage space for a Type S licensee. The cannabis manufacturing activity must be done in an area occupied only by one licensee at a time. Further, a secure storage space for the Type S licensee’s cannabis, cannabis concentrates, and cannabis products must be provided because the licensee will leave the shared-use facility and others will use the common-use areas, and is intended to prevent diversion.

Subsection (c) requires any part of the premises used for manufacturing activity that is a common-use area to be occupied by only one licensee at a time by restricting the days and/or hourstime period that each licensee may use the common-use area. During the assigned days and/or hourstime period one licensee shall have sole and exclusive occupancy of the common-use area. This restriction is necessary to meet the statutory requirement that a premises be limited to one licensee. This regulation requires the use of a schedule for use of the common-use areas because this allows cannabis manufacturing activity to be done in a shared-use facility by different Type S licensees by providing exclusive use of a portion of the common-use area to each Type S licensee.

Subsection (d) restricts the use of the shared-use facility to the primary licensee and the Type S licensees authorized by the Department to use the shared-use facility. No person can manufacture cannabis products without a license from the Department; this provision is required to clarify that even if a facility operates as a shared-use facility, any individual that uses the facility must be licensed. This regulation is necessary as the documentation provided will be examined by the Department to assure the cannabis manufacturing can be done with the licensees designated to use the shared-use facility. The department must have a regulation that assures it has documentation of all the licensees using the shared-use facility, and that no person or entity will use the shared-use facility for cannabis manufacturing without Department authorization.

Subsection (e) requires any cannabis product or other materials remaining after a Type S licensee ceases operation and discontinues use of its designated area to be disposed

of by the primary licensee consistent with the requirements of the Act and regulations. The regulation is needed to provide that any cannabis product or other materials left behind by a Type S licensee after its use of the common-use area is cannabis waste and cannot be used in order to prevent adulterated cannabis products.

Subsection (f) requires that the shared-use facility meet all applicable requirements of the Act and regulations. The regulation is needed to make clear to the regulated public that all licensees that use a shared-facility must meet all the requirements of the Act, and regulations promulgated under the Act, irrespective of the fact that it is a shared-use facility.

Subsection (g) requires the occupancy schedule to be prominently posted near the entrance to the shared-use facility. This provision is necessary as it further ensures consumer protection by preventing adulteration of cannabis products by making it clear to all who enter and use the facility what is the current occupancy schedule of the shared-use facility.

Subsection (h) states that the primary licensee may conduct manufacturing activities as permitted under its Type 7, Type 6, or Type N license and may use the common-use area during its scheduled time period. This provision clarifies activities allowed by the primary licensee to the regulated public, and that the primary licensee must also comply with the designated occupancy schedule, along with the Type S licensees, to assure that only one licensee at a time is using the common-use area for cannabis manufacturing.

Section 40196: No change to Initial Statement of Reasons

Section 40200. Security Plan. This section establishes the requirements that each licensee must include in a security plan for their manufacturing facility. The Act requires applicants for licensure to submit security protocols as required by the licensing authority (BPC §26051.5(b)(6)). Adequate security measures are a necessary component of preventing diversion and providing for employee safety.

Subsection (a) requires the security plan to include a description of the security measures taken to prevent access to the manufacturing premises by unauthorized personnel and to protect the physical safety of employees. This provision is reasonable necessary because the presence of cannabis or cannabis products at a manufacturing premises creates a risk of theft. Additionally, the cannabis industry is heavily cash-based, which creates further risk of theft. In order to protect the physical safety of employees and the integrity of the manufacturing process, it is necessary that manufacturers establish security procedures. In order to meet its responsibility under the Act (which requires the establishment of security protocols) it is reasonably necessary for the Department to require the following elements to be included in the security plan:

Paragraph (1): physical barriers to secure perimeter access and all points of entry. Physical barriers can include fencing, locks, or other means of preventing entry.

Paragraph (2): security alarm system capable of alerting personnel to breaches of physical barriers.

Paragraph (3): an identification and sign-in procedure for authorized personnel, suppliers, or visitors. This will help keep track of who is located onsite and if the person is authorized to be there.

Paragraph (4): maintaining the premises so that visibility and monitoring of the premises is possible. This requirement will ensure that there are fewer places for unauthorized persons to hide.

Paragraph (5): procedures for investigation of suspicious activities. This is intended to ensure that the licensee follows up on suspicious activities in a systematic manner.

Subsection (b) requires the security plan to include a description of the security measures taken to prevent against theft or diversion of cannabis and cannabis products. Similar to subsection (a), above, this provision is reasonably necessary so that the Department may comply with its responsibility to establish security protocols under the Act. Methods to meet this requirement must include:

Paragraph (1): establishing an inventory system. An inventory control system is necessary so that the licensee may ensure accurate accounting of the location and quantity of the operation's cannabis or cannabis products.

Paragraph (2): limit access of personnel within the premises to only those areas necessary to complete job duties, and to only those time periods scheduled for completion of such duties. This provision is necessary to ensure that no personnel have unknown access to cannabis or cannabis products, reducing the opportunity for theft.

Paragraph (3): supervising tasks with high potential for diversion in order to reduce the potential for theft.

Paragraph (4): providing areas in which personnel may store and access personal items, particularly purses, bags, or other receptacles that may be used in the theft of cannabis and cannabis products. These designated areas must be separate from the manufacturing areas.

Subsection (c) requires the plan to include the methods to secure and back-up electronic records in a manner that prevents unauthorized access and ensures the integrity of the records in maintained. ~~electronically secure, back up, and control access~~

~~to all electronic records.~~ Electronic records can provide information that can be used to gain access to the premises or identify vulnerabilities in the security system. This provision is reasonable necessary to protect the safety of personnel and the facility.

Section 40205. Video Surveillance. This section sets forth the minimum requirements for video surveillance system placement, technical requirements and record retention regulations that the Department considers reasonably necessary in order to provide security for the storage of cannabis products on a manufacturing premises in order to protect against instances of diversion. This is a statutory provision (BPC §26051.5(b))

Subsection (a) requires licensed premises to have a complete digital video surveillance system with a minimum camera resolution of 1280 x 720 pixels, capable of recording in any lighting conditions. This requirement is reasonably necessary to ensure that the surveillance system's cameras produce clear images regardless of the time of day or lighting conditions that might otherwise inhibit camera function. This provision is reasonably necessary to allow for the clear and certain identification of any person and activities in all areas required in this section in order to protect against the diversion of cannabis products. BPC §26051.5(b)(6) requires the Department to establish minimum security requirements for the storage of cannabis products at the manufacturing site.

Subsection (b) requires that all video surveillance cameras be installed in a manner that prevents them from being intentionally obstructed, tampered with or disabled, to the extent reasonably possible. This provision is reasonably necessary to ensure that camera placement is done in way to maximize the video surveillance system's purpose.

~~Subsections (c)(1) through (5) requires video surveillance of specific areas on the premises. where cannabis or cannabis products are weighed, packed, stored, quarantined, loaded, and unloaded for transportation, prepared, or moved within the premises. These requirements are reasonably necessary to monitor activities where there might be an opportunity for diversion.~~

~~Paragraph (1) requires video surveillance cover areas where cannabis or cannabis products are weighed, packed, stored, quarantined, loaded and unloaded for transportation, prepared, or moved within the premises. This provision is necessary in order to prevent theft, loss, or diversion;~~

~~Paragraph (2) requires video surveillance of limited-access areas. This provision is necessary to prevent theft, loss, or diversion;~~

~~Paragraph (3) requires video surveillance in security rooms. This provision is necessary to prevent theft, loss, or diversion;~~

~~Paragraph (4) requires video surveillance in all areas containing surveillance-system storage devices, which shall contain at least one camera to record the access points~~

to such an area. This provision is necessary to prevent theft, loss, or diversion; and

Paragraph (5) requires video surveillance of the interior and exterior of all entrances and exits to the premises. This provision is necessary to prevent theft, loss, or diversion.

Subsection (d) requires the surveillance system be capable of continuous 24 hour recording at a minimum of 15 frames per second. The standard capture rate for video is 30 frames per second. This requirement is in line with the Bureau of Cannabis Control's Video Surveillance regulations. The premises may be licensed by both the Department and the Bureau; the Department decided to conform to Bureau requirements in order to make compliance more straightforward for licensees.

Subsection (e) requires that all recording and monitoring equipment be stored in a secure room or area of the premises so that access is controlled. A secure room must have a commercial grade lock. This provision is reasonably necessary to ensure that recording and monitoring equipment is not tampered with.

Subsection (f) requires that licensees ensure that all surveillance recordings are kept for a minimum of 90 days. The 90 days requirement is in line with the Bureau's regulation §5044(i). An unlawful act or violation of the regulations may not be discovered until days or weeks later. A 90-day retention requirement ensures the licensee has recordings dating back to when an event may have occurred. This provision is reasonably necessary to allow for review by the Department and/or the licensee.

Subsection (g) provides the licensee must make available all video surveillance recordings on the licensed premises to the Department and states notice that all video surveillance recordings are subject to inspection by the Department and that copies of any video surveillance recording be provided to the Department upon request. BPC §20160 requires storage of all records on the premises. This provision is reasonably necessary to protect against instances of diversions, and to allow the Department to inspect any video surveillance recordings for enforcement purposes.

Subsection (h) requires that video recording equipment to include date and time generators which display the current date and time of recorded events. This provision is reasonably necessary to verify the time and date that the recorded event took place in the case of an investigation. This subsection further clarifies that the displayed date and time cannot significantly obstruct the view of recorded images, which is necessary to ensure video recordings can provide the Department with necessary and relevant information during an investigation.

