BUREAU OF MARIJUANA CONTROL
PROPOSED TEXT OF REGULATIONS

CALIFORNIA CODE OF REGULATIONS
TITLE 16
DIVISION 42. BUREAU OF MARIJUANA CONTROL
CHAPTER 5. TESTING LABORATORIES

Article 1. Chapter Definitions

§ 5237. Definitions

In addition to the definitions in the Medical Cannabis Regulation and Safety Act at Business and Professions Code section 19300.5 and section 5000 of this division, the following definitions apply to this chapter.

(a) "Acceptance criteria" is the specified limits placed on characteristics of an item or method that are used to determine data quality.

(b) "Accredited college or university" is a college or university accredited by a regional or national accrediting agency that is an accreditor recognized by the Secretary of the US Department of Education.

(c) "Action level" is the threshold value that provides the criterion for determining whether a sample passes or fails an analytical test.

(d) "Aliquot" is a portion of a sample that is used in an analysis.

(e) "Analyte" is a chemical, compound, element, bacteria, yeast, fungus, or toxin to be identified or measured.

(f) "Analytical batch" is a group of samples that is prepared together for the same analysis and analyzed sequentially using the same instrument calibration curve and that have common analytical quality-control checks.

(g) "Analytical method" is a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.

(h) "Batch" is a specific quantity of homogeneous medical cannabis goods and is one of the following types:

(1) "Harvest batch" is 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.

(2) “Manufactured cannabis batch” is either:

(A) An amount of cannabis concentrate or extract produced in one production cycle using the same extraction methods and standard operating procedures, and is from the same harvest batch.

(B) An amount of a type of manufactured cannabis produced in one production cycle using the same formulation and standard operating procedures.

(i) “Cannabinoid” is a chemical compound that is unique to and derived from cannabis.

(j) “CAS number” is the unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service.

(k) “CBD” is cannabidiol, Chemical Abstracts Service number 13956-29-1.

(l) “CBDA” is cannabidiolic acid, Chemical Abstracts Service number 1244-58-2.

(m) “CBG” is cannabigerol, Chemical Abstracts Service number 25654-31-3.

(n) “CBN” is cannabinol, Chemical Abstracts Service number 521-35-7.

(o) “Certificate of analysis” is the report prepared for the requester and the bureau under section 5334 about the analytical testing performed and results obtained by the testing laboratory.

(p) “Certified reference material” is a reference material prepared by a certifying body.

(q) “Concentrate” is manufactured cannabis that has undergone a process to concentrate one or more active cannabinoids, thereby increasing the product’s potency. Resin from glandular trichomes from a cannabis plant (“kief”) is a concentrate for purposes of the Act. A cannabis concentrate is not considered food, as defined by Health and Safety Code section 109935, or a drug, as defined by Health and Safety Code section 109925.

(r) “Data-quality assessment” is a scientific and statistical process that establishes whether the collected data are of the right type, quality, and quantity to support the data’s intended use.

(s) “Field duplicate sample” is a sample that is taken in the identical manner and from the same cannabis batch being sampled as the primary sample. It is analyzed separately from the primary sample and is used for quality control only.

(t) “Frequency” is the number of items occurring in a given category. Frequency may be determined by analytical method or laboratory-specific requirements for the purpose of accuracy, precision of the analysis, or statistical calculation.

(u) “Hashish” is compressed kief, as that is defined in subsection (x).

(v) “Increment” or “sample increment” is a smaller sample that, together with other increments, makes up the primary sample.

(w) “ISO/IEC” or “ISO” is the joint technical committee of the International Organization for Standardization and the International Electrotechnical Commission.

(x) “Kief” is a concentrate that is the resin from glandular trichomes from a cannabis plant.

(y) “Laboratory” is an entity that is a testing laboratory that is licensed by the bureau to conduct sampling and analyses of medical cannabis goods and includes the personnel, specialized apparatus, and instruments used to analyze medical cannabis goods.

(z) “Limit of detection” or “LOD” is the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit.

(aa) “Limit of quantitation” or “LOQ” is the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision.

(bb) “Matrix” is the component or substrate that contains the analyte of interest. “Matrices” is the plural.

(cc) “Matrix spike duplicate” is a duplicate sample prepared by adding a known quantity of a target analyte to a field sample matrix or to a matrix that is as closely representative of the matrix under analysis as possible.

(dd) “Matrix spike sample” is a sample prepared by adding a known quantity of the target analyte to a field sample matrix or to a matrix that is as closely representative of the matrix under analysis as possible.

(ee) “Medical cannabis goods” are medical cannabis, including dried flower, and manufactured medical cannabis products.

(ff) “Method blank” is an analyte-free matrix to which all reagents are added in the same volumes or proportions as are used in sample preparation.

(gg) “Moisture content” is the percentage of water in a dry sample, by weight.

(hh) “Non-target organism” is an organism that the test method or analytical procedure is not testing for. Non-target organisms are used in evaluating the specificity of a test method.

(ii) “Percent recovery” is the percentage of a measured concentration relative to the added (spiked) concentration in a reference material, matrix spike sample, or matrix spike duplicate.

(jj) “Practical experience” is hands-on post-secondary-education laboratory experience, using equipment, instruments, kits, and materials routinely found in a laboratory.

(kk) “Primary sample” is a portion of medical cannabis goods, or “sample,” collected from a medical cannabis batch for testing.

(ll) “Proficiency test” is an evaluation of a laboratory’s performance against pre-established criteria by means of interlaboratory comparisons of test measurements.

(mm) “Proficiency test sample” is a sample prepared by a party independent of the testing laboratory, with a concentration and identity of an analyte that is known to the independent party but is unknown to the testing laboratory and testing laboratory personnel.

(nn) “Quality assurance” is a set of operating principles that enable laboratories to produce defensible data of known accuracy and precision. Quality assurance encompasses employee training, equipment preventative maintenance procedures, calibration procedures, and quality-control testing, among other things.

(oo) “Quality control” is a set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control in which errors have been reduced to acceptable levels.

(pp) “Quality-control samples” are samples produced and used by a laboratory for the purpose of assuring quality control. Quality-control samples include but are not limited to blank samples, spike samples, duplicate samples, and reference material samples.

(qq) “Reagent” is a compound or mixture added to a system to cause a chemical reaction or test if a reaction occurs. A reagent may be used to tell whether or not a specific chemical substance is present by causing a reaction to occur with the chemical substance.

(rr) “Reference material” is a material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix. Reference material is used to document the bias of the analytical process.

(ss) “Reference method” is a method by which the performance of an alternate method is measured or evaluated.

(tt) “Relative percent difference” or “RPD” is a comparative statistic used to calculate precision or random error. RPD is calculated using the following equation:

$$\text{RPD} = \left|(\text{primary sample measurement} - \text{duplicate sample measurement})\right| / ([\text{primary sample measurement} + \text{duplicate sample measurement}] / 2) \times 100\%$$

(uu) “Relative standard deviation” or “RSD” is the standard deviation expressed as a percentage of the mean recovery. It is the coefficient of variation multiplied by 100. RSD is calculated using the following equation. If any results are less than the limit of quantitation, the absolute value of the limit of quantitation is used in the following equation:

$$\text{RSD} = (s / x) \times 100\%; \text{ where } s = \text{standard deviation and } x = \text{mean recovery}$$

(vv) “Requester” means a person who submits a request to a licensed testing laboratory for state-mandated testing of medical cannabis goods. The requester may be a licensed cultivator, licensed manufacturer, or licensed distributor.

(ww) "Sample" is a representative part of or a single item from a larger whole or group.

(xx) “Sample area” is the physical space within the distributor’s or laboratory’s premises in which sampling occurs.

(yy) “Sampler” is a testing laboratory employee who collects samples of medical cannabis goods for testing.

(zz) “Sanitize” is to sterilize, disinfect, or make hygienic.

(aaa) “Significant figures” are the number of digits used to express a measurement.

(bbb) “Standard operating procedure” is a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

(ccc) “Synthetic cannabinoid” is a designed compound with structural features that allow binding to the known cannabinoid receptors present in human cells and that produce psychoactive effects similar to those of cannabis.

(ddd) “Tamper evident” means that one or more one-time-use seals are affixed to the opening of a package, allowing a person to recognize whether or not the package has been opened.

(eee) “Target organism” is an organism that is being tested for in an analytical procedure or test method.

(fff) “Testing laboratory record” is information relating to the testing laboratory and the analyses it performs that is prepared, owned, used, or retained by the laboratory and includes electronic files and video footage.

(ggg) “THC” and “delta-9 THC” is tetrahydrocannabinol, Chemical Abstracts Service number 1972-08-3.

(hhh) “THCA” is tetrahydrocannabinolic acid, Chemical Abstracts Service number 23978-85-0.

(iii) “Validation” is the confirmation by examination and objective evidence that the particular requirements for a specific intended use are fulfilled.

(jjj) “Water activity” is a measure of the quantity of water in a product that is available and therefore capable of supporting bacteria, yeasts, and fungi. Water activity is reported in the unit A_w.

Authority: Sections 19302.1, 19304, 19342, 19343, 19344, and 19345, Business and Professions Code. Reference: Sections 19300.5, 19342, 19343, 19344, and 19345, Business and Professions Code.

Article 2. License Application

§ 5238. Application

In addition to the information required by section 5006 in this division, an applicant for a testing laboratory license shall provide the following information:

(a) Proof of ISO 17025 accreditation or proof that the applicant is in the process of applying or is preparing to apply for ISO 17025 accreditation;

(b) Laboratory-employee qualifications; and

(c) All required standard operating procedures.

Authority: Sections 19302, 19302.1, 19304, and 19322(a)(8), Business and Professions Code. Reference: Section 2105, Corporations Code and Section 19322, Business and Professions Code.

§ 5239. [RESERVED]

§ 5240. [RESERVED]

§ 5241. Premises diagram

A testing laboratory applicant shall provide all information required under section 5012 of this division. A testing laboratory applicant's premises diagram shall include a brief statement of the principal activity to be conducted in each room or partitioned area, including activities related to sample receiving, sample storage, record storage, microbiology and chemistry analysis, and office space.

Authority: Sections 19302, 19302.1, 19304, 19320(c), 19322(a)(8), and Business and Professions Code. Reference: Sections 19320(c), Business and Professions Code.

§ 5242. [RESERVED]

§ 5243. [RESERVED]

§ 5244. Provisional Testing Laboratory License

(a) A testing laboratory applicant that meets all qualifications for licensing except for ISO accreditation may apply to the bureau for a provisional testing laboratory license.

(b) An applicant for a provisional license shall include the information and documentation required for a license as required under section 5006, except that documentation of the laboratory's ISO 17025 accreditation is not required. Instead, documentation required under section 5238(a) is required.

(c) The bureau may grant the testing laboratory applicant a provisional license. The provisional license, if granted, expires 12 months from the date of issuance.

(d) The bureau has the discretion to renew a testing laboratory's provisional license. The bureau may renew a testing laboratory's provisional license if the laboratory has applied for ISO 17025 accreditation but has not yet been granted or denied accreditation. A testing laboratory shall provide evidence to the bureau of having submitted an application for ISO 17025 accreditation.

(e) If granted, a provisional license renewal expires after 180 calendar days.

(f) When a testing laboratory holding a provisional license receives ISO 17025 accreditation, the testing laboratory shall send proof of the accreditation to the bureau within five business days.

(g) When a laboratory holding a provisional license is denied ISO 17025 accreditation, the laboratory shall notify the bureau of the denial within 24 hours. The bureau shall revoke the provisional license when the laboratory is denied accreditation.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19341, 19342, and 19343, Business and Professions Code.

§ 5245. [RESERVED]

§ 5246. [RESERVED]

Article 3. Sampling Medical Cannabis Goods

§ 5247. Sampling Standard Operating Procedures

(a) A laboratory shall develop and implement sampling plans that are consistent with these regulations for obtaining samples of medical cannabis goods.

(b) A laboratory shall develop a separate sampling plan for each type of matrix. The sampling plan must be appropriate to the type of matrix to be analyzed such that a representative sample may be obtained.

(c) The sampling plans shall be signed and dated by the laboratory director and shall include the revision dates and authors. The laboratory director's signature denotes approval of the plan.

(d) The laboratory shall keep controlled copies of the sampling plans at the laboratory, and the sampling plans shall be available to laboratory personnel. Uncontrolled copies of the sampling plans shall be available to samplers in the field.

(e) The laboratory shall make the sampling plans available for inspection by the bureau if requested by the bureau.

Authority: Sections 19302.1, 19304, 19307, 19322, 19342, and 19343, Business and Professions Code. Reference: Sections 19307, 19327, 19322, 19342, 19343, and 19345, Business and Professions Code.

§ 5248. [RESERVED]

§ 5249. [RESERVED]

§ 5250. Sampling Requirements

(a) A laboratory shall obtain samples for the purposes of laboratory analyses for homogeneity; the presence or absence of various analytes, including cannabinoids, residual solvents, micro-organisms, pesticides, heavy metals, and mycotoxins; water activity and moisture content; and filth and foreign material, as required in this chapter. A laboratory may also obtain samples for an analysis for the presence and concentration of terpenes.

(b) Only the laboratory that collects samples shall be the laboratory that analyzes the collected samples.

(c) Only a trained sampler employed by the licensed testing laboratory may obtain samples for the laboratory.

(d) The sampler shall do the following when obtaining samples:

(1) Ensure area is as clean and free from contaminants and filth as possible and sanitize tools;

(2) Obtain both primary and duplicate samples from each batch;

(3) Assign a unique sample identifier to each sample and sample increment;

(4) Follow chain-of-custody protocols to ensure that sample integrity is such that it may be maintained from the point of collection to the receipt of the samples at the laboratory; and

(5) Wear the equipment required under section 5253.

Authority: Sections 19302.1, 19304, 19326, 19327, 19343, 19344, and 19345, Business and Professions Code. Reference: Sections 19327, 19342, 19343, 19344, and 19345, Business and Professions Code.

§ 5251.[RESERVED]

§ 5252. [RESERVED]

§ 5253. Sampler Personal Equipment

(a) A sampler shall wear the following items during the entire sampling process:

(1) Disposable protective coveralls or disposable lab coat or apron;

(2) Disposable nitrile gloves;

(3) Filtering dust mask;

(4) Safety goggles; and

(5) Hair net.

(b) The sampler shall change gloves between sampling different batches.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19342 and 19343, Business and Professions Code.

§ 5254. [RESERVED]

§ 5255. [RESERVED]

§ 5256. Sampling Tools

(a) The sampler shall sanitize all tools and equipment used in the sampling process.

(b) Sampling tools may include the following:

(1) Amber glass jars or containers with polytetrafluoroethylene (PTFE)-lined lids;

(2) A cooler with ice or cold packs;

(3) Cleaning supplies such as 10% bleach or 70% ethanol;

(4) Powder-free, nitrile, and sterile disposable gloves;

(5) A field balance capable of weighing material to within 1 gram of accuracy;

(6) Labels and permanent markers;

(7) Disinfecting wipes; and

(8) Spoons, spatulas, tongs, knives, pipettes, corers, and sampling thieves.

Authority: Sections 19302.1, 19304, 19343, and 19345, Business and Professions Code. Reference: Sections 19342, 19343, and 19345, Business and Professions Code.

§ 5257. [RESERVED]

§ 5258. [RESERVED]

§ 5259. Field Duplicate Sampling

(a) A sampler shall collect a field duplicate sample. The sampler shall collect the field duplicate sample from the same batch, at the same time, and in the same manner as the sampler collects the field primary sample.

(b) The field duplicate sample shall be separately stored and separately analyzed from the primary sample.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19342 and 19343, Business and Professions Code.

§ 5260. [RESERVED]

§ 5261. [RESERVED]

§ 5262. Storage and Handling of Samples

(a) Samplers shall place samples in tamper-evident containers as this is defined in section 5237(ddd).

(b) Samplers shall place samples in amber glass jars or containers with polytetrafluoroethylene (PTFE)-lined lids to avoid photo degradation of the sample. The sample shall be kept on ice in an ice chest, with a physical separation between the ice and the sample, and the temperature shall be maintained at 0 to 6 degrees Celsius.

Authority: Sections 19302.1, 19304, 19334, 19343, and 19345, and Business and Professions Code. Reference: Sections 19334, 19342, 19343, and 19345, Business and Professions Code.

§ 5263. [RESERVED]

§ 5264. [RESERVED]

§ 5265. Sample Field Log

The sampler shall use a sample field log to record the following information during each sampling event:

(a) Laboratory's name and license number;

(b) Sampler's name and title and the names of others onsite;

(c) Date and time sampling began;

(d) Distributor's name, address, and license number;

(e) Name, business address, and license number of the person who transports the samples to the laboratory;

(f) Sample matrix;

(g) Requested analyses;

(h) Total composite sample weight or count;

(i) Date and time each sample was obtained;

(j) Total batch size, by weight or count;

(k) Problems encountered and corrective actions taken;

(*l*) For each sample, the weight or count of each sample, the unique sample identification number, and the location within the batch from which the sample was taken;

(m) Any other observations from sampling, including major inconsistencies in the medical cannabis goods' color, size, or smell;

(n) Sampling conditions, including temperature; and

(o) Batch or lot number of the matrix.

Authority: Sections 19302.1, 19304, 19327, 19334, 19342, 19343, and 19345, Business and Professions Code. Reference: Sections 19321, 19322, 19327, 19342, 19343, 19344, and 19345, Business and Professions Code.

§ 5266. [RESERVED]

§ 5267. [RESERVED]

§ 5268. Sampling Unpackaged Harvest Batches

(a) Samples collected must be representative of the harvest batch being sampled.

(b) The sampler may obtain samples from unpackaged (loose) harvest batches directly from the container or containers in which the batch is held.

(c) A sampler may not collect samples from a harvest batch weighing more than 10 pounds. Samples collected from batches weighing more than 10 pounds shall be deemed invalid.

(d) The sampler shall sample by performing all of the following tasks:

(1) Draw samples from varying locations of the container, both vertically and horizontally. The sampler may obtain the necessary increments by following different paths through the batch container or by drawing the increments systematically at well-separated points along a heptagonal pattern.

(2) Remove the dried flower and place into an air-tight, sterile sample container as described in section 5256 that is capable of protecting the sample from contamination and degradation.

(3) Immediately and completely seal the sample container. The sampler shall seal all openings of the container so that it is tamper evident. The sampler shall initial and date each seal.

(4) Place the sealed sample containers into a tamper-evident, portable storage unit for transport. The storage unit must be kept at 0 to 6 degrees Celsius.

(5) Repack the remaining portion of the batch and replace any lids; and

(6) Complete a chain-of-custody form and sample field log.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19334, 19342, 19343, and 19343, Business and Professions Code.

§ 5269. [RESERVED]

§ 5270. [RESERVED]

§ 5271. Minimum Unpackaged Harvest Batch Sample Size

The sampler shall collect 0.5% of the total batch size. A laboratory may obtain greater amounts if the amount in the table is insufficient for the testing required.

Sample Size Requirements Based on Size of Harvest Batch

Batch size (pounds)	Required sample size (grams)
≤ 1.00	2.3
1.01 to 2.0	4.5
2.01 to 3.0	6.8
3.01 to 4.0	9.1
4.01 to 5.0	11.3
5.01 to 6.0	13.6
6.01 to 7.0	15.9

7.01 to 8.0	18.1
8.01 to 9.0	20.4
9.01 to 10.0	22.7

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19342 and 19343, Business and Professions Code.

§ 5272. [RESERVED]

§ 5273. [RESERVED]

§ 5274. Unpackaged harvest-batch sample increments

(a) The sampler shall collect a minimum of 7 and not more than 9 sample increments from each harvest batch. The table below shows the number of increments required for the primary sample, by batch size.

Number of Increments for the Primary Sample, Based on Batch Size

Batch size, pounds	≤ 2.0	2.01 to 4.0	4.01 to 6.0	6.01 to 8.0	8.01 to 10.0
Number of increments	7	7	8	8	9

(b) The sampler may collect more increments if doing so is required because of the analytical method or laboratory-specific procedures or to ensure that a sufficient quantity of material is available for all required tests. The sampler may collect only the amount necessary to conduct the required and requested testing.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19342 and 19343, Business and Professions Code.

§ 5275. [RESERVED]

§ 5276. [RESERVED]

§ 5277. Sampling of Packaged Medical Cannabis Goods

(a) For packaged medical cannabis goods, the sampler shall store and secure the sample, taking all of the following steps:

(1) Place into an air-tight, sterile sample container that is capable of protecting the sample from contamination and degradation.

(2) The sampler shall seal all openings of the container so that it is tamper evident. The sampler shall initial and date each seal.

(3) Place the sealed sample containers into a tamper-evident, portable storage unit for transport to the testing laboratory.

(4) Complete a chain-of-custody form and a field sample log.

Authority: Sections 19302.1, 19304, 19334, 19342, and 19343, Business and Professions Code. Reference: Sections 19334, 19342, 19343, and 19345, Business and Professions Code.

§ 5278. [RESERVED]

§ 5279. [RESERVED]

§ 5280. Sample Increments for Packaged Medical Cannabis Goods

(a) For batches that are packaged for retail sale, the minimum number of required sample increments required, by size of the batch, is in the table below. Each increment consists of 1 prepackaged unit.

Units in Batch	Number of Increments
2 – 15	2
16 – 50	3
51 – 150	5
151 – 500	8
501 – 3200	13
3201 – 35,000	20
35,001 – 500,000	32
500,001 and above	50

(b) The sampler may collect a greater number of increments if required because of an analytical method or laboratory-specific procedures or to ensure that a sufficient quantity of material is available for all required tests. The sampler may only collect the amount necessary to conduct the required and requested testing. A sampler may not collect samples from a harvest batch weighing more than 10 pounds.

(c) If an entire unit for sale is an insufficient quantity of material available for all required tests, multiple units for sale may be combined to create a single increment.

(d) The sampler or testing laboratory shall combine all primary sample increments to constitute one primary sample.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19342 and 19343, Business and Professions Code.

§ 5281. [RESERVED]

§ 5282. [RESERVED]

§ 5283. Homogeneity Tests for Edible Cannabis Products

(a) A laboratory shall perform a homogeneity test for THC or CBD, whichever is purported by the manufacturer to be the largest ingredient content, for each batch of edible medical cannabis product. If the amounts of THC and CBD are very similar (near 1:1), the laboratory shall test for homogeneity of THC.

(b) A homogeneity test requires at least 10 increments, collected separately than those collected for the field primary sample, from different regions of the manufactured cannabis batch, following procedures in sampling section 5277 and the laboratory's standard operating procedure for sampling. The laboratory shall determine the relative standard deviation of THC or CBD content between the 10 or more increments.

(c) The batch is homogeneous and "passes" homogeneity testing if the relative standard deviation, with no outliers, as assessed using the Grubb's outlier test with a significance level of 0.05, is less than 15% on average. If the relative standard deviation is greater than 15%, the batch "fails" the homogeneity test.

(d) If a homogeneity test is not performed or if a batch fails homogeneity testing, the batch fails and shall be destroyed.

(e) If the product batch passes homogeneity testing, the laboratory shall perform all other analyses required under this chapter.

Authority: Sections 19302.1, 19304, 19342, and 19343, Business and Professions Code. Reference: Sections 19326, 19342, and 19343, Business and Professions Code.

§ 5284. [RESERVED]

§ 5285. [RESERVED]

§ 5286. Chain-of-Custody Protocol

(a) Laboratories shall develop and implement a chain-of-custody protocol to ensure accurate documentation of the transport, handling, storage, and destruction of cannabis samples.

(b) The chain-of-custody protocol shall require the use of a chain-of-custody form that contains, at minimum, the following:

(1) Laboratory licensee's name, physical address, and license number of the laboratory collecting and analyzing the sample;

(2) Distributor licensee's name, physical address, and license number; and

(3) Information regarding each sample increment as follows:

(A) Unique sample-increment identifier as indicated on the sample container;

(B) Date and time of the sample-increment collection;

(C) The printed names and signatures of the laboratory samplers;

(D) All conditions, including sample temperature at time of collection and temperature of the cooler used for transport;

(E) The printed and signed name and signature of the person at the testing laboratory that received the samples; and

(F) The location of the sample within the testing laboratory storage area.

(c) Each time the sample changes custody between licensees, is transported, is removed from storage at the laboratory, or is destroyed, the date, time, and the names and signatures of persons involved in these activities shall be recorded on the chain-of-custody form.

Authority: Sections 19302.1, 19304, 19334, 19343, and 19345, Business and Professions Code. Reference: Sections 19327, 19334, 19342, 19343, and 19345, Business and Professions Code.

§ 5287. [RESERVED]

§ 5288. [RESERVED]

§ 5289. Sample Rejection

(a) When samples are received by a laboratory, the laboratory shall check whether the integrity of the samples has been maintained. The laboratory shall deem a sample compromised if one or more of the following has occurred. This list is not a comprehensive list of reasons for which a sample may be deemed compromised:

(1) Broken shipping container;

(2) Evidence that the sample has been tampered with, manipulated, adulterated, or contaminated;

(3) Evidence that the sample was not collected in the manner required by this chapter or the laboratory's sampling standard operating procedures;

(4) Missing or incomplete chain-of-custody form or sampling field log;

(5) The temperature of the sample is out of the required range; and

(6) Any other factor that may have negatively impacted the integrity of the sample since its collection.

(b) If the sample is rejected, the laboratory shall document the sampling or handling errors and shall re-sample.

Authority: Sections 19302.1, 19304, 19334, 19343, and 19345, Business and Professions Code. Reference: Sections 19327, 19334, 19342, 19343, and 19345, Business and Professions Code.

§ 5290. [RESERVED]

§ 5291. [RESERVED]

Article 4. Standard Operating Procedures

§ 5292. Standard Operating Procedures for Laboratory Processes

(a) A laboratory shall develop, implement, and maintain written standard operating procedures in accordance with the requirements of this chapter for the following testing laboratory functions and responsibilities:

(1) Calibration and maintenance of equipment and instruments;

(2) Chain-of-custody protocols;

(3) Data review and internal review processes;

(4) Analytical methods;

(5) Employee training;

(6) Premises and sample security;

(7) Quality-assurance and quality-control procedures;

(8) Recordkeeping and record retention;

(9) Sample preparation;

(10) Sample storage;

(11) Schedule and process for internal audits and corrective actions; and

(12) Disposal of cannabis-sample waste or leftover material.

(b) The laboratory director shall review, approve, sign, and date each standard operating procedure and each revision to a standard operating procedure. The standard operating procedures shall include the dates of issue and dates of revision, if any.

(c) A laboratory shall keep all standard operating procedures on the laboratory premises and in the field, as necessary, and shall ensure that each standard operating procedure is accessible to laboratory personnel during operating hours. A laboratory shall make the standard operating procedures accessible to the bureau upon request.

(d) A standard operating procedure is a "testing laboratory record" for purposes of the Act and these regulations.

Authority: Sections 19302.1, 19304, 19322, 19327, 19343, and 19345, Business and Professions Code. Reference: Sections 19322, 19327, 19334, 19342, 19343, and 19345, Business and Professions Code.

§ 5293. [RESERVED]

§ 5294. [RESERVED]

§ 5295. Standard Operating Procedures for Analytical Methods

(a) The testing laboratory shall take analytical measurements using methods and equipment that have been tested to ensure they are fit for the purpose of the required test.

(b) The analytical method standard operating procedure for each required test shall describe how the laboratory performs each method. At a minimum, the method standard operating procedure shall include the following elements:

(1) Identification (name) of the test method;

(2) List of analytes;

(3) Applicable matrices;

(4) Method sensitivity;

(5) Potential interferences;

(6) Analytical instruments;

(7) Consumable supplies, reagents, and standards;

(8) Sample preservation, storage, and hold time;

(9) Types, frequency, and acceptance criteria for quality-control samples;

(10) Types, frequency, and acceptance criteria for calibration standards;

(11) Procedure for analyzing analytical batch samples and frequency of quality-control samples;

(12) Data-quality assessment and acceptance criteria;

(13) Calculation of results; and

(14) Reagent, solution, and reference-material preparation.

Authority: Sections 19302.1, 19304, 19322, 19327, 19342, 19343, and 19344, Business and Professions Code. Reference: Sections 19322, 19326, 19327, 19342, 19343, and 19344, Business and Professions Code.

§ 5296. [RESERVED]

§ 5297. [RESERVED]

§ 5298. Testing Methodologies

(a) Laboratories shall develop and implement scientifically valid testing methodologies for the chemical, physical, and microbial analysis of medical cannabis goods. A method validated in

accordance with this section is deemed a scientifically valid testing methodology. A laboratory shall not perform testing using a method that has not been validated.

(b) To the extent practicable, the testing laboratory's testing methodologies shall comport with the following guidelines, which are incorporated herein by reference:

(1) US Food and Drug Administration's *Bacterial Analytical Manual*, 2016;

(2) AOAC International's *Official Methods of Analysis for Contaminant Testing of AOAC International*, 20th Edition, 2016;

(3) Methods of analysis for contaminant testing published in the 2016 *United States Pharmacopeia and the National Formulary (USP-NF)*; or

(4) If a laboratory wants to use an alternative scientifically valid testing methodology, the laboratory shall validate the methodology and submit the standard operating procedure for the new methodology to the bureau.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code. Reference: Sections 19322, 19326, and 19343, Business and Professions Code.

§ 5299. [RESERVED]

§ 5300. [RESERVED]

§ 5301. Validation of Non-Standard Test Methods and Modified Standard Test Methods

(a) A laboratory may use a nonstandard method; a laboratory-designed or -developed method; a standard method used outside its intended scope; or an amplification or a modified standard method for the analysis of samples.

(b) A laboratory shall validate a method it wants to use for the analysis of samples, for each matrix. The laboratory shall use one of the following guidelines, which are incorporated here by reference, for validating a method, depending on the type of method:

(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; or

(2) US Food and Drug Administration's *Guidelines for the Validation of Chemical Methods for the FDA FVM Program*, 2nd Edition, 2015.

(c) At minimum, the testing laboratory shall conduct a level-one (emergency-use) single-laboratory validation study for all methods for testing for microbiological impurities and comply with subsections (b) and (e)(1).

(d) At minimum, the laboratory shall conduct a level-one (emergency-use) single-laboratory validation study for all methods for testing for chemicals and shall comply with subsections (b) and (e)(2).

(e) In addition to following the Food and Drug Administration guidelines listed in subsection (b), a laboratory shall also include and address the following in the laboratory's level-one validation study.

(1) Microbiological-analysis method-validation studies.

Criteria	**Requirement**
Number of target organisms; inclusivity	5
Number of non-target organisms; exclusivity	5
Number of analyte levels per matrix: Qualitative methods	3 levels: high and low inoculum levels and 1 uninoculated level
Number of analyte levels per matrix: Quantitative methods	4 levels: low, medium and high inoculum levels and 1 uninoculated level
Replicates per food at each level tested	2 or more replicates per level
Reference method comparison	No

(A) For purposes of validating standards for microbiological analysis, the following definitions apply:

(i) "Exclusivity" is the specificity of the test method. It evaluates the ability of the method to distinguish the target organisms from similar but genetically distinct non-target organisms.

