USA Roundup: Federal,California, Maine,Texas

5 May 2017

FEDERAL

Federal SAFE Banking Act Would Normalize Banking for Canna-Businesses

CALIFORNIA

The Bureau of Medical Cannabis Regulation (BMCR) today announced that its proposed testing laboratories regulations for medical cannabis have been posted and the 45-day public comment period is now underway.

"These proposed testing laboratories regulations for medical cannabis follow the same process as those regulations announced last week," BMCR Chief Lori Ajax said. "We continue to move full force ahead to meet our target launch date and I want to encourage people to provide public comment and feedback to help meet our goal."

Individuals interested in reviewing the medical regulations for testing laboratories can do so by clicking on the below links:

http://bmcr.ca.gov/laws_regs/mcrsa_lab_notice.pdf ***NOTICE OF PROPOSED RULEMAKING FOR TESTING LABS***

http://bmcr.ca.gov/laws_regs/mcrsa_lab_ptor.pdf ***PROPOSED REGULATION TEXT***

http://bmcr.ca.gov/laws_regs/mcrsa_lab_isor.pdf ***INITIAL STATEMENT OF REASONS FOR LAB REGULATIONS***

Or, for more information, please visit the new Cannabis Web Portal, www.cannabis.ca.gov. At this site you will also find the proposed medical regulations that were released last week for licensing dispensaries, distribution and transporters.

Part of today's announcement includes the news of four public hearings for the purpose of public comment on the proposed regulations. The bureau encourages all interested stakeholders to review the proposed regulations and come to a hearing near you to provide feedback. Hearing dates and locations are as follows:

June 1, 2017 1:00 p.m. – 3:00 p.m. Adorni Center 1011 Waterfront Drive, Eureka, CA 95501
June 8, 2017 1:00 p.m. – 3:00 p.m. Junipero Serra Building 320 W. Fourth Street, Los Angeles, CA 90013
June 13, 2017 4:00 p.m. – 6:00 p.m. King Library, Second Floor 150 E. San Fernando Street, San

Jose, CA 95112
June 20, 2017 10:00 a.m. – 12:00 p.m. Department of Consumer Affairs, Hearing Room, S-102 1625 North Market Boulevard, Sacramento, CA 95834

Please note these dates, times and locations are different form the hearing dates for the regulations announced last week (Press Release).

Those who wish to provide feedback and are unable to attend one of the four listed sessions above, can get involved in the regulatory process by following the steps outlined here – http://www.bmcr.ca.gov/about_us/documents/17-065_public_comment.pdf.

There is currently budget trailer bill language designed to align the Medical Cannabis Regulation and Safety Act with Proposition 64, the Adult Use of Marijuana Act. If that bill passes, the bureau will withdraw these proposed regulations and propose a new set of regulations consistent with changes in the law.

However, public comments on the regulations published today are still very important.

Beginning a little more than a year ago, the Bureau kicked off its outreach efforts with nine informational sessions in locations all around the state. Those sessions were followed up last Fall by eight pre-regulatory stakeholder meetings with discussions centering on issues related to general licensing requirements, and specific concepts related to the regulation of medical cannabis dispensaries, distributors and transporters. The feedback from those sessions can be reviewed here – http://www.bmcr.ca.gov/meetings/summaries.shtml.

For additional information about BMCR, or to subscribe to email alerts to hear about updates as they become available, please visit our website – http://www.bmcr.ca.gov/.