Subsection (i) specifies the conditions under which multiple licensees can share surveillance systems. If multiple licensees operate in the same building, it is reasonable to allow sharing of the systems, rather than require numerous cameras cover the exact

same areas of the building. This requirement conforms with regulatory provisions of the Bureau, as the building may house both Bureau and Department licensees. Specifically, the requirements of this subsection are as follows and are reasonably necessary so that the Department can properly exercise its oversight authority:

Paragraph (1): Each applicant or licensee shall disclose on their premises diagram where the surveillance recordings are stored. This provision is reasonably necessary for the Department to have accurate records on how shared premises are surveilled;

Paragraph (2): Each applicant or licensee 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. This provision is reasonably necessary in order for accurate records to be kept regarding security SOPs in a shred space;

Paragraph (3): All licensees shall have immediate access to the surveillance recordings to produce them pursuant to the requirements of this section. This provision is necessary to ensure the prevention of theft, loss, or diversion in a shared-use space;

Paragraph (4): All licensees shall be held responsible and subject to discipline for any violations of the video surveillance requirements. This provisions is reasonably necessary to prevent theft, loss, or diversion and to ensure each shared-use space licensee meets all the requirements of this section in order to operate their manufacturing premises.

Section 40207. Notification of Theft, Loss, or Diversion. This section is adopted to provide the method by which a licensee must notify the Department of suspected theft, loss, or diversion of cannabis or cannabis products. Licensees must report the theft or diversion to the Department and local law enforcement within 24 hours of the discovery. The Department has determined 24 hours is an acceptable amount of time in which to report suspected theft, loss, or diversion, as it allows the licensee time to review security footage as necessary, check track and trace, and determine if theft or loss has taken place. Notification to the Department is necessary in order for the Department to properly exercise its oversight authority, ensure diversion does not occur, and fulfill its mandate to protect public health and safety.

Section 40220. Permissible Extractions. This section describes the types of extraction methods permissible in California. This provision is reasonably necessary to provide clarity to the regulated industry, establish the rules and regulations necessary for the Department to administer the Act, and to make specific any details involved in extraction methods that the regulated industry must comply with and/or that pose a threat to public health and safety. Protecting public health and safety is a statutory requirement. (BPC §26011.5.)

Subsection (a) Based on information collected during the pre-regulatory meetings, the Department has established the following general categories of extraction types: mechanical/~~solvent-less extractions~~, chemical extractions with nonvolatile solvents, chemical extraction using professional closed-loop CO₂ gas extraction systems, chemical extractions with volatile solvents, and any method authorized by the Department pursuant to subsection (b). These categories represent the existing methods of extraction to the best of the Department's knowledge, but leave open the possibility for as-yet unknown types of extraction, as the cannabis business is constantly innovating new methods for extraction.

Paragraph (1) allows mechanical ~~or solvent-less~~ extraction methods. ~~These methods include screen or presses or other solvent-less extraction methods, such as screens or presses.~~ Mechanical extractions pose little safety risk to personnel, so there is no need at this time to impose additional requirements on mechanical extraction methods. This provision is reasonably necessary in order to make explicit that mechanical extraction methods are permissible in California.

Paragraph (2) allows chemical extractions using a nonvolatile solvent. This subsection also establishes the requirement that non-hydrocarbon-based solvents be food-grade. Nonhydrocarbon-based solvents primarily include various types of fats and oils, such as butter or olive oil. Because some solvent residue may remain in a cannabis product after the extraction process is complete, requiring the use of food-grade solvents is necessary in order to ensure that the product is safe to consume. This provision is intended to clarify the requirements of a nonvolatile solvent and is necessary to implement the Department's mandate to set standards for manufacturing activities.

Paragraph (3) allows CO₂ extractions and Paragraph (4) allows for the use of volatile solvent extractions. Both types of extractions are required to be conducted in a professional closed loop system designed to recover the solvent used. This provision is reasonably necessary to protect public health and safety. If a closed loop system is not used, volatile solvent vapors can collect in the air, posing a serious risk of fire or explosion if a spark is applied. Similarly, CO₂ can also build in the air, posing a risk of asphyxiation to personnel. Without the use of a closed system, the residual solvent represents a safety risk for the facility operators and a potential health risk for consumers. Specific requirements of the closed loop system are included in Section 40226 of these regulations.

Paragraph (5) allow for any other method authorized by the Department pursuant to subsection (b). The cannabis industry is new and innovative, and new systems of extraction are likely to be developed as the industry grows.

Subsection (b) allows an applicant or licensee to request approval from the Department to use other extraction methods, provided that the applicant or licensee submits a detailed description of the extraction methods, including any documentation that

validates the method and any safety precautions to be used to mitigate any risk to public or worker safety or health. Although the methods allowed in subsection (a) represent the existing methods of extraction to the best of the Department's knowledge, additional extraction methods are likely to be developed. This subsection will allow an applicant or licensee to use other methods, provided that they can establish the safety of the method and is reasonably necessary to provide for public health and safety should additional extraction methods be developed.

Section 40222. Volatile Solvent Extractions. This section specifies the requirements for manufacturers using volatile solvents for extractions.

Subsection (a) requires that hydrocarbon-based solvents be of at least 99% purity. Otherwise, the solvent may contain impurities that could be harmful for human consumption. The Department has set this standard after discussion with the Manufactured Cannabis Safety branch scientific team. Solvents with a higher percentage of purity are available (such as 99.5% or 99.9%), but impurities would be present in such small amounts that the Department determined 99% purity was sufficient. This provision is necessary to protect the health of consumers.

Subsection (b) requires volatile solvent extractions to be conducted in a closed loop extraction system that meets the requirements specified in Section 40225. A volatile solvent can form a significant concentration of vapor. If that vapor is flammable, a fire or explosion can result. A closed loop extraction system reduces the risk of fire or explosion by recapturing the solvent so that the vapor does not build up. The requirements of a closed loop system are further described below. This provision is reasonably necessary to protect the safety of facility personnel and/or any members of the public in the vicinity of the manufacturing operation.

Subsection (c) prohibits volatile solvent extractions from occurring in an area zoned residential. This provision is necessary to protect public safety by reducing the threat of explosions to surrounding areas.

Section 40223 Ethanol Extractions. This section is necessary to provide clarity as to the requirements for ethanol extractions.

Subsection (a) clarifies that ethanol used for post-extraction processing shall be food-grade, as they are intended for human consumption. This is in line with Section 40220 regarding non-volatile food-grade solvents.

Subsection (b) requires that ethanol extraction operations shall be approved by the local fire code official and shall be operated in accordance with Division of Occupational Safety and Health (Cal/OSHA) regulations, as Cal/OSHA is the agency responsible for oversight of workplace safety, and any other relevant state and local requirements.

Section 40225. Closed-Loop Extraction System Requirements. This section establishes specific requirements for closed-loop systems for volatile solvent, CO₂, chlorofluorocarbon, hydrocarbon, or other fluorinated gas extractions. This provision is necessary because these solvents pose a public safety risk. Volatile solvents can build up vapor, leading to a risk of fire or explosion. CO₂ can also build up, posing a risk of asphyxiation to personnel and bystanders. Closed loop systems are designed to mitigate these risks. The following provisions are necessary in order to ensure that closed-loop systems comply with established safety standards in order to protect the public in accordance with the Act.

Subsection (a) requires extractions to be conducted using a professional closed loop system. It also requires the system to be commercially manufactured and bear a permanently affixed and visible serial number. This ensures the system was created by a company that is regulated for compliance with equipment design and safety standards. This provision is necessary to ensure that the system has been commercially manufactured and built to accepted industry codes intended to protect operator safety.

This subsection further requires a licensed engineer to certify that the system was commercially manufactured, is safe for its intended use, and is built to codes of recognized and generally accepted good engineering practices as specified in paragraphs 1-4, specifically by the American Society of Mechanical Engineers, American National Standards Institute, Underwriter's Laboratory, or the American Society for Testing and Materials. These organizations are widely accepted as preeminent experts on engineering practices. This provision is necessary because the Department does not have the required engineering expertise to know if a system is built to all applicable standards for safe operation. The Department must therefore rely on the expertise of licensed professional engineers capable of evaluating the system to ensure public safety. This provision is necessary to protect personnel safety.

Subsection (b) requires that the closed-loop system, any other equipment used, the extraction operation, and the facility are approved for use by the local fire code official and meet any required fire, safety, and building code requirements. This provision is necessary to ensure the systems are compliant with fire and building codes in order to protect the public and workers.

Subsection (c) clarifies the certification document required pursuant to subsection (a) shall contain the signature and stamp of a California-licensed professional engineer and the serial number of the extraction unit being certified. This provision is reasonably necessary in order to ensure equipment used in extraction is safe to use with the intended solvent and in the intended manner. Mechanical engineering is outside of the Department's area of expertise and needs to instead rely on professional experts in order to best protect public safety.

Subsection (d) requires the licensee to establish and implement written procedures to

document to ensure 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. A failure of a closed loop system could cause serious bodily injury or have possibly fatal consequences, and could also cause severe property damage. Equipment that is not operating properly could cause explosions, fires, or asphyxiation. It is of utmost importance that licensees routinely verify that the machinery is operating properly. Because of the variety of equipment in use, the Department is not mandating verification within a specified time period. Some types of equipment may need maintenance more often than other types. Rather, the Department expects that licensees will determine the frequency required to verify their specific equipment and provide evidence to the Department that the actions were performed.

Subsection (e) requires a licensee to develop standard operating procedures, good manufacturing practices, and a training plan prior to producing extracts. This subsection further requires any personnel using solvents or gases in a closed loop system to create extracts to be fully trained on how to use the system, have direct access to applicable safety data sheets, and handle and store solvents and gases safely. This subsection is necessary to minimize the potential threat to public safety posed by improperly trained personnel operating a closed loop extraction system.