(ii) "Inclusivity" is the sensitivity of the test method. It evaluates the ability of the test method to detect a wide range of target organisms by a defined relatedness.

(2) Chemical-analysis method validation studies.

(A) Matrix spike samples (laboratory-fortified matrix). When high-concentration standards for matrix spiking are unavailable, matrix spikes may be made through post-processing and -dilution spiking of samples before analysis, rather than direct sample-matrix spike. When high-concentration reference standards are available, laboratories shall employ direct spiking of the sample matrix.

(B) Reference materials and certified reference materials. Laboratories shall use reference materials validation studies when cannabis reference materials become available.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5302. [RESERVED]

§ 5303. [RESERVED]

Article 5. Laboratory Analyses and Reporting

§ 5304. Required Analyses

(a) At minimum, a laboratory shall develop and implement test methods and corresponding standard operating procedures following the requirements in sections 5298 and 5301 for the analyses of cannabinoids; residual solvents and processing chemicals; pesticides; microbiological impurities; mycotoxins; water activity and moisture content; filth and foreign material; and heavy metals.

(b) A laboratory shall develop and implement test methods and corresponding standard operating procedures for the analysis of terpenes. Terpenes need only be tested for if the cultivator, manufacturer, or distributor desires to claim on the labeling that the medical cannabis goods contain terpenes or if the cultivator, manufacturer, or distributor desires an analysis of terpenes for any other reason.

Authority: Sections 19302.1, 19304, 19322, 19327, 19342, 19343, and 19344, Business and Professions Code. Reference: Sections 19322, 19326, 19327, 19342, 19343, and 19344, Business and Professions Code.

§ 5305. [RESERVED]

§ 5306. [RESERVED]

§ 5307. Cannabinoids

(a) A laboratory shall test for and report measurements for the following cannabinoids:

(1) THC;

(2) THCA;

(3) CBD;

(4) CBDA;

(5) CBG; and

(6) CBN.

(b) For harvest-batch samples, a laboratory shall report, to 3 significant figures, the concentration in milligrams per gram (mg/g) dry-weight sample of the cannabinoids listed in subsection (a). The laboratory shall report this information in the certificate of analysis.

(c) For harvest-batch samples, a laboratory shall also calculate the dry-weight percent of cannabinoids listed in subsection (a) that are detected in the sample in the following way:

(1) Dry-weight percent THC = wet-weight percent THC / (1 – percent moisture / 100).

(2) Dry-weight percent CBD = wet-weight percent CBD / (1 − percent moisture / 100).

(3) Dry-weight percent THCA = wet-weight percent THCA / (1 − percent moisture / 100).

(4) Dry-weight percent CBDA = wet-weight percent CBDA / (1 − percent moisture / 100).

(5) Dry-weight percent CBG = wet-weight percent CBG / (1 − percent moisture / 100).

(6) Dry-weight percent CBN = wet-weight percent CBN / (1 − percent moisture / 100).

(d) For samples from manufactured cannabis batches, a laboratory shall report, to 3 significant figures, the concentration in milligrams per gram (mg/g) of the cannabinoids listed in subsection (a). The laboratory shall report this information in the certificate of analysis.

(e) A laboratory may test for and provide test results for additional cannabinoids if requested to do so by the requester of the laboratory testing.

(f) For the purposes of cannabinoid potency testing of manufactured cannabis products, the laboratory shall report that the sample "passed" cannabinoid potency testing if the concentration of THC does not exceed the labeled potency of THC, plus or minus 15 percent. A cannabis product fails potency testing if the amount or percentage of THC exceeds the labeled concentration of THC, plus or minus 15 percent.

(g) For the purposes of cannabinoid potency testing of manufactured cannabis products, the laboratory shall report that the sample "passed" cannabinoid potency testing if the concentration of CBD does not exceed the labeled concentration of CBD, plus or minus 15 percent. A cannabis product fails potency testing if the amount or percentage of CDB exceeds the labeled concentration of CBD, plus or minus 15 percent.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.
Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5308. [RESERVED]

§ 5309. [RESERVED]

§ 5310. Residual Solvents and Processing Chemicals

(a) A laboratory shall analyze samples of manufactured cannabis batches for residual solvents and processing chemicals. A laboratory does not need to analyze for residual solvents and processing chemicals in dried flower, kief, and hashish samples.

(b) The laboratory shall analyze the concentration of residual solvents present in each sample of manufactured cannabis batches in accordance with the table in subsection (c).

(c) For the purposes of residual-solvent testing, the laboratory shall report that the sample "passed" residual-solvent testing if the concentrations of residual solvents are at or below the following residual solvents and processing chemicals action levels:

Chemical Name	**CAS No.**	**Action Level for Medical Cannabis Goods Meant for Inhalation (ppm)**	**Action Level for All Other Medical Cannabis–Infused Goods (ppm)**
1,2-Dichloroethane	107-06-2	2	5
Acetone	67-64-1	750	5000
Acetonitrile	75-05-8	60	410
Benzene	71-43-2	1	2
Butane	106-97-8	800	5000
Chloroform	67-66-3	2	60
Ethanol	64-17-5	1000	5000
Ethyl acetate	141-78-6	400	5000
Ethyl ether	60-29-7	500	5000
Ethylene oxide	75-21-8	5	50
Heptane	142-82-5	500	5000
Hexane	110-54-3	50	290
Isopropyl alcohol	67-63-0	500	5000
Methanol	67-56-1	250	3000
Methylene chloride	75-09-2	125	600
Naphtha	8030-30-6	400	400
Pentane	109-66-0	750	5000
Petroleum ether	8032-32-4	400	400
Propane	74-98-6	2100	5000
Trichloroethylene	79-01-6	25	80
Toluene	108-88-3	150	890
Total xylenes (ortho-, meta-, para-)	1330-20-7	150	2170

(d) The testing laboratory shall report the solvents and processing chemicals listed in this section in parts per million (ppm) to 3 significant figures. The laboratory shall report this information in the certificate of analysis.

(e) The laboratory shall include in the certificate of analysis both the concentrations of solvents and processing chemicals in the sample and whether the sample "passed" or "failed" residual solvent and processing-chemicals testing.

(f) If the sample fails residual solvent testing, the batch fails laboratory testing.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5311. [RESERVED]

§ 5312. [RESERVED]

§ 5313. Residual Pesticides

(a) A testing laboratory shall test all samples for residual pesticides.

(b) Medical cannabis goods must not contain levels of pesticides above those listed in the following table:

	Edible Cannabis Products (ppm)	**Dried Cannabis Flowers (ppm)**	**All Other Processed Cannabis (ppm)**
Abamectin	0.02	0.02	0.02
Acephate	0.02	0.02	0.02
Acequinocyl	0.27	0.1	0.02
Acetamiprid	0.01	0.01	0.01
Aldicarb	0.01	0.01	0.01
Azoxystrobin	0.01	0.01	0.01
Bifenazate	1.0	0.1	0.1
Bifenthrin	0.01	0.01	0.01
Boscalid	0.01	0.01	0.01
Captan	1.0	0.7	0.05

Carbaryl	0.01	0.01	0.01
Carbofuran	0.01	0.01	0.01
Chlorantraniliprole	0.02	0.02	0.02
Chlordane	0.01	0.01	0.01
Chlorfenapyr	0.01	0.01	0.01
Chlorpyrifos	0.02	0.02	0.02
Clofentezine	1.3	0.1	0.04
Coumaphos	0.01	0.01	0.01
Cyfluthrin	0.01	0.01	0.01
Cypermethrin	1.0	1.0	0.5
Daminozide	0.01	0.01	0.01
DDVP (Dichlorvos)	0.02	0.02	0.02
Diazinon	0.01	0.01	0.01
Dimethoate	0.01	0.01	0.01
Dimethomorph	0.01	0.01	0.01
Ethoprop(hos)	0.01	0.01	0.01
Etofenprox	0.01	0.01	0.01
Etoxazole	0.46	0.1	0.05
Fenhexamid	1.7	0.1	0.08
Fenoxycarb	0.01	0.01	0.01
Fenpyroximate	0.5	0.1	0.1
Fipronil	0.01	0.01	0.01
Flonicamid	0.4	0.1	0.1
Fludioxonil	0.02	0.02	0.02

Hexythiazox	0.25	0.1	0.1
Imazalil	0.01	0.01	0.01
Imidacloprid	0.02	0.02	0.02
Kresoxim-methyl	3.6	0.1	0.02
Malathion	0.01	0.01	0.01
Metalaxyl	0.01	0.01	0.01
Methiocarb	0.01	0.01	0.01
Methomyl	0.01	0.01	0.01
Methyl parathion	0.01	0.01	0.01
Mevinphos	0.01	0.01	0.01
Myclobutanil	0.02	0.02	0.02
Naled	0.01	0.01	0.01
Oxamyl	0.026	0.5	0.2
Paclobutrazol	0.01	0.01	0.01
Pentachloronitrobenzene	0.03	0.1	0.1
Permethrin	2.5	0.5	0.02
Phosmet	0.12	0.1	0.02
Piperonyl butoxide	63.0	3.0	3.0
Prallethrin	0.5	0.1	0.02
Propiconazole	0.02	0.02	0.02
Propoxur	0.02	0.02	0.02
Pyrethrins	0.7	0.5	0.5
Pyridaben	4.4	0.1	0.02
Spinetoram	0.5	0.1	0.04

Spinosad	0.29	0.1	0.02
Spiromesifen	20.0	0.1	0.1
Spirotetramat	10.0	0.1	0.1
Spiroxamine	0.01	0.01	0.01
Tebuconazole	0.01	0.01	0.01
Thiacloprid	0.01	0.01	0.01
Thiamethoxam	0.01	0.01	0.01
Trifloxystrobin	25.0	0.1	0.02

(c) The laboratory shall report the levels detected in parts per million (ppm) to 3 significant figures in the certificate of analysis. If a sample is found to contain pesticides above the allowable amount listed in the tables in subsection (b), the sample "fails" pesticide testing. If the sample fails pesticide testing, the batch fails laboratory testing and may not be released for retail sale.

Authority: Sections 19302.1, 19304, 19342, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19331, 19332, 19343, and 19344, Business and Professions Code.

§ 5314. [RESERVED]

§ 5315. [RESERVED]

§ 5316. Microbiological Impurities

(a) A testing laboratory shall test all samples for microbiological impurities. For the purposes of microbiological testing, the laboratory shall report that the sample "passed" microbiological-impurity testing if the following are not detected:

(1) Shiga toxin–producing *Escherichia coli*: not detected in 1 gram;

(2) *Salmonella* spp.: not detected in 1 gram.

(b) The laboratory shall report whether the strains listed in subsection (a) are detected or are not detected in 1 gram. The laboratory shall report this information in the certificate of analysis. If the strains are detected, the batch fails laboratory testing and may not be released for retail sale.

(c) A laboratory is also required to test for the pathogenic *Aspergillus* species *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus* in all medical cannabis goods intended for consumption by inhalation, including but not limited to dried flower, kief, hashish, oil, and waxes.

(1) For the purposes of pathogenic *Aspergillus*-species testing, the laboratory shall report that the sample "passed" if the concentrations of the following *Aspergillus* species are not detected:

(A) *Aspergillus fumigatus*: not detected in 1 gram;

(B) *Aspergillus flavus*: not detected in 1 gram;

(C) *Aspergillus niger*: not detected in 1 gram; and

(D) *Aspergillus terreus*: not detected in 1 gram.

(2) If a pathogenic *Aspergillus* species is detected in a sample under (c)(1), the sample fails microbiological-impurity testing, and the batch fails laboratory testing and may not be released for sale. The laboratory shall report the results in the certificate of analysis.

(d) The laboratory may test for and provide test results for additional microorganisms if requested by the requester of the laboratory testing.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5317. [RESERVED]

§ 5318. [RESERVED]

§ 5319. Mycotoxins

(a) A laboratory shall analyze all samples for mycotoxins. The laboratory shall report that the sample "passed" mycotoxins testing if the concentration of mycotoxins is below the following standards:

(1) The total of aflatoxin B1, B2, G1, and G2: < 20 µg/kg of substance.

(2) Ochratoxin A: < 20 µg/kg of substance.

(b) The laboratory shall report, to 3 significant figures, in micrograms per kilograms (µg/kg), the mycotoxins listed in subsection (a) that are detected in the sample. The laboratory shall report this information in the certificate of analysis.

(c) The laboratory shall indicate in the certificate of analysis whether the concentrations of mycotoxins detected in the sample meets or exceeds the action levels established by this section and whether the sample "passed" or "failed" mycotoxin testing. If the sample fails mycotoxin testing, the batch fails laboratory testing and may not be released for retail sale.

(d) The laboratory may test for and provide test results for additional microorganisms if requested by the requester of the laboratory testing.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5320. [RESERVED]

§ 5321. [RESERVED]

§ 5322. Water Activity and Moisture Content

(a) A laboratory shall analyze a dried flower harvest-batch sample to determine its water-activity level. If the water activity is at or below 0.65 A_w, the sample "passes" water-activity testing.

(b) A laboratory shall analyze solid and semi-solid edible cannabis products to determine its water-activity level. If the water activity is at or below 0.85 A_w, the sample "passes" water-activity testing.

(c) The laboratory shall report the water-activity level of the sample in A_w to 2 significant figures. The laboratory shall report this information in the certificate of analysis.

(d) A laboratory shall analyze a dried flower harvest-batch sample to determine its moisture content. If the moisture content is at 5.0% to 13.0%, the sample "passes" moisture-content testing.

(e) The laboratory shall report the moisture content in percentage to the nearest tenth of one percent, by weight, of the dry sample. The laboratory shall report this information in the certificate of analysis.

(f) The laboratory may provide additional information on moisture content and water activity results if the laboratory determines it is important or if requested by the requester of the laboratory testing.

(g) If a harvest-batch sample "fails" water-activity or moisture-content testing, the harvest batch may be returned to the cultivator or person holding title for further drying and curing unless prohibited by these regulations. The harvest batch will then need to be retested for all tests required in this chapter.

Authority: Sections 19302.1, 19304, 19342, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19342, 19343, and 19344, Business and Professions Code.

§ 5323. [RESERVED]

§ 5324. [RESERVED]

§ 5325. Filth and Foreign Material

(a) A laboratory shall analyze all samples for filth and foreign material present in the sample. "Filth and foreign material" includes but is not limited to hair, insects, feces, packaging contaminants, and manufacturing waste and by-products.

(b) The laboratory shall report that the sample "passed" filth and foreign material testing if the concentration of filth and foreign material is at or below the filth and foreign material action levels in the following table:

Defect	**Action Level**
Mold or foreign material	Average of 5% or more, by weight
Mammalian excreta	Average of 1 mg or more per pound

(c) The laboratory shall report in the certificate of analysis whether the sample "passed" or "failed" filth and foreign-material testing. If it fails filth and foreign-material testing, the batch fails laboratory testing. A harvest batch that fails must be destroyed unless it can be remediated. Failed manufactured cannabis batches must be destroyed.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5326. [RESERVED]

§ 5327. [RESERVED]

§ 5328. Heavy Metals

(a) The laboratory shall analyze all samples for concentrations of the following heavy metals:

(1) Arsenic (As);

(2) Cadmium (Cd);

(3) Lead (Pb); and

(4) Mercury (Hg).

(b) The laboratory shall report the concentration of each heavy metal listed in subsection (a) in micrograms per gram (µg/g) in the certificate of analysis. The laboratory shall report that the sample "passed" heavy-metal testing if the concentrations of heavy metals listed in subsection (a) are below the following heavy metal action levels:

Heavy Metal	**Action Level for Medical Edible Cannabis Products, Suppositories, Sublingual Products, and Other Manufactured Products (µg/g)**	**Action Level for All Inhaled Medical Cannabis Goods (µg/g)**	**Action Level for Topical and Transdermal Medical Cannabis Goods (µg/g)**
Cadmium	0.5	0.2	5.0
Lead	0.5	0.5	10.0

Arsenic	1.5	0.2	3.0
Mercury	3.0	0.1	1.0

(c) The laboratory may test for and may provide test results for additional metals if the instrumentation detects additional metals in the samples or if requested by the requester of the laboratory testing.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5329. [RESERVED]

§ 5330. [RESERVED]

§ 5331. Terpenes

(a) If the cultivator's, manufacturer's, or distributor's product labeling says that the sample contains discrete terpenes, the laboratory shall test for those terpenes. The testing laboratory shall report to one-hundredth of a percent the concentration in percentage in the certificate of analysis.

(b) The laboratory shall also report a terpene measurement for a terpene requested to be tested for by the requester of the laboratory test.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5332. [RESERVED]

§ 5333. [RESERVED]

§ 5334. Certificate of Analysis

(a) The laboratory shall generate a certificate of analysis for each primary sample of a batch that it tests and provide the certificate of analysis to the distributor, the licensee who holds title to the batch, and the bureau within 2 business days of the completion of the analyses.

(b) The certificate of analysis shall, at a minimum, contain the following information:

(1) Licensed laboratory's name, mailing address, and physical address;

(2) Sample-identifying information, including matrix type and unique sample identifiers;

(3) Sample history, including date collected, date received by laboratory, and date or dates of sample preparations and analyses;

(4) The identity of the test methods used to analyze cannabinoids, residual solvents, pesticides, microbiological contaminants, mycotoxins, heavy metals, and, if applicable, terpenes;

(5) Test results for sample homogeneity, if applicable; cannabinoids; residual solvents; pesticides; microbiological contaminantion; mycotoxins; and, if applicable, terpenes;

(6) Test results for moisture content and water activity, and filth and foreign material;

(7) The reporting limit for each analyte tested;

(8) The total primary sample weight in grams, reported to 3 significant figures;

(9) Whether the primary sample and batch "passed" or "failed" laboratory testing; and

(10) The licensee for whom the testing was done, including license number, name, and batch number.

(c) The laboratory shall also report any other claim made by the manufacturer regarding any other cannabinoids present in the sample.

(d) The laboratory shall validate the accuracy of the information contained in the certificate of analysis, and the laboratory director shall sign and date the certificate of analysis.

(e) Failure to provide timely and accurate data is grounds for discipline.

Authority: Sections 19302.1, 19304, 19323, 19342, 19343, and 19344, Business and Professions Code. Reference: Sections 19326, 19342, 19343, and 19344, Business and Professions Code.

§ 5335. [RESERVED]

§ 5336. [RESERVED]

§ 5337. General Reporting Requirements

(a) A laboratory shall report on the certificate of analysis unknown or unidentified substances or materials detected during the analysis of the sample. A laboratory shall, within 24 hours, notify the bureau if a sample is found to contain levels of a contaminant not listed in these regulations that could be injurious to human health if consumed.

(b) If a sample's result exceeds an action level in this chapter, the laboratory shall report that the sample failed the particular test for which the result exceeds the action level, and the laboratory shall report that the sample failed testing in general unless otherwise provided for in these regulations.

(c) A laboratory shall report a sample containing synthetic cannabinoids as "failed."

(d) If a sample fails laboratory testing, the laboratory shall, within 2 business days, upload copies of the certificate of analysis to the track and trace system.

(e) If a sample passes testing, the laboratory shall, within 24 hours, enter "pass" into the track and trace system for the batch from which the sample came. The batch is then released for retail sale.

Authority: Sections 19302.1, 19304, 19343, and 19344, Business and Professions Code.
Reference: Sections 19326, 19343, and 19344, Business and Professions Code.

§ 5338. [RESERVED]

§ 5339. [RESERVED]

Article 6. Post-Testing Procedures

§ 5340. No Retesting Without Remediation

A batch may not be retested following a failed testing unless it has gone through a remediation process. Prior to retesting, the distributor shall provide to the testing laboratory a document specifying how the product was remediated. This document shall be kept by the laboratory and be available for inspection by the bureau.

Authority: Sections 19302.1, 19304, 19343, and 19345, Business and Professions Code.
Reference: Sections 19326, 19343, and 19345, Business and Professions Code.

§ 5341. [RESERVED]

§ 5342. [RESERVED]

§ 5343. Test-Sample Waste Disposal

(a) A laboratory shall destroy nonhazardous used or unused medical cannabis test samples in accordance with section 5080 of this division.

(b) A laboratory shall discard hazardous waste, including hazardous waste containing cannabis, in accordance with federal and state hazardous waste laws.

(c) The testing laboratory shall document the waste disposal procedures followed for each sample.

Authority: Sections 19302.1, 19304, 19327, 19343, and 19345, Business and Professions Code.
Reference: Sections 19326, 19327, 19343, and 19345, Business and Professions Code.

§ 5344. [RESERVED]

§ 5345. [RESERVED]

Article 7. Quality Assurance and Quality Control

§ 5346. Quality-Assurance Program

(a) A laboratory shall develop and implement a quality-assurance program that is sufficient to ensure the reliability and validity of the analytical data produced by the laboratory.

(b) A laboratory shall develop and maintain a written quality-assurance program manual that addresses all aspects of the laboratory's quality-assurance program, including but not limited to the following:

(1) Quality-control procedures;

(2) Laboratory organization and personnel training and responsibilities;

(3) Quality-assurance objectives for measurement data;

(4) Traceability of all data and analytical results;

(5) Equipment preventative maintenance;

(6) Equipment-calibration procedures and frequency;

(7) Performance and system audits;

(8) Corrective action;

(9) The keeping of quality-assurance records;

(10) Standardization of testing procedures; and

(11) Method validation.

(c) The laboratory director and quality-assurance manager, if there is one, shall review, amend if necessary, and approve the quality-assurance program and manual at least annually. The laboratory director shall also review and amend the quality-assurance program and manual whenever there is a change in methods, laboratory equipment, or laboratory director.

Authority: Sections 19302.1, 19304, 19322, and 19343, Business and Professions Code. Reference: Sections 19326, 19322, and 19343, Business and Professions Code.

§ 5347. [RESERVED]

§ 5348. [RESERVED]

§ 5349. Quality-Control Elements

(a) A laboratory shall run quality-control samples with every analytical batch of samples for chemical analysis. Of samples for chemical analysis, 10% to 20% must be quality-control samples. For microbiological analysis, quality-control samples shall be run as needed.

(b) A laboratory shall use quality-control samples in the performance of each assay for chemical and microbiological analyses.

(c) A laboratory shall analyze the quality-control samples in the exact same manner as the test samples to validate the laboratory testing results.

(d) Method blank sample for chemical analysis.

(1) A laboratory shall prepare and run one or more method blank sample for each analytical batch.

(2) A laboratory shall process a method blank sample with a batch of 10 to 20 samples along with and under the same conditions, including all sample-preparation steps, as the other samples in the analytical batch, to demonstrate that the analytical process did not introduce contamination.

(3) Whenever a method blank contains analytes of interest above the limit of detection (LOD) for that analysis, the laboratory shall run another re-prepared method blank and then subtract the average of the 2 method blanks from the results.

(4) If the method blank contains analytes of interest above the limit of quantitation (LOQ), it should be reanalyzed once. If the method blank is still above the limit of quantification, the laboratory should seek to locate and reduce the source of the contamination, and then the entire batch should be re-prepared and reanalyzed. If the method blank results still do not meet the acceptance criteria and reanalysis is not practical, then the laboratory cannot do the analysis until resolution of the issue. Resolution of the issue is the reduction of method blank measurements below the limit of quantification.

(e) Duplicate sample.

(1) The laboratory shall prepare and run a duplicate sample with every 10 to 20 samples for each analytical method.

(2) The acceptance criteria between the primary sample and the duplicate sample is less than 20% relative percent difference, as defined and calculated in section 5237(vv).

(f) Matrix spike samples.

(1) The laboratory shall prepare and run 1 or more matrix spike samples for each analytical batch.

(2) A laboratory shall calculate the percent recovery for quantitative chemical analysis by dividing the sample result by the expected result and multiplying that by 100. If interferences are present in the sample, results will be significantly higher or lower than the actual concentration contained in the sample. The acceptable percent recovery is 70% to 130%.

(3) If the percent recovery is outside of the range in (e)(2), the laboratory must investigate the cause, correct the problem, and re-run the batch of samples. If the problem persists, the laboratory must re-prepare the samples and run the analysis again if possible.

(g) Reference material and certified reference material for chemical analysis.

(1) The laboratory shall use a reference material for each analytical batch. It should be certified and obtained from an outside source if possible.

(2) If a reference material is not available from an outside source, the laboratory shall make its own in-house reference material. Reference material made in-house should be made from a different source of standards than what the calibration standards are made from. The test results

for the reference material must fall within the quality-control acceptance criteria. If it does not, the laboratory shall document and correct the problem and, if necessary, run the batch again.

(h) Calibration standards. The laboratory shall prepare calibration standards by serially diluting a standard solution to produce working standards used for calibration of the instrument and quantitation of analyses in samples.

(i) The laboratory shall generate a quality-control-sample report that includes quality-control parameters and measurements, analysis date, and matrix.

Authority: Sections 19302.1, 19304, 19322, and 19343, Business and Professions Code. Reference: Sections 19326, 19322, and 19343, Business and Professions Code.

§ 5350. [RESERVED]

§ 5351. [RESERVED]

§ 5352. Limits-of-Detection and Limits-of-Quantitation Calculations for Quantitative Analyses

(a) For chemical method analysis, the laboratory shall calculate the limit of detection using one of the following:

(1) Based on signal-to-noise ratio. The determination of the signal-to-noise ratio is performed by comparing measured signals from samples with known low concentrations of analytes with those of method blank samples and establishing the minimum concentration at which the analyte can be reliably detected. A signal-to-noise ratio of between 3:1 and 2:1 is acceptable for estimating the limit of detection.

(2) Based on the standard deviation of the response and the slope of calibration curve. Standard deviation of the response can be determined using 7 blank samples. The limit of detection for chemical methods must be less than one-tenth of the action level for each analyte. The limit of detection may be calculated as follows:

3.3 × standard deviation of the response / slope of the calibration curve

(3) Other methods published by the US Food and Drug Administration or the US Environmental Protection Agency.

(b) For chemical method analysis, the laboratory shall calculate the limit of quantitation using one of the following:

(1) Based on signal-to-noise ratio. The determination of the signal-to-noise ratio is performed by comparing measured signals from samples with known low concentrations of analyte with those of blank samples and establishing the minimum concentration at which the analyte can be reliably quantified. A signal-to-noise ratio of 10:1 is the minimum for reliable quantitation.

(2) Based on the standard deviation of the response and the slope. Standard deviation of the response can be determined from seven blank samples. The limit of detection may be calculated as follows:

10 × standard deviation of the response / slope of the calibration curve

(3) Other methods published by the federal US Food and Drug Administration or the US Environmental Protection Agency.

Authority: Sections 19302.1, 19304, 19322, 19342, and 19343, Business and Professions Code. Reference: Sections 19326, 19322, 19342, and 19343, Business and Professions Code.

§ 5353. [RESERVED]

§ 5354. [RESERVED]

§ 5355. Data Package

(a) The laboratory shall create a data package for each batch of samples a laboratory analyzes. The data package shall contain at minimum the following information:

(1) The name and address of the laboratory that performed the analytical procedures;

(2) The names, functions, and signatures of the laboratory personnel that performed sample preparation, analyses, and reviewed and approved the data;

(3) All sample and the batch quality-control sample results;

(4) Raw data for each sample

(5) Instrument raw data, if any;

(6) Instrument test method with parameters;

(7) Instrument tune report;

(8) All instrument-calibration data;

(9) Test-method worksheets or forms used for sample identification, characterization, and calculations, including chromatograms, sample-preparation worksheets, and final datasheets;

(10) Quality-control report with worksheets, forms, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis;

(11) Analytical batch sample sequence;

(12) The field sample log and the chain-of-custody form; and

(13) The certificate of analysis created as required under this chapter.

(b) Analytical results reported for dried flower samples must be reported on a dry-weight basis with the percent moisture also reported on the certificate of analyses, to allow back calculation of the result to a wet-weight basis.

(c) After the data package has been compiled, the laboratory director shall do the following:

(1) Review the analytical results for technical correctness and completeness;

(2) Verify that the results of each analysis carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively and that the measurements can be traced back;

(3) Approve the measurement results by signing and dating the data package prior to release of the data by the laboratory.

(d) The entire data package shall be kept for a minimum of 7 years and shall be made available upon request by the bureau or the requester of the laboratory testing.

Authority: Sections 19302.1, 19304, 19327, 19343, and 19345, Business and Professions Code. Reference: Sections 19326, 19327, 19343, and 19345, Business and Professions Code.

§ 5356. [RESERVED]

§ 5357. [RESERVED]

§ 5358. Required Proficiency Testing

(a) A laboratory shall participate in a proficiency-testing program provided by an ISO 17043 accredited proficiency-test provider, or a laboratory similar to one, at least once every six months.

(b) Laboratories shall rotate the proficiency tests among their analytical tests and among the staff in the laboratory so that all methods and all staff performing the methods have participated in proficiency tests over a reasonable planned period as defined in the laboratory quality-assurance manual.

(c) The laboratory shall participate in a proficiency-testing program and analyze the proficiency-test samples following the approved laboratory standard operating procedures and the same equipment that are used for testing of commercial medical cannabis goods.

(d) Laboratory employees who participate in a proficiency test shall sign corresponding analytical reports or attestation statements to certify that the proficiency test was conducted in the same manner as the laboratory ordinarily conducts testing of medical cannabis goods.

(e) The laboratory director shall review and approve all proficiency-test samples analyzed and results reported.

(f) The laboratory shall authorize the proficiency-test provider to release the results of the proficiency test to the bureau at the same time that the results are submitted to the laboratory. The laboratory shall also provide the results to the bureau within three business days of the laboratory receiving the results of the proficiency test.

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19326, 19327, and 19343, Business and Professions Code.

§ 5359. [RESERVED]

§ 5360. [RESERVED]

§ 5361. Successful Performance in a Proficiency Test

(a) A laboratory shall be found to have successfully participated in a proficiency test if test results were considered "satisfactory" for an analyte tested in a specific method or if the results demonstrate a positive identification of an analyte tested in a specific method, including quantitative results when applicable. Test results demonstrating a positive identification of 80% of the analytes, including quantitative results when applicable, are proof of a successful participation in a proficiency test. The reporting of a false-positive result is an "unsatisfactory" score for the proficiency test.

(b) A laboratory shall take corrective action and document corrective action when the laboratory meets the standards of subsection (a) but fails to score 100% on a proficiency test. A laboratory may not continue to report results for analytes that were deemed "unacceptable," "questionable," or "unsatisfactory."

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Sections 19326, 19327, and 19343, Business and Professions Code.

§ 5362. [RESERVED]

§ 5363. [RESERVED]

§ 5364. No Participation or Unsatisfactory Performance in a Proficiency Test

(a) Failure to participate in a proficiency test required in section 5358 may result in disciplinary action against the testing laboratory license.

(b) The repeated failure of proficiency tests may also subject the testing laboratory to disciplinary action against the testing laboratory license. For the purpose of this subsection, "repeated" means twice or more often in a three-year period and "failure" means anything other than successful performance as defined in section 5361 of this division.

(c) Within 30 days of receiving an "unacceptable," "questionable," or "unsatisfactory" proficiency test result, the laboratory shall submit to the bureau the proficiency-test results and detailed corrective action responses, which must include root-cause analysis and remedial action plans.