In addition, you can now follow the Bureau on social media!
Facebook: https://www.facebook.com/BMCRinfo/
Twitter: https://twitter.com/BmcrInfo

BUREAU OF MARIJUANA CONTROL CALIFORNIA CODE OF REGULATIONS TITLE 16, DIVISION 42 MEDICAL CANNABIS TESTING LABORATORIES NOTICE OF PROPOSED RULEMAKING

Notice is hereby provided that the Bureau of Marijuana Control (bureau), formerly named the Bureau of Medical Cannabis Regulation and the Bureau of Medical Marijuana Regulation, proposes to adopt the proposed regulations described below after considering all comments, objections, and recommendations regarding the proposed action. The bureau upon its own motion or at the instance of any interested party may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who

submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

PUBLIC HEARING

The bureau will be holding public hearings at the dates, times, and locations listed below at which time any person interested may present statements or arguments orally or in writing relevant to the action proposed. The locations listed below are wheelchair accessible. At the hearings, any person may present statements or arguments orally or in writing relevant to the proposed action described in the Informative Digest. The bureau may need to set a time-limit for each comment. Persons who make oral comments at a hearing may also submit a written copy of their testimony at a hearing.

June 1, 2017 1:00 p.m. – 3:00 p.m. Adorni Center 1011 Waterfront Drive, Eureka, CA 95501
June 8, 2017 1:00 p.m. – 3:00 p.m. Junipero Serra Building 320 W. Fourth Street, Los Angeles, CA 90013
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WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the bureau. Written comments, including those sent by mail, facsimile (FAX), or e-mail to the addresses listed below, must be received by the bureau at its office not later than 5:00 p.m. on June 20, 2017 or must be received by the bureau at a hearing. The bureau will consider only comments received at the bureau by that time. Submit comments to:

Lori Ajax, Chief Bureau of Marijuana Control 1625 North Market Blvd., Suite S-202 Sacramento, CA 95834FAX: (916) 574-8676E-mail: BMCR.comments@dca.ca.gov

AUTHORITY AND REFERENCE

Business and Professions Code section 19304 authorizes the bureau to adopt these proposed regulations. The proposed regulations implement, interpret, and make specific the Medical Cannabis Regulation and Safety Act (MCRSA) at Business and Professions Code section 19300 et seq.

INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

Summary of Current Laws and Regulations

The MCRSA, beginning at Business and Professions Code 19300, provides the framework for state regulation of commercial medical cannabis activity. The MCRSA requires the bureau to license testing laboratories. This is the only state law related to the testing of commercial medical cannabis goods and the testing laboratories which perform the required testing services.

Under the federal Controlled Substances Act (21 C.F.R. §801 et seq.) cannabis is illegal. However, the U.S. Department of Justice has issued guidance regarding the enforcement of cannabis activities in a memorandum issued by Deputy Attorney General James M. Cole on August 29, 2013, commonly referred to as the Cole Memorandum. There are no federal laws or regulations specifically related to testing laboratories for commercial medical cannabis goods.

Proposed Regulations

Specifically, this rulemaking action clarifies and makes specific licensing and enforcement criteria for commercial cannabis testing laboratories. Specifically, the regulations would provide requirements for the minimum standards for "passing" the statutorily required testing of medical cannabis goods for retail sale at dispensaries in California and the minimum laboratory-operation requirements, which would include requirements such as sampling procedures, personnel qualifications, standard operating procedures, and recordkeeping requirements.

These proposed regulations would set forth action levels, threshold values that provide the criterion for determining whether a medical cannabis goods sample passes or fails an analytical test, that the bureau considers to be both protective of public health and achievable by the cannabis industry. The proposed exposure limits are necessary to ensure, to the extent feasible, that no medical cannabis patient will suffer material impairment of health from exposure to contaminants in medical cannabis goods. The action levels proposed are for chemicals, foreign material, heavy metals, and microbiological impurities.

First, the proposed regulations would make clear the applicable meaning of key statutory terms and other terms used within the regulations.

Second, the proposed regulations would provide for application requirements that are specific to testing laboratories such as proof of ISO 17025 accreditation, specific requirements for the premises diagram, and requirements for obtaining a provisional license if an applicant meets all requirements for licensure with the exception of the ISO accreditation.

