SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Steven Glazer, Chair
2019 - 2020 Regular

Bill No:	AB 1458	**Hearing Date:**	August 8, 2020
Author:	Quirk		
Version:	January 23, 2020		
Urgency:	No	**Fiscal:**	Yes
Consultant:	Dana Shaker		

Subject: Cannabis testing laboratories

SUMMARY: Requires, for edible cannabis products, the certificate of analysis to report that the milligrams (mg) of Tetrahydrocannabinol (THC) per serving does not exceed 10 mg per serving, plus or minus 12% until January 1, 2022, and plus or minus 10% after January 1, 2022.

Existing law:

1) Establishes the Bureau of Cannabis Control under the Department of Consumer Affairs to administer and enforce the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) and the Control, Regulate and Tax Adult Use of Marijuana Act of 2016 (AUMA), which establishes a comprehensive system to control and regulate the distribution, transport, storage, and sale of cannabis products. (Business and Professions Code (BPC) § 26000 et seq.)

2) Requires licensed sellers of cannabis or cannabis products to have a representative sample tested by a licensed testing laboratory. (BPC § 26100(a))

3) Authorizes a testing laboratory to receive and test samples of cannabis or cannabis products from a qualified patient or primary caregiver, only if the qualifies patient or caregiver presents the qualified patient's valid physician's recommendation for cannabis for medicinal purposes. Prohibits a testing laboratory from certifying samples from a qualified patient or primary caregiver for resale or transfer to another party or licensee. Requires all tests performed by a testing laboratory for a qualified patient or primary caregiver to be recorded with the name of the qualified patient or primary caregiver and the amount of cannabis or cannabis product received. (BPC § 26104(d))

4) Defines "certificate of analysis" (COA) as the report prepared by the laboratory about the analytical testing performed and results obtained by the laboratory. (California Code of Regulations (CCR), Title 16, § 5700(q))

5) Requires a distributor after receipt of a certificate of analysis from a testing laboratory, or upon transfer from another distributor, before transporting the cannabis goods, to ensure, among other things, that the certificate is the proper certificate for the batch, is timely, is consistent with the label on the goods. (CCR, tit. 16, § 5307)

6) Requires any one cannabinoid, Total THC, and/or Total CBD claimed to be present on a label shall not be considered inaccurate if the difference in percentage on the certificate of analysis is plus or minus 10.0%. (CCR, tit. 16, § 5307.1(a))

7) Requires the terpenoid testing results on the label of any one terpenoid claimed to be present shall not be considered inaccurate if the difference in percentage on the certificate of analysis is plus or minus 10.0%. (CCR, tit. 16, § 5307.1(b))

This bill requires, for edible cannabis products, the certificate of analysis to report that the milligrams (mg) of Tetrahydrocannabinol (THC) per serving does not exceed 10 milligrams per serving, plus or minus 12% until January 1, 2022, and plus or minus 10% after January 1, 2022.

FISCAL EFFECT: According to the Assembly Appropriations Committee the bill will result in minor and absorbable costs to the BCC to promulgate regulations. There will also be ongoing staff costs, potentially in the hundreds of thousands of dollars, to BCC to review a potentially significant number of new tests and enforce compliance with the new requirements. Finally, there will be one-time costs of $100,000 to $150,000 to California Department of Food and Agriculture for system enhancements to the California Cannabis Track-and-Trace (CCTT) information technology system, including creating an audit trail of retest request and modified results, reports of contested results, amendments to training documents, and other changes.

COMMENTS:

1. **Purpose.** This bill is sponsored by the California Cannabis Manufacturer's Association. According to the Author, "[o]n February 1, 2019 the Bureau of Cannabis Control (BCC) released a Fact Sheet clarifying that a licensed testing laboratory shall deem an edible cannabis product sample to have passed testing if the THC per serving does not exceed 10 mg/serving plus 10% and/or if the THC per package does not exceed 100 mg/package plus 10%. However, there is an interpretation of the BCC regulations that reveals a conflict: *BCC Regulations §5307.1 states that a test is valid if this analysis is within plus or minus 10%, whereas §5724(d)(1) states that milligrams per serving must not exceed 10 milligrams of THC per serving.*

   To provide certain clarity for licensees and regulators alike, AB 1458 codifies the variance on both serving sizes and packages in statute. Prior emergency regulations provided for an upward/downward variance permission on both serving sizes and packages, and the proposed July 2018 regulations included testing variances of 10, 15, and 25% based on milligrams per serving size….AB 1458 codifies a lesser 12% variance with a 2022 sunset, reverting to 10% thereafter, allowing appropriate time for the maturation of the industry to meet the exceptional standards of California consumer protections. A temporary 12% variance is appropriate for consumer protection while allowing laboratories the necessary time to achieve testing results that are accurate, consistent, timely, and meet the stringent standards set forth in the regulations."

2. **Background.**

   State Regulation of Cannabis. In 1996, California first legalized cannabis for medical consumption via Proposition 215, also known as the Compassionate Use Act (the Act). Proposition 215 protected qualified patients and primary caregivers from prosecution related to the possession and cultivation of cannabis for medicinal

purposes. In 2003, the Legislature authorized the formation of medical marijuana cooperatives—nonprofit organizations that cultivate and distribute marijuana for medical uses to their members through dispensaries.

In 2015, the Legislature passed the Medical Cannabis Regulation and Safety Act (MCRSA). For the first time, MCRSA established a comprehensive, statewide licensing and regulatory framework for the cultivation, manufacture, transportation, testing, distribution, and sale of medicinal cannabis to be administered by the Bureau within Department of Consumer Affairs, DPH, and CDFA.