Subsection (f) requires the extraction operation to be operated in an environment with proper ventilation, controlling all sources of ignition where a flammable atmosphere is or may be present, and be operated in accordance with applicable Division of Occupational Safety and Health (Cal/OSHA) regulations and any other state and local requirements. This subsection is necessary to minimize the potential threat to public safety posed by closed loop systems.

Subsection (g) prohibits closed loop extraction operations from occurring in areas zoned residential. This is necessary to protect public safety.

Articles 3 & 4: Sections 40230 – 40264. No changes to the Initial Statement of Reasons. Although substantive changes have been made to this section in the modified text, the rationale and necessity initially stated are still relevant.

Section 40266. Product Complaints. This section is adopted to make specific the licensee's responsibilities related to product complaints. Product complaints are one method by which a licensee may be alerted to possible contamination or other product quality issues. A systematic approach to accepting and responding to product complaints is necessary to protect the public.

Subsection (a) requires that a qualified individual must review and investigate all product complaints. This provision is reasonably necessary to ensure that quality control

personnel have appropriate knowledge and experience, and that licensees are able adequately assess and investigate product complaints.

Subsection (b) requires quality control personnel to review and approve decisions regarding product complaints. This requirement is necessary to make specific the role of the quality control personnel in the product complaint process.

Subsection (c) requires that product complaint reviews and investigations performed by quality control personnel take into account all relevant batches and records associated with the product featured in the complaint. This requirement makes specific the responsibilities of the quality control personnel. A review of all records and relevant batches is necessary to properly evaluate if any manufacturing processes contributed to a failure in the product's quality.

Subsection (d) requires quality control personnel to maintain records regarding product complaints and any subsequent investigation. This provision is necessary in order for the Department to ensure that any potential public health threats have been adequately addressed. Paragraphs (1) – (7) of this provision (below) establish the records to be maintained and are necessary to ensure that accurate records are maintained by the licensee and are available for review by the Department for regulatory and/or inspection purposes. The specific records to be maintained in order to facilitate the review of product complaints are:

Paragraph (1): the name and description of the cannabis product involved. [This provision is necessary to ensure that the Department can accurately track specific cannabis products by name.](#)

Paragraph (2): the batch, lot, or control number of the cannabis product involved, if available. [This provision is necessary in cases of recall, the Department or licensee can identify other potentially impacted products.](#)

Paragraph (3): the date the complaint was received and the name, address, or telephone number of the complainant, if available. [This provision is necessary in order for the Department to contact the complainant and to keep accurate records of complaints against licensees.](#)

Paragraph (4): the nature of the complaint including, if known, how the product was used. [This provision is necessary in order for the Department to keep accurate records of complaints against licensees or known issues with a specific product.](#)

Paragraph (5): the reply to the complainant, if any. [This provision is necessary in order for the Department to keep records of proof of response to any complaints received by the licensee.](#)

Paragraph (6): findings of the investigation and any follow-up action taken when an investigation is performed. This provision is necessary for The Department to ensure that the licensee has investigated complaints and has responded

Paragraph (7): If an investigation is not conducted, the licensee is required to keep records of the reasons the licensee did not investigate the complaint. This provision is necessary to ensure that The Department may review said records to ensure that licensees have justifiable reasons for not investigating a complaint.

Subsection (e) defines “product complaint” and is reasonably necessary in order to provide clarity to the regulated industry.

Section. 40268 Recalls. This section requires each licensee to establish written recall procedures. In the event of product contamination, public health protection necessitates a recall of the contaminated product(s) in order to mitigate the threat to public health. Advance preparation of recall procedures is, likewise, necessary to protect public health. This section requires each licensee to establish and implement written recall procedures in the event that cannabis products are found to be misbranded or adulterated, and establishes that such procedures must include the following:

Subsection (a): the factors necessitating the recall. A recall plan is not going to be effective if the licensee does not know what circumstances would trigger it. This provision is necessary to protect public health.

Subsection (b): the personnel responsible for a implementing a recall. In cases in which quick action is needed, the personnel responsible for implementing a recall should already be known to the licensee and be prepared to take the established actions.

Subsection (c): notification protocols. Licensees must have mechanisms in place to contact the necessary persons in the event of a recall so that the product does not remain in the stream of commerce. The notification protocols must include the following:

Paragraph (1): a mechanism to contact all customers that have, or could have, obtained the recalled product. In the case of a manufacturer initiated recall, it is necessary that a manufacturer contact all customers (including other manufacturers or distributors) in a timely manner. Such communication may include outreach via media, if necessary and appropriate. This provision is necessary to protect the public in cases of recalled products.

Paragraph (2): a mechanism to contact any licensees that supplied or received the recalled product. Retailers and distributors may still have recalled product on hand. In order to ensure the products are not sold to consumers, the licensee must be able to notify other licensees who may hold the product. This provision is necessary for the

protection of the public health by ensuring that recalled products do not make their way into the market.

Paragraph (3): instructions for the return or destruction of the recalled product by the general public or other licensee. Notification of a recall must provide holders of the product with information on how to return or dispose of the product. Certain types of products might need special handling, such as vape cartridges recalled due to faulty batteries.

Subsection (d): procedures for the collection and destruction of any recalled product. This provision is necessary to ensure that licensees have procedures in place in advance to address collection and destruction of recalled product. Without established procedures, products collected during a recall may not be properly handled or destroyed, posing a further threat to public health.

Paragraph (1) requires that recalled products that are intended to be destroyed be quarantined for a minimum of 72 hours, and that the Department must be notified of such quarantine. Depending on when the recall occurs, the Department may need time to determine whether inspection and sampling of the recalled products is needed and to travel to the premises, without causing undue burden on the licensee to store potentially large quantities of a product meant for destruction. This notification and holding time is necessary so that the Department has sufficient time to inspect products and take samples if such activities are warranted.

Paragraph (2) requires that, following the quarantine period, the licensee shall render the recalled product unusable and unrecognizable on video as specified in section 40290 (Disposal of Cannabis and Cannabis Products) in order to prevent diversion. These requirements are necessary to ensure that recalled product is not diverted.

Subsection (e) requires the licensee to enter destruction events into the track-and-trace database. This provision is reasonably necessary to prevent diversion of recalled cannabis products.

Subsection (f) requires the licensee to notify the Department within 24 hours of initiating a recall. This provision is necessary in order to ensure dangerous or adulterated products are removed from the shelves as quickly as possible to protect the public from adulterated products.

Section 40270: No change to the Initial Statement of Reasons

Section 40272. Dried Meat Processing. This section provides the processes a licensee must adhere to in order to create dried meat products. In the April 2017 version of the regulations, meat products of any kind were prohibited. Numerous public comments were received arguing for the safety of dried meat products that are properly

processed. After further research, the Department concurred with the comments and this proposal has been amended to accommodate the request. The United States Department of Agriculture (USDA) [is the governmental authority that oversees meat processing and](#) provides guidance for traditional jerky manufacturing. This section establishes that dried meat must be processed in accordance with that guidance. This section further establishes that meat for processing must be obtained from commercially-available sources. The slaughtering process provides a significant opportunity for introduction of microbes, which is why it is so heavily regulated by the USDA. Limiting licensees to the use of commercially available meat, rather than slaughtering it, is necessary to protect public health.

[Section 40275: No change to Initial Statement of Reasons.](#)

Section 40277. Weights and Measures. This section is necessary to ensure the weighing devices used to weigh cannabis or cannabis products are consistent with requirements set forth in the Business and Professions Code in order to ensure accuracy of the quantity of products being tracked and sold.

Subsection (a) requires weighing devices used by a licensee to be approved, tested, and sealed in accordance with the requirements in Chapter 5 (commencing with Section 12500) of Division 5 of the Business and Professions Code, and registered with the county sealer consistent with Chapter 2 (commencing with 12240) of Division 5 of the Business and Professions Code. Approved and registered devices shall be used whenever:

Paragraph (1) Cannabis or cannabis product is bought or sold by weight or count;

Paragraph (2) Cannabis or cannabis product is packaged for sale by weight or count;

Paragraph (3) Cannabis or cannabis product is weighed or counted for entry into the track-and-trace system; and

Paragraph (4) The weighing device is used for commercial purposes as defined in section 12500 of Business and Professions Code.

Subsection (b) this subsection defines the term “count” as the numerical count of individual cannabis product units. This provision is necessary for clarity to the regulated industry.

Subsection (c) requires commercial shipments of cannabis and cannabis products to be weighed by a licensed weighmaster. [This provision is required under BPC §26060\(b\)\(1\).](#)

Section 40280. Training Program. This section is necessary to clarify the responsibility of the licensee to implement a training program in order to ensure that all

personnel are qualified for their job duties. Competent and qualified personnel are less likely to endanger public safety, personnel safety, or product safety and quality.

Subsection (a) establishes the minimum requirements of the training program that a licensee must implement. The following paragraphs are necessary in order to make specific the requirements all manufacturer training programs must include in order to protect public health and safety.

Paragraph (1): establishes a deadline of 30 days from the start of the employment date for personnel to receive training on the elements specified in subparagraphs (A)-(F) below. This provision is reasonably necessary to ensure that personnel will receive, ~~in a timely manner,~~ the information they need to safely perform their duties and to safely respond to emergency situations. Thirty days was determined to be a reasonable time in which to require employees to receive training, without being overly onerous on the business. Training sessions can be held one time per month to cover all employees hired in that timeframe. The required training elements are as follows:

Subparagraph (A) - identification and communication of health and safety hazards. This provision is reasonably necessary to protect the safety of the facility personnel and members of the public in the area where the licensed premises is located.