Third, the proposed regulations would set forth minimum requirements for the sampling of medical cannabis goods. These requirements include what must go into a testing laboratory's sampling protocol, training requirements for laboratory agents who will be obtaining samples ("samplers"), and how samples are to be stored. The proposed sampling regulations also make specific the enabling statute in MCRSA that requires the laboratory agent collecting the sample to use a "statistically valid sampling method."

Fourth, the proposed regulations would provide the minimum standards for laboratory standard operating procedures including procedures for laboratory processes, analytical methods, and testing methodologies. The regulations would also set out what the bureau considers to be acceptable ways to validate a "nonstandard" method.

Fifth, the proposed regulations would provide the standards for the analyses of cannabinoids, moisture content, water activity, residual solvents and processing chemicals, pesticides, microbiological impurities, mycotoxins, filth and foreign material, heavy metals, and terpenes. The regulations would also set forth general reporting requirements and require testing laboratories to generate a certificate of analysis for each sample of a batch of medical cannabis goods that it tests; containing necessary information to identify the testing laboratory, identify the sample, identify the test methods, and provide the test results.

Sixth, the proposed regulations would provide requirements for post-testing procedures. These requirements would include a requirement that a batch may not be retested following a failed testing unless it has gone through a remediation process and requirements for disposal of the testing sample.

Seventh, the proposed regulations would set requirements for the minimum components of a quality-assurance program and what must be contained in the quality-assurance manual. These requirements include the use of method blank samples, field duplicate samples, and matrix spike samples (or laboratory control samples). These requirements would also include proficiency testing, which is a blind testing of a laboratory's ability to perform analyses, as well as set out how to calculate the limit of detection and limit of quantitation, spell out recordkeeping requirements, and require an annual internal audit.

Eighth, the proposed regulations provide for laboratory employee education and experience requirements. Specifically, the regulations would require that a testing laboratory have a laboratory director and that the laboratory director meet certain educational and experience requirements. The regulations would also require that analysts and supervisory analysts meet some minimum qualifications in order to ensure laboratories are run by competent and trained persons.

Ninth, the proposed regulations would set laboratory-specific security requirements including requiring that testing laboratories develop and implement security protocols, preventing unauthorized access to areas of the laboratory where cannabis is present, ensuring that medical cannabis goods are stored properly and ensuring electronic data is properly stored.

Lastly, the regulations would provide for laboratory-specific substantially related crimes that would prevent the applicant from obtaining a license and prohibiting a laboratory that has had its license revoked from engaging in activities that would meet the definition of a cannabis testing laboratory under Business and Professions Code section 19300.5(x) or reapplying for a testing laboratory license with the bureau for a period of three years after the date of revocation.

Anticipated Benefit of the Proposed Regulations:

The broad objectives of these regulations are to ensure that the medical cannabis goods sold to consumers from licensed dispensaries are safe for consumption. The proposed regulations are expected to benefit the health and welfare of California residents. The testing laboratory regulations are intended to ensure that all medical cannabis goods are first tested for a number of harmful substances before they are sold to patients. The proposed regulations prevent the sale of medical cannabis goods that have not been tested or have failed testing. It is expected that the proposed regulations will result in a large decrease or elimination of sales of medical cannabis that contain harmful substances. Additionally, the proposed regulations will ensure that the testing results printed on the label of products will contain accurate information. The regulations also seek to advance worker safety, public health, and environmental safety by providing rules for testing.

Evaluation of Inconsistency/Incompatibility with Existing State Regulations:

The bureau has determined that these proposed regulations are not inconsistent or incompatible with existing regulations. After conducting a review for any regulations that would related to or affect this area, the bureau has concluded that these are the only regulations that concern the state licensing and enforcement of commercial cannabis testing laboratories.

Evaluation of Inconsistency/Incompatibility with Existing Federal Regulations:

Under the federal Controlled Substances Act (21 C.F.R. §801 et seq.) cannabis is illegal. However, the U.S. Department of Justice has issued guidance regarding the enforcement of cannabis activities in a memorandum issued by Deputy Attorney General James M. Cole on August 29, 2013, commonly referred to as the Cole Memorandum. The bureau has determined that these proposed regulations are not inconsistent or incompatible with the guidance provided by the federal government in the Cole Memorandum.