(d) Within 180 days of an unsatisfactory proficiency test result, the laboratory shall submit to the accrediting body and the bureau a written report showing whether the laboratory successfully implemented the corrective action.

(e) The laboratory shall not report analytes for which the laboratory failed the proficiency test unless and until the laboratory satisfactorily remedies the cause of the failure for that analyte, as proven to the bureau by the report required under subsection (d).

(f) The laboratory shall analyze only the analytes for which proficiency-test results were considered "satisfactory."

(g) The laboratory shall not accept samples or analyze the analytes for which proficiency test results were considered "unacceptable," "questionable," or "unsatisfactory" until the corrective

action has been taken and the problem resolved. The testing laboratory shall enroll in the next available round of proficiency tests. Such enrollment should be documented in the corrective action plan initiated in response to a proficiency-test failure as defined in section 5361 of this division.

Authority: Sections 19302.1, 19304, 19311, 19312, 19327, and 19343, Business and Professions Code. Reference: Sections 19311, 19312, 19327, and 19343, Business and Professions Code.

§ 5365. [RESERVED]

§ 5366. [RESERVED]

§ 5367. Internal audit

(a) A laboratory shall conduct an internal audit at least once per year or according to the ISO accrediting body's requirement, whichever is more frequent.

(b) The internal audit must cover everything required to be covered by ISO 17025 internal-audit standards.

(c) Within three business days of completing the internal audit, the laboratory shall submit the results of the internal audit to the bureau.

(d) Failure to conduct an internal audit or failure to submit the results of an internal audit to the bureau may subject the laboratory to a citation or disciplinary action against the testing laboratory license.

Authority: Sections 19302.1, 19304, 19311, 19312, 19327, and 19343, Business and Professions Code. Reference: Sections 19311, 19312, 19327, and 19343, Business and Professions Code.

§ 5368. [RESERVED]

§ 5369. [RESERVED]

§ 5370. Additional Testing Laboratory Recordkeeping Requirements

(a) A laboratory shall maintain analytical testing laboratory records in such a manner that the analyst, date the analysis was performed, the approver of the certificate of analysis and data package, test method, and materials used can be determined by the bureau. Testing laboratory recordkeeping may be on paper or on electronic, magnetic, or optical media and shall be stored in such a way that the data are readily retrieved when requested by the bureau. If the testing laboratory recordkeeping is not on paper, the laboratory must be able to produce them in hard copy for the bureau upon request. All testing laboratory records must be kept for a minimum of 7 years. The bureau shall be allowed access to all electronic data, including standards records, calibration records, extraction logs, laboratory notebooks, and all other laboratory-related documents listed below.

(b) A laboratory shall maintain all documents, forms, records, and standard operating procedures associated with the laboratory's methods as they relate to medical cannabis testing.

(c) A laboratory shall keep and make available to the bureau the following records:

(1) Personnel qualification, training, and competency documentation, including but not limited to resumes, training records or a training database, continuing education records, analytical proficiency testing records, and demonstration of competency records or attestations for laboratory work. These records shall be kept current.

(2) Method verification and validation records, including method modification records, method detection limit and quantitation limit determination records, ongoing verification records such as proficiency test records, and reference material analysis records.

(3) Quality-control and quality-assurance records, including the laboratory's quality-assurance manual and control charts with control limits.

(4) Chain-of-custody records, including chain-of-custody forms, field sample logs, sample-receipt records, sample-description records, sample-rejection records, laboratory information management system (LIMS) records, sample-storage records, sample-retention records, and disposal records.

(5) Purchasing and supply records, equipment-services records, and other equipment records, including purchase requisition records, packing slips, supplier records, and certificates of analysis.

(6) Laboratory equipment installation records, maintenance records, and calibration records. These shall include the date and name of the person performing the installation of, calibration of, or maintenance on the equipment, with a description of the work performed, maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records, and daily verification-of-calibration records.

(7) Customer service records. These include contracts with customers; customer request records; certificates of analyses; customer-transaction records; customer-feedback records; records related to the handling of complaints and nonconformities; and corrective-action records pertaining to complaints.

(8) Nonconforming work and corrective action records. These include corrective-action reports, nonconformance records, nonconformities-resolved-by-correction records, customer-notification records of nonconformities, internal-investigation records, and implementation of corrective action and resumption of work records.

(9) Internal- and external-audit records. These records include audit checklists, standard operating procedures, and audit observation and findings reports. These records must include the date and name of the person or persons performing the audit.

(10) Management review records. These records include technical data review reports and final management-review reports. They must include review date and the identity of the reviewer.

(11) Laboratory data reports, data review, and data approval records, which must include the analysis date and the name of the analysts. These records include instrument and equipment identification records, records with unique sample identifiers, analysts' laboratory notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data, and test-method raw data.

(12) Proficiency testing records, including the proficiency test schedule, proficiency test reports, data-review records, data-reporting records, nonconforming work and corrective action records, and quality-control and quality-assurance records related to proficiency testing.

(13) Electronic data, backed-up data, records regarding the protection of data, and laboratory-security records. These records include raw unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, authorized personnel records and laboratory-access records, and surveillance- and security-equipment records.

(14) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' laboratory notebooks and logbooks, supplier records, and certificates of analysis, and all other data-related records.

(15) Laboratory contamination and cleaning records, including autoclave records, acid-wash logs and records, and general laboratory-safety and chemical-hygiene protocols.

(d) If the records are missing or incomplete, or if a laboratory does not produce the records for the bureau upon request, the bureau may take disciplinary action against the licensee.

Authority: Sections 19302.1, 19304, 19311, 19312, 19327, and 19343, Business and Professions Code. Reference: Sections 19311, 19312, 19327, and 19343, Business and Professions Code.

§ 5371. [RESERVED]

§ 5372. [RESERVED]

Article 8. Employee Education and Experience Requirements

§ 5373. Personnel Qualifications

(a) Laboratory employees shall meet the experience and education requirements specified by this section. For an employee who attended a college or university not located in the United States or its territories, the requirement that the college or university be accredited is satisfied if the educational credentials of the employee are found, by a credential evaluation service, to be equivalent to those of a person who attended an accredited US college or university.

(b) A person who performs analytical tasks shall meet the experience and educational requirements of a testing analyst and be able to demonstrate proper performance of the analytical tasks.

(c) Laboratory director. To be a laboratory director of a licensed testing laboratory under the Act, a person must satisfy one of the following:

(1) Hold a doctoral degree in a chemical or biological science from an accredited college or university and have completed 3 years of full-time, post-education practical experience in a laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body;

(2) Hold a master's degree in a chemical or biological science from an accredited college or university and have completed 5 years of full-time practical experience in a post-education laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body; or

(3) Hold a bachelor's of science degree in a chemical or biological science from an accredited college or university and have completed 7 years of full-time, post-education practical experience in a laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body.

(d) In addition to meeting the educational requirements, the laboratory director shall be capable of satisfactorily fulfilling all of the following core responsibilities:

(1) Overseeing and directing the scientific methods of the laboratory;

(2) Ensuring that the testing laboratory achieves and maintains quality standards of practice; and

(3) Supervising all testing laboratory personnel.

(e) Supervisory analyst. To be a supervisory analyst of a licensed testing laboratory under the Act, a person must satisfy one of the following

(1) Satisfy the laboratory-director qualification criteria;

(2) Hold a doctoral degree and have completed at least 1 year of full-time, post-education practical experience in a laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body;

(3) Hold a master's degree and have completed 2 years of full-time, post-education practical experience in a laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body; or

(4) Hold a bachelor's of science degree in a chemical or biological science from an accredited college or university and have completed 3 years of full-time, post-education practical experience in a laboratory performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body.

(f) Laboratory testing analyst. To be a laboratory testing analyst of a licensed testing laboratory under the Act, a person must satisfy one of the following:

(1) Satisfy the qualification criteria required for a laboratory director;

(2) Satisfy the qualification criteria required for supervisory analyst; or

(3) Hold a bachelor's degree in one of the chemical or biological sciences from an accredited college or university; or

(4) Have completed at least 2 years of college coursework from an accredited college or university and at least 1 year of full-time, non-education-related practical experience in a

laboratory performing analytical scientific testing in which the testing methods are or were recognized by an accrediting body.

(g) Sampler. To be a sampler at a licensed testing laboratory under this Act, a person must satisfy all of the following:

(1) Be 21 years old or older;

(2) Have completed at least 2 years of college coursework; and

(3) Have completed the minimum training requirements set forth in section 5376(a).

Authority: Sections 19302.1, 19304, and 19343, Business and Professions Code. Reference: Section 19343, Business and Professions Code.

§ 5374. [RESERVED]

§ 5375. [RESERVED]

§ 5376. Training Requirements for Samplers

(a) The testing laboratory shall ensure that a sampler is trained in the following areas:

(1) The scientific basis of cannabis sampling for chemical and microbiological tests;

(2) Theory of sampling, including common sampling errors and ways to identify and minimize errors;

(3) Maintenance of sample integrity;

(4) The proper completion of chain-of-custody forms;

(5) Sample-collection procedures for each medical cannabis goods matrix;

(6) An overview of relevant statutes and regulations;

(7) The proper selection, use, and maintenance of sampling tools and equipment;

(8) Practical, hands-on application with representative samples; and

(9) Sample observations that should be recorded and how to record those observations during sampling.

(b) The laboratory shall maintain documentation proving that the training required under subsection (a) has been given to and completed by the sampler.

(c) A laboratory shall retain training records for samplers for 7 years, whether or not the sampler remains employed by the laboratory.

Authority: Sections 19302.1, 19304, 19327, 19342, and 19343, Business and Professions Code. Reference: Sections 19327, 19342, and 19343, Business and Professions Code.

§ 5377. [RESERVED]

§ 5378. [RESERVED]

§ 5379. Verification of Personnel Qualifications

(a) A laboratory shall verify and maintain documentation of qualifications of its employees. A laboratory shall maintain records that show the following:

(1) The colleges and universities attended by the employee and the names and addresses of the colleges and universities, the major course of study, dates of attendance, degrees conferred, and completion date;

(2) Official transcripts from the registrar of the colleges and universities attended by the employee showing all courses, course credits, degrees conferred, and dates degrees were conferred and;

(3) Records from credential evaluation services, including translations of transcripts from non-English-language colleges and universities.

(b) Documentation of a person's experience includes the following:

(1) Laboratory name and address, dates of employment, number of hours per week employed, and a description of the laboratory testing performed by the person; and

(2) Signed documentation of such experience from the facility's laboratory director or equivalent.

Authority: Sections 19302.1, 19304, 19327, and 19343, Business and Professions Code. Reference: Sections 19327 and 19343, Business and Professions Code.

§ 5380. [RESERVED]

§ 5381.[RESERVED]

Article 9. Laboratory Security

§ 5382. Premises Security

(a) A laboratory shall develop and implement security protocols that are capable of preventing diversion, theft, and loss of medical cannabis samples.

(b) The security protocol shall be documented in writing and available to all laboratory personnel during normal business hours.

Authority: Sections 19302.1, 19304, 19322, 19323, 19327, 19334, and 19343, Business and Professions Code. Reference: Sections 19322, 19323, 19327, 19334, and 19343, Business and Professions Code.

§ 5383. [RESERVED]

§ 5384. [RESERVED]

§ 5385. [RESERVED]

§ 5386. [RESERVED]

§ 5387. [RESERVED]

§ 5388. Access Control

(a) A laboratory shall deter the unauthorized entrance into areas within the laboratory where medical cannabis is present by controlling access to those areas through doing all of the following:

(1) Limiting access to only certain personnel and for the sole purpose of executing their specific job function and duties;

(2) Implementing an access-control-card system capable of preventing unauthorized access through access control points. The system must record the transaction history of all entrants;

(3) Using a security alarm system as required in section 5074 of this division; and

(4) Maintaining a visitor arrival and departure log, which must contain, at minimum, the name of the visitor, date and time of arrival and departure, and the purpose of the visit.

Authority: Sections 19302.1, 19304, 19322, 19323, 19327, and 19334, Business and Professions Code. Reference: Sections 19322, 19323, 19327, and 19334, Business and Professions Code.

§ 5389. [RESERVED]

§ 5390. [RESERVED]

§ 5391. [RESERVED]

§ 5392. [RESERVED]

§ 5393. [RESERVED]

§ 5394. [RESERVED]

§ 5395. [RESERVED]

§ 5396. [RESERVED]

§ 5397. Storage Areas

(a) A laboratory shall store cannabis secured with a commercial-grade lock in a room or cabinet capable of preventing diversion, theft, and loss. Secured areas must be locked at all times except when managing or retrieving a secured item or items. A laboratory shall store medical cannabis samples and items apart and away from non-medical-cannabis samples and items. The testing laboratory shall designate secured areas for storage of the following:

(1) Test samples of medical cannabis goods;

(2) Waste containing cannabis;

(3) Reference standards for analysis of cannabinoids;

(4) Any controlled substances related to cannabinoids; and

(5) Records of analytical tests, including certificates of analyses and data packages.

Authority: Sections 19302.1, 19304, 19322, 19323, 19327, 19334, 19343, and 19345, Business and Professions Code. Reference: Sections 19322, 19323, 19327, 19334, 19343, and 19345, Business and Professions Code.

§ 5398. [RESERVED]

§ 5399. [RESERVED]

§ 5400. Electronic Data

(a) Laboratories shall store all raw unprocessed instrument output data files and processed quantitation output files at the laboratory on some form of electronic, magnetic, or optical media. A laboratory shall allow access to these records for inspection and audit.

(b) Laboratories shall install, manage, and maintain password-protection for electronically stored data, including the data listed in subsection (a).

Authority: Sections 19302.1, 19304, 19327, 19334, and 19343, Business and Professions Code. Reference: Sections 19327, 19334, and 19343, Business and Professions Code.

§ 5401. [RESERVED]

§ 5402. [RESERVED]

§ 5403. Notification of Discrepancy

(a) Laboratories shall notify the bureau within 24 hours of discovering any of the following:

(1) An unexplained loss of 5% or more of the inventory of unpackaged and unused harvest-batch samples held at the laboratory;

(2) An unexplained loss of 1 or more units of packaged medical cannabis batch samples held at the laboratory; or

(3) Diversion or theft of medical cannabis or any other criminal activity pertaining to the operation of the laboratory.

Authority: Sections 19302.1, 19304, 19334, and 19343, Business and Professions Code. Reference: Sections 19334 and 19343, Business and Professions Code.

§ 5404. through 5499. [RESERVED]

BUREAU OF MARIJUANA CONTROL
CALIFORNIA CODE OF REGULATIONS TITLE 16, DIVISION 42
MEDICAL CANNABIS TESTING LABORATORIES
INITIAL STATEMENT OF REASONS

HEARING DATES: June 1, 2017; June 8, 2017; June 13, 2017; June 20, 2017

SUBJECT MATTER OF PROPOSED REGULATIONS: Medical Cannabis Testing Laboratories

SECTIONS AFFECTED: 5237, 5238, 5241, 5244, 5247, 5250, 5253, 5256, 5259, 5262, 5265, 5268, 5271, 5274, 5277, 5280, 5283, 5286, 5289, 5292, 5295, 5298, 5301, 5304, 5307, 5310, 5313, 5316, 5319, 5322, 5325, 5328, 5331, 5334, 5337, 5340, 5343, 5346, 5349, 5352, 5355, 5358, 5361, 5364, 5367, 5370, 5373, 5376, 5379, 5382, 5388, 5397, 5400, and 5403.

BACKGROUND

The Medical Cannabis Regulation and Safety Act (MCRSA or Act) provides a statutory framework for the licensing of commercial cannabis businesses within the State of California. The MCRSA established the Bureau of Medical Cannabis Regulation, which through the passage of proposition 64, was renamed the Bureau of Marijuana Control (bureau) within the Department of Consumer Affairs (DCA). The bureau was created to license and regulate dispensaries, distributors, transporters, and testing laboratories under the MCRSA. Until now, the state has not comprehensively regulated the medical cannabis industry. The bureau's proposed regulations address the specific implementation for testing laboratories to be regulated by the bureau pursuant to the MCRSA. General licensing regulations as well as distributor, transporter, and dispensary regulations have been proposed in another rulemaking package. Additionally, manufacturer licenses will be issued and regulated by the California Department of Public Health (CDPH) and cultivator licenses will be issued and regulated by the California Department of Food and Agriculture (CDFA). While developing all medical cannabis regulations, the three licensing authorities worked cooperatively to strive for consistency in areas of overlap and to create a system that allows for reasonable regulation of the industry as a whole. The bureau and the Department of Public Health worked very closely to develop the proposed testing laboratory regulations.

TESTING LABORATORIES

STATEMENT OF PURPOSE, PROBLEM, RATIONALE, AND BENEFITS

The MCRSA makes clear that the protection of the public is paramount. In keeping with that, the MCRSA requires that the bureau develop procedures for ensuring that all medical cannabis goods are tested prior to delivery to a dispensary for retail sale to medical cannabis patients. The MCRSA requires that all medical cannabis goods be tested by testing laboratories licensed by the bureau for a variety of attributes for the protection of the public. Through the proposed testing

laboratory regulations, the bureau aims to ensure the medical cannabis goods offered for sale are safe for human consumption. The bureau also aims to ensure medical cannabis patients receive accurate information regarding the medical cannabis goods they consume.

First, the MCRSA requires the bureau, with assistance from the CDPH, to develop health-protective levels for moisture content, contaminants, residual solvents, microbiological impurities, and foreign material. Consumable medical cannabis goods are at risk of contamination similar to other consumable products. Contamination may occur during various stages of the cultivation, harvest, extraction, processing, and packaging processes. Some of the types of contamination that can make a medical cannabis good unsafe involves pesticides, residual solvents and processing chemicals, microbiological impurities, heavy metals, and foreign material. These proposed regulations aim to set forth action levels that the bureau considers are both protective of public health and achievable by 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. As such, these contaminants are discussed in greater detail:

Chemicals
During the cultivation and manufacturing process, injurious chemicals can contaminate medical cannabis goods. For instance, solvents are used to extract, in concentrated amounts, cannabinoids from dried flower. Some of the chemicals used as solvents may linger after the processing is finished. When present in products intended for human consumption, excessive amounts of these residual solvents and processing chemicals may pose risks to human health.

Microbiological impurities
Some *Escherichia coli* (*E. coli*) strains can cause human disease. One strain produces a toxin called Shiga toxin, which can result in serious illness. Because of the low infectious dose required for disease causation, the bureau proposes there be zero tolerance for the presence of Shiga toxin–producing *E. coli* in medical cannabis goods.

In addition, the presence of *Salmonella* in cannabis has been documented and, in 1981, resulted in a multistate outbreak. It has also been associated with gastrointestinal disease in both healthy and in immunocompromised populations. The bureau proposes testing for all *Salmonella* strains.

There have been a number of cases involving immunocompromised people who have become ill, or died, from inhaling *Aspergillus*. *Aspergillus* is a fungus that can cause serious health problems. Certain *Aspergillus* strains can cause a variety of immune-reaction lung disorders, ranging from asthma, allergic bronchopulmonary aspergillosis, and hypersensitivity pneumonitis to invasive systemic fungal infections. The bureau proposes testing for this fungus.

Mycotoxins
Mycotoxins are toxic substances produced by certain fungi that can grow on human food and animal feed grain. Human exposure to mycotoxins, through ingestion, inhalation, and dermal contact, has been associated with severe human health impacts that include necrosis, cirrhosis, and carcinomas. The bureau proposes requiring testing for certain mycotoxins.

Foreign material
Medical cannabis products may be injurious to health if they consist in whole or in part of any filthy, putrid, or decomposed substances or is otherwise contaminated by any added poisonous or added deleterious substance. This may occur if the medical cannabis goods have been stored, prepared, or packed under unsanitary conditions.

Heavy metals
Cannabis plants are known to uptake metals from contaminated growth media (for example, soil), which increases the risk of adverse health effects associated with the consumption of medical cannabis goods. For example, exposure to lead may cause neurological, reproductive, developmental, immune, cardiovascular, and renal health effects. And mercury shows toxicological effects such as neurological, corrosive, hematopoietic, and renal effects as well as cutaneous disease (acrodynia).

Second, the proposed regulations set minimum standards for testing laboratories. There are inherent challenges to regulating an industry that has not been federally regulated and has only been newly regulated in other states. With regard to cannabis testing laboratories, one challenge the bureau faced when developing these proposed regulations was lack of generally accepted validated methods for the testing of cannabis. Therefore, it was imperative the bureau include regulations regarding how to go about validating testing methods. Another challenge was that there are no certified reference materials for cannabis. Therefore, the bureau proposes that laboratories create their own reference materials until reference materials may be obtained from an outside party, where most other reference materials come from. Additionally, because ISO, the accreditation body for testing laboratories, is a private organization not under the control of the bureau, nor subject to public-record disclosure laws, it was necessary for the bureau to develop its own minimum standards for laboratories. These standards aim to ensure that the laboratories that are testing the medical cannabis goods before retail sale are adhering to laboratory practices that result in accurate information that will be provided to medical cannabis patients through the labeling of medical cannabis goods. These proposed standards would allow the bureau to ensure laboratories maintain high operational standards and conduct valid tests. These testing laboratory standards include ones for sampling procedures, testing-method validation, quality assurance, and laboratory personnel qualifications.

Sampling

Proper sampling collection may be far more consequential than laboratory measurement errors. If a sample of something is improperly obtained, the measurement data that is gathered through analyzing the sample puts the measurement data it produces into question. Proper sampling is therefore critical to obtaining relevant and valid data.

In these regulations, the bureau proposes fairly detailed minimum sampling requirements. 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 MCRSA provision that requires the laboratory agent collecting the sample to use a "statistically valid sampling method." A statically valid sampling method is necessary to ensure that the medical cannabis goods samples accurately and precisely represent the characteristics of the batches from which they were taken.

Method Validation

An analytical procedure is developed to test a defined characteristic of a substance against established acceptance criteria for that characteristic. This is called a "method," or a "test." To ensure the method used results in reliable, valid data, the method must be "validated" before it is used to produce usable results. Method validation is a process by which a method is tested to ensure it is producing valid results.

Because it is only fairly recently that cannabis has been a substance that is tested for impurities by laboratories, and because the federal government does not regulate this industry, there are few validated methods for the testing of cannabis. Therefore laboratories will have to validate their own methods for the testing of medical cannabis.

The laboratory's analytical instrumentation and methodology should be selected based on the intended purpose and scope of the analytical method. Parameters that may be evaluated during method development are specificity, linearity, limits of detection (LODs) and limits of quantitation (LOQs), range, accuracy, and precision.

These proposed regulations set out what the bureau considers to be acceptable ways to validate a "nonstandard" method, which will be used for testing medical cannabis goods. In developing these proposed method-validation regulations, the bureau looked to guidelines and other resources used in other industries.

Quality Assurance

Quality assurance is a set of operating principles that enable laboratories to produce defensible data of known accuracy and precision. These operating principles form a laboratory quality system and are documented in a laboratory's quality-assurance manual. These regulations propose the minimum components of a quality-assurance program and what must be contained in the quality-assurance manual.

The bureau's proposed quality-assurance program includes requirements for quality-control samples. The bureau proposes to require the use of method blank samples, field duplicate samples, and matrix spike samples (or laboratory control samples). The proposed regulations also set out how to calculate the limit of detection and limit of quantitation. They also spell out recordkeeping requirements and require an annual internal audit. Together these proposed regulations will assist in providing accurate testing and guidance for how to ensure accurate testing.

The bureau is also proposing required proficiency testing. Proficiency testing is a blind testing of a laboratory's ability to perform analyses. The bureau proposes requiring testing laboratory licensees participate in a proficiency testing carried out by an ISO 17043 accredited laboratory so that every analyst and every method used by the laboratory is eventually tested. This is an important check on the ability of laboratories to provide accurate data.

Personnel

The education and experience level of the personnel of a testing laboratory is very important. Many of the required tests in these proposed regulations are complex and must be done by persons with specialized training. Therefore, the bureau proposes in these regulations to require testing laboratories licensed by the bureau to have a laboratory director. It is also proposed that analysts and supervisory analysts meet some minimum qualifications. This is done to ensure laboratories are run by competent and trained persons, to ensure accurate testing, and to ensure public safety.

SPECIFIC PURPOSE, NECESSITY, AND RATIONALE FOR EACH PROPOSED ADOPTION

The bureau proposes to add sections 5237, 5238, 5241, 5244, 5247, 5250, 5253, 5256, 5259, 5262, 5265, 5268, 5271, 5274, 5277, 5280, 5283, 5286, 5289, 5292, 5295, 5298, 5301, 5304, 5307, 5310, 5313, 5316, 5319, 5322, 5325, 5328, 5331, 5334, 5337, 5340, 5343, 5346, 5349, 5352, 5355, 5358, 5361, 5364, 5367, 5370, 5373, 5376, 5379, 5382, 5388, 5397, 5400, and 5403 of Division 42 of Title 16 of the California Code of Regulations, as follows.

The following sections are proposed for numbering purposes only and possible future rulemaking. They are not proposed in this rulemaking to contain any regulatory language, but are included for clarity for the reader.

Reserved sections are 5239, 5240, 5242, 5243, 5245, 5246, 5248, 5249, 5251, 5252, 5254, 5255, 5257, 5258, 5260, 5261, 5263, 5264, 5266, 5267, 5269, 5270, 5272, 5273, 5275, 5276, 5278, 5279, 5281, 5282, 5284, 5285, 5287, 5288, 5290, 5291, 5293, 5294, 5296, 5297, 5299, 5300, 5302, 5303, 5305, 5306, 5308, 5309, 5311, 5312, 5314, 5315, 5317, 5318, 5320, 5321, 5323, 5324, 5326, 5327, 5329, 5330, 5332, 5333, 5335, 5336, 5338, 5339, 5341, 5342, 5344, 5345, 5347, 5348, 5350, 5351, 5353, 5354, 5356, 5357, 5359, 5360, 5362, 5363, 5365, 5366, 5368,

5369, 5371, 5372, 5374, 5375, 5377, 5378, 5380, 5381, 5383, 5384, 5385, 5386, 5387, 5389, 5390, 5391, 5392, 5393, 5394, 5395, 5396, 5398, 5399, 5401, 5402, and 5404 through 5499.

CHAPTER 5. TESTING LABORATORIES

ARTICLE 1. CHAPTER DEFINITIONS

§ 5237. Definitions

This proposed section is necessary because the definitions contained in it will provide predictability to licensees and work to avoid confusion regarding various terms used in this chapter. Along with the definitions in section 5000, the proposed definitions in this section apply to this chapter, as well as the definitions at Business and Profession Code section 19300.5.

Proposed subsection (a) defines "acceptance criteria" to mean the specified limits placed on characteristics of an item or method that are used to determine data quality. Acceptance criteria are process defined in standard operating procedures and are compared with certain measures (such as precision, accuracy, representativeness, comparability, and completeness) to determine the validity of collected data.

Proposed subsection (b) defines "accredited college or university" to mean a college or university accredited by a regional or national accrediting agency that is an accreditor recognized by the Secretary of the United States Department of Education. This definition is necessary to clarify requirements for testing laboratory personnel to ensure they are competent in performing analytical testing and related tasks. The Department of Education provides oversight over the postsecondary accreditation system through its review of all federally recognized accrediting agencies. The department holds accrediting agencies accountable by ensuring that they enforce their accreditation standards effectively. Also, as a part of the Department's oversight roles, the Secretary of Education is required by law to publish a list of nationally recognized accrediting agencies that the Secretary determines to be reliable authorities as to the quality of education or training provided by the institutions of higher education and the higher-education programs they accredit. More information on accreditation can be found at https://www.ed.gov/accreditation (visited February 24, 2017).

Proposed subsection (c) defines "action level" to mean the concentration of an analyte at, above, or below which triggers an action, such as passing or failing an analytical test. An action level is the threshold value that provides the criterion for choosing between alternative actions. It is a common term in regulatory schemes and is necessary for setting the limitation criteria for various laboratory tests.

Proposed subsection (d) defines "aliquot" to mean a portion of a sample that is used in an analysis. This definition is necessary to provide the clarification to the readers.

Proposed subsection (e) defines "analyte" to mean a chemical, compound, element, bacterium, yeast, fungus, or toxin to be identified or measured. This definition clarifies what is considered an analyte for testing purposes.

Proposed subsection (f) defines "analytical batch" to mean a group of samples that are prepared together for the same analysis and analyzed sequentially using the same instrument calibration curve and that have common analytical quality-control checks. This definition enables the regulated public to distinguish between an analytical batch and other "batches" as that word is used elsewhere in the regulations. Analytical batches contain quality-control samples as required in these proposed regulations.

Proposed subsection (g) defines "analytical method" to mean a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample. A laboratory must create standard operating procedures for all analytical methods the laboratory performs, as required in these proposed regulations.

Proposed subsection (h) defines "batch" in the same way in which the Act defines it at Business and Professions Code section 19300.5(c). It is repeated in the regulations for the convenience of the reader.

Proposed subsection (i) defines "cannabinoid" to mean a chemical compound that is unique to and derived from cannabis. This definition is the same definition as in the Act at Business and Professions Code section 19300.5(e) and is repeated in the regulations for the convenience of the reader.

Proposed subsection (j) defines "CAS number" to mean the unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service. Using CAS numbers allows for a reliable reference to a specific substance. This is necessary for clarity because many substances have various names and because disciplines use different names for the same substance.

Proposed subsection (k) defines "CBD" as cannabidiol, Chemical Abstracts Service number 13956-29-1. This definition is necessary to ensure the regulated community has the same understanding of what this substance is.

Proposed subsection (l) defines "CBDA" as cannabidiolic acid, Chemical Abstracts Service number 1244-58-2. This definition is necessary to ensure the regulated community has the same understanding of what this substance is.

Proposed subsection (m) defines "CBG" as cannabigerol, Chemical Abstracts Service number 25654-31-3. This definition is necessary to ensure the regulated community has the same understanding of what this substance is.

Proposed subsection (n) defines "CBN" as cannabinol, Chemical Abstracts Service number 521-35-7. This definition is necessary to ensure the regulated community has the same understanding of what this substance is.

Proposed subsection (o) defines "certificate of analysis" to mean the report prepared by the laboratory after testing under section 5334 about the analytical testing performed and results obtained. "Certificate of analysis" is used in the enabling statute, and this definition specifies what that document is.

Proposed subsection (p) defines "certified reference material" to mean a reference material prepared by a certifying body. "Reference material" is defined in these regulations, also. Preparation of a certified reference material sample is a necessary component of quality-control procedures when conducting sample analysis; therefore clarifying this term is necessary.

Proposed subsection (q) defines "concentrate" to mean manufactured cannabis that has undergone a process to concentrate one or more active cannabinoids, thereby increasing the product's potency. Resin from glandular trichomes from a cannabis plant ("kief") is a concentrate for purposes of the Act. A cannabis concentrate is not considered food, as defined by Health and Safety Code section 109935, or a drug, as defined by Health and Safety Code section 109925. This definition is nearly the same as that for "cannabis concentrate" in the Act at Business and Professions Code section 19300.5(g). It is necessary to specify what is considered a "concentrate" to distinguish it from other cannabis products.