Subparagraph (B) – identification of hazards presented by all solvents used at the facility. This provision is necessary as some solvents used for cannabis manufacturing poses health and/or fire risks. Requiring personnel to be trained on the hazards posed by solvent will protect the safety of the facility personnel as well as the safety of the public in the area the licensed premises is located.

Subparagraph (C) – emergency procedures. In order to protect the safety of facility personnel, it is necessary that all personnel be trained in appropriate emergency procedures. Such training will protect facility personnel, as well as the nearby public and/or any emergency crews that might be affected due to an emergency at the licensed premises.

Subparagraph (D) – security procedures. This subparagraph is necessary to ensure the participation of all facility personnel in maintaining the security of the licensed premises in order to prevent instances of harm caused by improper handling of volatile or otherwise dangerous chemicals during the manufacturing process. This provision is reasonably necessary to protect the safety of the personnel and members of the public within the vicinity of the licensed premises, as well as to ensure the safety and quality of products with the potential to impact consumer safety and/or public health.

Subparagraph (E) – recordkeeping requirements. This requirement is part of the implementation of the records requirement specified in BPC §26160. The communication of record-keeping requirements to all personnel and the participation of

all personnel is necessary in order to provide the Department with current and accurate records of all relevant activities.

Subparagraph (F) – training requirements. This provision requires the licensee to inform their personnel of all training program requirements, and allows the licensee to include additional training requirements as appropriate. This provision is necessary to clarify the licensee’s responsibilities regarding the training of personnel so that the licensee may comply with the requirements of this section.

Paragraph (2): Establishes the specific training requirements that personnel must undertake prior to independently operating any aspect of the manufacturing process. These requirements are necessary to ensure personnel are qualified for their specific tasks. Unqualified or improperly trained personnel may pose a safety hazard to themselves, their supervisors, their fellow personnel, and/or to members of the public within the vicinity of the licenses premises. It is therefore necessary that personnel demonstrate an understanding of the procedures in which they are involved in order to protect public health and safety. Protecting public health and safety is a stated intention of the Act. The specific training elements of the training that must be provided to personnel are:

Subparagraph (A) – an overview of the manufacturing process and its standard operating procedures. This requirement is necessary to ensure that personnel are familiar with all relevant details regarding their specific duties.

Subparagraph (B) – quality control procedures. This requirement is necessary to ensure that personnel are familiar with procedures affecting the quality and safety of the cannabis product(s).

Subparagraph (C) – hazard analysis and control procedures. This requirement is necessary to ensure that personnel engaged in a process involving an identified hazard(s) are aware of the control procedures used to protect the safety and/or quality of the cannabis product(s).

Subparagraph (D) – the proper and safe usage of equipment or machinery. This requirement is necessary to ensure the personnel are knowledgeable as to the safe and proper use of facility equipment and machinery. Proper usage may help to reduce accidents and hazards affecting persons within the facility or within the vicinity of the licensed premises.

Subparagraph (E) – safe work practices, including appropriate use of any safety equipment. This requirement is necessary to ensure that personnel are aware of the practices intended to protect their safety and the safety of all persons in and around the licensed premises.

Subparagraph (F) – cleaning and maintenance requirements. This requirement is necessary to ensure that personnel are knowledgeable of procedures for cleaning and maintaining manufacturing areas, equipment and utensils, to minimize contamination of cannabis products. Contaminated products pose a health risk to personnel and/or members of the public.

Subparagraph (G) – emergency operations, including shutdown procedures. This requirement is necessary to ensure that, in the event of an emergency, personnel know what actions to take to minimize or prevent hazardous situations. As some of the processes employed in cannabis manufacturing may create or exacerbate hazardous situations, personnel knowledge of the emergency shutdown procedures is necessary in order to increase the likelihood that personnel will respond quickly to address such situations in the event of an emergency.

Subparagraph (H) – any additional information reasonably related to a person’s job duties. This requirement is necessary to ensure that personnel are aware of all information related to their job duties so that those duties will be performed in such a way as to protect personnel, public, and product safety.

Paragraph (3) requires a licensee that produces edible cannabis products to ensure that all personnel who prepare, handle, or package edible products successfully complete a food handler course accredited by the American National Standards Institute (ANSI). ANSI is a non-profit organization that develops widely accepted standards in a variety of industries, as well as performing accreditations to assess the competence of organizations’ conformance to standards. ANSI does not directly provide training courses, but rather accredits third-party providers of training.

The requirement for edible product manufacturers is modeled after the Department’s Cottage Food Program, which requires cottage food manufacturers to complete ANSI-accredited food handler courses within 30 days of licensure and every 3 years subsequent. Food handler courses cover the basic information on handling edible products to keep them safe for consumers, including personal hygiene, cross-contamination, temperature controls, and other elements of proper food safety. This requirement is reasonably necessary to ensure that licensees and personnel have the basic knowledge required for product safety, and in order to comply with HSC §113790 et seq. Food handler training can be done through online courses and costs roughly \$10-15 per course. Because a significant amount of training is required for new employees, these proposed regulations require that all personnel take the training within 90 days from the start of employment, rather than the 30 days required for cottage food manufacturers, and again every 3 years during employment. The 90-day timeline is intended to ensure that manufacturing operations have the knowledge necessary to protect public safety without imposing an undue burden on the regulated industry, and allows employers to train quarterly as new employees are hired. The three year

refresher period is intended to ensure those holding food handling cards keep up with any changes in regulations and code.

Paragraph (4) requires the licensee to ensure all personnel receive annual refresher training and that the information included in such trainings be updated as needed to ensure relevance and applicability. This provision is necessary in order to ensure that personnel remain informed of the most relevant safety and/or procedural information relating to their duties so that they will be better able to protect public health and safety.

Subsection (b) requires the licensee to maintain a written training record. This requirement is necessary so that the Department's inspectors can verify the licensee's compliance with the requirements of this subsection specified in paragraphs (1)-(4) below. As untrained personnel may pose a safety hazard to themselves, their supervisors, their fellow personnel, and/or to members of the public within the vicinity of the licensed premises, it is necessary to establish reasonable controls, such as verification of personnel participation in training requirements, in order to protect public safety. The training record must include, at a minimum:

Paragraph (1): a list of all personnel at the manufacturing premises, including, at minimum, the name and job duties of each. This provision is necessary so that the Department may protect public health and safety by ensuring compliance with the training standards specified in section 40280 et. seq. of this regulatory proposal.

Paragraph (2): documentation of all training topics and dates of training completion for all personnel. This provision is reasonably necessary for the Department to verify the licensee's compliance with the established training requirements.

Paragraph (3): the signature of the individual personnel and the licensee verifying receipt and understanding of each training or refresher training completed by the personnel. This provision is necessary so that the Department can verify licensee and personnel compliance with training requirements.

Paragraph (4): official documentation such as certificates or permits attesting to the successful completion of required training by personnel. This provision is necessary so that the Department can verify licensee and personnel compliance with training requirements.

Subsection (c) clarifies that a licensee is allowed to designate specific personnel to implement the required training and training verification activities described in section 40280 et. seq. provided such personnel have met the training requirements described in subsection 40280, subsection (b), et. seq. above. This provision is necessary to provide clarity to the licensee.

Subsection (d) clarifies that a licensee operating under a temporary license shall have applicable personnel complete training no later than 90 days after the effective date of the annual license. Added to provide a timeframe in which licensees in operation prior to the issuance of an annual license must train their existing employees. The requirement is clear for new employees, but not for existing employees. The Department selected a 90-day timeline is necessary to conform with the existing timeline to receive the food handler certification.

Section 40282. Inventory Control – Cannabis and Cannabis Products. This section establishes the requirement that the licensee must implement and maintain a written inventory control process for cannabis and cannabis products in order to prevent diversion. This section is reasonably necessary to protect the public from acts of diversion which may result in harm to public health and safety

Subsection (a) requires that a licensee implement and establish a written inventory control plan that accounts for the location and disposition of all cannabis and cannabis products at the licensed premises. The inventory control plan enables the licensees to keep track of the physical location of cannabis and cannabis products. While the track-and-trace requirements will log cannabis and cannabis product in and out of the facility, the inventory control plan will document where in the facility any cannabis or cannabis product is located. Keeping strict control over the location of cannabis will reduce potential for diversion. This provision is reasonably necessary to reduce the potential for diversion of cannabis or cannabis products which may cause harm to public health and safety.

Subsection (b) requires a licensee to reconcile all on-hand inventory of cannabis and cannabis products with the records in the track-and-trace database at least once every 30 days. This provision is reasonably necessary to ensure that all cannabis and cannabis products are accounted for on a regular basis so as to prevent opportunities for diversion. The April 2017 version of the regulations required reconciliation to happen every business day. Numerous comments indicated that this was an overly burdensome requirement. After further review, the Department concurred. In consultation with the other licensing authorities, the Department has amended the regulation to require reconciliation of on-hand inventory with inventory in track-and-trace every 30 days, which was deemed to be sufficiently frequent to ensure potential diversion is discovered while video surveillance recordings are still available without creating undue burden on the licensee.

Subsection (c) requires the licensee to conduct an audit if a discrepancy is found between the inventory and the track-and-trace database. This provision is reasonably necessary to ensure that the source of the discrepancy is identified and that appropriate measures are taken to rectify the discrepancy.