Incorporation by Reference:

The following documents are incorporated into the regulations by reference:

(1) US Food and Drug Administration's Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition, 2015.
(2) US Food and Drug Administration's Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition, 2015.
(3) United States Pharmacopeia and the National Formulary (USP-NF), 2016.

DISCLOSURES REGARDING THE PROPOSED ACTION

The bureau has made the following initial determinations:

Mandate on local agencies and school districts: None.

Cost or savings to any state agency: None.

Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630: None.

Other nondiscretionary cost or savings imposed on local agencies: None.

Cost or savings in federal funding to the state: None.

Cost impacts on a representative private person or business: The laboratory testing requirements within the proposed regulations are expected to increase the cost of medical cannabis by approximately $407 a pound. This will affect cultivators, manufacturers, and distributors who will be paying for the required testing. This will also affect dispensaries as well as medical cannabis patients who will be paying an increased price for medical cannabis goods due to the increased cost for the required testing.

Statewide adverse economic impact directly affecting businesses and individuals: Although the proposed action will directly affect businesses statewide businesses, the bureau concludes that the adverse economic impact, including the ability of California businesses to compete with businesses in other states, will not be significant.

Significant effect on housing costs: None.

Small Business Determination: The bureau has determined that the proposed regulations would not affect small businesses. It is expected that all of the medical cannabis testing laboratories will not be considered a small business as defined in the Administrative Procedure Act.

Results of the Standardized Regulatory Impact Analysis

The bureau worked with the University of California Agricultural Issues Center (AIC) to prepare the Standardized Regulatory Impact Analysis (SRIA). The SRIA analyzed the regulatory impact of all the bureau's regulations, including those for distributors, transporters, and dispensaries which were previously proposed. The SRIA was submitted to the California Department of Finance on February 28, 2017. Below is a summary of the SRIA.

(A) The creation or elimination of jobs within the state.

It is expected that the regulations will result in the creation of approximately 2,071 new jobs in the state of California. Of these expected jobs, 1,290 new jobs will be in the laboratory testing sector.

(B) The creation of new businesses or the elimination of existing businesses within the state.

The regulations are expected to lead to the creation of approximately 20 new testing laboratory businesses throughout the state.

(C) The competitive advantages or disadvantages for businesses currently doing business within the state.

The regulations are expected to result in competitive advantages for some business who are operating in California and competitive disadvantages for other businesses operation within California. The limitations on vertical integration are expected to create a competitive disadvantage for businesses that are currently operating under a vertically integrated model and will have to adjust their operations to comply with the new rules. However, the few testing laboratories that are currently in operation will likely have a competitive advantage as they are already operating in what is expected to be an expanding sector.

(D) The increase or decrease of investment in the state.

The regulations are expected to result in an increase in investment in California. The revenue within the medical cannabis industry is expected to increase by about $113 million. This increase in revenue is expected to be accompanied by an increase in investment. Additionally, many businesses under the regulations will require additional investment in security equipment and other costs of complying with the regulatory requirements. It is expected that a large amount of increased investment will be the laboratory testing sector. New testing laboratories will be established and investment will be required to ensure that existing testing laboratories meet the requirements of the regulations.

(E) The incentives for innovation in products, materials, or processes.

It is expected that the regulations will create an incentive for innovation. This is most notable in the laboratory testing sector. As stated above, the requirements for testing laboratories will require significant levels of investment due to the creation of new businesses. The types of testing required by the regulations are currently very costly. Therefore, there is an incentive for testing laboratories to develop and use new equipment and processes that will enable the laboratory to perform the required tests in a more efficient way.

(F) The benefits of the regulations, including, but not limited to, benefits to the health, safety and welfare of California residents, worker safety, and the state's environmental quality of life, among any other benefits identified by the agency.