Proposed subsection (r) defines "data-quality assessment" to mean a scientific and statistical process that establishes whether the collected data are of the right type, quality, and quantity to support the data's intended uses. Data collected from laboratory testing should only be considered valid upon a data-quality assessment prior to the release of the certificate of analysis to the requester and the bureau. This type of assessment is consistent with ISO 17025 quality-control procedures. Having a clearly defined term allows for clarity.

Proposed subsection (s) defines "field duplicate sample" to mean a sample that is taken in the identical manner and from the same cannabis batch being sampled as the primary sample. It is analyzed separately from the primary sample and is used for quality control only. The use of a field duplicate is to validate the sampling procedures used; it can be used as a measure of the sampling-point representativeness. Clearly defining this term brings clarity for the licensee.

Proposed subsection (t) defines "frequency" as the number of items occurring in a given category. Frequency may be determined by analytical method or laboratory-specific requirements for the purpose of accuracy, precision of the analysis, or statistical calculation.

Proposed subsection (u) defines "hashish" to mean compressed kief. "Kief" is defined in proposed subsection (x). This definition is necessary to explain what cannabis product is considered hashish because different products require different tests. For instance, in the

proposed regulations, a laboratory does not need to analyze hashish for residual solvents and processing chemicals.

Proposed subsection (v) defines "increment" and "sample increment" as a smaller sample that, together with other increments, compose the primary sample. The sampler will collect a number of increments, which, combined, will be the primary sample for that batch.

Proposed subsection (w) defines "ISO/IEC" or "ISO" to mean the joint technical committee of the International Organization for Standardization and the International Electrotechnical Commission. This definition is necessary to clarify the meaning of ISO/IEC as used in the Act at Business and Professions Code section 19342(a).

Proposed subsection (x) defines "kief" to mean a concentrate that is the resin from glandular trichomes from a cannabis plant. This definition is in line with the definition of "cannabis concentrate" in the Act at Business and Professions Code section 19300.5(g). It is necessary to explain what cannabis product is considered kief because different products require different tests. For instance, in these proposed regulations, a laboratory does not need to analyze kief for residual solvents and processing chemicals.

Proposed subsection (y) defines "laboratory" to mean a testing laboratory that is licensed by the bureau to conduct sampling and analyses of medical cannabis goods and includes the personnel and instruments used to analyze medical cannabis goods. This definition is in line with the definition of "testing laboratory" in the Act at Business and Professions Code section 19300.5(ak).

Proposed subsection (z) defines "limit of detection" or "LOD" to mean the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit. This definition is commonly used in the laboratory-testing industry, and providing the definition brings clarity to the regulations. Reporting the limit of detection is a necessary component of method validation as well as quality-control procedures when conducting sample analysis.

Proposed subsection (aa) defines "limit of quantitation" or "LOQ" to mean the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision. This definition is commonly used in the laboratory-testing industry and providing the definition buys clarity to the regulations. Reporting the limit of quantitation is a necessary component of method validation as well as quality-control procedures.

Proposed subsection (bb) defines "matrix" as the component or substrate that contains the analyte of interest, "matrices" is the plural. Matrices in the medical cannabis field include dried flower, hashish, kief, oil, edible cannabis products, and other medical cannabis goods. The definition is necessary for clarity.

Proposed subsection (cc) defines "matrix spike duplicate" to mean a duplicate sample prepared by adding a known quantity of a target analyte to a sample matrix or a matrix very similar to the sample matrix. See the explanation in the rationale behind section (dd) below.

Proposed subsection (dd) defines "matrix spike sample" to mean a sample prepared by adding a known quantity of the target analyte to a sample matrix or a matrix very similar to the sample matrix. A matrix spike sample is used to determine the effects of matrix interferences on analytical accuracy of a sample. A laboratory control samples is an analyte-free matrix spike with known concentration of target analytes that is used to measure the analytical accuracy and determine laboratory precisions.

However, because there are not cannabis references standards available yet, and because licensed testing laboratories will be testing a very wide variety of matrices, it may not be possible for a laboratory to use a laboratory control sample. When that is the case, the laboratory shall use the matrix from the field sample.

These proposed regulations define a "matrix spike sample" as either (1) a matrix that is from the primary field sample (a true matrix spike sample) or (2) a matrix very similar to the sample matrix (ie, a laboratory control sample). Both types of samples are referred to here as "matrix spike samples." This definition provides clarity for the testing licensee.

Proposed subsection (ee) defines "medical cannabis goods" to mean medical cannabis, including dried flower, and manufactured medical cannabis products. This broad definition is necessary to keep the regulatory language simple and easy to read.

Proposed subsection (ff) defines "method blank" to mean an analyte-free matrix to which reagents are added in the same volumes or proportions as are used in sample preparation. A method blank is used to control for potential laboratory-introduced contamination and to ensure laboratory contamination does not result in false-positive results. Preparation of a method blank sample is a necessary component of quality-control procedures, and providing the definition lends clarity to the regulations.

Proposed subsection (gg) defines "moisture content" to mean the percentage of water in a dry sample, by weight. This definition clarifies the meaning of the term as it is used in the Act at Business and Professions Code section 19342(c)(1).

Proposed subsection (hh) defines "non-target organism" to mean an organism that the test method or analytical procedure is not testing for. Non-target organisms are used in evaluating the specificity of a test method; therefore this definition is needed.

Proposed subsection (ii) defines "percent recovery" to mean the percentage of a measured concentration relative to the added (spiked) concentration in a reference material, matrix spike sample, or matrix spike duplicate. Percent recovery allows for determination of how much of the

original substance (added at the beginning of an experiment) one ends up with or gets back at the end of the experiment. It is necessary to determine the validity of your test method or a particular matrix effect on the spiked analyte.

Proposed subsection (jj) defines "practical experience" to mean hands-on laboratory experience, using equipment, instruments, kits, and materials routinely found in a laboratory. This definition is necessary to explain what kind of experience is required for a person to hold certain positions in a bureau-licensed laboratory.

Proposed subsection (kk) defines "primary sample" to mean a portion of medical cannabis goods, or "sample," collected from a medical cannabis batch for testing. This definition is necessary to distinguish this sample from a field duplicate sample, as defined in subsection (s).

Proposed subsection (ll) defines "proficiency test" to mean an evaluation of a laboratory's performance against pre-established criteria by means of interlaboratory comparisons of test measurements. Proficiency testing is a necessary component of ISO accreditation and is a common way to test and regulate laboratories. This is a term commonly used in the industry and is provided here for clarity.

Proposed subsection (mm) defines "proficiency test sample" as a sample prepared by a party independent of the testing laboratory, with a concentration and identity of an analyte that is known to the independent party but is unknown to the testing laboratory and testing laboratory personnel. This definition is necessary to distinguish this type of sample from other samples submitted by requesters to the laboratory. A proficiency test sample is used to conduct proficiency testing, and the result of that testing is used by ISO and by regulators to evaluate whether a laboratory is competent of doing such testing.

Proposed subsection (nn) defines "quality assurance" to mean a set of operating principles that enable laboratories to produce defensible data of known accuracy and precision. Quality assurance encompasses employee training, equipment preventative maintenance procedures, calibration procedures, and quality-control testing, among other things. Note that this definition is not the same as the one for "quality assurance" as applies to distributors in the MCRSA. Rather, "quality assurance" as used in this chapter is the commonly used term used in laboratory settings.

Proposed subsection (oo) defines "quality control" to mean a set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control in which errors have been reduced to acceptable levels. "Quality control" is a term commonly used in the laboratory industry and provides clarity for the regulations.

Proposed subsection (pp) defines "quality-control samples" to mean samples produced and used by a laboratory for the purpose of assuring quality control. Quality-control samples include but

are not limited to blank samples, spike samples, duplicate samples, and reference material. This broad definition is necessary to simplify the regulatory language.

Proposed subsection (qq) defines "reagent" to mean a compound or mixture of chemicals used in laboratory analyses. A reagent may be used to tell whether a specific chemical substance is present by causing a reaction to occur with the chemical substance. This definition is necessary to identify the substances used in the analytical process and is a common term.

Proposed subsection (rr) defines "reference material" to mean a material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix. Reference material is used to document the bias of the analytical process. Reference material is a necessary component of a laboratory's quality-control procedures required to ensure confidence in test results.

Proposed subsection (ss) defines "reference method" as a method by which the performance of an alternate method is measured or evaluated. A reference method is necessary for method-validation studies. Method-validation studies must include comparison to a recognized reference method to demonstrate equivalence or increased performance, the significance of which must be determined statistically. The US Food and Drug Administration requires that all new methods be validated against an agreed-upon reference method if one exists.

Proposed subsection (tt) defines "relative percent difference" or "RPD" to mean a comparative statistic used to calculate precision or random error. RPD must be calculated using the following equation:

$$\text{RPD} = \left|(\text{sample measurement} - \text{duplicate-sample measurement})\right| \,/\, ([\text{sample measurement} + \text{duplicate-sample measurement}] / 2) \times 100\%$$

Relative percent difference is used to compare two quantities while taking into account the "sizes" of the things being compared. It is an important statistical tool used to ascertain precision or random error of measurement between two samples. Defining it here brings clarity when the term is used within the regulation.

Proposed subsection (uu) defines "relative standard deviation" or "RSD" to mean the standard deviation expressed as a percentage of the mean recovery. It is the coefficient of variation multiplied by 100. RSD must be calculated using the following equation. If any results are less than the limit of quantitation, the absolute value of the limit of quantitation is used in the following equation:

$$\text{RSD} = (s / x) \times 100\%; \text{ where } s = \text{standard deviation and } x = \text{mean recovery}$$

Relative standard deviation is used to determine how precise experimental data are. The more precise the data is, the smaller the RSD. This definition clarifies the meaning when the term is used in the regulations.

Proposed subsection (vv) defines "requester" to mean a person who submits a request to a licensed testing laboratory for state-mandated testing of medical cannabis goods. The requester may be a licensed cultivator, licensed manufacturer, or licensed distributor. It is important to clearly define who the requester is for proper test analysis reporting and recordkeeping.

Proposed subsection (ww) defines "sample" (noun) to mean a representative part of or a single item from a larger whole or group. The term "sample" is used in the context of laboratory testing and within these regulations.

Proposed subsection (xx) defines "sample area" to mean the physical space within the distributor's or laboratory's premises in which sampling occurs.

Proposed subsection (yy) defines "sampler" to mean a testing-laboratory employee who collects samples of medical cannabis goods for testing. The definition of "sampler" is necessary to clearly define the type of personnel in charge of collecting samples of medical cannabis goods for testing.

Proposed subsection (zz) defines "sanitize" to mean to sterilize, disinfect, or make hygienic. This definition is necessary to provide clarity on how clean the sampling area or working area in a laboratory needs to be. Proper sanitization of the sampling areas is required to minimize sample contamination.

Proposed subsection (aaa) defines "significant figures" to mean the number of digits used to express a measurement. Significant figures of a number are defined as digits that carry meaning contributing to its measurement resolution. In analytical chemistry, uncertainty of a measurement is expressed in the number of significant figures in an analyte-concentration report. By rounding off a result to a certain number of significant figures, we indicate that all digits but the last are known definitely and that only the last digit has uncertainty associated with it. Defining this term as used in the regulations provides clarity to the licensee.

Proposed subsection (bbb) defines "standard operating procedure" to mean a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action. Standard operation procedures are necessary for the laboratory to achieve efficiency and uniformity of performance while also reducing misunderstandings and failures to comply to with laboratory practices

Proposed subsection (ccc) defines "synthetic cannabinoid" to mean a designed compound with structural features that allow binding to the known cannabinoid receptors present in human cells and that produce psychoactive effects similar to those of cannabis. This term is used in laboratory testing and brings clarity to the regulations.

Proposed subsection (ddd) defines "tamper evident" to mean that one or more one-time-use seals are affixed to the opening of a package, allowing a person to recognize whether or not the

package has been opened. The “tamper evident” definition is necessary to clearly define the minimum way in which one may pack something that allows for detection of any interference with the package.

Proposed subsection (eee) defines “target organism” to mean an organism that is being tested for in an analytical procedure or test method. This definition is necessary in order to clearly specify the identity of organisms that the analytical test is targeting in a potential pool of other contaminating organisms. Target organisms are used in the context of microbial method-validation requirements to determine the sensitivity and specificity of the method for a particular microbial pathogen.

Proposed subsection (fff) defines “testing laboratory record” to mean information relating to the testing laboratory and the analyses it performs that is prepared, owned, used, or retained by the laboratory and includes electronic files, video footage, and other types of recordings. This definition is necessary to clarify what type of information the laboratory needs to prepare, own, use, and retain in order to manage the evidence of a laboratory’s activities. Records are needed for the bureau to ensure it may understand a laboratory’s activities.

Proposed subsection (ggg) defines “THC” and “delta-9 THC” to mean tetrahydrocannabinol, Chemical Abstracts Service number 1972-08-3. This definition is needed to clearly identify the nature of the cannabinoid for which chemical testing is required. This cannabinoid is the principal psychoactive constituent of cannabis.

Proposed subsection (hhh) defines “THCA” to mean tetrahydrocannabinolic acid, Chemical Abstracts Service number 23978-85-0. This definition is necessary to clearly identify the nature of the cannabinoid for which chemical testing is required. THCA is a non-psychoactive cannabinoid found in raw and live cannabis. As cannabis dries, THCA slowly converts to THC. Heat expedites this conversion in a process known as decarboxylation, which happens, for instance, when medical cannabis goods are smoked or vaporized.

Proposed subsection (iii) defines “validation” to mean the confirmation by examination and objective evidence that the particular requirements for a specific intended use are fulfilled. Validation is necessary to determine whether a particular test method or analytical equipment is fit for its intended use.

Proposed subsection (jjj) defines “water activity” to mean a measure of the quantity of water in a product that is available and therefore capable of supporting bacteria, yeasts, and mold. Water activity is reported in the unit A^w. This term is used in the regulations thus the definition provides clarity to the licensee.

ARTICLE 2. LICENSE APPLICATION

§ 5238. Application

The purpose of this proposed section is to clarify specific requirements for applications for testing laboratories. In addition to the general application requirements in section 5006, applications for testing laboratories require additional information that is not necessary for applications for other license types.

Proposed subsection (a) would require that an application for a testing laboratory license include proof of ISO 17025 accreditation or proof that the applicant has applied or is in the process of applying for accreditation. Business and Professions Code section 19342 requires that all licensed testing laboratories adopt standard operating procedures using methods consistent with ISO 17025. The code section also requires that a licensed testing laboratory be accredited by a body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement.

Proposed subsection (b) would require that an application for a testing laboratory license include information establishing the qualifications of laboratory employees. Proposed sections 5373, 5376, and 5379 of this chapter describe requirements for personnel qualifications and training for licensed testing laboratories. This proposed subsection requires that the applicant provide the required personnel information at the time of application. Since the qualifications and training of testing laboratory personnel are necessary to the operation of the testing laboratory, this section is needed.

Proposed subsection (c) would require that an application for a testing laboratory license include all of the required standard operating procedures. Proposed sections 5292 and 5295 of this chapter list the required standard operating procedures that a licensed testing laboratory must maintain.

§ 5241. Premises Diagram

This proposed section specifies the requirements for a premises diagram found in proposed section 5012 of this division as applied to testing laboratory license applications. The proposed section requires that an applicant for a testing laboratory license include in their premises diagram a description of which testing laboratory activities are expected to be conducted in each physical area of the premises. The bureau has determined that a detailed understanding of the testing laboratory premises and the activities that occur on specific areas of the premises are necessary for the effective regulation and enforcement of testing laboratories.

§ 5244. Provisional Testing Laboratory License

This proposed section would allow a testing laboratory that has not yet obtained ISO 17025 accreditation be granted a provisional license if the laboratory meets all other testing-laboratory requirements for licensure. As the ISO process is complicated, this provision will allow testing labs to operate during the process. Proposed subsection (a) states this.

Proposed subsection (b) specifies that an applicant for a provisional testing laboratory license would need to submit all required documentation as if applying for a regular testing laboratory license except for the proof of ISO accreditation. For laboratories who have applied but have not received accreditation yet or who are preparing to apply, it is proposed that those laboratories provide as part of the application documentation confirming their intent to become ISO accredited.

Proposed subsection (c) would have the provisional license expiring after 12 months from its issuance. The next two subsections (d) and (e) allow the bureau to renew the provisional license for an additional 180 days if the laboratory has applied for ISO accreditation. These provisions allow testing laboratories to operate before obtaining ISO accreditation, which at times can take over a year. The bureau is proposing this provisional license and renewal for testing laboratories that have not yet obtained ISO accreditation because, without such provisions in the law, initially there may be shortage of testing laboratories in California to test medical cannabis products, as testing and ISO accreditation have not previously been required.

Proposed subsection (d) requires that, if a provision license expires, the bureau may renew the license for 180 days, if the testing laboratory provides in its application for renewal proof that it has applied for ISO 17025 accreditation. The bureau realizes it may take a long time to get ISO accreditation and is giving provisional-license holders time to apply.

Subsection (e) proposes that the provisional license renewal expire after 180 days.

Proposed subsection (f) would require a laboratory with a provisional license to provide proof of having obtained ISO accreditation within five business days. This will allow the bureau to begin the process of issuing a permanent license.

Proposed subsection (g) requires, in compliance with Business and Professions Code section 19343(c), that a laboratory with a provisional license that is denied ISO accreditation to notify the bureau within 24 hours. It is proposed that the bureau will then revoke the provisional license, as the laboratory will no longer meet the requirements for a personal license.

ARTICLE 3. SAMPLING OF MEDICAL CANNABIS GOODS

§ 5247. Sampling Standard Operating Procedures

This proposed section would require a testing laboratory to develop a sampling plan and prescribes what needs to be in the sampling plan. Sampling is one of the most important aspects of laboratory testing. Sampling errors can have a devastating effect on data relevancy and validity. In addition, MCRSA at Business and Professions Code section 19342(b) requires an agent from the testing laboratory to obtain samples according to a "statistically valid sampling method."

Proposed subsections (a) and (b) would require a laboratory to develop sampling plans that conform to these regulations for each type of matrix (for example, dried flower, oils, tinctures, kief) that will be sampled by the laboratory. Because there are a variety of medical cannabis goods, a proper sampling plan must address each type of good (matrix) and how it should sampled to ensure the samples are representative of the batch and do not become contaminated. A representative sample is one that was taken using procedures that ensure the sample proportionally reflects the different properties of the batch.

Proposed subsection (c) would require the laboratory director to sign off on the sampling plans. The laboratory director would be responsible for ensuring the sampling plans are statistically valid and conform to these regulations. This ensures the laboratory is properly organized and capable of obtaining samples in compliance with the sampling requirements.

Proposed subsection (d) would require that official copies are kept and tracked ("controlled") at the laboratory and that uncontrolled copies are available to samplers (sampling agents) when in the field for their reference. The controlled copy will be the official sample plan that is maintained so that no confusion exists regarding the plan in effect. This will help to ensure the sampler does not unjustifiably deviate from the sampling plan.

Proposed subsection (e) would simply require the laboratory to make the sampling plans available to the bureau upon request. This would ensure the bureau could compare the way a sample was taken and the appropriate sampling plan. If a laboratory deviated from its sampling plan, the sample obtained may have led to invalid data.

§ 5250. Sampling Requirements

This proposed section would establish the general requirements of all medical-cannabis-related sampling activities by a licensed testing laboratory. As stated above, sampling is an incredibly important aspect of obtaining valid testing data. It is the start of the testing process.

Proposed subsection (a) would require that samples for analysis be used for the required analyses under these regulations. The sampler may also collect samples for the analysis of terpenes if requested to do so (for instance, because the labeling the cultivator or manufacturer wishes to use specifies which terpenes the medical cannabis goods contain).

In addition, in proposed subsection (b), the bureau proposes that the collection of samples and the analysis of the samples be done by the same laboratory. This is important because there are chain-of-custody requirements in the MCRSA at Business and Professions Code sections 19342 and 19343, and because testing results from a laboratory are more likely to be valid if the laboratory is responsible for both the sampling and the testing.

Proposed subsection (c) would require that only a laboratory's trained sampler obtain samples for the laboratory. Having a specific trained person or persons performing sampling is more likely to result in good sampling procedures and therefore better samples.

Proposed subsection (d)(1) specifies that the sampler must ensure the sampling area is clean and that the sampler's tools are sanitized. This is necessary to avoid contamination of the sample. Sampling tools, sample contact surfaces, the sampler's body, or any environmental conditions could cause contamination of the cannabis samples, which would lead to invalid and inaccurate test results.

Proposed subsection (d)(2) would require that, for each batch being sampled, the sampler obtain both primary and field duplicate samples. Field duplicate samples are meant to be as identical to the primary samples as possible and therefore must be taken at the same time and under the same condition as the primary sample.

Proposed subsection (d)(3) would require that the sampler generate a unique sample ID for each sample and sample increment. This number should be placed on the sample-container label and chain-of-custody form as required elsewhere in these regulations. At the laboratory, the analyst will have only this sample ID, without any other identifying sample information, to avoid conscious or unconsciousness bias during analysis.

Proposed subsection (d)(4) specifies that the sampler must ensure that the integrity of the sample is capable of being maintained from the point the sample is taken until the sample arrives at the laboratory. This will provide greater assurances the testing will be accurate.

Proposed subsection (d)(5) would require the sampler wear the personal equipment specified in proposed section 5253 to avoid contamination of the sample.

§ 5253. Sampler Personal Equipment

This section establishes the requirement of the proper personal equipment that the sampler must wear to protect the batch and sample taken from the batch from contamination that could be introduced by the sampler.

Proposed subsection (a) specifies the types of equipment that would be required to be worn by the sampler. The sampler must wear a disposable lab coat to cover the sampler's whole body to prevent the contamination of the sample from the contact of the sampler's clothes.

Disposable nitrile gloves would also be required. Nitrile gloves are highly puncture resistant and provide a stronger barrier of protection and offer greater chemical resistance, so they can protect the sampler from the possible microorganisms, pesticide residuals and chemical solvent residuals in cannabis samples. They are also latex-free, so the sampler with a latex allergy can work safely and comfortably.

Next, the sampler must also wear a dust mask to protect the sample from contamination that could be introduced by the sampler's mouth. The sampler must also wear safety goggles, and, last, the sampler must wear a hair net to prevent hair from contaminating the sample.

Proposed subsection (b) would require that the sampler change gloves before sampling a new batch to reduce cross-contamination among the different sampling batches.

§ 5256. Sampling Tools

This proposed section establishes the general provision required of all cannabis sampling tools. This section specifically addresses the individual sampling tools and equipment that might be needed in the sampling process carried out by the sampler. Preventing contamination of the samples is vital to the accuracy and therefore reliability of test results. A sampler's tools may vary in size, shape, and material, depending on the matrix being sampled. This section is necessary to illustrate the wide array of tools that may be needed to accurately sample medical cannabis goods. The testing laboratory may select which among these tools is appropriate depending on the matrix being sampled. Similar, alternative tools may be used in the sampling process.

This proposed section is also necessary because the maintenance of clean equipment and tools will minimize accidents that may lead to contamination when coming into direct contact with cannabis products.

Proposed subsection (a) would require all tools be sanitized prior to their use in sampling to avoid contamination of the sample. Preventing contamination of the samples is vital to the accuracy and therefore reliability of test results.

Proposed subsection (b) gives examples of common sampling tools that may be used. This provision is necessary to clarify the types of tools that the bureau considers appropriate for sampling medical cannabis goods. Although each laboratory will develop its own sampling protocols, including which sampling tools and equipment to use, the bureau recommends adopting this subsection to aid the regulated community in its selection of appropriate tools and equipment. This section is intended to promote proper sampling methodologies.

Proposed subsection (b)(1) specifies the type of the containers that should be used to hold the samples. Amber glass jars or containers with polytetrafluoroethylene (PTFE)-lined lids are useful for blocking light, which is important for preserving the sample and preventing degradation. PTFE is very nonreactive and safe for cannabis samples. PFTE-lined lids should be used with the amber glass jar or containers or any other darkened type of jar or container.

Proposed subsection (b)(2) specifies that the samples may be kept at a cold temperature after sampling through delivery to the laboratory. This cold-chain system can reduce sample deterioration, chemical changes, and microbial growth.

Proposed subsection (b)(3) specifies the sanitization methods that may be used to sanitize supplies and the sampling area that touches the batch and samples. These supplies are necessary to reduce the risk of contamination during sampling. The bureau recommends adopting this section into the sampling SOP so that the sampler is informed of the level of sanitation supplies

(supplies that are at least as effective as 10% bleach or 70% ethanol cleaning supplies) that the bureau considers appropriate for sanitizing the tools and area used in the sampling process.

Proposed subsection (b)(4) specifies the type of gloves that may be used to cover the sampler's hands during sampling. They must be disposable, so that they may frequently be changed if necessary. There should be no powder, lubricant, or any additives on the gloves that can cause the contamination of the samples. Nitrile gloves are highly puncture resistant and provide a strong barrier of protection and offer great chemical resistance, which minimizes chemical reactions with the samples when they are contacting each other. Gloves should be sterilized, if possible, before use to remove microbial contaminants.

Proposed subsection (b)(5) proposes what the accuracy of the balance needed to measure the sample taken from the batch would be. Its minimum measurement capacity must be no greater than 1 gram. This section is necessary to ensure accurate weighing and recording of samples obtained from the distributor's premises.

Proposed subsection (b)(6) proposes that the sampler must prepare labels to attach on the sample container and fill out the information as required per section 5265 and 5268(d)(3). The sampler must use permanent marker to write the sampling information on the label to prevent deleting or smearing the ink. This can also prevent the alteration or modification of the records, which ensures accurate and precise information.

Proposed subsection (b)(7) specifies the cleaning, swabbing, or wiping materials that could be used to sanitize and disinfect tools or the sampling area. A kind of Teri wipes or Kimwipes could be used for this purpose.

Proposed subsection (b)(8) specifies the tools that may be used to take a certain amount or portion of sample from the batch, depending on the sample matrix. The testing laboratory can develop or modify the sampling tools similar to those listed in this proposed section. Spoons could be used to take relatively large amount of powder or small grain sizes of samples. Spatulas could be used to take a relatively small amount of powder or small particle-size samples. Tongs could be used to take or pick relatively large pieces of samples. Knives could be used to separate or cut batches. Pipettes could be used to take or suck up liquid samples. Corers could be used to take a certain range of sample size based on the diameter of corer. Sampling thieves could be used to select or separate a discrete particle size of sample through a net or mesh.

§ 5259. Field Duplicate Sampling

This proposed section establishes the purpose and importance of field duplicate sampling. The field duplicate sample is designed to be identical to the original sample (primary sample) and is taken to gain precision information on homogeneity, handling, shipping, storage and preparation, and analysis. Duplicate sampling is used to identify possible field variations. This section is necessary to ensure that the field duplicate sample is identical to the primary sample in that both are obtained under the same conditions and from the same batch. Obtaining a proper field

duplicate sample requires that the duplicate is necessary for generating precise information on homogeneity, handling, shipping, storage and preparation, and contaminant analysis.

Proposed subsection (a) requires that the sampler collect field duplicate samples in the same manner, at the same time, and from the same batch as the field primary samples.

This is the common accepted practice of collecting field duplicate samples. This proposed section is necessary to ensure that the field duplicate sample is identical to the primary sample in that both are obtained in the same way as the primary sample.

Proposed subsection (b) requires that the field duplicate sample be stored and analyzed separately from the primary sample. These samples are run to establish the analytical accuracy and precision for a sample batch. This provision is necessary to ensure the accuracy, and therefore the reliability, of the analytical test results. Commingling of the two samples could result in mixing up the samples and therefore could negatively impact data.

§ 5262. Storage and Handling of Samples

Proposed subsection (a) would require the use of tamper-evident containers. Tamper-evident containers are necessary because is necessary for the laboratory to know whether the sample has been tampered with or whether a sample has been adulterated during transport from the sampling area to the laboratory. If a sample has been tampered with, it must be rejected by the laboratory, because the sample may have been contaminated, which would lead to invalid measurements.

Proposed subsection (b) would require samplers to use certain equipment for the storage of samples. It also would require that samples be kept at 0 to 6 degrees Celsius. This is the temperature at which samples are least likely to decompose or change. Temperatures above 6 degrees Celsius can promote bacterial and fungal growth.

§ 5265. Sample Field Log

Proposed subsection (a) specifies that the sampler record the laboratory name and license number. This provision is necessary to identify the laboratory responsible for sampling and analysis and to document the laboratory's valid license or lack thereof.

Proposed subsection (b) specifies that the sampler record the name of the persons involved in or present during the sampling process. This provision is necessary to identify the persons responsible for sampling or who may attest to the sampling process as it occurred. This provision is necessary to enable the bureau to identify the parties responsible in the event of alleged incidents of noncompliance, errors in sampling, contamination, or similar issues.

Proposed subsection (c) specifies that the sampler must record the time and date when the sample was collected. This provision is necessary to enable the bureau to identify potential problems relating to the sampling and other activities occurring at the distributor premises.

Proposed subsection (d) specifies that the sampler must record the distributor name, location, and license number. This provision is necessary to identify the distributor from which samples were obtained and to document the distributor's valid license or lack thereof. This provision is also necessary to demonstrate where the sampling occurred.

Proposed subsection (e) specifies that the sampler must record the location and license number. This provision is necessary to identify who transported the medical cannabis samples to the designated laboratory. This provision is also necessary to enable the bureau and licensees to identify the parties responsible in the event of alleged incidents of noncompliance, missing samples, damaged sample containers, poor handling of samples, or similar issues that may occur in transit to the laboratory.

Proposed subsection (f) specifies that the sampler must record the matrix type being sampled (for example, dried flower, oil, resin). This information is necessary to aid the laboratory in determining the required analytical method for each sample upon receipt of the sample at the laboratory. The bureau proposes this provision to ensure that samples are appropriately routed for analysis and that the sample is not unnecessarily exposed to environmental contaminants before analysis occurs.

Proposed subsection (g) specifies that the sampler must record the type of analysis requested of the laboratory for the collected sample. This provision is necessary to assist the laboratory employees in properly routing the samples for the analyses required under these regulations or additionally requested by the medical cannabis batch title holder or other licensee.

Proposed subsection (h) specifies that the sampler must record the total sample amount by weight or number. This information is necessary to accurately trace sample quantity accepted at the laboratory and to determine the amount used or disposed of. The bureau proposes this provision as a means to prevent diversion.

Proposed subsection (i) specifies that the sampler must record the date and time each sample was obtained. This is necessary to track the process for accuracy.

Proposed subsection (j) specifies that the sampler must record the total batch size in weight or by count. This information is necessary to enable the sampler to determine the number of samples and increments that it is necessary to collect.

Proposed subsection (k) specifies that the sampler must record any problems or deviations from the sampling plan and the reconciliatory action taken to solve the problem or problems. The sampler must follow the standard operating procedures for sampling, but if a deviation from it is necessary, such deviation must be recorded. This is common practice for environmental laboratories.