Subsection (d) requires that if the inventory reconciliation or audit conducted pursuant to subsections (b) and (c) respectively reveal a discrepancy that is more than five percent of the documented inventory, that the licensee notifies the Department within 24 hours of the discovery in order to document any loss, theft, or diversion as quickly as possible in order to keep records accurate. The Department understands 100% accuracy in inventory may be unrealistic and does not want to create a situation in which licensees constantly notify the Department of small amounts of missing inventory. However, due to the nature of the licensee's inventory, the Department must be aware of potentially stolen or diverted cannabis or cannabis products. This provision is necessary in order for the Department to be made aware of discrepancies quickly and in order to maintain accurate records.

Section 40290: No change to Initial Statement of Reasons.

Section 40292: No change to Initial Statement of Reasons.

Section 40300. Prohibited Products. This section provides the types of cannabis products that are prohibited due to their increased risk to public health. The Department's statutory mandate in BPC §26011.5 is to place public health and safety as the paramount factor in determining policy. The Department has determined that the following products pose a higher risk to public health, either due to the nature of the product itself or because the manufacturing process used for the product has a higher risk of contamination.

Subsection (a) prohibits infusion of alcoholic beverages, as defined by BPC §23004, and clarifies that an alcoholic beverage does not include tinctures that meet the requirements of Section 40308. The concurrent consumption of alcohol and cannabis has been shown to result in increased peak concentration of cannabinoids in the blood and plasma of human subjects. This concurrent consumption has the potential of altering the effect of the intended dosage of cannabis products, as well as increasing the level of physiological and psychological impairment of cannabis users.

Furthermore, BPC §26054(a) prohibits the sale of alcoholic beverages at a licensed premises; therefore, no licensee can sell an alcoholic beverage infused with cannabis.

Finally, this subsection clarifies that tinctures meeting the requirements of Section 40308 are not prohibited. Tinctures are a very common cannabis delivery system, particularly in the medicinal market. Tinctures are made by combining cannabis plant material with a medium – typically glycerin or ethanol – to create a product that is intended to be consumed sublingually in small doses. Further discussion on tinctures is included under Section 40308.

Subsection (b) prohibits any product containing any non-cannabinoid additive that would increase potency, toxicity, or addictive potential, or that would create an unsafe

combination with other psychoactive substances. This includes adding any caffeine that is not naturally occurring in foods such as coffee and chocolate. Naturally occurring caffeine is difficult to remove and is generally understood by the public to be contained in coffee and chocolate. There is currently very limited scientific data available on the full health effects of cannabis use at various doses and frequency, and on the combination of cannabis with other psychoactive substances. It is not possible, therefore, to know with any certainty the full scope of potentially dangerous or damaging physiological and/or psychological effects that may occur with concurrent use of cannabis and other physiologically and/or psychologically active substances. This subsection further specifies that the prohibited additives include nicotine and caffeine. The FDA has determined that caffeine (a stimulant) in certain alcoholic (a depressant) beverages is an “unsafe food additive” due to the unpredictable negative effects of the two substances. Cannabis can similarly behave as a depressant, causing the same unsafe combination with caffeine as does alcohol. In order to protect public health, the Department has made a determination to prohibit caffeine in cannabis products.

Subsection (c) prohibits any cannabis product that must be held at or below 41 degrees Fahrenheit to keep it safe for human consumption. Certain products are capable of supporting the growth of infectious or toxigenic microorganisms if held above 41° F. This prohibition is necessary to protect cannabis product consumers from foodborne illnesses that might cause serious illness or death. The FDA has developed a method by which food processors may determine if their product needs to be held below 41° F to keep it safe for human consumption. A manufacturer can use this guidance to determine whether the product will need to be kept cold. If so, the product cannot be infused with cannabis. Examples of such products include cream or custard-filled pies; pies or pastries which consist in whole or in part of milk or milk products, or eggs; and meat-filled pies or pastries.

There are two exceptions to the restriction on refrigerated products: juice that is processed in accordance with the requirements of Section 40270, and infused butter manufactured in accordance with subsection (f). After juice has been pasteurized, or otherwise processed to reduce microorganisms, it presents a reduced public health threat, although it may be necessary to keep the juice product at a reduced temperature. Infused butter is allowed by statute to be manufactured as a cannabis product. Without this exception, it appears as if there is a contradiction between the allowance of butter and juice and the prohibition on refrigerated products.

Subsection (d) prohibits any thermally processed low-acid cannabis product packed in a hermetically sealed container, that, if it were a food, would be subject to the manufacturing requirements of Title 21, CFR, Part 113 and subsection (e) prohibits any acidified cannabis product that, if it were a food, would be subject to the manufacturing requirements of Title 21, CFR, Part 114. The Department has chosen to use the definition in the Federal Food and Drug regulations so that manufacturers can more

easily compare their cannabis product to the manner in which the FDA would regulate the identical food product. The types of products covered in this prohibition present a significant risk of botulism contamination if not properly processed. The pathogen *Clostridium botulinum*, which causes botulism, is a common microorganism in the environment. When held in anaerobic conditions, such as those created by vacuum packing or canning, the microorganism can proliferate, creating a potent neurotoxin. The spores are heat-resistant and can survive in foods that are incorrectly or minimally processed. Almost any type of food that is not very acidic (pH above 4.6) can support the growth of the microorganism.¹ Botulism has a high mortality rate and is especially concerning for immunocompromised individuals. It is necessary to prohibit the manufacture of these products because of the potential public health threat.

Subsection (f) prohibits any juice that is not shelf-stable or that is not processed in accordance with Section 40270. Numerous types of microorganisms can be found on fresh fruits and vegetables, including yeasts, molds, *Pseudomonas*, *Erwinia*, *Salmonella* spp., *Shigella* spp., *Y. enterocolitica*, *E. coli* O157:H7, *L. monocytogenes*, *C. botulinum*, and *B. cereus*. Fruits and vegetables, including juices, that are not subjected to a type of processing that can destroy the microorganisms (such as pasteurization), can pose a significant threat to human health, especially for immunocompromised individuals.

Subsection (g) prohibits dairy products of any kind, as prohibited by subdivision (t) of section 26001 of the Act, 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 (as allowed by Food and Agriculture Code section 37104). The statutory prohibition on cannabis-infused dairy products is included in the regulations in order to provide clarity and ease of use by including all prohibited products in one section.

Subsection (h) prohibits meat products other than dried meat products prepared in accordance with Section 40272. Meat offers a rich environment for microbial growth. In order to be processed safely, very careful handling and processing is required. In addition to HACCP controls, meat must be handled in accordance with specific guidelines issued by the United States Department of Agriculture. Due to the high potential for contamination and corresponding risk to public health, the Department has determined that a prohibition on meat products other than dried meat product is necessary to protect public health.

Subsection (i) prohibits seafood products of any kind. Seafood is highly susceptible to microorganism growth. Because of the potential public health threat, seafood-related cannabis products of any kind are prohibited.

¹ USFDA, Bad Bug Book, The, Foodborne Pathogenic Microorganisms and Natural Toxins (2012).

Subsection (j) prohibits 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. This subsection further clarifies that candy or snack food items may be used as ingredients in a cannabis products, provided that the candy or snack food is unrecognizable in the final product and the label does not list the candy or snack food. BPC §26130(b)(5) prohibits edible products that could be easily confused with non-cannabis candy and food. This provision is intended to reduce potential confusion for consumers and reduce the possibility of unintentional consumption.

Subsection (k) prohibits any cannabis product that the Department determines, on a case-by-case basis, is attractive to children, as defined in Section 40410. This provision is necessary as the industry is constantly evolving and developing new product names and packaging, and the Department must be able to review products that may be attractive to children in a frequently changing market landscape;

Subsection (l) prohibits any cannabis product that the Department determines, on a case-by-case basis, is easily confused with commercially available foods that do not contain cannabis. This provision is necessary as new products are constantly being developed, and the Department must be able to review cannabis products for similarity to commercially available foods in a constantly changing market landscape.

Subsection (m) prohibits any cannabis product in the shape of, or imprinted with the shape of, a human being, either realistic or caricature, animal, insect, or fruit. Edible products are statutorily prohibited from being designed to be appealing to children (BPC § 26130(c)). The Department has determined that products in the specified shapes are especially appealing to children. Products intended to be consumed by children, such as fruit snacks, are frequently shaped like animals, insects, or fruit. This prohibition is intended to reduce the possibility that a child may be attracted to the cannabis product. This restriction is also based on a similar restriction in Oregon.

Section 40305: No change to Initial Statement of Reasons.

Section 40306: No change to Initial Statement of Reasons.

Section 40308: No change to Initial Statement of Reasons.

Section 40315: No changes to Initial Statement of Reasons

Section 40330. Failed Product Batches. This section establishes the requirements for cannabis products that fail testing requirements.

Subsection (a) requires a cannabis product batch that fails any testing requirement established by the Bureau to be destroyed unless a corrective action plan for

remediating or reprocessing is approved by the Department. A product batch that fails testing requirements is considered to be adulterated. However, BPC §26110(c)(2) specifies that the Department may allow a failed cannabis batch to be transported to a manufacturer for remediation. This section further provides that corrective action plans shall be approved by the Department on a case-by-case basis. Given the variety of types of cannabis products and the range of contaminants for which the cannabis batch may fail testing, it is not feasible at this time for the Department to establish comprehensive requirements in regulation. Therefore, this section clarifies that failed product batches shall be destroyed unless:

Paragraph (1) the cannabis product can be remediated by relabeling pursuant to subsection (d).

Paragraph (2) a corrective action plan for remediation or reprocessing is approved by the Department pursuant to subsection (e). Cannabis or cannabis concentrate that failed testing requirements would not be suitable to move in the supply chain unless a remediation plan is approved by the department as it is considered adulterated. The manufacturer licensee is responsible for ensuring that they can remediate the product prior to receiving it. They would submit the plan to the Department, upon approval, accept the product to be remediated according to the plan. This section is necessary to provide an opportunity for failed cannabis batches to be retested without a licensee violating other sections of the regulations.