The laboratory testing requirements are expected to provide a benefit to the public. The laboratory testing requirements are expected to identify the medical cannabis goods that may be unsafe for public consumption and remove them from the market. Under the testing requirements in the regulation, only the medical cannabis goods that have been thoroughly

tested and approved for consumption will be sold. Any medical cannabis goods that do not pass the testing will not be allowed to enter the market. Preventing potentially harmful products from entering the market will likely benefit the health and welfare of California residents.

Summary of Comments from the Department of Finance and Bureau Responses

The bureau received a letter from the California Department of Finance, March 29, 2017, containing comments from the Department of Finance (DOF) regarding the Standardized Regulatory Impact Statement (SRIA) submitted by the bureau. The letter contained three comments suggesting augmentation of the SRIA.

"First, the SRIA must include an estimate of the local revenue and expenditure increases from the state regulating medical cannabis. While collecting fees at the local level is not under the control of the state, there will be other impacts from local fees. These local choices will affect the overall value to companies of complying with the state regulations, and the SRIA must include assumptions about these effects. For example, the assumption that local regulatory costs will be low enough that companies will choose to comply is essential to having a legal medical cannabis sector."

The bureau has responded to DOF's first comment by including a more detailed discussion of the impact that the proposed regulations are expected to have on local revenue and expenditures in the SRIA. The discussion is in section 11 of the SIRA. With an assumed average local tax rate of 5%, it is expected that the proposed regulations will result in an increase in local revenue by approximately $7 million.

"Second, the impacts of the manufacturers regulations should be compared with both the current economic situation (without recreational use), and with the future situation that allows for recreational use. This is necessary so as not to mislead the reader by only accounting for the benefits of medical manufacturer regulations. For example, the IMPLAN calculations all show increases in investment, jobs, and GDP for the state as a result of medical cannabis regulations when compared with only recreational cannabis being available, but investment and jobs in the medical cannabis sector will actually shrink compared with the current situation where both medical and recreational cannabis are unregulated. Both aspects are important to discuss for the impacts to be understood by the reader."

The bureau has responded to DOF's second comment by including a more detailed discussion comparing the expected economic effects of the proposed regulations with the current economic situation within section 6.4 of the SRIA. Compared to the 2016 unregulated scenario, it is expected that the regulations would cause a 60% decrease in the total quantity of medical cannabis, a 56% decrease in annual revenue, a 10% lower price if taxes are excluded, and a 11.4% higher price when taxes are included. However, it is important to note that the regulations will be taking effect after the passage of proposition 64 which legalized the adult use of cannabis for individuals over the age of 21. Therefore, this comparison is merely for a point of reference and is not a measurement or estimate of the actual effects of the regulation.

“Finally, the SRIA must also discuss in greater detail the interactions between transporters and the laboratories and dispensaries. Laboratories see a large increase in demand for their services, medical cannabis dispensaries continue to see demand (albeit at lower levels than at the end of 2016), but the transport sector is largely assumed to have few effects. However, given the licensing and particular requirements for transport of medical cannabis, there should be entry of new businesses into this sector, or additional demand for services at least. These costs should also be accounted for in transactions with laboratories, manufacturers, and dispensaries.”

The bureau has responded to DOF’s third comment by including a more detailed discussion about the effect that the regulations may have on transporters in section 8.2 of the SRIA. The bureau expects that a large majority of medical cannabis transportation will be conducted by businesses that hold a transportation license in addition to a distribution license, cultivation license, and/or a manufacturing license. However, there is a possibility of smaller, specialty medical cannabis transportation businesses being created.

CONSIDERATION OF ALTERNATIVES

In accordance with the Government Code Section 11346.5(a)(13), the bureau must determine that no reasonable alternative considered by the bureau or that has otherwise been identified and brought to the attention of the bureau would be more effective in carrying out the purpose for which this action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law.