Proposed subsection (l) specifies that the sampler must record the weight or count and the unique identifier of, and the location from which the sample was obtained from the batch. This provision is necessary to enable the bureau to trace back to batches from which failed samples were obtained. The ability to trace-back to batches will enable the bureau to efficiently and quickly halt the distribution and manufacturing of cannabis that does not pass the requisite laboratory testing.

Proposed subsection (m) specifies that the sampler must record abnormal conditions or observations or inconsistencies within the batch. This provision is necessary to determine whether any of the observations may have affected sampling or the results of the analyses.

Proposed subsection (n) specifies that the sampler must record the environmental conditions during sampling such as temperature, light, and humidity. This provision is necessary to determine whether any environmental conditions may have affected the results of analyses.

Proposed subsection (o) specifies that the sampler must record the batch or lot number of the matrix for which samples were obtained. It is necessary to know later whether the batch passed and may be sold, or failed and may not be sold unless remediated or destroyed.

§ 5268. Sampling Unpackaged Harvest Batches

Proposed subsection (a) specifies that the medical cannabis samples obtained from a harvest batch must be representative of the harvest batch. This provision is necessary to ensure uniformity in the quality and constituents of all products derived from that batch. Statistically representative sampling procedures are statutorily mandated.

Proposed subsection (b) specifies that the sampler may collect samples of dried flower directly from the container or containers in which the batch is stored. This provision is necessary to clarify the location from which samples may be obtained.

Proposed subsection (c) specifies that the sampler may not collect samples from a harvest batch that is greater than 10 pounds. This provision is necessary to clarify the maximum size of a harvest batch from which a sampler may obtain samples. The bureau's reason for imposing a harvest-batch size limit is to increase the accuracy of the tests performed by ensuring that representative samples are being taken from each batch. Placing a maximum limit on the size of a batch for testing will also allow for more-manageable sample collection, transportation, storage, and testing.

Also, bad actors could hide "dirty" medical cannabis (for example, cannabis laced with a lot of pesticides) with clean cannabis in the hopes that that "dirty" section is not sampled or that a small enough amount of it is sampled that it would still not result in failing laboratory testing. The bureau has also determined that setting the harvest-batch size maximum at 10 pounds is reasonable given current industry practices, where the average batch size of dried flower is approximately 15 pounds.

Proposed subsection (d)(1) specifies that the sampler must obtain samples from varying locations of the container, both vertically and horizontally, at well-separated points along a heptagonal pattern. This is a common practice for sampling.[1] This provision is necessary to ensure systematic sampling such that the samples obtained are representative of the entire harvest batch.

Proposed subsection (d)(2) specifies that upon obtaining a dried-flower sample from the batch, the sampler must place the sample into an air-tight, sterile sample container that is capable of protecting the sample from contamination and degradation. This provision is necessary to clarify the standard for sampling containers. The bureau proposes this subsection because it clearly articulates the type of container a sampler must use to store harvest-batch samples.

Proposed subsection (d)(3) specifies that upon collection of a sample, the sampler must immediately and completely seal the sample container with a tamper-evident seal. This provision is necessary to ensure the integrity of the sample from the point of collection to the point of analysis and to provide the laboratory with a way to tell whether the sample has been tampered with. This provision further specifies that the sampler shall initial and date each seal. This provision is necessary to identify the laboratory agency who performed the sampling, and on what date, for auditing purposes.

Proposed subsection (d)(4) specifies that the sampler must place the sealed sample containers into a tamper-evident, portable storage unit for transport that must be kept at 0 to 6 degrees Celsius. The reasons for this provision are two-fold: first, this provision clarifies that the unit in which samples are transported to the laboratory must be tamper evident. Use of a tamper-evident transportable unit will deter diversion of cannabis samples to illicit markets and make evident to the laboratory whether any abnormalities occurred in the handling of the samples from the point of collection to the point of analysis.

Second, this provision is necessary to ensure that the sample is not overheated and therefore does not degrade during transport. Degradation of a sample would result in a sample not being representative of the batch. This provision further specifies that the samples must be kept in an environment with a temperature between 0 and 6 degrees Celsius. This provision is necessary because temperatures above 6 degrees Celsius promotes bacterial and fungal growth, thereby creating unreliable test results. Temperatures below 0 degrees Celsius may negatively impact the integrity of the sample, thus producing test result that do not accurately reflect the batch from which the samples were obtained. Therefore, the bureau recommends that samples obtained from a distributor be stored at temperatures within the indicated range.

Proposed subsection (d)(5) specifies that the sampler must repack the portion of the harvest batch that is not collected for sampling. This provision is necessary to clarify that it is the sampler's responsibility to ensure that the remaining batch portion is re-packed in a container and any lids

[1] Emma Popek. *Sampling and Analysis of Environmental Chemical Pollutants: A Complete Guide*. San Diego, CA: Academic Press; 2003. Pages 105 through 118.

are replaced. This provision is intended to ensure that the remaining batch portion is protected from degradation and contamination so as to maintain its market viability and ensure the samples are representative.

Proposed subsection (d)(6) specifies that that the sampler must complete a chain-of-custody form and a sample field log during sampling. This provision is necessary to ensure complete documentation of the sampling process. This provision is also required of laboratories under ISO 17025 accreditation standards to allow for traceability of samples.

§ 5271. Minimum Unpackaged Harvest-Batch Sample Size

Proposed section 5271 specifies the minimum weight of samples that the sampler must collect to meet the requisite gram weight per harvest batch sample. The total weight of the sample should be at minimum 0.5% of the weight of the batch but that more may be collected if that amount in not sufficient to complete the required tests using the validated methods of the particular laboratory that is collecting the sample. See the explanation for sections 5274 and 5280 in this document for further justification for the minimum sample amount required.

§ 5274. Unpacked Harvest-Batch Sample Increments

Proposed subsection (a) specifies that a sampler must collect a minimum of 7 and no more than 9 sample increments from each unpackaged harvest batch. This provision is necessary because at least 7 but not more than 9 increments are necessary to allow a laboratory to reliably determine the average concentration of analytes present in a representative cannabis sample and, by extension, the harvest batch.

Data on chemical concentrations in samples present challenges for estimating the average concentration. If the contaminants in a batch are present in the same concentration throughout the batch (that is, "homogeneous"), then accurately estimating the average concentration of analytes throughout the batch poses no significant difficulties. In such cases, all sampling approaches would yield the same average concentration and thus would provide a reliable estimate of the mean concentration of analytes.

However, the bureau expects that dried-flower medical cannabis is heterogeneous given the intricate, non-uniform structure of the cannabis flower. Greater heterogeneity increases the difficulty in estimating the average concentration of analytes through sampling.[2] Thus, the bureau proposes requiring a sampler to collect at least 7 and no more than 9 increments. This number of increments will allow a laboratory to reliably analyze the concentration of analytes in an expectedly heterogeneous dried-flower sample.

Even the most comprehensive sampling protocols introduce some degree of sampling error. The bureau's goal is for laboratories to provide a reliable estimate of the average (that is, the

[2] Interstate Technology Regulatory Council. Incremental Sampling Methodology, Representative Sampling, Confident Decisions. http://www.itrcweb.org/ism-1/. Accessed March 28, 2017.

arithmetic mean) contaminant concentration in a batch, recognizing that any individual sample may over- or underestimate the mean to some degree. In practice, the estimated variance is often viewed as an overall measure that includes the contribution of many sources of error. The estimated variance can be used to quantify an upper confidence limit (UCL) for the mean for all samples.[3,4,5]

Confidence levels are expressed in terms of a confidence coefficient. In practice 90%, 95%, and 99% confidence levels are often used, with 95% being the most commonly used. The "95% upper confidence level of the arithmetic mean" is a value that, when repeatedly calculated for randomly drawn subsets of size n from a population, equals or exceeds the population arithmetic mean 95% of the time. The arithmetic mean is calculated by adding up all the numbers in a data set and dividing the result by the total number of data points. The UCL can be calculated using the following formula:

$$\mathrm{UCL} = \overline{X} + t \times \frac{S_{\overline{X}}}{\sqrt{n}}$$

where

UCL = Upper confidence limit

$\overline{X}$ = mean of all samples

$S_{\overline{X}}$ = standard deviation of all samples

t = number obtained from Student's *t*-test table with n-1 degree of freedom

n = number of increments/samples need to take from the batch

From the formula, it is clear that the UCL is controlled by two factors: As n increases, the UCL gets closer to the true mean from the $\sqrt{n}$ term. That is, one way to obtain more-precise estimates for the mean is to increase the sample size.

The larger the sample standard deviation, the higher the UCL. This simply means that noisy data—that is, data with a large standard deviation—are going to generate wider intervals than will data with smaller standard deviations.

[3] Robert J. Klee, Guidance for Calculating the 95% Upper Confidence Level for Demonstrating Compliance with the Remediation Standard Regulations, State of Connecticut, Department of Energy and Environmental Protection, 2014. http://www.ct.gov/deep/lib/deep/site_clean_up/remediation_regulations/95ucl_guidance.pdf. Accessed March 28, 2017.

[4] National Institute of Standards and Technology (NIST), NIST/SEMATECH e-Handbook of Statistical Methods, http://www.itl.nist.gov/div898/handbook/. Accessed March 28, 2017.

[5] Snedecor, George W. and Cochran, William G. (1989). *Statistical Methods*, Eighth Edition. Iowa State University Press.

t Table[6]

cum. prob	t .50	t .75	t .80	t .85	t .90	t .95	t .975	t .99	t .995	t .999	t .9995
one-tail	0.50	0.25	0.20	0.15	0.10	0.05	0.025	0.01	0.005	0.001	0.0005
two-tails	1.00	0.50	0.40	0.30	0.20	0.10	0.05	0.02	0.01	0.002	0.001
Df											
1	0.000	1.000	1.376	1.963	3.078	6.314	12.71	31.82	63.66	318.31	636.62
2	0.000	0.816	1.061	1.386	1.886	2.920	4.303	6.965	9.925	22.327	31.599
3	0.000	0.765	0.978	1.250	1.638	2.353	3.182	4.541	5.841	10.215	12.924
4	0.000	0.741	0.941	1.190	1.533	2.132	2.776	3.747	4.604	7.173	8.610
5	0.000	0.727	0.920	1.156	1.476	2.015	2.571	3.365	4.032	5.893	6.869
6	0.000	0.718	0.906	1.134	1.440	1.943	2.447	3.143	3.707	5.208	5.959
7	0.000	0.711	0.896	1.119	1.415	1.895	2.365	2.998	3.499	4.785	5.408
8	0.000	0.706	0.889	1.108	1.397	1.860	2.306	2.896	3.355	4.501	5.041
9	0.000	0.703	0.883	1.100	1.383	1.833	2.262	2.821	3.250	4.297	4.781
10	0.000	0.700	0.879	1.093	1.372	1.812	2.228	2.764	3.169	4.144	4.587
11	0.000	0.697	0.876	1.088	1.363	1.796	2.201	2.718	3.106	4.025	4.437
12	0.000	0.695	0.873	1.083	1.356	1.782	2.179	2.681	3.055	3.930	4.318
13	0.000	0.694	0.870	1.079	1.350	1.771	2.160	2.650	3.012	3.852	4.221
14	0.000	0.692	0.868	1.076	1.345	1.761	2.145	2.624	2.977	3.787	4.140
15	0.000	0.691	0.866	1.074	1.341	1.753	2.131	2.602	2.947	3.733	4.073
16	0.000	0.690	0.865	1.071	1.337	1.746	2.120	2.583	2.921	3.686	4.015
17	0.000	0.689	0.863	1.069	1.333	1.740	2.110	2.567	2.898	3.646	3.965
18	0.000	0.688	0.862	1.067	1.330	1.734	2.101	2.552	2.878	3.610	3.922
19	0.000	0.688	0.861	1.066	1.328	1.729	2.093	2.539	2.861	3.579	3.883
20	0.000	0.687	0.860	1.064	1.325	1.725	2.086	2.528	2.845	3.552	3.850
21	0.000	0.686	0.859	1.063	1.323	1.721	2.080	2.518	2.831	3.527	3.819
22	0.000	0.686	0.858	1.061	1.321	1.717	2.074	2.508	2.819	3.505	3.792
23	0.000	0.685	0.858	1.060	1.319	1.714	2.069	2.500	2.807	3.485	3.768
24	0.000	0.685	0.857	1.059	1.318	1.711	2.064	2.492	2.797	3.467	3.745
25	0.000	0.684	0.856	1.058	1.316	1.708	2.060	2.485	2.787	3.450	3.725
26	0.000	0.684	0.856	1.058	1.315	1.706	2.056	2.479	2.779	3.435	3.707
27	0.000	0.684	0.855	1.057	1.314	1.703	2.052	2.473	2.771	3.421	3.690
28	0.000	0.683	0.855	1.056	1.313	1.701	2.048	2.467	2.763	3.408	3.674
29	0.000	0.683	0.854	1.055	1.311	1.699	2.045	2.462	2.756	3.396	3.659
30	0.000	0.683	0.854	1.055	1.310	1.697	2.042	2.457	2.750	3.385	3.646
40	0.000	0.681	0.851	1.050	1.303	1.684	2.021	2.423	2.704	3.307	3.551

Upper confidence limits for the mean can be used to answer the following questions:

1. What is a reasonable estimate for the mean?

2. How much variability is there in the estimate of the mean?

3. Does a given target value fall within the confidence limits?

In the case of sampling cannabis harvest-batch samples, we need to know how many samples we need to take from a batch to decide that the whole batch is in compliance.

[6] San Jose State University, t-table, http://www.sjsu.edu/faculty/gerstman/StatPrimer/t-table.pdf. Accessed March 28, 2017.

For example, at 95% confidence level, and an action level of 1 ppm, how many increments are needed? It depends on the sample mean and the RSD (relative standard deviation) of the sample. A 1-ppm action level means the UCL should be less than 1 ppm.

Therefore,

$$1 \geq \overline{X} + t \times \frac{S_{\overline{X}}}{\sqrt{n}}$$

Assuming the sample mean is 0.8 ppm and RSD of the samples is 30%, let's solve the equation for *n*:

$$1 \geq 0.8 + t \times \frac{0.24}{\sqrt{n}}$$

$$n \geq (\frac{t}{0.833})^2$$

When $n = 6$ ($t = 2.015$, obtained from the *t* table), this equation is valid. This means it is necessary to take at least 6 increments to be 95% confident that the batch is not over the 1-ppm action level.

When there is a batch where the sample mean is much closer to a 1-ppm action level, more increments are needed.

Assuming we have a batch with a sample mean of 0.9 ppm and the RSD of the samples is 20%.

When the sample mean is closer to a 1-ppm action level, more increments are needed. Assuming the sample mean is 0.9 ppm and the RSD of the samples is 20%, at least 11 increments would be needed for testing to determine that the batch is not over the 1-ppm action level.

The closer the sample mean is to the action level and the greater the RSD, the more samples are needed to demonstrate representativeness of the whole sampling batch.

In general, 7 to 9 increments are necessary to ensure the whole batch is not exceeding the 1-ppm action level. This number of increments is also reasonable because it is not too burdensome on the cultivators, distributors, and manufacturers that request the tests.

Proposed subsection (b) specifies that the sampler may collect more than the minimum sample size of 0.5% of the total harvest-batch weight when the required testing methodologies of the laboratory call for a greater sample. This subsection is necessary to ensure that a laboratory obtains a sufficient sample for the tests to produce valid data. This section also specifies that the sampler may collect only the amount necessary for the required and requested testing. This is necessary to ensure that the sampler does not obtain an excessive amount of samples so that it becomes burdensome to the industry.

§ 5277. Sampling of Packaged Medical Cannabis Goods

This proposed section addresses the sampling of medical cannabis goods that have already been packaged for retail sale. This section applies to both packaged harvest batches and packaged manufactured medical cannabis goods.

Proposed subsection (a)(1) specifies that the container in which the sample is placed must be air-tight, sterile, and capable of protecting the sample from contamination and degradation. This provision is necessary to ensure the integrity of the sample from the point of collection to the point of analysis. This provision makes clear how a sampler may comply with the storage and security procedures involved in sampling cannabis.

Proposed subsection (a)(2) specifies that the sampler seal all openings of the sample container to ensure that the container is tamper evident. This provision is necessary to assure the laboratory, upon receipt of the sample, that the sample was not exposed to contamination or degradation while in transport. This provision further specifies that the sampler must initial and date each seal. This provision is necessary to identify the laboratory employee who performed the sampling, and on what date, for auditing purposes.

Proposed subsection (a)(3) specifies that the sampler place the collected samples into a portable, tamper-evident storage unit for transportation. This provision is necessary to clarify that the unit in which samples are transported to the laboratory must be tamper evident. Use of a tamper-evident transportable unit will deter diversion of cannabis samples to illicit markets and make evident to the laboratory any abnormalities that may have occurred in the handling of the samples from the point of collection to the point of receipt.

Proposed subsection (a)(4) specifies that the sampler must complete a chain-of-custody form and a sample field log during sampling. This provision is necessary for sample traceability and to ensure the bureau and businesses are able to track where the product is and what, if anything, happened to it.

§ 5280. Sample Increments for Manufactured Cannabis Products

Proposed subsection (a) specifies the number of increments required to be obtained per sample of packaged harvest or manufactured cannabis batches per units in the batch. Determination of the number of increments per sample is adopted from the ORELAP-SOP-002 Rev.2.0[7] and ORELAP-SOP-003 Rev.2.0.[8] The required number of increments per sample based on ORELAP-SOP-002 Rev.2.0 and ORELAP-SOP-003 Rev.2.0 varies depending upon the size of units for sale (see the table in this subsection in the regulation text title "Number of Increments Required per Number of Total Units").

[7] ORELAP-SOP-002 Rev 2.0 Protocol for collecting samples of Cannabis Concentrates and Extracts, Oregon Environmental Laboratory Accreditation Program, 2016.
[8] ORELAP-SOP-003 Rev 2.0 Protocol for Collecting Samples of Cannabinoid Products, Oregon Environmental Laboratory Accreditation Program, 2016.

According to the US Food and Drug Administration's (FDA's) Current Good Manufacturing Practices (CGMP) issued January 2011, "Samples must represent the batch under analysis and the sampling plan must result in statistical confidence."[9]

There are several factors that must be considered when determining the appropriate sample size by weight and increments needed, including the risk levels associated with the product, costs associated with producing the product, and costs associated with inspection, measuring, and testing.

The Bayesian version of the Success-Run Theorem (based on binomial distribution) is one useful method that can be used to determine an appropriate risk-based sample size for process validations. For certain probabilities or for certain incidences of non-compliance, the number of samples to be taken may be calculated from the following equation:

$$1 - p = (1 - i)^n$$

Where p is the probability and i is the incidence of non-compliant residues in the batch (both expressed as fractions, not percentages) and n is the number of samples.

Therefore,

$$n = \frac{\ln(1 - p)}{\ln(1 - i)}$$

For example, below is a table found in *Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLS* (CAC/GL 33-1999).[10]

Number of randomly selected primary samples required for a given probability of finding at least one non-compliant sample in a batch of meat or poultry, for a given incidence of non-compliant residues in the batch.

Incidence of non-compliant residues in the batch, %	Minimum number of samples (n_o) required to detect a noncompliant residue with the following probabilities, by confidence level		
	90%	95%	99%
90	1	-	2
80	-	2	3
70	2	3	4
60	3	4	5
50	4	5	7

[9] Guidance for Industry, Process Validation: General Principles and Practices, Food and Drug Administration (FDA), 2011. https://www.fda.gov/downloads/Drugs/Guidances/UCM070336.pdf. Accessed March 28, 2017.
[10] Food and Agriculture Organization of the United Nations. *Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLS*. www.fao.org/input/download/standards/361/CXG_033e.pdf. Accessed March 28, 2017.

40	5	6	9
35	6	7	11
30	7	9	13
25	9	11	17
20	11	14	21
15	15	19	29
10	22	29	44
5	45	59	90
1	231	299	459
0.5	460	598	919
0.1	2302	2995	4603

Note to table: The table assumes random sampling. Also, where the number of primary samples indicated in the table is more than about 10% of units in the total batch, the number of primary samples taken may be fewer and should be calculated as follows:

$$n = \frac{n_O}{1 + (n_O - 1)/N}$$

Where

n = minimum number of primary samples to be taken

n_O = number of primary samples given in the table above

N = number of units capable of yielding a primary sample in the batch.

It can be seen that the amount of the sample required is much larger when there is only a small amount of the sample that is over the action level. If you have 1% of the batch contaminated, you will need to measure at least 299 samples to detect the contaminated sample at a 95% confidence level.

Based on statistical research, the requisite amount of samples to collect for reliable analysis at a 95% confidence level would likely result in a financial burden to the regulated entity. In light of this undesired consequence, the bureau has determined that a lesser number of samples should be required. The bureau is proposing this 0.5% minimum and increment numbers because it is the bare-minimum sample number that allows for statistical analysis.

Proposed subsection (b) specifies that a sampler may collect a greater number of increments than those indicated in the table in proposed subsection (a) if this is needed to perform any analytical method or because of laboratory-specific procedures. This provision is necessary to ensure that the sampler collects a sufficient quantity of material for all required tests. This provision also specifies that the sampler may only collect the amount necessary to conduct the required and requested testing. This provision is necessary to prevent the waste of expensive product by clarifying that a sampler may not collect excessive amounts of medical cannabis goods.

Additionally, a sampler may not collect samples form a batch exceeding 10 pounds. This is consistent with the weight limit for unpackaged cannabis.

Proposed subsection (c) specifies that multiple units for sale may be combined to create a single increment in the event that an entire unit for sale is an insufficient quantity of material available for all required tests. This provision is necessary to clarify that the sampler is permitted to combine multiple units for sale to comply with the sampling requirements of these regulations and the laboratory's testing methodologies.

Proposed subsection (d) clarifies that increments of a primary sample must be combined in order to constitute a primary sample. This proposed subsection is necessary to explain how to obtain a proper primary sample of packaged products for testing. The proposed subsection clarifies that the multiple increments taken for testing as specified in the table above are to be combined together to create a single primary sample for testing.

§ 5283. Homogeneity Test for Edible Cannabis Products

Proposed section 5283 establishes the requirement of homogeneity testing of manufactured edible cannabis product batches for either THC or CBD content, whichever cannabinoid the manufacturer claims to be the larger component of the product. Homogeneity testing for the main potency ingredient of either THC or CBD is necessary to ensure the consumer gets the correct dosage in their products and ensures consumer safety. Visits to the emergency room resulting from cannabis consumption are usually due to the overconsumption of edible cannabis products, often accidental. Ensuring that one-quarter of a candy bar does not contain 100% of the THC of the candy bar would go a long way in preventing accidental overconsumption. It is therefore proposed that homogeneity testing be required so that this is prevented.

Proposed subsection (a) requires that the homogeneity test be done for THC or CBD content for each batch of edible cannabis products. THC or CBD, whichever is present as the main ingredient, should be spread throughout a product evenly and not concentrated in any one area. The bureau proposes that, if THC and CBD are present in close or equal amounts that the homogeneity of the THC be tested for. This is because of THC's greater psychoactive properties.

Proposed subsection (b) proposes that the number of increments used for testing be at least 10 increments from different regions of the batch. This is proposed to help ensure that sampling accurately represents the product.

CDPH found that 10 increments is the minimum number needed to assure that the samples accurately portray the batch being sampled to assure the homogeneity test captures the variation in product manufacturing. Typically, sampling plans should consider the process of production of the material and gauge where sampling should occur. For the production of products, at a minimum, samples should be collected near the beginning, middle, and end of the production batch to capture variation internally for the production process. During each stage of beginning, middle, and end of the batch-sampling process, enough samples should be collected for statistical

analysis. Minimally, this requires at least 3 to 4 samples for each stage, resulting in the 10-increment requirement. CDPH relied upon US FDA guidance for the pharmaceutical industry regarding stratified in-process dosage-unit sampling and assessment. This guidance recommends a minimum of 20 appropriately spaced in-process dosage-unit sampling points.[11] Sampling-plan guidance under the USP-NF recommends sampling at least 10 units and recommends obtaining more depending on product type.[12]

Subsection (c) proposes that the batch "pass" homogeneity testing when it has a relative standard deviation of less than 15% on average with no outlying increments for THC or CBD (that is, a result that deviates markedly from other increments in the batch). Grubb's outlier test is a standard statistical method to test for outliers in data sets. The requirements in this subsection set acceptable limits for uniformity of edible cannabis products, ensure consumer safety so that consistent active ingredients are uniformly distributed, and ensure product quality for consumers.

Proposed subsection (d) requires that if the homogeneity tests is not performed or fails, then the batch fails testing and the products may not be sold and must be destroyed. This is a requirement to protect consumers and assure that they receive a consistent product. Consumers will need to have a consistent dosage in their products to know what effect to expect when they consume edible cannabis product.

Proposed subsection (e) requires that, if the edible cannabis product passes homogeneity testing, it will also have to pass all other required tests under these proposed regulations.

§ 5286. Chain-of-Custody Protocol

Proposed section 5286 specifies the documentation required that will work to guarantee the identity and integrity of the samples from collection through reporting of the test results by a licensed testing laboratory.

Proposed subsection (a) specifies the responsibility of the testing laboratory that the laboratory must generate chain-of-custody protocol for samples and provide the sampler proper training regarding whole sampling activity and chain-of-custody documentation.

Proposed subsection (b)(1) specifies that the chain-of-custody form must contain the laboratory licensee's name, physical address, and license number of the laboratory collecting the sample. This provision is necessary to allow the bureau and all licenses that handle medical cannabis samples to identify the laboratory responsible for sampling and analysis of the samples.

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[11] Guidance for Industry, Powder Blends and Finished Dosage Units — Stratified In-Process Dosage Unit Sampling and Assessment, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), October 2003, Pharmaceutical CGMPs, https://www.fda.gov/ohrms/dockets/98fr/03d-0493-gdl0001.doc. Accessed March 30, 2017.

[12] The United States Pharmacopeial Convention, Revision Bulletin Official August 1, 2014, ⟨561⟩ Articles of Botanical Origin, http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/gc_561.pdf . Accessed March 30, 2017.

Proposed subsection (b)(2) specifies that the chain-of-custody form must contain the distributor licensee's name, physical address, and license number. This provision is necessary to allow the bureau and all licensees that handle medical cannabis samples to identify the distributor from whom the medical cannabis sample was obtained.

Proposed subsection (b)(3) specifies that the chain-of-custody form must contain information regarding each sample increment. At the laboratory, all information on the chain-of-custody form is needed to transfer into the computer system like LIMS (laboratory information management system). A new laboratory's sample identification number can be generated from LIMS, or the original identification number on the chain-of-custody form can be used at the laboratory. The analyst should use only the sample identification number without any sample information during analysis to avoid the unconscious bias.

This proposed subsection is necessary to allow the laboratory and the bureau to track each sample and sample portion.

Proposed subsection (b)(3)(A) specifies that the sampler must record, on the chain-of-custody form, the unique sample or increment identification number that is labeled on the sample container. Depending on the sampling batch size, the quantity of samples or increments will differ. Therefore, unique, creative, and clear identification is required to avoid confusion and overlap. This section is necessary for the purpose of identifying and tracking medical cannabis or medical cannabis products.

Proposed subsection (b)(3)(B) specifies that the sampler must record the date and time that the sample increment was obtained on the chain-of-custody form. This information is necessary to demonstrate the integrity of all of the sampling action and be able to trace back where increments came from in a batch.

Proposed subsection (b)(3)(C) specifies that the sampler or samplers who participate in the sampling must sign the chain-of-custody form after sampling. This information is necessary to identify the laboratory employees who are responsible for the sampling process.

Proposed subsection (b)(3)(D) specifies that the sampler must record all environmental sampling conditions on the chain-of-custody form, such as temperature at sampling time, cooler temperature for sample containers, abnormal moisture, light, and sanitization conditions. This information is necessary to verify that the sample is not unnecessarily exposed to environmental contaminants beforehand that may alter the accuracy and therefore reliability of test results.

Proposed subsection (b)(3)(E) specifies that all persons related to sample possession, including the person receiving the sample at the testing laboratory, must print and sign his or her name on the chain-of-custody form when sample possession is transferred. This subsection is necessary for identifying any irregularity or suspicious finding related to testing activity during an investigation by the laboratory or the bureau.

Proposed subsection (b)(3)(F) specifies that the testing laboratory must record on the chain-of-custody form where the samples are stored in the laboratory facility. This subsection is necessary for identifying any irregularity or suspicious finding related to testing activity during an investigation by the laboratory or the bureau.

Proposed subsection (b)(4) or (c) clarifies that chain-of-custody form must contain information documenting each time the sample changes custody between licensees, is transported, changes custody within the laboratory, or is destroyed. This provision is necessary to allow the bureau to identify issues of noncompliance in the handling of medical cannabis samples.

§ 5289. Sample Rejection

Proposed subsection (a) specifies the conditions under which a testing laboratory may reject a cannabis product sample after its transportation to the laboratory. Conditions under which a laboratory may reject a sample include a broken shipping container; evidence that the sample has been tampered with, manipulated, adulterated, or contaminated; evidence that the sample was not collected in the manner required by this chapter or the laboratory's sampling standard operating procedures; a missing or incomplete chain-of-custody form or sample field log; or an exceedance of the temperature in which the sample may be stored.

In addition, in proposed subsection (a)(6), the laboratory may, at its discretion, reject the sample for any other factor that may have negatively impacted the integrity of the sample since its collection. This section is necessary to ensure the accuracy and reliability of the laboratory analysis. A sample that arrives to the laboratory in an unsecured, inadequate, or otherwise noncompliant container risks being contaminated. As such, any analysis run on the sample is not representative of the batch from which the sample was obtained and will not yield reliable test results.

Subsection (b) proposes that the laboratory document errors and re-sample if necessary when a sample is rejected.

ARTICLE 4. STANDARD OPERATING PROCEDURES

§ 5292. Standard Operating Procedures for Laboratory Processes

Proposed section (a) enumerates the standard operating procedures (SOPs) for medical cannabis testing that must be developed and implemented by the licensee. These SOPs are necessary to ensure that each licensee is conducting business in a manner consistent with these regulations and for the benefit of public health and safety. The items listed in (a)(1) – (a)(12) are typical for laboratory SOPs.

Proposed subsection (b) specifies that the laboratory director shall review, approve, sign, and date each SOP and each revision to an SOP. This provision is necessary to ensure that the analytical results of each test are reviewed and verified for accuracy by the laboratory employee who is authorized to oversee and direct the scientific methods of the laboratory; ensure that the

testing laboratory achieves and maintains quality standards of practice; and supervise all testing-laboratory personnel. This section also specifies that the sampling plans include the revision dates and authors. This provision is necessary to document the incidents on which the plans were modified.

Proposed subsection (c) specifies that a laboratory shall keep all SOPs on the laboratory premises and, when necessary, in the field. This provision further specifies that the laboratory must ensure that each SOP is accessible to laboratory personnel during operating hours. This requirement is necessary to ensure that laboratory personnel have access to and are adequately informed of the laboratory SOPs for each function of the laboratory. The provision further specifies that the SOPs must be available to the bureau upon request.

Proposed subsection (d) ensures it is clear that SOPs are a "testing laboratory record" for purposes of this chapter and must be made available to the bureau upon request.