Subsection (b) specifies that remediation and reprocessing shall also comply with requirements and procedures established by the Bureau. The Bureau also has statutory authority in BPC §26110(c)(2) to establish requirements for remediation. This provision is necessary to inform manufacturer licensees that the Bureau may have additional requirements to be aware of.

Subsection (c) specifies that, except as provided in subsection (d), edible cannabis products that fail laboratory testing cannot be remediated. Reprocessing edible products poses a public health risk as it increases the potential for contamination to be introduced into the product. This section further provides that cannabis products that contain contaminant levels that render the product adulterated cannot be mixed with other cannabis products to decrease the contaminant level to an acceptable range. This requirement is adopted from the USFDA food manufacturing regulations ([21 C.F.R. § 110](#)) and is necessary to protect public health and safety.

Subsection (d) states that a cannabis product that is determined to be labeled with an incorrect amount of any cannabinoid or terpenoid can be remediated by relabeling the product with the correct information based on the certificate of analysis, provided that the THC limits in Section 40315 are met.

Paragraph (1) further provides that if the relabeling is to be done by the distributor, the manufacturer must notify the Department within three business days. The Department has determined three business days is a reasonable amount of time to identify the need to relabel, perform the relabeling, and notify the Department of said activities. This notification shall be given to the Department via email and shall include a copy of the Certification of Analysis for the batch and the name and license number of the licensee relabeling the product. The Department needs to be informed of product batches in which cannabinoids do not conform to the intended cannabinoid content. Such discrepancies may indicate problems with the manufacturing process and in order to properly exercise its oversight authority, the Department must be notified.

Subsection (e) requires that expect as provided in subsection (d), any cannabis product batch, including edible cannabis products, that fails laboratory testing or quality assurance shall not be remediated or reprocessed unless the Department has approved a corrective action plan submitted by the manufacturer licensee. The section further clarifies that the corrective action plan must include a description of the how the product or harvest batch will be remediated. Corrective action plans regarding remediation of edible cannabis products that do not meet the standards under subsection (d) will be reviewed by the Department on a case-by-case basis. BPC §26110(c)(2) states a cannabis batch that fails testing may be transported to a manufacturer for remediation as allowed by the Department. BPC §26133(c) states if an adulterated or misbranded product is embargoed by the Department, it can be corrected by proper labeling or additional processing under the supervision of the Department. Taken together, the Department has interpreted the statute to require Department oversight of remediation of failed cannabis batches. This provision is necessary to ensure remediation is done in a manner that protects public health.

Subsection (f) requires remediation, reprocessing, or the use of a failed harvest batch to be documented in the manufacturing records. This provision is necessary to ensure that in cases of recall, the Department has accurate information. This subsection further clarifies that remediated batches or cannabis products produced from remediated batches are required to go through full testing again. This provision is necessary to protect public health and ensure that remediated batches or products made from remediated batches are safe for consumption.

Section 40400: No change to Statement of Reasons

Section 40401: No change to Statement of Reasons

Section 40403: No change to Statement of Reasons

Section 40404. Labeling Requirements: Pre-Rolls and Packaged Flower. This section contains the labeling requirements for packages of pre-rolls and dried flower. Required information is divided into the primary panel and the information panel as

described below. During the effective period of the emergency regulations, the Department received numerous questions regarding the requirements for packages of cannabis and pre-rolls. Based on the volume of questions received, the Department has established the following requirements that align with the requirements of the Act:

Subsection (a) requires the labeling for a package of pre-rolls or packaged flower include a primary panel information with type size of no less than 6 point font, [the minimum allowable under the USFDAs food labelling guidelines \(21 C.F.R. § 201.66 and § 40405\(a\) of these regulations\)](#), that contains the following information:

Paragraph (1) requires the identity of the product. This provision is reasonably necessary so that the flower or pre-roll from each batch may be tracked once released from the manufacturing facility. Tracking is critical for recall purposes, as well as for enabling the licensee to investigate their manufacturing processes for any failures that might be responsible for a product recall.

Paragraph (2) requires the net weight of cannabis in the package in both metric and U.S. customary units. BPC §26120(c)(1)(B)(2) requires the listing of the net weight for dried flower.

Paragraph (3) requires the universal symbol. The cannabis product symbol provides a method of informing people that the product contains cannabis and helps to protect public health and safety by reducing the potential for unintended consumption.

Paragraph (4) requires the cannabinoid content as specified in Section 40409(b). THC and CBD content is one of the primary elements consumers will look for when purchasing a cannabis product, prominently displaying content levels on the primary panel of a label will ensure that this information is easily accessible to the consumer

Subsection (b) requires that the informational label for a package of pre-rolls of packaged flower shall include the following information in a type size no less than 6 points font and in relation to the size of the informational panel and container:

Paragraph (1) requires the unique identifier issued by the track-and-trace system. This is a statutory requirement.

Paragraph (2) requires the licensed cultivator or licensee packaging the product (either the legal business name or the registered DBA listed on the license certificate), and its contact number or website address.

Paragraph (3) requires the date of packaging for retail sale. This informs the consumer when the flower or pre-roll was packaged for sale and in turn how long it has been on the shelf.

Paragraph (4) requires the label to include 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.”

Subsection (c) clarifies that nothing in this section prohibits the inclusion of additional information on the label, provided that the label does not violate the requirements of Section 40410.

Section 40405. Primary Panel Labeling Requirements: Manufactured Products to describe the requirements of the label’s “primary panel.” The “primary panel” is defined in Section 40100 as the part of the label that is most likely to be shown to the customer under conditions of retail sale (i.e. the “front” of the product package). The primary panel contains the basic information the consumer will need to make informed decisions capable of affecting their health and safety. [The concept of a primary panel was modeled after the USFDA requirements for labeling \(21 C.F.R. § 101.1\).](#)

Subsection (a) establishes the minimum size for the text of a label’s primary panel as 6 point font [or no less than 1/12 of an inch.](#) Product information will not be effective if it is too small to read. Food manufacturing regulations set the minimum text size as 1/16 of an inch, roughly the equivalent of 4.5 point font. Due to the nature of cannabis products, this provision is intended to ensure that information can be easily read by the consumer and any other individual who may have access to the product, in order to mitigate instances of unintended consumption that pose a threat to public health and safety.

Paragraph (1) requires the identity of the product to be printed on the label [in a text size reasonably related to the most prominent printed matter on the panel.](#) Identity of the product is defined in Section 40100 as the name by which the product is most commonly known. Further provisions of this regulation require opaque packaging of edible products, thereby obscuring the product from view. The product identity will ensure consumers have accurate information on the contents of the package.

Paragraph (2) requires that the label include the cannabis product symbol, which is defined in Section 40412. The cannabis product symbol provides another method of informing people that the product contains cannabis and helps to protect public health and safety by reducing the potential for unintended consumption.

Paragraph (3) requires the label on a cannabis product to provide the net weight or volume of the contents of the package, listed in both metric and U.S. customary units.

While BPC §26120(c)(1)(B)(2) only requires the listing of the net weight for dried flower, the Department made the policy decision that the net weight or volume should be listed for all cannabis products. This is a standard requirement in food manufacturing so that consumers can verify the contents of the package are in accordance with what has been purchased.

Paragraph (4) requires the cannabinoid content as specified in Section 40409. This provision is necessary to clarify that specific information related to cannabinoid content is required to be on the primary panel of the label. Because THC and CBD content is one of the primary elements consumers will look for when purchasing a cannabis product, prominently displaying content levels on the primary panel of a label will ensure that this information is easily accessible to the consumer.

Subsection (b) allows any additional information to be added to the label, including the content of other cannabinoids or terpenes to be printed on the label if the information has been verified by a licensed testing laboratory. Many familiar with cannabis attribute certain effects to specific terpenes, and some consumers are interested in knowing the specific terpenes in the product—and the same can be said of cannabinoids. Because there are over 100 known terpenes and a strain of cannabis could contain multiple terpenes, the Department is concerned that requiring a full listing could negatively impact the readability and effectiveness of the product label. However, in the interest of truth in labeling, if specific terpenes or other cannabinoids are claimed to be present that information must be validated by an independent laboratory.

Section 40406: No change to Statement of Reasons

Section 40408. Informational Panel Labeling Requirements to specify the information that needs to be included on the remaining portion of the label, known as the “informational panel.” The informational panel is defined in Section 40100 as the remaining portions of the label that are not the primary panel. The following paragraphs establish the information that needs required to be included on the informational panel:

Paragraph (1) of subsection (a) requires the name of the licensed manufacturer and a contact number or website address. For purposes of product complaints, consumers must to be able to contact the manufacturer of a product.

Paragraph (2) of subsection (a) requires the date of manufacture and packaging. This is a statutory requirement and is included here so that all cannabis product labeling requirements can easily be found by the public or the regulated industry.

Paragraph (3) of subsection (a) specifies that the GOVERNMENT WARNING mandated by statute in BPC §26120 (c)(1)(A) and (B) and outlined in §40404(b)(4) is required to be printed on the informational panel. This specification is necessary to provide clarity

to the regulated industry as to where on the label the mandated statement is required to be printed.

Paragraph (4) of subsection (a) requires that the label include the statement “FOR MEDICAL USE ONLY” if the product meets certain specifications. BPC §26120(c)(8) requires that medicinal cannabis products sold at a retailer be labeled with the above statement. This provision makes specific that statutory requirement by establishing that products that ~~are either~~ (subparagraph A) the manufacturer intends the product to be sold only to medicinal customers; (subparagraph B) the product is an orally-dissolving product containing more than 100 mg of THC in the package; or (subparagraph C) the product is a topical cannabis product or ~~cannabis orally-consumed~~ concentrate and contains more than 1,000 mg THC per package. This provision is necessary to clarify which products are required to be labeled as FOR MEDICAL USE ONLY.

