Date of Hearing: April 23, 2019

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 1458 (Quirk) – As Amended April 12, 2019

SUBJECT: Cannabis testing laboratories.

SUMMARY: Allows for a certificate of analysis assigned to a tested cannabis product to be changed in cases of human error as well as codifying an upward and downward variance in valid testing results.

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)

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 § 26104Defines "certificate of analysis" 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)

4) 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)

THIS BILL:

1) Allows for a certificate of analysis assigned to a tested cannabis product to be changed in cases of human error.

2) 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 15% until January 1, 2022, and plus or minus 10% after January 1, 2022.

3) Authorizes a manufacturer to contest the testing results or to request a retest of the batch and would authorize a testing laboratory to amend a certificate of analysis to correct minor errors.

4) Directs the Bureau of Cannabis Control to develop and adopt regulations which allows a certificate of analysis to be challenged by a manufacturer should the manufacturer believe that the certificate of analysis is erroneous, and there is a documented processes that explains the manufacturers reasoning.

FISCAL EFFECT: Unknown. This bill is keyed fiscal by Legislative Council.

COMMENTS:

Purpose. This bill is sponsored by the *California Cannabis Manufacturer's Association*. According to the sponsor, "The regulated cannabis industry is at risk. The legal market has been unable to drive out the remnants of underground cannabis markets, and there are serious concerns that under current regulation regulations the black market may never be driven out. AB 1458 allows cannabis manufacturers to avoid unnecessary and costly waste when a certificate of analysis (COA) is erroneous due to human error or problems in the testing process. Currently there is no way to amend a COA, and if a manufacture knows or believes there is an error they must either destroy their product, or sell it with what they believe is incorrect labeling. AB 1470 allows for a sensible process to correct and amend COAs, ensuring the longevity of the regulated market while protecting consumer safety."

Background. California began regulating medical marijuana with the passage of the Compassionate Use Act in 1996, which exempted patients and their primary caregivers from criminal liability under state law for the possession and cultivation of marijuana. 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. The Medical Marijuana Regulation and Safety Act (Act) passed in 2015, which created a comprehensive state licensing system for the commercial cultivation, manufacture, retail sale, transport, distribution, delivery, and testing of medical cannabis.

In 1996, California voters passed Proposition 215, legalizing the use of medical cannabis in the state. The state began regulating medical cannabis in 2016 and, later that year, California voters passed Proposition 64, which legalized the recreational use of cannabis, beginning in 2018. Under Proposition 64, adults 21 years of age or older can legally grow, possess, and use cannabis for nonmedical purposes, with certain restrictions.

Testing Requirements. 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.

Edibles and THC. The following chart, using industry standards, shows how strong edibles of a given THC mg dosage are, in relation to your tolerance to cannabis. The variance is an important factor and crucial to consumer protection.

Tolerance	**THC mg**
Users with no tolerance	1.5 - 5 mg
Users who smoke multiple times per week	2 - 12 mg
Users who regularly eat edibles and have tolerance to edibles	10 - 30 mg
High tolerance to edibles	30 - 60 mg
Very high tolerance to edibles	60 - 100 mg+

Food products containing cannabis extract (edibles) have emerged as a popular and lucrative facet of the legalized market for both recreational and medicinal cannabis. The many formulations of cannabis extracts used in edibles present a unique regulatory challenge for policy makers. Though edibles are often considered a safe, discreet, and effective means of attaining the therapeutic and/or intoxicating effects of cannabis without exposure to the potentially harmful risks of cannabis smoking, little research has evaluated how ingestion differs from other methods of cannabis administration in terms of therapeutic efficacy, subjective effects, and safety. The most prominent difference between ingestion and inhalation of cannabis extracts is the delayed onset of drug effect with ingestion. Consumers often do not understand this aspect of edible use and may consume a greater than intended amount of drug before the drug has taken effect, often resulting in profoundly adverse effects.