§ 5295. Standard Operating Procedures for Analytical Methods

Proposed subsection (a) specifies that the laboratory must employ analytical methods and equipment that have been tested to ensure they are fit for the purpose of the required test. This section is necessary to ensure consistency of operation among the laboratories and to safeguard against inaccurate or otherwise unreliable data.

Proposed subsection (b) specifies that the analytical method SOP for each required test must describe how the laboratory performs each method. Subsections (b)(1) – (b)(14) are necessary to clarify the minimum standards for SOPs relating to analytical procedures. Also, this provision is necessary to ensure consistency of operation among the laboratories and to safeguard against inaccurate or otherwise unreliable data.

§ 5298. Testing Methodologies

Proposed subsection (a) specifies, in line with Business and Professions Code section 19342(c) that laboratories must develop and implement scientifically valid testing methodologies for the chemical and microbial analysis of medical cannabis goods.

Proposed subsection (b) specifies the acceptable guidelines and reputable scientific standards by which the laboratory may rely upon in developing testing methodologies. Subsections (b)(1), (b)(2) and (b)(3) include guidelines from the US Food and Drug Administration (FDA), the AOAC's published methods, and monographs published by the US Pharmacopeial Convention (*USP-NF*). It is proposed that testing methodologies comport with these standards because they are widely recognized as containing robust, reliable, and fit-for-purpose methods that are used nationally and internationally in laboratory analyses.

Proposed subsection (b)(4) also specifies that a laboratory is allowed to submit to the bureau any alternative scientifically valid testing methodology that the licensee intends to use if it sends the standard operating procedure (SOP) for that method to the bureau. A laboratory may use the

method as long as the SOP is provided to the bureau, and the bureau will be able to see what new methods are being used in the industry, and ensure that the laboratory is following its SOP. This provision is necessary because it allows the bureau to consider and evaluate the scientific validity of alternative methodologies and to hold laboratories accountable. This provision also allows room for the emergence of new, innovative methods and changes in industry norms.

§ 5301. Validation of Non-Standard Test Methods and Modified Standard Test Methods

Proposed section 5301 specifies the minimum requirements that the testing laboratories must adhere to for validation of non-standard test methods and modified standard test methods used in cannabis testing. Method validation is a process by which a laboratory confirms by examination, and provides objective evidence, that the particular requirements for specific uses of a test method are fulfilled. It serves to demonstrate that the method can detect and identify an analyte or analytes in one or more matrices to be analyzed, on one or more instruments or platforms and with a demonstrated sensitivity, specificity, accuracy, trueness, reproducibility, ruggedness, and precision to ensure that the results are meaningful and appropriate to make a decision.[13] As of this time, there are no established standard methods for microbiological or chemical testing of cannabis; thus it is imperative for the bureau to set guidelines for new method validation by the medical cannabis testing laboratories.

Proposed subsection (a) specifies the types of methods that a laboratory may use for sample testing. A testing laboratory may use a non-standard method; a laboratory-designed or -developed method; a standard method used outside its intended scope; or a modified standard method for the analysis of samples. A non-standard method is any method that is used to test for an analyte of interest but that is not adopted by the industry as the standard method (may include analytical instrument company's developed methods, etc.). A laboratory-designed or -developed method is an in-house developed method. Standard method used outside is intended scope may be a method found in the *Bacteriological Analytical Manual* (*BAM*)[14] that is intended for use in microbial testing of food products but not tested on cannabis. As of now, there are no standard methods for cannabis, so a modified standard method would apply to future situations when standard methods become available when any modifications to those methods would need to be validated according to guidelines set forth in this section.

Proposed subsection (b) makes it clear that all laboratories are required to follow the FDA's published guidelines listed below for validation of both microbiological and chemical analytical methods. FDA's expert scientific committee has established these criteria that aim to ensure that

[13] FDA Foods and Veterinary Medicine Science and Research Steering Committee. *Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds*, 2nd Edition. US Food and Drug Administration. https://www.fda.gov/ScienceResearch/FieldScience/ucm273423.htm. Accessed March 29, 2017.

[14] US Food and Drug Administration. *Bacteriological Analytical Manual* (*BAM*). http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm. Accessed March 30, 2017.

all laboratory methods meet the highest analytical standards possible for their intended purpose. CDPH and the bureau believe that all medical cannabis testing laboratories should follow these FDA guidelines when validating their methods to ensure that the methods are fit for their intended use. The laboratory is required to validate all methods used for the analysis of samples for each different matrix type.

Proposed subsection (c) specifies the extent of validation that each microbiology laboratory is required to conduct. All licensed microbiology testing laboratories are required, at minimum, to conduct a level-one (emergency-use) single-laboratory validation study for all qualitative and quantitative methods for testing of microbiological impurities following specific validation requirements listed in the "Validation Standards for Microbiological Analysis" table in subsection (e). A level-one validation study includes the lowest level of validation; it means that all the work will have been done by one laboratory. In a level-one validation study, sensitivity and specificity (inclusivity and exclusivity) has been tested but only using a limited number of strains. Level-one validation studies are intended for methods needed in emergency situations. These are methods developed or modified for the detection of an analyte or a matrix not previously recognized or identified as a threat to public safety.[15]

Proposed subsection (d) specifies the extent of validation that each chemistry laboratory is required to conduct. All licensed chemistry testing laboratories are required, at minimum, to conduct a level-one (emergency-use) single-laboratory validation study for all qualitative and quantitative methods for chemical testing of medical cannabis products.

Proposed subsection (e)(1) specifies the exact parameters, in addition to those listed in *Guidelines for Method Validation for the Detection of Microbial Pathogens in Food and Feeds*,[16] required for validation of microbiological methods. The "Validation Standards for Microbiological Analysis" table in this subsection explicitly details the number of organisms needed for inclusivity (sensitivity) and exclusivity (specificity); the number of analyte levels per matrix (for both quantitative and qualitative methods); and the number of replicates per matrix at each level tested. It also states that there is no requirement for reference-method comparison, because, at this time, there is not a reference method for microbiological testing of cannabis. The reason for this additional specification is that in the US guidelines, these parameters are left to be determined by the subject-matter experts.[17] The numbers proposed are a minimum requirement

[15] FDA Foods and Veterinary Medicine Science and Research Steering Committee. *Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds*, 2nd Edition. US Food and Drug Administration. https://www.fda.gov/ScienceResearch/FieldScience/ucm273423.htm. Accessed March 29, 2017.

[16] FDA Foods and Veterinary Medicine Science and Research Steering Committee. *Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds*, 2nd Edition. US Food and Drug Administration. https://www.fda.gov/ScienceResearch/FieldScience/ucm273423.htm. Accessed March 29, 2017.

[17] FDA Foods and Veterinary Medicine Science and Research Steering Committee. *Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds*, 2nd Edition.

needed to give the bureau confidence in the test methods intended for use in medical cannabis testing without being too burdensome to the testing laboratories for conducting their method-validation studies.

Proposed subsection (e)(2)(A) specifies the matrix spike samples and reference materials or certified reference materials implementation in cannabis chemical-analysis method validation. Matrix spike samples and reference materials or certified reference materials are important components in the determination of analyte recoveries, matrix interferences, method accuracy, and precision in chemical-analysis method validation.

Ideally, matrix spiking of samples should be done directly with samples and then carried through the entire analysis to account for interferences. However, high concentrations of cannabis standards for spiking the matrix samples are not available currently due to their limited availabilities under federal law; therefore, recoveries will not be statistically relevant with low concentration standards. In addition to general guidelines for routine procedures,[18] a reasonable alternative approach that has been developed in the Food and Drug Laboratory Branch at the California Department of Public Health in which one would add cannabinoid standards after sample processing and dilution and calculate recovery. Some interference will be accounted for using this approach, but not all.

Proposed subsection (e)(2)(B) specifies that, when high concentrations of matric spike standards and reference materials or certified reference materials for cannabinoids are available, testing laboratories are required to use them.

ARTICLE 5. REQUIRED ANALYSES AND REPORTING

§ 5304. Required Analyses

Proposed section 5304 establishes the types of analysis that must be performed by the laboratory for each sample of cannabis product obtained from a distributor.

Proposed subsection (a) clarifies the minimum analytical methods and SOPs that a laboratory must develop and implement. Analysis is required for cannabinoids; moisture content; water activity; residual solvents and processing chemicals; pesticides; microbiological impurities; mycotoxins; filth; and heavy metals. This section is necessary to comply with the statutory requirements of the Act at Business and Professions Code section 19300 *et seq*. These tests are necessary to ensure that consumers of medical cannabis are informed of the level of

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US Food and Drug Administration. https://www.fda.gov/ScienceResearch/FieldScience/ucm273423.htm. Accessed March 29, 2017.

[18] US Food & Drug Administration Office of Foods and Veterinary Medicine, Guidelines for the Validation of Chemical Methods for the FDA FVM Program, April 2015. https://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM273418.pdf. Accessed March 28, 2017.

contaminants, additives, and cannabinoid potency in each cannabis product offered for sale at a licensed dispensary.

Proposed subsection (b) specifies that a laboratory must develop and implement test methods and corresponding SOPs for the analysis of terpenes. Such analysis need only be performed if either the product label makes any claim as to the content of terpenes in the product or such analysis is requested by the title holder. This provision is necessary to clarify when, and under what circumstances, a laboratory must perform analysis of medical cannabis goods to determine the concentration of terpenes.

§ 5307. Cannabinoids

Proposed section 5307 adds explanatory language to clarify the requirements in the Business and Professions Code section 19344.

Proposed subsection (a) lists the six cannabinoids that are required for testing for each batch of the medical cannabis goods under section 19344 of the MCRSA. It is repeated here for clarification and consistency.

Proposed subsection (b) specifies what information should be included and how to report the potency test results in the certificate of analysis for harvest-batch samples based on industry standard. The bureau proposes mandating the reporting of cannabinoid content be in dry-weight percent—and this percent will be required on the labeling of the medical cannabis goods—which will allow for the uniformity of reporting of cannabinoids across the state. Correcting for moisture and reporting dry-weight percent reveals the concentration of the cannabinoids in the solids of the medical cannabis goods.

Reporting wet-weight concentration may lead to differing measurements due to the amount of moisture in that particular product. Therefore, moisture correction (that is, calculating and reporting in dry-weight concentration) is necessary to ensure consumers may compare cannabinoid concentrations in medical cannabis goods that have varying moisture contents. This requirement would allow consumers to know that they are directly comparing the potency of different batches, regardless of the moisture make-up of those products. The federal Environmental Protection Agency requires dry-weight correction under some analytical protocols, and the Department of Defense requires reporting on a dry-weight basis for their contract laboratories.

Proposed subsection (c) makes clear that the dry-weight percentage of the cannabinoids listed in proposed subsection (a) should be reported in the certificate of analysis and how it should be calculated. The calculation formula is based on [$CD = CW / Ps \times 100$],[19] where CD is concentration corrected for dry weight; CW is wet-weight concentration; and Ps is percent solid.

[19] Environmental Chemistry Consulting Services, Ask the Chemist Vol. 2 - Dry Weight vs. Wet Weight Results, 2011, http://www.eccsmobilelab.com/resources/literature/?Id=117. Accessed March 28, 2017.

This equation is mathematically equivalent as [Ps = 1 – percent moisture] to remove the portion of moisture from medical cannabis goods.

Proposed subsection (d) specifies what information should be included and how to report the potency test results in the certificate of analysis for manufactured cannabis batch samples, based on industry standard. This will ensure consistent reporting on the certificate of analysis.

Proposed subsection (e) states that a cannabis testing laboratory may test for any other cannabinoids that are not required by law to be tested for and provide those test results to the customer upon request. This is to allow businesses to provide more information on their product labels about certain properties of the product.

Proposed subsection (f) makes clear that a laboratory must report that a sample passes testing for cannabinoid potency testing only if the only if the concentration of THC is within 15 percent of the labeled concentration of THC. If the concentration of THC in the sample is greater than or less 15 percent of the labeled concentration of THC, the batch from which the product was taken may not be sold by a dispensary. This requirement will ensure that cannabis product labels accurately reflect the concentration of the active, therapeutic ingredients contained in the product. THC is a psychoactive ingredient in cannabis products and a primary ingredient that consumers evaluate the concentration of when selecting a cannabis product for purchase. A tolerance of plus or minus 15% variance protects consumers while allowing for variation in manufacturing processes. Proper labeling is critical to ensuring that medical cannabis users are sufficiently informed of product potency and can make informed decisions when purchasing medical cannabis products.

Proposed subsection (g) makes clear that a laboratory must report that a sample passes testing for cannabinoid potency testing only if the concentration of CBD is within 15 percent of the labeled concentration of CDB. If the concentration of CBD in the sample is greater than or less 15 percent of the labeled concentration of CBD, the batch from which the product was taken may not be sold by a dispensary. CBD is associated with pain relief and is a primary ingredient that consumers evaluate the concentration of when selecting a cannabis product for purchase. A tolerance of plus or minus 15% variance protects consumers while allowing for variation in manufacturing processes. Proper labeling is critical to ensuring that medical cannabis users are sufficiently informed of product potency and can make informed decisions when purchasing medical cannabis products.

§ 5310. Residual Solvents and Processing Chemicals

Proposed subsection (a) specifies that a laboratory must analyze samples of manufactured cannabis batches for residual solvents and processing chemicals. Solvents are used to extract, in concentrated amounts, cannabinoids from dried flower. Processing chemicals are used in the manufacturing of cannabis products and may include machine lubricants and product packaging. When present in products intended for human consumption, excessive amounts of residual solvents and processing chemicals may pose risks to human health. Thus, this provision is necessary to ensure that manufactured cannabis products intended for human consumption and use do not contain residual solvents and processing chemicals in excess of the action levels established by CDPH for the bureau.

Further, this provision clarifies that dried flower, hashish, and kief need not be tested for residual solvents and processing chemicals. The rationale for this exemption is that dried flower, hashish, and kief are variant forms of the unprocessed cannabis plant and therefore are not expected to contain residual solvents or processing chemicals.

Proposed subsection (b) specifies that a laboratory must analyze samples of manufactured cannabis products for the residual solvents and processing chemicals listed below in the table in subsection (c) of the regulations. This provision is necessary to clarify that a laboratory need only test for the specific residual solvents and processing chemicals listed in the table.

Proposed subsection (c) makes clear that a laboratory must report that a sample of manufactured cannabis passes testing for residual solvents and processing chemicals only if the levels of such analytes do not meet or exceed the action levels established by CDPH for the bureau. If a sample fails testing, the batch from which the product was taken may not be sold by a dispensary.

In addition, proposed subsection (c) contains a table that lists the specific residual solvents and processing chemicals, along with their respective action levels, for which a laboratory must analyze samples of manufactured cannabis products.

Proposed Residual Solvents and Processing Chemicals

Chemical Name	**CAS No.**	**Action Level for Medical Cannabis Goods Meant for Inhalation (ppm)** [20]	**Action Level for All Other Medical Cannabis–Infused Goods (ppm)** [21]
1,2-Dichloroethane	107-06-2	2	5
Acetone	67-64-1	750	5000
Acetonitrile	75-05-8	60	410
Benzene	71-43-2	1[22]	2
Butane	106-97-8	800[23]	5000

[20] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.
[21] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.
[22] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.
[23] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.

Chemical Name	CAS No.	Action Level for Medical Cannabis Goods Meant for Inhalation (ppm) [20]	Action Level for All Other Medical Cannabis–Infused Goods (ppm) [21]
Chloroform	67-66-3	2[24,25]	60
Ethanol	64-17-5	1000[26]	5000
Ethyl acetate	141-78-6	400	5000
Ethyl ether	60-29-7	500	5000
Ethylene oxide	75-21-8	5	50[27]
Heptane	142-82-5	500	5000
Hexane	110-54-3	50[28]	290
Isopropyl alcohol	67-63-0	500	5000
Methanol	67-56-1	250	3000
Methylene chloride	75-09-2	125	600
Naphtha	8030-30-6	400	400
Pentane	109-66-0	750[29]	5000
Petroleum ether	8032-32-4	400[30]	400

[24] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.
[25] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.
[26] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.
[27] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.
[28] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.
[29] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.
[30] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.

Chemical Name	CAS No.	Action Level for Medical Cannabis Goods Meant for Inhalation (ppm) [20]	Action Level for All Other Medical Cannabis–Infused Goods (ppm) [21]
Propane	74-98-6	2100[31]	5000
Trichloroethylene	79-01-6	25[32]	80
Toluene	108-88-3	150	890
Total xylenes (ortho-, meta-, para-)	1330-20-7	150	2170

Determination of recommended solvents and processing chemicals

In determining which residual solvents and processing chemicals to require a laboratory to test for, the bureau relied on the research and expertise of CDPH. CDPH surveyed the medical cannabis laboratory testing standards in Colorado,[33] Massachusetts,[34] Nevada,[35] and Washington.[36] (Many states that have legalized medical cannabis use have not yet adopted standards for residual solvents and processing chemical. Therefore, CDPH's review of other jurisdictions' regulations was limited.) CDPH also conducted online research to determine the most common solvents and processing chemicals used in the extraction process.[37] Finally, CDPH

[31] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.
[32] California Department of Industrial Relations. PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS Table AC-1. https://www.dir.ca.gov/title8/5155table_ac1.html. Accessed March 29, 2017.
[33] Colorado Administrative Code section 212-2.712. State of Colorado. Code of Colorado Regulations. https://www.colorado.gov/pacific/sites/default/files/Retail%20Marijuana%20Rules%20through%2001302015.pdf. Accessed March 29, 2017.
[34] Massachusetts State. Department of Public Health. Bureau of Health Care Safety and Quality. Medical Use of Marijuana Program. Exhibit 7(a) Concentration Limits for Residual Solvents. http://www.mass.gov/eohhs/docs/dph/quality/medical-marijuana/lab-protocols/finished-mmj/final-exhibit-7-residual-solvent-limits.pdf. Accessed March 29, 2017.
[35] Nevada Administrative Code section 453A.592. Authorized methods, equipment, solvents, gases and mediums. http://dpbh.nv.gov/uploadedFiles/dpbh.nv.gov/content/Reg/MedMarijuana/dta/Policies/MME022%20Residual%20Solvent%20Testing%20for%20Medical%20Marijuana%20Independent%20Laboratories.pdf. Accessed March 29, 2017.
[36] Washington State Legislature. WAC 314-55-104. Marijuana processor license extraction requirements. http://app.leg.wa.gov/WAC/default.aspx?cite=314-55-104. Accessed March 29, 2017.
[37] Cannabis Cure Team. Making Cannabis Oil. http://www.cannabiscure.info/cannabis-oil/. Accessed March 29, 2017.

received information from California laboratories on the types of solvents and processing chemicals that are routinely detected in cannabis products.

Determination of recommended action levels

In determining the acceptable action levels for each residual solvent and processing chemical listed, the action levels adopted by other jurisdictions were researched as well as those established by the Division of Occupational Safety and Health (Cal/OSHA)[38] of the California Department of Industrial Relations, the US Pharmacopeial Convention (USP),[39] the National Institute for Occupational Safety and Health (NIOSH),[40] and the American Conference of Governmental Industrial Hygienists (ACGIH).[41]

Considering the standards adopted by other states, federal standards, and industry guidelines, alongside the potential exposure routes of contaminants from medical cannabis goods to consumers, it was determined that two sets of action levels are necessary: one to apply to cannabis goods meant for inhalation and the other to all other cannabis-infused goods.

Residual Solvents and Processing Chemicals Action Levels

Action levels for inhaled medical cannabis goods

One set of action levels applies to smoked or vaporized medical cannabis goods (for example, concentrates, oils, and waxes). These products bypass the liver and directly enter the bloodstream, thereby causing rapid delivery. Pulmonary assimilation of inhaled THC causes a maximum plasma concentration within minutes, and psychotropic effects start within seconds to a few minutes. By contrast, with oral ingestion of medical cannabis goods, psychotropic effects set in with a delay of 30 to 90 minutes, depending on the dose, because the cannabinoids are metabolized by the liver and absorbed through the gut.[42] The lungs are far more permeable to macromolecules than are any other portal of entry into the body.[43]

CDPH determined that the action levels established for airborne contaminants are appropriate to use for smoked or vaporized cannabis products because of the similar exposure route. In California, occupational health and safety standards are established by the California Department

[38] State of California. Cal/OSHA Department of Industrial Relations. https://www.dir.ca.gov/dosh/. Accessed March 29, 2017.
[39] USP (U.S. Pharmacopeia) home. http://www.usp.org/. Accessed March 29, 2017.
[40] NIOSH (National Institute for Occupational Safety and Health)-Home https://www.cdc.gov/niosh/. Accessed March 29, 2017.
[41] ACGIH (American Conference of Governmental Industrial Hygienists) home. http://www.acgih.org/home. Accessed March 29, 2017.
[42] Grotenhermen F. Pharmacokinetics and pharmacodynamics of cannabinoids. *Clin Pharmacokinet.* 2003; 42(4):327-60. https://www.ncbi.nlm.nih.gov/pubmed/12648025. Accessed March 29, 2017.
[43] Patton, John, et al. The Lungs as a Portal of Entry for Systemic Drug Delivery. *American Thoracic Society Journals*, Vol. 1, No. 4 Dec 01, 2004. http://www.atsjournals.org/doi/full/10.1513/pats.200409-049TA. Accessed March 29, 2017.

of Industrial Relations' California Division of Occupational Safety and Health (Cal/OSHA). Cal/OSHA protects workers from safety hazards, provides consultative assistance to employers, and establishes safety-hazard thresholds for airborne contaminants.[44] Occupational exposure generally occurs from inhaling contaminants or extended dermal exposure with a contaminant. Cal/OSHA establishes standards for the allowable average exposure to a contaminant over a short period of time (typically 15 minutes). The Short Term Exposure Limits (STELs) are based on the assumption that exposure will not occur more than 4 times a day.

By comparison, Cal/OSHA also establishes Permissible Exposure Levels (PELs) based on an assumed 8-hour exposure rate. The PELs are lower than the STELs. Recognizing the potential inability of manufacturers to meet the very low PELs, the proposed language recommends adopting the STELs.

However Cal/OSHA has not established STELs for some of the chemicals listed in the table in this subsection, specifically butane, chloroform, ethanol, pentane, and propane. As such, CDPH relied on the STELs established by the National Institute for Occupational Safety and Health (NIOSH) and the American Conference of Governmental Industrial Hygienists (ACGIH) were relied upon. NIOSH is the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. ACGIH is a professional scientific association that provides guidance to industrial hygiene and occupational and environmental health and safety communities on workplace exposures to chemical substances and physical agents. After reviewing the STELs recommended by these entities adopting such action levels are recommended.

Generally, the recommended STELs for smoked and vaporized concentrates are several magnitudes less than the action levels established by the USP. This is because STELs are established for airborne contaminants, which immediately enter the bloodstream, whereas USP standards are established for pharmaceutical products, which are digested. Thus, the rationale for recommending STELs is that smoking or vaporizing cannabis is more closely akin to exposure to airborne contaminants in an occupational setting for short increments of time.

However, in the case of benzene and trichloroethylene, USP provides action levels lower than the STELs. USP provides action levels of 2 ppm for benzene and 80 ppm for trichloroethylene. Comparatively, the STEL for benzene is 5 ppm, and the STEL for trichloroethylene is 100 ppm. In light of this, CDPH recommends adopting the Cal/OSHA PELs for these two compounds because the PELs are lower than the STELs and therefore more protective of public health. Benzene is a carcinogen and highly toxic to human health. Trichloroethylene is also toxic to human health with inhalation at high levels. As such, the most protective action level is recommended.

[44] Cal/OSHA. Occupational Safety and Health Standards Board. Title 8. California Code of Regulations. Section 5155. Airborne Contaminants. http://www.dir.ca.gov/title8/5155.html. Accessed March 29, 2017.

In the case of hexane, there is no STEL for that compound. As such, CDPH recommends adopting the Cal/OSHA PEL of 50 ppm. Hexane is classified by USP as Class 2 and is very dangerous.

In the case of butane, there is no STEL for that compound. CDPH recommends adopting the Cal/OSHA PEL 800 ppm. The primary risk of exposure to butane is narcosis, which occurs at high exposure levels. Exposure at 10,000-ppm butane for 10 minutes causes drowsiness, but there are no reports of systemic toxicity or irritation at this level.[45] Humans exposed to 1000 ppm for a single 8-hour day, or at 500 ppm for 2-week periods of 8-hour workdays, showed no harmful subjective or abnormal physiological responses but did show a reduced visual evoked response (VER)-wave amplitude during the second week.[46] Currently CAL/OSHA is establishing a PEL of 800 ppm TWA for butane, and ACGIH and NIOSH both adopted 800 ppm of butane for their exposure limits. As such, CDPH recommends adopting the Cal/OSHA PEL of 800 ppm for butane to ensure maximum protection of consumers against the significant risks of drowsiness and other narcotic effects of exposure to butane.

In the case of propane, there is no STEL for that compound. CDPH therefore recommends using the NIOSH Immediately Dangerous to Life or Health (IDLH) level of 2100 ppm. Propane is an asphyxiant, meaning that the chemical prevents the body from using the oxygen it takes in.[47] It has been reported that brief inhalation exposures at 10,000 ppm cause no symptoms in humans.[48] The lower explosive limit (LEL) of propane is 21,000 ppm, and NIOSH set the IDLH concentration of propane at 2100 ppm. Based on acute inhalation toxicity data in humans,[49,50] the IDLH for propane was set at 2100 ppm based strictly on safety considerations (that is, being only 10% of the LEL). The PEL of propane of Cal/OSHA is 1000 ppm, and the STEL is not established yet. CDPH recommends adopting the NIOSH IDLH of 2100 ppm to ensure safety of consumers as it relates to medical cannabis concentrates.

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[45] NIOSH (National Institute for Occupational Safety and Health). Butane. https://www.cdc.gov/niosh/pel88/106-97.html Accessed March 29, 2017.
[46] NIOSH (National Institute for Occupational Safety and Health). Butane. https://www.cdc.gov/niosh/pel88/106-97.html Accessed March 29, 2017.
[47] ACGIH (American Conference of Governmental Industrial Hygienists) [1991]. Propane. In: *Documentation of the Threshold Limit Values and Biological Exposure Indices*. 6th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists, pp. 1286-1287.
[48] Braker W, Mossman AL [1980]. *Matheson Gas Data Book*. 6th ed. Secaucus, NJ: Matheson Gas Products, pp. 615-623.
[49] ACGIH (American Conference of Governmental Industrial Hygienists) [1991]. Propane. In: *Documentation of the Threshold Limit Values and Biological Exposure Indices*. 6th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists, pp. 1286-1287.
[50] Braker W, Mossman AL [1980]. *Matheson Gas Data Book.* 6th ed. Secaucus, NJ: Matheson Gas Products, pp. 615-623.

Action level for all other medical cannabis–infused goods

A second set of action levels is proposed for edible cannabis products and other cannabis products that do not immediately enter the bloodstream. Edible cannabis products are digested and metabolized prior to impacting the patient. THC oral absorption is slow and unpredictable.[51] The active ingredients in edible cannabis products are absorbed more slowly by the human body compared with smoked and vaporized medical cannabis concentrates. As such, the proposed language recommends that, for edible cannabis products, adoption of action levels established by the US Pharmacopeial Convention (USP), which are based on ingestion by oral consumption. Under Business and Professions Code section 19344 subsection (b), residual levels of volatile organic compounds set by the bureau must be at or below the specifications set by the USP General Chapter 467 on residual solvents.

USP has established action levels for volatile organic compounds used or produced in the manufacturing of pharmaceuticals. USP categorizes these solvents in three classes: Class 1, Class 2, and Class 3. USP Class 1 solvents are highly toxic to human health and should be avoided in the production of consumable products.[52] USP Class 2 solvents are associated with less severe toxic effects than Class 1 but should be limited in use or formation during the manufacturing of consumable products.[53] USP Class 3 solvents are the least toxic of the three and may be used when practical. Other solvents that are generally considered safe for the production of pharmaceuticals are also included in the list.[54] However, USP has not established standards for naphtha, petroleum ether, butane, propane, ethylene oxide, and isopropyl alcohol.

For naphtha and petroleum ether, the standard established by ACGIH for naphtha of 400 ppm is recommended in the proposed language. Because naptha and petroleum ether are very similar compounds derived from petroleum products, using the ACGIH action level for naptha for both chemicals is appropriate. For butane and propane, an action level of 5000 ppm is proposed. This is the action level from USP for pentane, and, because pentane is a compound very similar to butane and propane, a 5000-ppm action level for butane and propane is proposed. For isopropyl alcohol, a 5000-ppm action level, which is the USP action level for ethanol is proposed. Isopropyl alcohol and ethanol are both very safe. For ethylene oxide, there are no USP or Cal/OSHA PELs. Therefore the proposal recommends using the action level of 50 ppm, which is the action level adopted by Oregon for cannabis testing.

[51] Karschner, E. Plasma Cannabinoid Pharmacokinetics following Controlled Oral Δ9-Tetrahydrocannabinol and Oromucosal Cannabis Extract Administration. *Clin Chem*. 2011 Jan; 57(1): 66–75. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3717338/pdf/nihms486958.pdf. Accessed March 29, 2017.
[52] USP (U.S. Pharmacopeia). <467> Residual Solvents. https://hmc.usp.org/sites/default/files/documents/HMC/GCs-Pdfs/c467.pdf. Accessed March 29, 2017.
[53] USP (U.S. Pharmacopeia). <467> Residual Solvents. https://hmc.usp.org/sites/default/files/documents/HMC/GCs-Pdfs/c467.pdf. Accessed March 29, 2017.
[54] USP (U.S. Pharmacopeia). <467> Residual Solvents. https://hmc.usp.org/sites/default/files/documents/HMC/GCs-Pdfs/c467.pdf. Accessed March 29, 2017.

Recognizing that the production of pharmaceuticals may involve the use of many more solvents and processing chemicals[55] than those used in the production of cannabis, the regulation proposes to include only those solvents and processing chemicals that are currently known to be used in the production of cannabis products. In addition, it is proposed to include naphtha and petroleum ether because both have known application in the cannabis manufacturing process. Other chemicals are included because they have known application as a solvent used for extraction and also may be an impurity in a primary solution used in the extraction process.

It is necessary to require laboratories to analyze cannabis product samples for chemicals listed by USP in Class 1, Class 2, and Class 3 to ensure the protection of the public's health by requiring products contain no residual solvents or processing chemicals at or above the applicable action level.

The CDPH recommended USP Class 1 solvents include 1,2-Dichloroethane and benzene. These chemicals are extremely hazardous in the case of ingestion, eye contact (irritant), and inhalation. They are also carcinogenic.

The CDPH recommended USP Class 2 solvents include acetonitrile, dichloromethane, chloroform, hexane, methanol, toluene, and total xylenes (ortho-, meta-, para-). These chemicals are hazardous in case of skin contact (irritant), eye contact (irritant), ingestion, and inhalation.

The recommended USP Class 3 solvents include acetone, ethanol, ethyl acetate, ethyl ether, pentane, and isopropyl alcohol. These chemicals are recognized as having low acute and chronic toxicity if ingested or inhaled.