Paragraph 5 of subsection (a) requires all product ingredients to be listed in descending order of predominance by weight or volume. Listing ingredients in descending order of predominance is a commonly accepted standard for product labeling required by the USFDA 21 C.F.R., Part 101. Subpart A. This provision is intended to provide clarity and ease of access to ingredient information to the public in order that they may make safe and informed choices regarding the consumption of cannabis products. This paragraph further clarifies that subingredients (for example, if chocolate chips are an ingredient in the product, the ingredients of the chocolate chips are considered subingredients) can be listed parenthetically after the ingredient (subparagraph A) or can be listed among the individual ingredients in descending order of predominance (subparagraph B).

To illustrate using chocolate chip cookies as an example:

- Subparagraph A addresses an ingredient list as: Enriched Flour (wheat flour, niacin, iron, folic acid), Semisweet Chocolate Chips (sugar, chocolate, cocoa butter, dextrose, soy lecithin), Sugar, Baking Soda, Natural and Artificial Flavor.
- Subparagraph B would permit the same ingredient list to be: Enriched Flour, Semisweet Chocolate Chips, Sugar, Baking Soda, Natural and Artificial Flavor, chocolate, cocoa butter, niacin, iron, folic acid, dextrose, soy lecithin.

Paragraph (6) of subsection (a) requires major food allergens included in the product to be listed. This is a statutory requirement. This provision further specifies that any ingredient, flavoring, coloring, or incidental additive containing a major food allergen must also be noted on the information panel. Allergic individuals may react to allergens used as both primary and/or component ingredients in a cannabis product, necessitating that the Department clarify that *all* potential sources of food allergen allergens must be considered and listed on the informational panel in order to protect the health of the consumer.

Paragraph (7) of subsection (a) requires the names of artificial ~~food~~ colorings used in the product. Some individuals are sensitive to artificial food colorings; this requirement is necessary to protect the health of the consumer.

Paragraph (8) of subsection (a) requires that edible product labels list the amount of sodium, sugar, carbohydrates, ~~protein~~, and total fat per serving in grams or milligrams. This is a standard practice for food-related labeling required by the FDA, 21 CFR, Part 101. Subpart A. However, this section is not intended to be used as a nutritional guide as required by the FDA for food, it will provide consumers with information necessary to protect their health.

Paragraph (9) of subsection (a) requires instructions for use and any preparation necessary prior to use to be listed. Instructions for use or application can cover a wide variety of information, such as how to determine a serving for edible products, how to consume tinctures, how to prepare the skin for transdermal products, or whether the product should be shaken prior to use. Instructions for use are best provided by the manufacturer and must be included on the label so that the consumer can easily find the information.

Paragraph (10) of subsection (a) allows the manufacturer to print an expiration, “best by” or “use by” date on the label. Stability studies to determine a date by which a product retains its best quality are common and well-established in food and drug manufacturing, but the same level of study has not been conducted on cannabis. If a manufacturer chooses to establish a best by date, this provision specifies where on the labeling the information should be included. If the manufacturer elects not to include a best by date, consumers will still be able to ascertain the product’s freshness through the required date of manufacture printed on the label.

Paragraph (11) of subsection (a) requires the unique identifier issued by the track-and-trace system. This is a statutory requirement. It is included here for clarity. This paragraph also allows the manufacturer to include a batch or lot number.

Paragraph (12) of subsection (a) If the cannabis product is perishable or is perishable after opening, the statement, “KEEP REFRIGERATED” or “REFRIGERATE AFTER OPENING,” as applicable. This subsection is necessary in order to ensure public health through the prevention of the growth of bacteria or other adulterations or pathogens in edible cannabis products.

Subsection (b) establishes the minimum size for the text of a label’s informational panel as 6 point font or no less than 1/12 of an inch, for the same reasons as specified for the primary panel. However, because some cannabis product packaging may be too small to include all of the required information, subsection (c) allows that the information may be provided through supplemental labeling (such as an insert). This provision is

necessary so that the consumer is provided with readable information needed to protect their health.

Subsection (d) repeats the language in Section 40405(b) for the informational panel.

Section 40409: No change to Statement of Reasons

Section 40410: No change to Statement of Reasons

Section 40411: No changes to the Statement of Reasons.

Section 40412: No change to Statement of Reasons

Section 40415. Packaging. This section establishes the requirements to which packaging for manufactured cannabis products must adhere.

Subsection (a) requires that the packaging protect the product from contamination and does not expose the product to any toxic or harmful substance. Protecting cannabis products against contamination between manufacturing and purchase by the consumer is the basic function of a package and helps to ensure against negative health impacts to public safety. Furthermore, an adulterated product is one whose container is composed of any poisonous or deleterious substance. This provision is reasonably necessary for the Department to ensure products are not adulterated and are safe for human use or consumption.

Subsection (b) requires that the package be tamper-evident. This is a statutory requirement under BPC §26120(a).

Subsection (c) requires the packaging to be ~~child-resistant as specified in Section 40417. A key element of public health protection is decreasing the likelihood that children or unsuspecting adults could accidentally ingest cannabis products. Child-resistant packaging is a statutory requirement (BPC §26120(a)) and is necessary to protect public health and safety~~ resealable, if the product has multiple uses. This is a statutory requirement under BPC §26120(a). The Department has clarified that a resealable package is only required if a product has multiple uses as there is no regulatory or public safety purpose to create a resealable package for a product with a one-time use.

Subsection (d) prohibits the packaging from imitating any package used for products typically marketed to children. The Act prohibits the packaging of cannabis products from being appealing to children (BPC §26120(b)). If cannabis product packaging resembles packaging commonly used for children's products, children could be confused between products at great risk to their health. This provision is reasonably necessary to protect public health and safety.

Subsection (e) requires the packaging to be opaque if the package contains an edible product. Many cannabis products resemble traditional food products that may be especially appealing to children, including cookies, brownies, candies, chocolates, and beverages, and which may be confused with traditional items if glimpsed through transparent packaging. This provision is therefore reasonably necessary in order to mitigate situations in which a child may accidentally ingest a cannabis product that looks like a traditional food product. This section further defines an amber bottle as opaque for the purposes this subsection. Amber bottles are commonly used for medication and beer, products that are not intended for consumption by children. The Department believes that amber bottles – a packaging form that is culturally associated with adult products – will provide sufficient public health protection.

Subsection (f) provides that bottles may utilize a single, clear, vertical strip no wider than 0.25 inches for the purpose of determining serving amounts. This size was determined by the Department to be a reasonable size for viewing of the cannabis product inside the bottle sufficient to determine the amount consumed, without being so broad as to negate the purpose of an opaque bottle, based on bottles currently in use in the market. During the effective period of the emergency regulations, the Department received numerous requests to allow for this exception to the requirement for opaque bottles. The Department determined that this exception was a reasonable allowance that will provide for greater consumer understanding, without threatening the public health protection purpose of opaque packaging requirements.

Section 40500. Record Keeping Requirements. This section defines the specific records related to commercial cannabis activity that each licensee must maintain, and the requirements, including timeframes and location, for retaining these records. Licensee are required by statute to keep accurate records on the premises and record retention is fundamental to an effective regulatory oversight program. It is necessary for required records and documentation to be retained and made readily available to Department staff. In the absence of specific record retention requirements, licensees would have the discretion to dispose of or destroy business records that often serve as the primary basis for determining statutory and regulatory compliance.

Subsection (a) requires a licensee to maintain specified documents on the premises at all times and to make the records available to the Department upon request. These are statutory requirements in BPC §26160(c) and (d).

Paragraphs (1), (2), and (3): the licenses issued by the Department, other state licensing authorities, and the local jurisdiction, and further requires the Department-issued license to be prominently displayed. This protocol is widely used by licensing agencies for many types of licenses. This section is necessary to clarify the Department's expectation of a licensee to post their license and to provide regulatory bodies consistency in their ability to verify state licensure.

Paragraph (4): the premises diagram. In conducting a records review, the Department must be able to readily access the premises diagram.

Paragraph (5): the current standard operating procedures. Standard operating procedures are an important oversight tool for Department staff. When conducting an inspection, the Department will need ready access to the standard operating procedures currently in use by the licensee.

Paragraph (6): shipping manifests. This paper record trail provides an important tool to track the movement of cannabis throughout the chain and to ensure that licensees are only conducting business with other licensees.

Paragraph (7): personnel records, including training logs. Personnel records are necessary for the Department to determine whether personnel are trained in accordance with requirements.

Paragraph (8): contracts with other licensees regarding commercial cannabis activity. This section is necessary in order for the Department to accurately track sales between licenses to ensure prevention of theft, loss, or diversion.

Paragraph (9): Financial records related to the commercial cannabis activity. This provision is necessary so the Department can ensure that commercial activities are conducted with other licensees, and so that other oversight agencies can track that appropriate taxes are being paid.

Paragraph (10): sales invoices and receipts. This is a statutory requirement in BPC §26161 and is included here for clarity to the regulated industry.

Paragraph (11): any other documentation or record required by law to be kept by the licensee. This provision is necessary to clarify to licensees the retention requirements for all required records and documentation.