Edibles have become popular among users in states where cannabis is legal for recreational or medicinal purposes (or both). For example, in Colorado in 2014, 1.96 million units of edible medicinal cannabis-infused products and 2.85 million units of edible retail cannabis-infused products were sold, which accounted for about 45 percent of the total cannabis sales in the state.

When a consumer purchases edibles, it should have packaging and an informative labeling. The consumer relies on the label carefully to figure out how much THC is contained in that edible, and then determine how much of it you should actually be consumed. Industry indicates that 10 milligrams is roughly one “dose” of THC.

A recommended option for beginners, or those who simply don’t know how much one dose of 10 milligrams will affect them, is to choose a brand or product that comes in 5-milligram doses. Often, they are specifically created for newcomers as well as people who just happen to have a low tolerance.

Current Related Legislation. AB 404 (Stone) of the current legislative session allows a cannabis testing laboratory to amend a certificate of analysis to fix minor errors and to retest a sample if the test result falls outside the specifications authorized by law, the Bureau of Cannabis Control authorizes the test, and the test was compromised due to equipment malfunction, staff error, or other circumstances allowed by the Bureau.

AB 1288 (Cooley) of the current Legislative Session, requires information captured by the cannabis "track and trace" program to include details on the date and location of retail sale to a customer, and requires the Department of Food and Agriculture, in consultation with the Bureau, to ensure that the "track and trace" program is fully integrated into the California Law Enforcement Telecommunications System by July 1, 2020.

AB 1461 (Quirk) of the current Legislative Session, makes technical, non-substantive changes to the Business and Professions Code Section 26104, which describes several obligations and restrictions relating to cannabis testing laboratories.

SB 153 (Wilk) of the current Legislative Session, revises provisions regulating the cultivation and testing of industrial hemp

Prior Related Legislation. SB 837 (Budget and Fiscal Review, Chapter 32, Statutes of 2016) clarified that licensed operators may test cannabis and cannabis products in-house for quality assurance purposes.

AB 243 (Wood, Chapter 688, Statutes of 2015) requires CDFA, DPR, the State Department of Public Health, the Department of Fish and Wildlife, and the State Water Resources Control Board to promulgate regulations or standards relating to medical cannabis and its cultivation, as specified, and establishes licensing fees, fines, and penalties.

AB 266 (Bonta et al., Chapter 689, Statutes of 2015) established the Act for the licensure and regulation of medical cannabis and establishes the Bureau of Medical Cannabis Regulation within the DCA.

SB 643 (McGuire, Chapter 719, Statutes of 2015) set standards for the licensed cultivation and physician prescription of medical cannabis; establishes a track and trace program for the transportation of medical cannabis; and authorizes counties to impose a tax on medical cannabis.

ARGUMENTS IN SUPPORT:

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."

ARGUMENTS IN OPPOSITION:

None on file.

POLICY ISSUE(S) FOR CONSIDERATION:

This bill is, in part, duplicative of AB 404 (Stone) of the current legislative session, which allows a cannabis testing laboratory to amend a certificate of analysis to fix minor errors and to retest a

sample if the test result falls outside the specifications authorized by law, the Bureau of Cannabis Control authorizes the test, and the test was compromised due to equipment malfunction, staff error, or other circumstances allowed by the Bureau. This bill may be unnecessary as the intent of AB 404 (Stone) is identical.

In addition, when looking at the variance requirement for edible cannabis products and the certificate of analysis to report that the milligrams of THC per serving does not exceed 10 milligrams per serving, plus or minus 15% until January 1, 2022 causes concern. Lowering industry standards so early in regulation will open industry up for further scrutiny.

It is important for consumers to know, as close as possible, how many milligrams of THC they are ingesting. This will only assist the consumer in making informed decisions in regards to dosages. Keeping in mind that consuming a first dose of 10 milligrams can be too much for some people – taking many different aspects into account (i.e. smaller body mass, new to ingesting edibles, empty stomach, etc.). If the variance is increased to plus or minus 15% this could have unintended consequences to the end user.

REGISTERED SUPPORT:

Southern California Coalition

REGISTERED OPPOSITION:

None on file.

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