Acetone is considered by the federal Food and Drug Administration as a GRAS (generally recognized as safe) substance and as such is considered safe for use in food to a certain level. It has been rated as a GRAS substance when present in food at concentrations ranging from 5000 ppm to 8000 ppm.[56]

In addition to the USP Class 1, Class 2, and Class 3 listed chemicals, it is also proposed to require laboratories to test products for additional chemicals that have known application in the manufacturing of cannabis products and that pose substantial human health risks. These chemicals include butane, which is known to cause drowsiness and narcosis when inhaled at high levels. The human health risks associated with propane are similar to those associated with butane. Such chemicals also include naphtha, which is an extremely volatile solvent and can explode when exposed to high temperatures. There are concerns expressed by some that naphtha might be carcinogenic. Some commonly available forms of naptha contain impurities that may

[55] USP (U.S. Pharmacopeia). <467> Residual Solvents. https://hmc.usp.org/sites/default/files/documents/HMC/GCs-Pdfs/c467.pdf. Accessed March 29, 2017.
[56] Organization for Economic Co-operation and Development (OECD) SIDS Initial Assessment Report (SIAR) for 9th SIAM. UNEP Publications. ACETONE. http://www.inchem.org/documents/sids/sids/67641.pdf. Accessed March 29, 2017.

also have harmful human health properties of their own. The human health risks associated with petroleum ether are similar to those associated with butane and naphtha.

Subsection (d) specifies that the testing laboratory must report the level of residual solvents and processing chemicals detected in a cannabis sample to 3 significant figures in parts per million. This provision is necessary to create uniformity and consistency in reporting. Uniform and consistent reporting is necessary to enable both the bureau and licensees to objectively compare analytical reports. In addition, this provision specifies that the laboratory must report the test results for analysis of residual solvents and processing chemicals detected in a cannabis sample in the certificate of analysis. This requirement is necessary to ensure that the entity that requested the analytics be provided accurate and complete information about the samples tested.

Subsection (e) specifies that the laboratory must report on the certificate of analysis for each sample tested whether the sample passed or failed the analytical test for residual solvents and processing chemicals. This provision is necessary because the batch may only be sold to consumers if the sample tested from the batch passed the residual solvent and processing chemicals test. Cannabis products made from a batch whose sample failed the residual solvent and processing chemicals test may not be offered for sale unless it has been remediated, if that is possible, and tested again. In addition, this provision clarifies that the concentration of residual solvents and processing chemicals detected in a cannabis sample must be reported in the certificate of analysis. This provision is necessary to enable the requester of the test and the bureau to verify the degree to which the sample either passed or failed the analysis.

Proposed subsection (f) proposes that if the sample fails residual solvent testing, the batch fails laboratory testing. This is because the bureau believes these chemicals may not be present in medical cannabis goods.

§ 5313. Residual Pesticides

Proposed subsection (a) requires the bureau to adopt regulations based on California's Department of Pesticide Regulation's (DPR's) guidelines for pesticide residue in processed cannabis products.

Proposed subsection (b) requires the guidelines differentiate between maximum allowable levels for edible cannabis products, dried cannabis flowers, and all other processed cannabis.

This list is composed of 66 pesticide active ingredients currently used on cannabis. It was compiled from information collected in Colorado, Oregon, Washington, Nevada, and California and encompasses news articles[57,58,59,60] test results, regulatory guidelines,[61,62] and anecdotal

[57] David Migoya and Ricardo Baca. October 2, 2016. "State issues massive recall of pesticide-tainted marijuana." *Denver Post*. http://www.denverpost.com/2016/03/17/state-issues-massive-recall-of-pesticide-tainted-marijuana/. Accessed on April 4, 2017.

information from cannabis cultivators and state regulators. DPR then divided the listed pesticides into two broad categories:

> *Category I*: pesticides with the maximum allowable limit set above the minimum detection limit used by the California Pesticide Residue Monitoring Program.
>
> *Category II*: pesticides with the maximum allowable limit set above the minimum detection limit of the California Pesticide Residue Monitoring Program and based on human-health considerations for the different consumption categories.

Category I: Includes pesticides that DPR identifies as having human health or environmental concerns. DPR determined that 42 of the listed pesticides fall under this category based on at least one of the following human health or environmental concerns:

High Acute Toxicity: Pesticides with high acute toxicity are hazardous to human health when consumed.

Ground Water Protection List: DPR lists pesticides with chemical characteristics that make them likely to move into groundwater on the Groundwater Protection List at section 6800(b) in Title 3 of the California Code of Regulations. DPR is concerned about the potential environmental impacts to groundwater caused by the use of these pesticides for cannabis cultivation.

Neonicotinoid: Neonicotinoids are a class of pesticides. The federal Environmental Protection Agency (US EPA) has stopped new registrations of neonicotinoid pesticides pending a determination about potential impacts to pollinators. DPR is concerned about the potential environmental impacts to pollinators caused by the use of these pesticides for cannabis cultivation.

Restricted Materials: DPR designates certain pesticides as "restricted materials" if they have a higher potential to cause harm to public health, farm workers, domestic animals, honeybees, the

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[58] Alicia Lozano. October 27, 2016. "Pesticides in cannabis pose a growing problem for cannabis consumers." *LA Weekly*. http://www.laweekly.com/news/pesticides-in-marijuana-pose-a-growing-problem-for-cannabis-consumers-7526808. Accessed on April 4, 2017.

[59] Melia Robinson. December 15, 2016. "Marijuana can be covered in pesticides, fungi, and mold—even if it's legal." *Business Insider*. http://www.businessinsider.com/marijuana-bacteria-contamination-health-concerns-2016-12. Accessed on April 4, 2017.

[60] Matthew Glasser and Joel Grover. February 22, 2017. "Pesticides and pot: lab results, company statements." http://www.nbclosangeles.com/news/local/Pesticide-Laced-Pot-Lab-Results-Company-Statements-I-Team-414526923.html. Accessed on April 4, 2017.

[61] Cannabis Safety Institute. *Pesticide Use on Cannabis*. June 2015. http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/CSI-Pesticides-White-Paper.pdf. Accessed on April 4, 2017.

[62] Farrer DG. *Technical Report: Oregon Health Authority's Process to Decide Which Types of Contaminants to Test for in Cannabis*. Oregon Health Authority. 2015 December. https://public.health.oregon.gov/PreventionWellness/marijuana/Documents/oha-8964-technical-report-marijuana-contaminant-testing.pdf. Accessed on April 4, 2017.

environment, wildlife, or other crops as compared to other pesticides. DPR is concerned about potential human health and environmental impacts caused by the use of restricted materials on cannabis.

Not Registered in California: Pesticides that are not registered for use in California. DPR has not approved these pesticides for any use in California.

No Food Uses: Pesticides that are not registered for any food use sites in California. Because these products have not been approved for use on food crops there has been no analysis of levels that are safe for human consumption.

Category I Pesticides:

Each Pesticide is Identified With the California Pesticide Residue Monitoring Program Minimum Detection Limit and the Reason for Concern

	Detection Limit (ppm)	**Human Health or Environmental Concern**
Abamectin	0.02	High Acute Toxicity
Acephate	0.02	Ground Water Protection List
Acetamiprid	0.01	Neonicotinoid
Aldicarb	0.01	Not Registered in CA
Azoxystrobin	0.01	Ground Water Protection List
Bifenthrin	0.01	High Acute Toxicity
Boscalid	0.01	Ground Water Protection List
Carbaryl	0.01	Restricted Material
Carbofuran	0.01	Not Registered in CA
Chlorantraniliprole	0.02	Ground Water Protection List
Chlordane	0.01	Not Registered in CA
Chlorfenapyr	0.01	No Food Uses
Chlorpyrifos	0.02	Restricted Material
Coumaphos	0.01	No Food Uses
Cyfluthrin	0.01	High Acute Toxicity
Daminozide	0.01	No Food Uses
DDVP (Dichlorvos)	0.02	No Food Uses
Diazinon	0.01	Ground Water Protection List
Dimethoate	0.01	Ground Water Protection List
Dimethomorph	0.01	Ground Water Protection List
Ethoprop(hos)	0.01	High Acute Toxicity
Etofenprox	0.01	Mosquito Only
Fenoxycarb	0.01	Not Registered in CA
Fipronil	0.01	High Acute Toxicity
Fludioxonil	0.02	Ground Water Protection List

Imazalil	0.01	No Food Uses
Imidacloprid	0.02	Ground Water Protection List
Malathion	0.01	Ground Water Protection List
Metalaxyl	0.01	Ground Water Protection List
Methiocarb	0.01	Ground Water Protection List
Methomyl	0.01	Ground Water Protection List
Methyl parathion	0.01	Not Registered in CA
Mevinphos	0.01	Not Registered in CA
Myclobutanil	0.02	Ground Water Protection List
Naled	0.01	High Acute Toxicity
Paclobutrazol	0.01	No Food Uses
Propiconazole	0.02	Ground Water Protection List
Propoxur	0.02	No Food Uses
Spiroxamine	0.01	Not register in CA
Tebuconazole	0.01	Ground Water Protection List
Thiacloprid	0.01	Not register in CA
Thiamethoxam	0.01	Ground Water Protection List

For these pesticides DPR recommends the most stringent residue level—the level of detection. That is, a sample fails if one of these analytes is found at or above the detection level. The detection levels referenced above are the same levels used by the California Department of Food and Agriculture laboratory for raw produce analyzed under the California Pesticide Residue Monitoring Program.

Category II: The remaining 24 pesticides are listed below. For these pesticides, DPR recommends maximum allowable residue levels in cannabis that are above the minimum limit of detection of the California Pesticide Residue Monitoring Program, based on human-health considerations for each of the consumption categories. That is, a sample fails if one of these analytes if found at a level above those listed here. DPR recommends differentiating between forms of consumption because each has unique human health considerations that currently cannot be addressed under a single level.

Edible cannabis products: DPR scientists calculated the levels using the method used in the PRMP to evaluate potential health risks from illegal pesticide residue detected on raw produce. The maximum residue level is calculated by using the lowest available reference dose (RfDs)—the daily exposure to the human population that is likely to be without an appreciable risk of deleterious effects—together with an estimated daily maximum consumption rate. The consumption rate is 100 grams per kilogram of body weight (100 g/kg). DPR used this consumption rate as a surrogate for the actual rate of consumption for edible cannabis products. This rate is currently used for human health evaluations made under the PRMP.

Dried cannabis flower: DPR used tobacco as a surrogate based on the similar patterns of smoke inhalation. Levels for dried cannabis flower are based on one of the following:

Guidance Residue Levels (GRLs) established by the Centre Coopération pour les Recherches Scientifiques Relatives au Tabac (CORESTA), an organization established under French law to promote international cooperation in scientific research relative to tobacco and its derived products; or

US EPA registration data guidelines, which waive the requirement that pesticide registrants submit pyrolysis data to US EPA's Health Effects Division as part of an application to register a pesticide product for use on tobacco when the expected residue level on the tobacco at the time of harvest is less than 0.1 ppm. This indicates that US EPA does not believe that there is any reviewable acute health effect caused by inhaling tobacco smoke with less than 0.1 ppm of pesticide residue.

Other processed cannabis products: DPR used the pesticide-specific tolerance for either cottonseed oil or the lowest available tolerance for that active ingredient based on the assumption that manufacturing cottonseed oil is similar to manufacturing cannabis concentrates. Due to the lack of available information on cannabis consumption using a vape machine, none of the levels is above the lowest recommended level for dried cannabis flower used for smoking.

Category II Pesticides:

Pesticides Listed With the Maximum Allowable Limit for Each of the Three Types of Consumption

	Edible Cannabis Products (ppm)	**Dried Cannabis Flowers (ppm)**	**All Other Processed Cannabis (ppm)**
Acequinocyl	0.27	0.1	0.02
Bifenazate	1.0	0.1	0.1
Captan	1.0	0.7	0.05
Clofentezine	1.3	0.1	0.04
Cypermethrin	1.0	1.0	0.5
Etoxazole	0.46	0.1	0.05
Fenhexamid	1.7	0.1	0.08
Fenpyroximate	0.5	0.1	0.1
Flonicamid	0.4	0.1	0.1
Hexythiazox	0.25	0.1	0.1
Kresoxim-methyl	3.6	0.1	0.02
Oxamyl	0.026	0.5	0.2
Pentachloronitrobenzene	0.03	0.1	0.1
Permethrin	2.5	0.5	0.02
Phosmet	0.12	0.1	0.02
Piperonyl butoxide	63.0	3.0	3.0
Prallethrin	0.5	0.1	0.02
Pyrethrins	0.7	0.5	0.5

Pyridaben	4.4	0.1	0.02
Spinetoram	0.5	0.1	0.04
Spinosad	0.29	0.1	0.02
Spiromesifen	20.0	0.1	0.1
Spirotetramat	10.0	0.1	0.1
Trifloxystrobin	25.0	0.1	0.02

These levels are intended only to address the human health effects of pesticide residue on processed cannabis.

Proposed subsection (c) proposes that if the sample fails pesticide testing, the batch fails laboratory testing. This is because the DPR believes these chemicals should not be present in medical cannabis goods. Further, the bureau proposes that if the batch fails pesticide testing, it may not be remediated. This is because remediation of these chemicals is not possible.

§ 5316. Microbiological Impurities

Section 5316 specifies that the testing laboratories must test all medical cannabis samples for microbiological impurities. This proposed section establishes the type of microbial contaminants that harvest-batch samples and manufactured cannabis batch samples (that is, all samples) must be tested for and establishes the corresponding action levels.

Proposed subsection (a) specifies that the testing laboratories must report that the sample "passed" microbiological impurity testing if the microbiological impurities are not detected in 1 gram of substance.

Proposed subsection (a)(1) and (2) shows the strains that must be tested for in all medical cannabis goods. It is proposed that Shiga toxin–producing *Escherichia coli (E.coli)* strains and all *Salmonella* strains be tested for. The action levels of not detected in 1 gram are based on levels recommended by the American Herbal Pharmacopeia[63] and on the Cannabis Safety Institute's report on microbiological safety testing.[64] Although the latter source says that dried and cured cannabis is not a likely vehicle for pathogenic *E. coli*, Shiga toxin–producing *E. coli* may be present nonetheless, and the bureau determined that testing for it is protective of public health, particularly for those with compromised immune systems.

Shiga toxin–producing *E. coli* (STEC) strains are of particular concern. They are capable of causing human disease by producing a toxin called Shiga toxin. People of any age can become infected. The immunocompromised population is more likely to develop severe illness and

[63] Roy Upton, Mahmoud ElSohly et.al. *Cannabis Inflorescence Cannabis spp. Standards of Identity, Analysis, and Quality Control*. Scott's Valley, CA: American Herbal Pharmacopeia; 2013. Book must be purchased to be accessed.

[64] Cannabis Safety Institute. *Microbiological Safety Testing of Cannabis*. May 2015. Pages15-16. Available at: http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/Microbiological-Safety-Testing-of-Cannabis.pdf. Accessed March 30, 2017.

complications called hemolytic uremic syndrome, but even healthy populations can become seriously ill from this toxin. Because of the low infectious dose required for disease causation, there is zero tolerance for the presence of any Shiga toxin–producing *E. coli* in all medical cannabis goods.

Salmonella is a genus of bacteria capable of causing gastrointestinal disease in both healthy as well as immunocompromised populations. Its presence in cannabis has been well documented and includes a multistate outbreak in 1981. Because of the low infectious dose required for disease causation, the bureau recommends zero tolerance for the presence of *Salmonella* of all strains in all medical cannabis goods.

Proposed subsection (b) would require a laboratory to report in the certificate of analysis whether or not these bacteria are present. If one or more of the bacteria are present, the sample and corresponding batch fails microbiological testing and therefore fails laboratory testing. If the testing is failed then the medical cannabis goods may not be sold.

Proposed subsection (c) specifies that a laboratory is required to test for specific fungal pathogenic *Aspergillus* species in anything meant to be inhaled: *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus*. This testing is required for all medical cannabis goods intended for consumption by inhalation, such as dried flower, kief, hashish, oil, and waxes. When inhaled, each of these four *Aspergillus* species are known to cause a variety of lung disorders, ranging from asthma, allergic bronchopulmonary aspergillosis, and hypersensitivity pneumonitis to invasive systemic fungal infections in immunocompromised hosts (people with weakened immune systems). The association between cannabis use and invasive and allergic pulmonary aspergillosis has been documented in a number of clinical cases involving immunocompromised hosts.[65,66,67,68]

Aspergillus is a genus of mold (type of fungus) that causes aspergillosis and is very common both indoors and outdoors, so exposure to these fungal spores is very common. For people with healthy immune systems, breathing in *Aspergillus* is minimally harmful. However, for people with weakened immune systems, breathing in *Aspergillus* spores can cause an infection in the

[65] Cescon DW, Page AV, Richardson S, Moore MJ, Boerner S, Gold WL. Invasive Pulmonary Aspergillosis Associated with Marijuana Use in a Man with Colorectal Cancer. Journal of Clinical Oncology. 2008;26(13):2214-2215. http://ascopubs.org/doi/pdf/10.1200/JCO.2007.15.2777. Accessed March 29, 2017.
[66] Sutton S, Lum BL, Torti FM. Possible risk of invasive pulmonary aspergillosis with marijuana use during chemotherapy for small cell lung cancer. Drug Intelligence and Clinical Pharmacy. 1986;20(4):289-291. https://www.ncbi.nlm.nih.gov/pubmed/3009125. Article must be purchased to be accessed.
[67] Yousef Gargani, Paul Bishop, and David W. Denning. Too many mouldy Joints – Marijuana and Chronic Pulmonary Aspergillosis. Mediterranean Journal of Hematology and Infectious Diseases. 2011;3(1). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3103256/pdf/mjhid-3-e2011005.pdf. Accessed March 29, 2017.
[68] Randa Hamadeh, Abbas Ardehali, Richard M. Locksley, Mary K. York. Fatal Aspergillosis Associated with Smoking Contaminated Marijuana, in A Marrow Transplant Recipient. Chest. 1988;94(2):432-433. http://www.sciencedirect.com/science/article/pii/S0012369216334845.

lungs or sinuses that can spread to other parts of the body.[69] There are approximately 180 species of *Aspergillus*, but only a few are known to cause infections in humans.[70]

Aspergillus fumigatus is the most common *Aspergillus* species to cause disease in an immunocompromised host. It is known as the most frequent cause of invasive fungal infection in immunosuppressed individuals, which includes patients receiving immunosuppressive therapy for autoimmune or neoplastic disease, organ transplant recipients, and AIDS patients.[71]

The association between *Aspergillus fumigatus* and invasive pulmonary aspergillosis with patient cannabis use has been well documented.[72] Therefore, it is imperative that we test medical cannabis goods intended for inhalation for this potentially deadly organism.

Aspergillus flavus is also known for its pathogenicity in humans. *Aspergillus flavus* is an opportunistic human and animal pathogen, causing pulmonary aspergillosis in immunocompromised individuals. In addition, many *Aspergillus flavus* strains produce significant quantities of toxic compounds, known as mycotoxins, that are harmful to humans. *Aspergillus flavus* has been shown to be a significant contaminant of cannabis.[73] Therefore, it is important to test medical cannabis goods intended for inhalation for this potentially deadly organism.

Aspergillus niger is another one of the most common pathogenic species of the genus *Aspergillus*. This fungal species is ubiquitous in soil and is also commonly reported from indoor environments. Some strains of *Aspergillus niger* have been reported to produce mycotoxins.[74]

Aspergillus terreus, along with *A. niger*, *A. flavus*, and *A. fumigatus*, has been detected in illicit cannabis samples.

Because of this and its implications in pulmonary aspergillosis among immunocompromised persons,[75,76] it is important to test all medical cannabis goods intended for inhalation for these potentially deadly organisms.

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[69] Centers for Disease Control and Prevention. Sources of Aspergillosis. https://www.cdc.gov/fungal/diseases/aspergillosis/causes.html. Accessed March 29, 2017.
[70] Center for Disease Control and Prevention. Sources of Aspergillosis. CDC. https://www.cdc.gov/fungal/diseases/aspergillosis/causes.html. Accessed March 29, 2017.
[71] J. Antunes, A. Fernandes, L. Miguel Borrego, P. Leira-Pinto, J. Cavaco. Cystic Fibrosis, atopy, asthma and ABPA. Allergologia et immunopathologia. 2010;38(5):278-284. http://www.elsevier.es/en-revista-allergologia-et-immunopathologia-105-linkresolver-cystic-fibrosis-atopy-asthma-abpa-S0301054610001515. Accessed March 29, 2017.
[72] Cescon DW, Page AV, Richardson S, Moore MJ, Boerner S, Gold WL. Invasive Pulmonary Aspergillosis Associated with Marijuana Use in a Man with Colorectal Cancer. Journal of Clinical Oncology. 2008;26(13):2214-2215. http://ascopubs.org/doi/pdf/10.1200/JCO.2007.15.2777. Accessed March 29, 2017.
[73] Paul E. Verweij, Jos J. Kerremans, Andreas Voss. Fungal contamination of tobacco and marijuana. *JAMA*. 2000;284(22):2875. http://jamanetwork.com/journals/jama/fullarticle/1031109. Accessed March 29, 2017.
[74] Schuster E., Dunn-Coleman N., Frisvad J., van Dijck P. On the safety of Aspergillus niger – a review. Applied Microbiology and Biotechnology. 2002;59(4):426-435. http://link.springer.com/article/10.1007%2Fs00253-002-1032-6. Article must be purchased to be accessed.

Proposed subsection (c)(1) specifies that all testing laboratories shall report that the sample "passed" only if the four pathogenic *Aspergillus* species were not detected in 1 gram of sample.

Subsection (c)(2) states that if any of the four listed pathogenic species are detected in 1 gram of the sample, the medical cannabis sample fails the microbiological impurity testing and therefore fails laboratory testing.

Proposed subsection (d) specifies that a testing laboratory may test for and report more microorganisms if requested to by the entity requesting testing. The bureau believes this will grant requestors with flexibility to test for more contaminants than are required if they wish to ensure their product is very safe.

§ 5319. Mycotoxins

Proposed subsection (a) specifies the identity and action levels of mycotoxins (toxins produced by fungi) that are to be tested by licensed laboratories in all medical cannabis goods. The medical cannabis goods will "pass" the mycotoxin test if the levels are below 20 µg/kg (micrograms per kilogram) of substance. This section is necessary to ensure that the medical cannabis goods are free of specified mycotoxins or contain levels of these mycotoxins that will not adversely affect the health of the consumer who purchases medical cannabis goods from a licensed dispensary.

Mycotoxins are toxic substances produced by certain fungal organisms that can grow on human food and animal feed grain. Human exposure to mycotoxins includes ingestion, inhalation, and dermal contact.[77] Among mycotoxins, the most widely recognized risk comes from aflatoxins and Ochratoxin A.

Aflatoxins are toxic substances produced by two major *Aspergillus* species: *Aspergillus flavus* and *Aspergillus parasiticus*.[78] Aflatoxins are both acutely and chronically toxic in animals and humans. The disease primarily attacks the liver, causing necrosis, cirrhosis, and carcinomas. There are four main types of aflatoxins: B1, B2, G1, and G2, based on their fluorescence under the UV light (blue or green) and relative chromatographic mobility during thin-layer

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[75] Schuster E., Dunn-Coleman N., Frisvad J., van Dijck P. On the safety of Aspergillus niger – a review. Applied Microbiology and Biotechnology. 2002;59(4):426-435. http://link.springer.com/article/10.1007%2Fs00253-002-1032-6. Article must be purchased to be accessed.

[76] Steven L. Kagen, Viswanath P. Kurup, Peter G. Sohnle, Jordan N. Fink. Marijuana smoking and fungal sensitization. Journal of Allergy and Clinical Immunology. 1983;71(4):389-393. http://www.sciencedirect.com/science/article/pii/0091674983900672?via%3Dihub.

[77] M. Peraica, B. Radic, A. Lucic & M. Pavlovic. Toxic effects of mycotoxins in humans. Bulletin of World Health Organization. 1999;77(9):754-766. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2557730/pdf/10534900.pdf. Accessed March 28, 2017.

[78] Bennett JW and Klich M. Mycotoxins. *Clinical Microbiology Reviews*. 2003;16(3):497-516. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC164220/pdf/0050.pdf. Accessed March 28, 2017.

chromatography.[79] Many substrates support growth and aflatoxin production by aflatoxigenic molds. Natural contamination of cereals, figs, oil-seeds, nuts, tobacco, and other commodities is a common occurrence.[80] Because of the broad scope of agricultural products found to be contaminated with aflatoxins, the bureau proposes to require all medical cannabis and its products be tested for four aflatoxin levels (four major aflatoxin types of B1, B2, G1, and G2).

Ochratoxins are secondary metabolites of *Aspergillus* and *Penicillium* strains found on a variety of food commodities.[81] The most toxic and frequently encountered of all ochratoxins is Ochratoxin A. Ochratoxin A has been shown to be nephrotoxic, immunosuppressive, carcinogenic, and teratogenic in all experimental animals tested thus far.[82] Ochratoxin A has been found in barley, oats, rye, wheat, coffee beans, and other plant products.[83] Because of its presence in a variety of agricultural plant products, CDPH and the bureau propose that all medical cannabis goods be tested for Ochratoxin A.

Action levels for mycotoxins proposed in these regulations are based on those established by the federal Food and Drug Administration[84] as well as on discussions with other states currently regulating cannabis testing.[85,86]

Proposed subsection (b) specifies the reporting units for mycotoxins listed in subsection (a). It states that the results shall be reported to 3 significant figures in micrograms per kilogram (µg/kg) and such shall appear in the certificate of analysis. These significant figures are an amount that will provide needed precision.

Proposed subsection (c) specifies that the testing laboratory shall clearly indicate on its certificate of analysis whether the concentration of mycotoxins detected in a given sample meets or exceeds the action levels established by this section and thus whether the sample "passed" or

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[79] Bennett JW and Klich M. Mycotoxins. *Clinical Microbiology Reviews*. 2003;16(3):497-516. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC164220/pdf/0050.pdf. Accessed March 28, 2017.
[80] Bennett JW and Klich M. Mycotoxins. *Clinical Microbiology Reviews*. 2003;16(3):497-516. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC164220/pdf/0050.pdf. Accessed March 28, 2017.
[81] Bennett JW and Klich M. Mycotoxins. *Clinical Microbiology Reviews*. 2003;16(3):497-516. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC164220/pdf/0050.pdf. Accessed March 28, 2017.
[82] Bennett JW and Klich M. Mycotoxins. *Clinical Microbiology Reviews*. 2003;16(3):497-516. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC164220/pdf/0050.pdf. Accessed March 28, 2017.
[83] Bennett JW and Klich M. Mycotoxins. *Clinical Microbiology Reviews*. 2003;16(3):497-516. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC164220/pdf/0050.pdf. Accessed March 28, 2017.
[84] FDA Foods and Veterinary Medicine Science and Research Steering Committee. Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition. US Food and Drug Administration. https://www.fda.gov/ScienceResearch/FieldScience/ucm273423.htm. Accessed March 29, 2017.
[85] VICAM. Mycotoxin Testing is Vital to the future of the Medical Marijuana Industry. http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjctb242PzSAhVE0mMKHbPoDuMQFggrMAA&url=http%3A%2F%2Fvicam.com%2FLiteratureRetrieve.aspx%3FID%3D229610&usg=AFQjCNHTt5S5_4t3-mefp5Ke8Aot83NmJQ. Accessed March 29, 2017.
[86] Nevada Administrative Code of Correctness. NAC 453A.658. Chapter 453A. Medical Use of Marijuana. Production and Distribution of Medical Marijuana. Requirements for Independent Testing Laboratories.

"failed" mycotoxin testing. These results are necessary to determine if the medical cannabis goods may be sold.

Proposed subsection (d) states that the testing laboratory may test for and provide test results for additional mycotoxins if requested by the requester of the laboratory testing. The bureau believes this will grant requestors with flexibility to test for more contaminants than are required if they wish to ensure their product is very safe.

§ 5322. Water Activity and Moisture Content

Section 5322 proposes requiring testing of certain medical cannabis samples for water activity and moisture content before release of the batch to dispensaries for sale. If a harvest batch fails either of these tests, as defined in this proposed section, the failed batch may be returned to the cultivator for further drying and curing. If edible cannabis products fail the testing under this section, the batch must be destroyed. These tests are necessary to ensure a long-enough storage shelf life to allow the medical cannabis goods to be stored without becoming unfit for consumption or sale. The water-activity and moisture-content action levels proposed here aim to minimize growth of fungi and bacteria.

Proposed subsections (a) and (d) specify the action levels for water activity and water content in dried flower harvest-batch samples. In plants, microorganisms such as mold are perhaps the most important quality issue in cannabis production.[87] Outdoor plants are exposed to a wide variety of fungal species. Indoor plants are exposed to less of these and can potentially be kept cleaner. In practice, however, many indoor plants are exposed to inappropriate watering, humidity, fertilizer, or ventilation conditions. All of these can contribute to very high levels of mold. Even under ideal conditions, it is possible that small numbers of cells or spores capable of causing human disease may be present on plant material from contact with air, soil, or water. If any of these species are capable of replicating aggressively, either on dried plant material or upon contact with humans, they could be a threat to human health.

Moisture present in herbal products is a primary determinant of the ability of microorganisms to thrive and rise to harmful levels post distribution. The Dutch Office of Medical Cannabis (OMC) requires that the moisture content of cannabis at the time of quality control (directly after packaging) be between 5% and 10%. The Dutch OMC also suggests moisture content of dry material (crude cannabis after packaging) not exceed 15%.[88,89,90] In addition, commercial labs

[87] Cannabis Safety Institute, Microbiological Safety Testing of Cannabis, May 2015. http://cannabissafetyinstitute.org/wp-content/uploads/2015/06/Microbiological-Safety-Testing-of-Cannabis.pdf. Accessed March 28, 2017.

[88] Association of Public Health Laboratories, Guidance for State Medical Cannabis Testing Programs, May 2016. https://www.aphl.org/AboutAPHL/publications/Documents/EH-Guide-State-Med-Cannabis-052016.pdf. Accessed March 28, 2017.

[89] American Herbal Pharmacopoeia (AHP), Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control, 2013.

from various states have reported that the optimal levels of properly cured medicinal cannabis should contain a moisture-content level between 6% and 9% and no greater than 15%.[91,92] Therefore, 5% to 13% is proposed as an acceptable and health-protective level.

The Dutch OMC suggests testing for water activity and requiring water-activity levels fall below 0.65 A_w.[93] This will ensure the absence of microbial growth on cannabis products during storage and prior to sale. Other states have set this level for water activity of dried flower as well. CDPH believes this is a health-protective level.