Subsection (b) requires records to be kept for a period of seven years. This is a statutory requirements (BPC §26161) and is included here for ease of the regulated industry. This subsection further provides that outdated standard operating procedures shall be maintained in a way that onsite employees cannot mistakenly access outdated information. During the public comment period for the rescinded medical cannabis regulation package, the Department received concerns that keeping standard operating procedures for seven years could create confusion for employees. This provision has been added to clarify that the licensee must keep the records, but maintain them in a manner so that employees cannot mistakenly access them.

Subsection (c) requires all documentation to be maintained in English. This is necessary to ensure documentation can be properly read and understood by the Department and other oversight agencies. However, the Department acknowledges that there may be a legitimate business need to keep and to provide employees information in languages other than English. This subsection is necessary to clarify that documents are allowed to be maintained in other languages as needed, provided that the documentation is also kept in English.

Section 40505. Sales Invoices and Receipts. Every sale or transport of cannabis or cannabis products from one licensee to another licensee must, per statute, be recorded on a sales invoice or receipt. Sales invoices and receipts may be maintained electronically and must be filed in such a manner as to be readily accessible for examination by employees of the regulating agencies. This section is necessary to prevent the diversion of product to the illegal market during transfer and to allow the opportunity for the Department, other state licensing authorities, any state or local law enforcement, and the California Department of Tax and Fee Administration to verify legitimacy of the sale and off-site movement of cannabis or cannabis products. This section is further necessary to ensure that licensees are tracking movement of product prior to their inventory being in track and trace; and that these records are retained after inventory is inputted in track and trace.

Subsection (a) requires that the licensee shall prepare a sales invoice or sales receipt for every sale, transport, or transfer of cannabis product 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. [This provision is required under BPC §26161\(a\).](#)

Subsection (b) requires that each sales invoice or receipt shall include the following information so that sales can be tracked back to the point of origin:

Paragraph (1) Name, address, and license number of the seller. [The name and address of the seller is required by required under BPC §26161\(b\); the requirement to add the license number was included so the licensing agencies can ensure the parties to the sale are licensed;](#)

Paragraph (2) Name, address, and license number of the purchaser. [The name and address of the seller is required by required under BPC §26161\(b\)\(1\); the requirement to add the license number was included so the licensing agencies can ensure the parties to the sale are licensed;](#)

Paragraph (3) Date of sale, transport, or transfer. [This information is required under BPC §26161\(b\)\(2\).](#)

Paragraph (4) Invoice or receipt number. This information is required under BPC §26161(b)(2).

Paragraph (5) Kind, quantity, size, and capacity of packages of cannabis or cannabis product sold, transported, or transferred. This information is required under BPC §26161(b)(3).

Paragraph (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. This information is required under BPC §26161(b)(4).

Subsection (c) states that 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. This provision is necessary so licensees can calculate the proper sales price to record on the invoice and is modeled after the California Department of Tax and Fee Administration’s emergency cannabis tax regulation, Section 3700 of Chapter 8.7 of Title 18 of Division 2 of the California Code of Regulations.

Subsection (d) requires that invoices and receipts for the sale, transport, or transfer of cannabis or cannabis products shall not be comingled with invoices covering other commodities. This provision is reasonably necessary in order to keep accurate records of sales and prevent diversion and is required under BPC §26161(a).

Article 2. Track-and-Trace System. Licensees are required by statute to utilize the track-and-trace system established and administered by CDFA. This article establishes the requirements for manufacturer licensees in their use of track-and-trace, which is designed to record the movement of cannabis and cannabis products and monitor commercial cannabis activity.

This Article is required in order for Department regulations to be consistent with CDFA’s regulations on the track-and-trace system. CDFA is the lead agency and has established the requirements for all licensees. This provision is included in the Department regulations so manufacturer licensees understand the requirements for using the track-and-trace system. All subsequent sections and their subsections are required to conform Department regulations with requirements established by CDFA.

Section 40510: No change to Initial Statement of Reasons

Section 40512: No change to Initial Statement of Reasons

Section 40513: No change to Initial Statement of Reasons

[Section 40515: No change to Initial Statement of Reasons](#)

[Section 40517: No change to Initial Statement of Reasons](#)

[Section 40525: No change to Initial Statement of Reasons](#)

Section 40550. Inspections. This section establishes the Department's inspection authorities to enforce the Act and these regulations.

Subsection (a) establishes that the Department and its inspectors or agents may conduct an on-site inspection prior to issuing a new or renewal license. This provision is reasonably necessary because the Department and its inspectors or agents need to be able to conduct on-site inspections to compliance with the provisions of the Act and these regulations.

Subsection (b) establishes the Department and its inspectors or agents' authority must have ~~free~~ access at reasonable business hours to the manufacturing premises, storage areas, records, production processes, labeling, and packaging processes, and conveyances used in the manufacture, storage or transportation of cannabis products so that they may determine compliance with the provisions of the Act and these regulations. Inspection shall include all pertinent equipment, raw material, finished and unfinished materials, containers, packaging, and labeling that may have a bearing on whether the cannabis product complies with the Act and these regulations. This provision is reasonably necessary because the Department and its inspectors or agents need to have free access to the premises used to manufacture cannabis products to determine compliance with the provisions of the Act and these regulations.

Subsection (c) states that the Department may inspect any record or document that has a bearing on whether the labeling, advertising, or marketing of a cannabis product complies with the requirements of BPC §26150. If a licensee claims a health benefit, the claim must be supported as described in other provisions of this proposal. This subsection is necessary to clarify that the Department may inspect those documents to ensure compliance.

Subsection (d) establishes that the Department may collect a sample or specimen of any cannabis product or ingredient during an inspection and that the inspector will leave a receipt describing any sample obtained prior to concluding the inspection. This provision is reasonably necessary because the Department may collect a sample or specimen of cannabis product or ingredient during an inspection to determine compliance with the provisions of the Act and these regulations.

Subsection (e) establishes that the Department must provide the licensee a copy of the results of any sample analysis or determinations. This section establishes the licensee's

right to know the results of any sample analysis or determinations. This provision will help the licensee comply with the provisions of the Act and these regulations.

Subsection (f) establishes that the Department may conduct investigations concerning the adulteration, misbranding, false or misleading advertising or marketing, or unlicensed production of any cannabis product. Investigations will include entry and inspection of any place where any cannabis product is suspected of being manufactured or held in violation of the Act or these regulations. This provision is reasonably necessary for the Department to fulfill its mandate to protect public health.

Section 40551: No change to Initial Statement of Reasons

Section 40570. Emergency Decision and Order. This section provides the circumstances under which the Department may issue an emergency decision and order for temporary, interim relief. Government Code §§11460.10 through 11460.80 allow state departments to establish emergency procedures to prevent or avoid immediate danger to the public health, safety, or welfare. This section is necessary to specify the circumstances under which the Department may exercise its authority in order to fulfill the mandate of BPC §26011.5 (protection of public health and safety).

Subsection (a) states that the Department may issue an emergency decision and order for temporary interim relief to prevent or avoid immediate danger to the public health, safety, or welfare. There are situations in which continued operation of the cannabis manufacturing premises may present an immediate danger to the public – for instance, if the closed loop extraction system is faulty (potential for explosions or fire) or an event has occurred that would contaminate cannabis or cannabis products (a sewer pipe bursts in the cannabis facility). Alternatively, there may be circumstances under which continued operation of a manufacturing facility may allow the operator to destroy evidence to avoid detection of improper manufacturing practices or illegal activity.

This subsection incorporates circumstances under which the federal Food, Drug and Cosmetic Act allows for suspension of a license (21 USC 350d(b)(1)). Specifically, this subsection includes, but is not limited to, the following circumstances:

Paragraph (1): The Department determines that a cannabis product manufactured, processed, packed, or held at the licensee's premises has a reasonable probability of causing serious adverse health consequences or death.

Paragraph (2): The Department determines that insanitary or other conditions at the licensee's premises exist that could lead to the adulteration of finished cannabis products, and has a reasonable probability of affecting the safety of finished cannabis products.

Paragraph (3): The Department observes or has information that conditions at the licensee's premises exist that present an immediate risk to worker or public health and safety.

Paragraph (4): To prevent illegal diversion of cannabis or cannabis products, or other criminal activity at the licensee's premises.

Paragraph (5): To prevent the destruction of evidence related to illegal activity or violations of the Act.

Subsection (b) establishes the various forms of temporary, interim relief that may occur. The Department will exercise its authority on a case-by-case basis to fulfill its statutory mandate to protect public health and safety.

Paragraph (1): temporary suspension of a license.

Paragraph (2): An order to segregate or isolate specified cannabis products.

Paragraph (3): An order prohibiting the movement of cannabis products from the premises or the receipt of cannabis or cannabis products at the premises.

Paragraph (4): An order to cease some or all manufacturing operations at the premises.

Paragraph (5): An order prohibiting the sale of specified cannabis products.

Paragraph (6): An order for the recall of cannabis products.

Subsection (c) requires the Department to include a brief explanation of the factual and legal basis for the emergency decision. The emergency decision will be effective upon issuance. This provision consistent with the requirements of Government Code section 11460.50 and is necessary so that the licensee is aware of the reasons for which the action is being taken.

Subsections (d), (e), and (g) establish the procedures for issuance, hearing, and judicial review of the decision. These sections are consistent with Government Code §§ 11460.40, 11460.60, 11460.80 and are standard administrative procedures necessary to protect the licensee's due process rights.

Subsection (f) provides for the appeal of a final administrative decision to the Cannabis Control Appeals Panel as provided by BPC §26043. This is an additional administrative procedure afforded licenses by the Act to protect the licensee's due process rights.

Subsection (h) clarifies that the emergency decision and order provisions in this section are in addition to, and does not preclude the Department's additional authority for the

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recall of products pursuant to BPC §26132, to embargo products pursuant to BPC §26133, and to take any other action available to it under the Act.