The proposed testing laboratory regulations impose a maximum batch size of 10 pounds for testing. The proposed regulations are expected to increase the cost of medical cannabis by $407 a pound. The bureau considered two alternatives to the 10 pound batch limit. The bureau considered a lower-cost alternative in which no batch size limit would be set. This alternative would be expected to increase the cost of medical cannabis by $177 a pound, or $230 less than the proposed regulations. The bureau also considered a higher-security alternative in which a batch size limit of 5 pounds would be imposed. A smaller batch size limit may lead to more accurate testing results. This alternative would be expected to increase the cost of medical cannabis by $624, or $217 more than the proposed regulations.

The bureau has determined that despite being less costly, the lower-cost alternative is expected to result in a smaller increase in revenue when compared to the expected increase from the proposed regulations. In addition, the lower-cost alternative may result in test results that may be inaccurate. The bureau has also determined that the higher-security alternative will likely result in a smaller increase in revenue when compared to the expected increase from the proposed regulations. Additionally, the increase cost of testing is of concern because the higher the cost of compliance, the more likely so businesses will remain in the illegal market. The incremental increase in accuracy that may be obtained from the smaller batch size limit do not warrant the additional costs which may be an incentive for businesses to remain in the illegal

market. Therefore, the bureau has decided to proceed with the proposed regulations instead of the two alternatives considered.

CONTACT PERSONS

Inquiries concerning the proposed administrative action may be directed to:

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The backup contact person for these inquiries is:

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Please direct requests for copies of the proposed text (the “express terms”) of the regulations, the initial statement of reasons, the modified text of the regulations, if any, or other information upon which the rulemaking is based to Ms. Croyts-Schooley at the above address.

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, AND RULEMAKING FILE

The bureau will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the above address. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulations, the initial statement of reasons, and technical, theoretical, and/or empirical studies, reports, or documents relied upon. Copies of materials may be obtained by contacting Ms. Croyts-Schooley at the address or phone number listed above.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After holding the hearings and considering all timely and relevant comments received, the bureau may adopt the proposed regulations substantially as described in this notice. If the bureau makes modifications which are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the bureau adopts the regulations as revised. Please send requests for copies of any modified regulations to the attention of Ms. Croyts-Schooley at the address indicated above. The bureau will accept written comments on the modified regulations for at least 15 days after the date on which they are made available.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Upon its completion, copies of the Final Statement of Reasons may be obtained by contacting Ms. Croyts-Schooley at the above address.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations in underline and strikeout can be accessed through our website at www.bmcr.ca.gov.

MAINE

The Marijuana Legalization Implementation Committee (MLIC) has been busy for the last two weeks. The primary topic of focus has been the licensing regime for all levels of the adult use market.
MPRM provided testimony on lab licensing, and was asked to provide additional information on testing requirements, suggestions for lab licensing, and cross investment. In addition, representatives from MPRM provided testimony and additional materials on licensing priorities that the committee should focus on as it refines the licensing requirements for Maine.
Last week, and the beginning part of this week, MLIC also focused on testing and labeling standards, which were included in the Marijuana Legalization Act, but the committee explored whether to strengthen the requirements and whether changes were necessary. MPRM provided testimony in favor of strong packaging and labeling standards, including the need for expedited lab licensing so packaging and labeling can accurately reflect the contents of marijuana products.

TEXAS

Texas medical marijuana bill passes committee with 76 legislators in supportTEXAS

http://txcann.com/texas-medical-marijuana-bill-passes-committee-76-legislators-support/

A bill to allow patients access to whole plant medical marijuana has passed out of committee. This comes after a long hearing earlier in the week, followed by an outpouring of calls and emails.

HB 2107 was voted in favor 7-2 by members of the Texas House Public Health Committee today according to Heather Fazio with Texans for Responsible Marijuana Policy, a coalition group who promoted the legislation.

It now proceeds to the Calendar Committee for a vote on whether it will be scheduled to be heard by the full Texas House of Representatives.

This is the first comprehensive bill of its kind to be passed out of committee.

More At Link