Shortly following the passage of MCRSA in November 2016, California voters passed Proposition 64, the "Control, Regulate and Tax Adult Use of Marijuana Act" (Proposition 64), which legalized adult-use cannabis. Less than a year later in June 2017, the California State Legislature passed a budget trailer bill, SB 94 (Committee on Budget and Fiscal Review, Chapter 27, Statutes of 2017), that integrated MCRSA with Prop 64 to create MAUCRSA, the current regulatory structure for both medicinal and adult-use cannabis. Beginning in 2018, Proposition 64 permitted adults 21 years of age or older can legally grow, possess, and use cannabis for nonmedical purposes, with certain restrictions.

Cannabis Testing. MAUCRSA requires cannabis in its final form to be laboratory tested prior to sale. Cannabis testing laboratories are required to evaluate the levels of contaminants of cannabis samples, including residual solvent, processing chemicals, foreign material (such as hair and insects) and microbiological impurities. Testing also determines the concentrations of active chemicals and to ensure compliance with safety standards.

In addition to information pertaining to the product's chemical profiles and contaminants, the COA documents administrative information about the laboratory, the distributor or microbusiness, dates and signatures, and other non-testing data which can be subject to simple data entry mistakes. Once issued, current law prohibits amending a COA or retesting samples, and the cannabis must be either remediated or destroyed. (However, the Bureau has indicated that, in limited circumstances, it has allowed a failed batch to be re-sampled and re-tested with another laboratory when the original laboratory clearly failed to meet quality control acceptance criteria.)

Edibles and THC. In recent years, edibles have emerged as a popular product in the legalized recreational and medical cannabis market. Edibles are given a different strength depending on a person's tolerance. For example, the suggested amount of THC mg for users with no tolerance is 1.5-5 mg, whereas the suggested amount for people with a very high tolerance to edibles is 60-100 mg+ of THC. Knowing a person's particular tolerance is important to ensure consumer protection and consumer safety.

There are also risks with the amount of cannabis a consumer might consume, given that ingestion produces a delayed onset of drug effect as opposed to inhalation.

Labeling, then, is a critical way for a consumer to tell how much of that particular product is safe for that person to consume. Industry indicates that 10 milligrams is

roughly one "dose" of THC. A recommended option for beginners or those unaware of how one dose of 10 milligrams will affect them is to choose a brand or product that comes in 5-milligram doses. Often, these products are created for new customers and those with a low tolerance.

Regulatory Inconsistency. According to the Author, in February of 2019, BCC released a Fact Sheet clarifying that a product sample would be considered as have "passed testing" if the THC per serving dose did not exceed 10 mg/serving plus 10% and/or if the THC per package does not exceed 100 mg/package plus 10%. However, the BCC regulations provided a conflicting interpretation. One regulation provided that a test is valid if the above analysis is within plus or minus 10%. The second analysis provided that the mg per serving must not exceed 10 mg of THC per serving. To resolve this confusion and to provide industry with time to comply with California's strong consumer protection standards, the bill codifies a variance in statute, requiring the COA report that THC mgs per serving do not exceed 10 mgs per serving, plus or minus 12% until January 1, 2022, and plus or minus 10% after January 1, 2022.

3. **Arguments in Support.** The California Cannabis Industry Association states, "Under current BCC regulations, the potency of THC listed on the COA may not exceed plus or minus 10% of the actual potency on the product. While this requirement makes sense for products such as raw cannabis flower or concentrates, it poses challenges for edible cannabis products when tested. This is because the current regulations dictate that potency levels may not exceed 10mg per serving and provides no variance. Consequently, if a cannabis product exceeds 10mg of THC per serving the product receives a failed COA and must be remediated or destroyed. As result, one-fifth of all edible products in the cannabis supply chain fail quality assurance testing. It is important to note that the absence of an allowable variance is unreasonable and more restrictive than pharmaceutical standards."

   The California Cannabis Manufacturers Association (CCMA) states, "While CCMA agrees that the cannabis industry should be held to the same standard of other comparable industries, we believe that regulations should reflect the infancy that the industry, processes, and technology are currently in. There is still significant variation in lab testing; combined with the reality that powder-based, transdermal and inhalable pharmaceuticals are more homogeneous and therefore more easily and accurately tested than the wide array of cannabis consumables (gelatin-based, baked goods, chocolate variations, etc.) and inedible products, the current variance is unreasonably low. Taking into consideration that nearly one-fifth of cannabis products failed California testing standards in 2018, CCMA believes that holding manufacturers and distributors to standards that can't be met is unreasonable."

   CMG/Caliva writes, "we urge the Senate Business, Professions, and Economic Development Committee to support AB 1458 (Quirk), which would provide some reasonable flexibility to the variance of THC per serving in a cannabis product….Under existing law, the variance is too rigidly restrictive and leads to the unnecessary and sometimes unjustified destruction of product based on a variation that could be attributable to human error or minor issues with the testing process."

The Southern California Coalition states, "The testing of cannabis manufactured products is an essential part of quality assurance. Because considerable expense is entailed in manufacturing cannabis products and the sourced ingredients are tested prior to manufacture to avoid contaminating the final product, it would be highly unusual for a manufactured product to fail testing. While both the manufacturer and the testing labs exercise extreme caution failed batches do sometimes occur. This bill gives the manufacturer and the laboratory the option to determine the source of the failure, correct it and retest. For instance, if laboratory equipment was not properly cleaned after a prior test, various residues might show up in a subsequent test."

SUPPORT AND OPPOSITION:

Support:

California Cannabis Manufacturers Association (Sponsor)
California Cannabis Industry Association
CMG/Caliva
Southern California Coalition

Opposition:

None on file.

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