Proposed subsection (b) specifies the action levels for water activity in solid and semi-solid edible cannabis products. To come up with the action levels, CDPH referenced water-activity levels of foods. Most foods have a water activity level above 0.95, which is more than enough to support the growth of bacteria, yeasts, and mold. The amount of available moisture can be reduced to a point that will inhibit the growth of the organisms. If the water activity of food is controlled at 0.85 A_w or below in the finished product, it is not subject to the FDA regulations in Title 21 (sections 108 regarding permits, 113 regarding thermally processed low-acid foods packaged in hermetically sealed containers, and 114 regarding acidified foods).[94]

Edible cannabis products are as likely to become contaminated as any similar processed or prepared commercial food product. But because of its unique attributes, cannabis is the least likely component to be the source of contamination in any food product. Cannabis is present in foods as an extract of the plant material. This plant material is dried to a safe level before extraction. And then, either during or after extraction, it is usually subject to a decarboxylation process that serves as a heat-kill step. The vast majority of the extraction processes are themselves sterilizing. Once these extracts are added to food, the food can always be mishandled or subject to "temperature abuse," which raises the chances of contamination. But these are threats that face all foods, and the only pathogen of real concern on cannabis, *Aspergillus*, is not infectious when the route of administration is oral consumption (not inhalation). Therefore, action levels for food are an appropriate source for creating these action levels.

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[90] Willem K. Scholten, MSc, Pharm, MPA, Office of Medicinal Cannabis of the Pharmaceutical Affairs Directorate, Ministry of Health, Guidelines for Cultivating, Cannabis for Medicinal Purposes [Voorschriften voor de Verbouw van Cannabis voor Medicinale Doeleinden], Cannabis Ther 3:51-61. 2003. https://www.cannabis-med.org/data/pdf/2003-02-4_0.pdf. Accessed March 28, 2017.

[91] DigipathLabs, Moisture Residue Analysis. http://digipathlabs.com/moisture-residue-analysis/, 2015. Accessed March 28, 2017.

[92] Analytical 360, Moisture Analysis. http://analytical360.com/cannabis-analysis-laboratory/interpreting-your-laboratory-data, 2015. Accessed March 28, 2017.

[93] Willem K. Scholten, MSc, Pharm, MPA, Office of Medicinal Cannabis of the Pharmaceutical Affairs Directorate, Ministry of Health, Guidelines for Cultivating, Cannabis for Medicinal Purposes [Voorschriften voor de Verbouw van Cannabis voor Medicinale Doeleinden], Cannabis Ther 3:51-61. 2003. https://www.cannabis-med.org/data/pdf/2003-02-4_0.pdf. Accessed March 28, 2017.

[94] US Food and Drug Administration, Dept. of Health Education, and Welfare Public Health Service, Water Activity (aw) in Foods, Date: 4/16/84, Number: 39. http://www.fda.gov/ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/ucm072916.htm. Accessed March 28, 2017.

Proposed subsections (c) and (e) specify testing laboratory reporting requirements for water activity and water content. This information shall be reported in the certificate of analysis to be reported to the bureau and the requesters of the testing. This is necessary because requesters need to know the results of the tests.

Proposed subsection (f) states that the laboratory may provide additional information related to water activity and moisture content upon request or if the laboratory finds other activity. This provision is necessary to clarify that the laboratory may provide addition information beyond that which is required by these regulations.

Subsection (g) proposes allowing harvest batches that failed moisture content or water activity testing be returned to the cultivator or person holding title for further drying and curing. The bureau believes this is a reasonable approach that will prevent the unnecessary destruction of medical cannabis. Oregon has followed a similar approach.[95]

§ 5325. Filth and Foreign Material

Section 5325 proposes that medical cannabis goods meet the requirements specified in this section before release for retail sale to dispensaries; otherwise the failed products shall be destroyed or go through remediation procedures. This test is necessary to ensure that the batch is in good sanitary condition and safe for consumption without more than a minimal amount of filth and foreign material. All food products and other products have some amount of the type of filth and foreign material described in this section. And the federal government has standards for how much filth and foreign material may be in foods. A similar approach was taken here.

The Act, at Business and Professions Code section 19344, requires medical cannabis goods be tested for foreign material.

Proposed subsection (a) states that a testing laboratory is required to test for filth and foreign material in all samples. It also specifies what needs to be tested and looked for as "filth and foreign material."

Proposed subsection (b) specifies the defect action levels. Currently, there are a couple states (Alaska and Colorado) that refer to filth testing in their regulations but do not set action levels and required test methods. In addition, some commercial laboratories publish websites or booklets regarding filth testing but do not recommend action levels nor test methods.

Because there is a lack of studies about filth and foreign material in medical cannabis, it was necessary to reference the US Food and Drug Administration's *Defect Levels Handbook—The*

[95] Oregon Labs Technical Advisory Committee, Meeting Summary and Recommendations for Cannabis Testing, 2015. https://www.oregon.gov/olcc/marijuana/Documents/Agendas/LABS_SummaryandRecommendations_070215.pdf. Accessed March 28, 2017.

Food Defect Action Levels.[96] The table below shows the defect action levels in some relevant common foods, especially plant foods.

Relevant Examples and Their Defect Action Levels Posted in Defect Levels Handbook

PRODUCT	DEFECT (Method)	ACTION LEVEL
Apple Butter	Mold (AOAC 975.51)	Average of mold count is 12% or more
	Rodent filth (AOAC 945.76)	Average of 4 or more rodent hairs per 100 grams of apple butter
	Insects (AOAC 945.76)	Average of 5 or more whole or equivalent insects (not counting mites, aphids, thrips, or scale insects) per 100 grams of apple butter
	DEFECT SOURCE: Mold - post harvest infection. Rodent hair - post harvest and/or processing contamination with animal hair. Whole or equivalent insects - preharvest, and/or post harvest and/or processing insect infestation,	
Bay (Laurel) Leaves	Mold (MPM-V32) *	Average of 5% or more pieces by weight are moldy
	Insect filth (MPM-V32)	Average of 5% or more pieces by weight are insect-infested
	Mammalian excreta (MPM-V32)	Average of 1 mg or more mammalian excreta per pound after processing
	DEFECT SOURCE: Mold - preharvest infection. Insect infestation - preharvest and/or post harvest and/or processing insect infestation. Mammalian excreta - post harvest and/or processing animal contamination	
Cassia (or)	Mold	Average of 5% or more pieces by

[96] US Food and Drug Administration, Defect Levels Handbook: The Food Defect Action Levels, February 2005 https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/ucm056174.htm. Accessed March 28, 2017.

Cinnamon Bark, Whole	(MPM-V32)	weight are moldy
	Insect filth (MPM-V32)	Average of 5% or more pieces by weight are insect-infested
	Mammalian excreta (MPM-V32)	Average of 1 mg or more mammalian excreta per pound
	DEFECT SOURCE: Mold - post harvest mold infection. Insect infestation - post harvest and/or processing. Mammalian excreta - post harvest and/or processing animal contamination.	
Coffee Beans, Green	Insect filth and insects	Average 10% or more by count are insect-infested or insect-damaged
	(MPM-V1)	Note:
		If live external infestation is present use the Compliance Policy Guide (CPG) titled " Food Storage and Warehousing-Adulteration-Filth" (CPG 580.100) in accordance with "Interpretation of Insect Filth" (CPG 555.600)
	Mold (MPM-V1)	Average of 10% or more beans by count are moldy
	DEFECT SOURCE: Insect infested/damaged - preharvest and/or post harvest and/or processing insect infestation, Mold - post harvest and/or processing infection	
Marjoram, Whole Plant, Unprocessed	Insect filth and/or mold (MPM-V32)	Average of 5% or more pieces by weight are insect-infested or moldy
	Mammalian excreta (MPM-V32)	Average of 1 mg or more mammalian excreta per pound
	DEFECT SOURCE: Insect infestation - preharvest and/or post harvest and/or processing, Mold - post harvest and/or processing infection, Mammalian excreta - post harvest and/or processing animal contamination	

Marjoram, Ground	Insect filth (AOAC 975.49)	Average of 1175 or more insect fragments per 10 grams
	Rodent filth (AOAC 975.49)	Average of 8 or more rodent hairs per 10 grams
	DEFECT SOURCE: Insect fragments - preharvest and/or post harvest and/or processing insect infestation, Rodent hair - post harvest and/or processing contamination with animal hair or excreta	
Marjoram, Unground	Insect filth (AOAC 985.39)	Average of 250 or more insect fragments per 10 grams
	Rodent filth (AOAC 985.39)	Average of 2 or more rodent hairs per 10 grams
	DEFECT SOURCE: Insect fragments - preharvest and/or post harvest and/or processing insect infestation, Rodent hair - processing contamination with animal hair or excreta	

Proposed subsection (c) states that the testing laboratory shall report a "passed" or "failed" result in the certificate of analysis. It is proposed that a failed harvest batch may be returned for remediation but that manufactured cannabis batches that fail must be destroyed. Failed harvest batches may be remediated through various means but manufactured batches cannot. Filth cannot be removed from manufactured batches.

§ 5328. Heavy Metals

Section 5328 proposes the heavy metals that should be tested for and at what action levels the sample will be deemed to have failed heavy metal testing. These action levels have been established to protect the health of consumers of medical cannabis goods and reduce the risk of adverse health effects. Action levels were established in units of micrograms per gram of substance (µg/g).

Proposed subsection (a) specifies the four heavy metals that would be required for testing for each batch. The elements cadmium (Cd), lead (Pb), arsenic (As), and mercury (Hg) are all listed as Class 1 elemental impurities in drug products by the US Food and Drug Administration.[97] Testing for these four heavy metals is necessary because they are human toxicants that have

[97] *Q3D Elemental Impurities Guidance for Industry*. Food and Drug Administration (FDA), 2015. https://www.fda.gov/downloads/drugs/guidances/ucm371025.pdf. Accessed March 28, 2017.

limited or no useful biological function in human organisms. Cadmium (Cd) and arsenic (As) are both known to be genotoxic and are human carcinogens. Exposure to lead (Pb) may cause neurological, reproductive, developmental, immune, cardiovascular, and renal health effects. Mercury (Hg) shows toxicological effects including neurological, corrosive, hematopoietic, and renal effects and cutaneous disease (acrodynia).

These elements are widely distributed in the global environment in soil, water, and fertilizer. Cannabis plants are known to pull up and accumulate these metals from the contaminated environment.[98] Therefore, it is important to test each cannabis sample for these elements to protect public health and reduce the potential risk of adverse health effects associated with the consumption of medical cannabis goods.

Proposed subsection (b) establishes action levels for cadmium (Cd), lead (Pb), arsenic (As), and mercury (Hg) based on the permitted daily exposures (PDEs) of two different sample intake routes, oral and inhalation. The PDEs give the maximum permitted quantity of each element that may be contained in the maximum daily intake of a drug product. The PDEs used to calculate the action level in this table (µg/day) have been established on the basis of safety data and are recommended by the US Food and Drug Administration.[99] Edible cannabis products are usually taken orally (eaten), whereas dried flowers and cannabis concentrates may be taken into the human body through inhalation. Some individual's consume up to 10 grams of cannabis or cannabis products each day.[100] Therefore, the action levels were calculated using 10 grams per day from the PDE for each element. For topical cannabis products, the action levels were established based on FDA guidance[101,102] and Health Canada guidance.[103]

Proposed subsection (c) states that a cannabis testing laboratory may test for any other metals that are not required by this regulation and provide test results to the entity requesting the testing.

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[98] Bieby Voijant Tangahu, Siti Rozaimah Sheikh Abdullah, Hassan Basri, Mushrifah Idris, Nurina Anuar and Muhammad Mukhlisin, A Review on Heavy Metals (As, Pb, and Hg) uptake by Plants through Phytoremediation, International Journal of Chemical Engineering, Volume 2011, Article ID 939161, doi:10.1155/2011/939161. Accessed March 28, 2017.

[99] Q3D Elemental Impurities Guidance for Industry. Food and Drug Administration (FDA), 2015. https://www.fda.gov/downloads/drugs/guidances/ucm371025.pdf. Accessed March 28, 2017.

[100] 420Magazine, How Many Grams/Day Is The Average Patient Prescribed, https://www.420magazine.com/forums/medical-cannabis-lounge/158520-how-many-grams-day-average-patient-prescribed.html. Accessed February 13, 2017.

[101] FDA's Testing of Cosmetics for Arsenic, Cadmium, Chromium, Cobalt, Lead, Mercury, and Nickel Content, Food and Drug Administration (FDA), 2016. http://www.fda.gov/cosmetics/productsingredients/potentialcontaminants/ucm452836.htm. Accessed March 28, 2017.

[102] Lead in Cosmetic Lip products and Externally Applied Cosmetics: Recommended Maximum Level Guidance for Industry, Food and Drug Administration (FDA), 2016. https://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm452623.htm. Accessed March 28, 2017.

[103] Guidance on Heavy Metal Impurities in Cosmetics, Health Canada, 2016, http://www.hc-sc.gc.ca/cps-spc/pubs/indust/heavy_metals-metaux_lourds/index-eng.php. Accessed March 28, 2017.

The bureau believes this will grant requestors with flexibility to test for more contaminants than are required if they wish to ensure their product is very safe.

§ 5331. Terpenes

Proposed section 5331 adds explanatory language to clarify when terpenes must be tested for in compliance with Business and Professions Code section 19344.

Proposed subsection (a) clarifies the language in Business and Professions Code section 19344 about when and how the laboratory shall test and report the terpenes in the sample that are listed on the label of the batch. Terpenes are generally recognized as safe and as having no adverse health effects to human beings.[104] Therefore, the bureau recommends adopting this provision to permit optional testing for terpenes. The reason for this subsection is to ensure consistency between the product and the labeling.

Proposed subsection (b) states that a laboratory may test and report the results for terpene analysis if the sample requestor asks the laboratory to do so. Licensees requesting testes should have results of those tests proved to them.

§ 5334. Certificate of Analysis

Proposed subsection (a) this section proposes that the laboratory issue a certificate of analysis (COA) for each primary sample of a batch, as required by Business and Professions Code section 19344, to demonstrate that the product is fit for dispensing by a licensed dispensary. This section further specifies that the laboratory shall provide the COA to the distributor, the sample requester, and the bureau within a reasonable time frame of two days. This is necessary to provide information to the involved parties regarding whether the medical cannabis goods may go to a dispensary for sale.

Proposed subsection (b) this section specifies the information that should be reported in the COA. This section is necessary because subsections (1), (2), and (3) allow the requester and the bureau to trace back the sample information; subsections (4) and (7) show the validity of the testing and the data; and subsections (5), (6), (8), and (9) provides the test results and whether the batch passed or failed. Subsection (10) requires information regarding whom the testing was performed for, such as the licensee's name, license number, and batch number of the batch tested.

Proposed subsection (c) states that the laboratory should also report other cannabinoids claimed by the manufacturer on the label but that are not required to be tested for under the Act. This section is necessary to ensure consumer protection by ensuring that whatever a manufacturer claims on its products labels is accurate.

[104] EB Russo, Taming THC: potential cannabis synergy and phytocannabinoid-terpenoid entourage effects, British Journal of Pharmacology (2011), 163, 1344-1364. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3165946/. Accessed March 28, 2017.

Proposed subsection (d) would require that the information contained in the certificate of analysis be accurate. It proposes that the laboratory director would sign and date and thus be responsible for the information provided in the certificate of analysis, another step in ensuring the information is accurate.

Proposed subsection (e) proposes that if the laboratory fails to provide timely and accurate data, the laboratory will be disciplined. This subsection is necessary to set forth the bureau's authority to take disciplinary action for failure to comply with this provision. It is meant to protect customers of the laboratory and to ensure medical cannabis does not go missing.

§ 5337. General Reporting Requirements

This proposed section adds explanatory language to clarify the requirements at Business and Professions Code section 19344.

Proposed subsection (a) specifies that the laboratory shall report any unknown or unidentified substances or materials detected in the sample other than the ones that are listed in this chapter. This section also specifies that if a sample is found to contain any contaminants that could be harmful to public health, then the laboratory must notify the bureau about the finding within 24 hours. This section is necessary because these regulations only list analytes that are already known to have adverse health effects on human beings. With time and the development of analytical chemistry techniques, people may find more contaminants that are not listed in these regulations but that could harm public health. These substances or contaminants, if detected, should be reported by the laboratory to the bureau to ensure the protection of public health.

Proposed subsection (b) defines what is considered to be a "fail" of a particular test. This section also specifies that if a sample failed any particular test, then the laboratory shall report the sample failed testing in general unless a section of these regulations exempts them from a total "failure." This section is necessary because if any contaminants in the sample exceeds the action level, then the sample is harmful to public health and therefore should be not be released for retail sale.

Proposed subsection (c) proposes that any sample containing synthetic cannabinoids fails laboratory testing. This section is necessary because studies have associated synthetic cannabinoid use with psychotic episodes days after use, some of which have resulted in death. They have been shown to be unsafe to the public and to have no known medicinal benefits for consumers.[105,106] Because of the risks associated with use of synthetic cannabis, it is important to test for synthetic cannabinoid impurities in medical cannabis goods.

Proposed subsection (d) specifies that if a sample fails testing, the laboratory must upload copies of the certificate of analysis to the track and trace database within 2 business days. This section is

[105] Luzak J. Synthetic marijuana not a "medicinal product." *Eur. J. Risk Reg.* 2014;5:548-552.
[106] O. Cottencin, B. Rolland, and L. Karila, New Designer Drugs (Synthetic Cannabinoids and Synthetic Cathinones): Review of Literature, Current Pharmaceutical Design, 2014, 20(25), 4106-4111.

necessary because it allows the bureau to track failed samples to ensure that the batches from which the sample was taken will not be sent to dispensaries for retail sale.

Proposed subsection (e) specifies that if a sample passes testing, the laboratory shall enter "pass" into the track and trace database for the batch within 24 hours. This section is necessary because it ensures timely release of the batches that pass testing, so that the product can be moved rapidly.

ARTICLE 6. POST-TESTING PROCEDURES

§ 5340. No Retesting Without Remediation

Section 5340 proposes that once a batch fails an official state-mandated laboratory test, it may not be sampled and tested again unless it has gone through a process of remediation as allowed under this division. It is proposed that a laboratory not allow for the second testing of a batch unless the requester of the testing provides a document outlining the process of remediation taken to cure the batch of any defects. This document shall be kept by the laboratory and be made available to the bureau upon request. This provision will help ensure that medical cannabis goods are be cured of any deficiency before retesting to assist with public safety.

§ 5343. Test-Sample Waste Disposal

Section 5343 proposes that laboratories destroy nonhazardous and hazardous used or unused medical cannabis test samples in accordance with applicable law. This section regarding sample waste management is necessary for preventing direct and indirect hazards of exposure to laboratory employees and the environment. This section is also necessary to prevent diversion of unused medical cannabis goods to the unregulated market. This section further requires that the laboratory document its waste-disposal procedures. This provision is necessary to allow for the bureau to ensure that the laboratory is operating in compliance with the applicable waste-disposal requirements.

ARTICLE 7. QUALITY ASSURANCE AND QUALITY CONTROL

§ 5346. Quality-Assurance Program

Subsection (a) proposes that a laboratory develop and implement a quality-assurance program that is sufficient to ensure valid results. It is the laboratory's responsibility to ensure the data and measurements they produce are of known accuracy and precision and all steps in the analytical process can be traced back. A quality-assurance program encompasses a range of activities that enables a laboratory to achieve and maintain a high level of accuracy and proficiency despite changes in test methods and volumes of matrices analyzed.

Proposed subsection (b) would require a laboratory to develop a quality-assurance program manual that addresses all aspects of the laboratory's quality-assurance program. This is necessary because it is a standard practice that most reliable laboratories follow.

Proposed subsection (b)(1) would require the manual to include quality-control procedures. This includes using with proper quality-control samples at a frequency that allows for verification of data produced, which would, at minimum, include those in section 5349 to verify the accuracy of the analytical data.

Proposed subsection (b)(2) would require the manual include laboratory organization and personnel training and responsibilities. Sustaining high-quality personnel management is important for quality assurance. This part of the manual should address persons responsible for carrying out corrective actions when problem are identified. Having a quality-assurance manager in the laboratory is always a good idea but is not required under these regulations. The environment in which the work is conducted must be well controlled. It should be clean and tidy, have adequate space in which to work without risk to employees or to the analytical sample, and there should be sufficient storage space for glassware, chemicals, samples, and consumables. It is also essential that there are adequate numbers of appropriately trained staff available to undertake all of the required tasks. The laboratory should provide and train the laboratory employees so that they have the proper knowledge to perform their duties. These measures will work to prevent errors during analytical work.

Proposed subsection (b)(3) would require quality-assurance objectives for measurement data. The quality-assurance program manual should include the objectives to clarify what the data should look like and the minimum quality standards those data must meet. This is done by setting a measurement system that operates in a state of statistical control, meaning errors have been reduced to acceptable levels. This is necessary to ensure the quality of data.

Proposed subsection (b)(4) would require the quality-assurance program manual address the traceability of all data and analytical results. The ability to trace data and results to determine whether there have been data errors is necessary, not just for the laboratory to assure quality data, but for the person or entity who requested the testing and for the bureau. This subsection is necessary to ensure the laboratory, and the bureau, may go back and detect measurement errors and procedure errors.

Proposed subsection (b)(5) would require the manual address equipment preventative maintenance. This involves ensuring laboratory equipment can be maintained in the proper operating conditions such that the equipment is properly tuned and calibrated and reliable for the analyses undertaken, which is also addressed in subsection (b)(6).

Proposed subsection (b)(6) would require the manual address the proper equipment-calibration procedures and frequency of calibration. Calibration is the process of standardizing an instrument's response in order to perform quantitative analyses. The laboratory must determine

what these standards are and maintain them at levels that are well within the limits normally established for the equipment or that are recommended for the care of the particular piece of equipment. Determining calibration curves is part of this procedure. These calibration standards should be checked by the laboratory director and corrected if necessary.

Frequent checks on the reliability of equipment must also be performed. This includes calibration checks on all relevant equipment, including balances. The frequency of these checks will depend on the stability of the equipment in question.

Proposed subsection (b)(7) would require performance and system audits. This is a typical requirement for a regulated laboratory.

Proposed subsection (b)(8) would require the manual to address what corrective action is taken and when it is necessary. This is a typical requirement for a regulated laboratory.

Proposed subsection (b)(9) would require the keeping of quality-assurance records. This is a typical requirement for a regulated laboratory.

Proposed subsection (b)(10) would require the standardization of testing procedures established in the standard operating procedures of the laboratory. This is a typical requirement for a regulated laboratory.

Proposed subsection (b)(11) would require the manual address method validation such as how to go about validating a method. This requirement would enable the bureau and possibly the consumer to ensure methods used in analyses are properly validated in compliance with sections 5298 and 5301 of these proposed regulations.

Proposed subsection (c) specifies the duty and the role of the laboratory director and the quality-assurance manager if the laboratory has one. The laboratory director and the quality-assurance manager if there is one is responsible for regularly inspecting all aspects of the laboratory system to ensure staff compliance, reporting on such inspections and audits to management if necessary, and for recommending improvements. In practice, this will involve regularly checking the facility and procedures as they are performed and conducting regular audits. An audit may include tracing an analytical sample back through the system using the data package, from final report of measurements to sample gathering, and ensuring that all appropriate steps have been taken and records kept.

§ 5349. Quality-Control Elements

This proposed section specifies the importance, types, roles, and application of the quality-control samples for the analysis of testing laboratory. Proposed subsections (a) through (c) establish the necessary types and numbers of quality-control samples that must be included in analytical sample batches in both potency and contaminants analyses. The quality-control samples must be prepared using the standard operating procedure, and most quality-control

samples, except the reagent blank samples and calibration standard samples, must be prepared using the same sample-preparation method as the primary sample.

Proposed subsection (a) specifically requires that a testing laboratory run quality-control samples with every analytical batch of samples. For chemical analyses, it specifically requires that the amount of quality-control samples be 10% to 20% of the analytical batch for chemical analyses, and, for microbiological analyses, quality-control samples shall be run as needed. For chemical analyses, this level sufficiently demonstrates the validity of sample results.

It is necessary to include quality-control samples in every analytical batch because quality control is an essential aspect of ensuring that data released are fit for the purpose determined by the quality objectives. Quality-control samples are used to measure accuracy, precision, contamination, and matrix effects.

Proposed subsection (b) specifically requires that a testing laboratory use quality-control samples in the performance of each assay for chemical and microbiological analyses. This is necessary because quality-control-sample results are used as an essential aspect of ensuring that data released by the testing laboratory is fit for the purpose. Quality-control samples are used to measure method accuracy, precision, contamination, and matrix effects. The requirement for the testing laboratories to use quality-control samples in every analytical batch is also necessary to be able to trace the integrity of the data and to hold laboratories accountable for testing, thus detouring testing laboratories from dry-labbing ("dry-labbing" is the act of delivering fictional results in lieu of performing actual laboratory testing).

Proposed subsection (c) specifically requires a testing laboratory to analyze quality-control samples in the exact same manner as the test samples to validate and verify the laboratory testing results. It is necessary for quality-control samples to be handled and prepared in the same way that primary samples are to confirm or "verify" that the validated method works. Furthermore, this is necessary because if a quality-control-sample result does not meet the predetermined control limit, then the laboratory can investigate where the discrepancy is coming from. For example, method blank quality-control samples are used to verify that all labware and reagents are free of contamination. If the method blank result is higher than the predetermined threshold, and the quality-control sample was handled in the same way as the test samples, the laboratory will be able to deduce where the contamination is coming from. Quality-control-sample results are used for monitoring the continuing validity or legitimacy of analytical methods.

Proposed subsection (d) specifies the use of the method blank samples for quality control during chemical analysis. Method blank samples show whether laboratory contamination caused false positive results. These should be analyzed with each analytical batch of samples.

Proposed subsection (d)(1) would require one or more method blank samples be run with each analytical batch that is run. This is standard in environmental labs.

Proposed subsection (d)(2) would require the analysis of a method blank sample with a batch of 10 to 20 samples and that they be tested under the same conditions, including sample preparation, as the other sample in the batch. This is to ensure laboratory contamination during the analytical process did not contaminate the prepared samples.

The method blank sample should not yield a value higher than that allowed by the acceptance criteria. Subsection (d)(3) lays out the steps to take when a method blank contains analytes of interest above the limit of detection. If this occurs, the laboratory shall re-prepare the batch and then re-run that batch. This procedure checks laboratory interference and the limit of detection of the assay.

Proposed subsection (d)(4) would determine what a laboratory would do if the limit of quantitation (LOQ) is lower than the method-blank results. If the signal in the method blank is higher than the LOQ, the analyst must find the source of the contaminant and try to reduce or eliminate the contamination. It could be from bad column action, poor detector function, or improper separating conditions in the analytical instrument which can cause the carry-over from the multiple analyses. For example, lead can be found not only in the sample but also in most laboratory environments such as air, water, glassware, or equipment. After corrective action, the batch should be re-prepared and analyzed.

Proposed subsection (e) specifies the application of the duplicate sample for quality control during analysis. Because the samples are analyzed using the same method, equipment, and reagents, the same bias should affect all results. Consequently, duplicate analyses are only useful for checking sampling analysis, analytical precision, and reproducibility.

Proposed subsection (e)(1) would require a duplicate sample would be run with every 10 to 20 samples of each analytical batch.

Proposed subsection (e)(2) would require that the acceptance criteria between the primary sample and the duplicate sample be less than 20% relative percent difference. This proposed section is necessary to clarify the acceptance criteria for duplicate samples and primary samples. Acceptance criteria are expressed as relative percent difference (RPD) and are a measure of precision of the overall sample-collection process.

For sampling plans, a field duplicate is collected and analysis results for this sample and the data are compared with the primary sample collected. This is done to gauge that the analytical precision of the sampling is consistent with the sampling data-quality objective. The objective in this case is that the precision between primary and field samples is within 20%. Oregon has undergone detailed training with a statistical sampling consultant contractor and developed a sampling plan that is appropriate for the cannabis industry, given the high value of the products

and inhomogeneity that may be present. The bureau proposes adopting guidance from Oregon[107] in absence of better-validated sampling plans published in scientific literature.

Proposed subsection (f) specifies the application of the matrix spike samples for quality control during analysis. It is proposed that at least 1 spike sample be included with every analytical sample batch to verify the analytical accuracy and precision or to test for matrix effects. (See explanation in definitions section for "matrix spike sample.")

Percent recovery (%R) must be within 70% and 130% and shall be calculated as follows:

$\%R = ([SSR - SR]) / SA \times 100$

where

SSR = Spiked sample result

SR = Sample result

SA = Spike added

The spike level should be at or near midrange of the calibration.

This is a standard quality-control measure, and the acceptable values proposed here (70% to 130%) are based on a published method in a water matrix from the US Environmental Protection Agency[108] and methods for drug testing (content uniformity) from US Food and Drug Administration.[109]

Proposed subsection (g) specifies the application of the reference material and certified reference material for quality control during analysis. It is highly recommended that laboratories use certified reference materials rather than a laboratory-made one, if possible. Certified reference materials are matrix-matched materials with assigned target values and assigned ranges for each variable, reliably determined from data obtained by repeated analyses. Usually, commercially available ones may be purchased from an outside source and used for accuracy control. Until

[107] ORELAP-SOP-002 Rev 3.1 Protocol for collecting samples of Cannabis Concentrates and Extracts, Oregon Environmental Laboratory Accreditation Program, 2016. https://public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Documents/sop-002.pdf. Accessed March 30, 2017.

[108] US Environmental Protection Agency, Measurement of N-Methylcarbamoyloximes and N-Methylcarbamates in Water by Direct Aqueous Injection HPLC with Postcolumn Derivatization, Method 532.1, EPA # 815-B-01-002, September 2001. https://www.epa.gov/sites/production/files/2015-06/documents/epa-531.2.pdf. Accessed March 28, 2017.

[109] US Food and Drug Administration, ORA Laboratory Procedure: Methods, Method Verification and Validation, Effective Date:10-01-03, Revised: 08-29-14. https://www.fda.gov/downloads/ScienceResearch/FieldScience/LaboratoryManual/UCM092147.pdf. Accessed March 28, 2017.

such certified reference materials exist for cannabis, however, a laboratory may create its own reference material.

Proposed subsection (h) addresses how to prepare calibration standards. When analyst prepares the working standards by dilution based on the standard operating procedure, the linearity and the range of the standards must be established prior. Regularly checking the standard solutions may be needed because the old solutions could have deteriorated. It is also needed to verify the storage conditions, the age of solutions, and their expected shelf-life. A calibration standard sample of the middle concentration may be used at first or between the analytical batches as an initial certification verification sample or continuous certification verification sample to check the accuracy and the system stability for the analysis.

Proposed subsection (i) requires the laboratory to generate a quality-control-sample report that includes quality-control parameters and measurements, analysis date, and matrix. This subsection is necessary because a laboratory must have a record showing the quality control results so that data can be used to evaluate the accuracy and precision of the primary sample results.

§ 5352 Limit-of-Detection and Limit-of-Quantitation Calculations for Quantitative Analyses

In this proposed section, the bureau proposes ways for testing laboratories to determine limits of detection and limits of quantitation.

Proposed subsections (a) and (b) specify that the testing laboratories shall determine limit of detection (LOD) and limit of quantitation (LOQ) following one of the options in the subsections (a)(1) through (3) and subsections (b)(1) through (3). Currently, there are many methods and approaches from various sources (for example, the US Environmental Protection Agency (EPA), the US Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, the Association of Official Analytical Chemists, and the American Chemical Society) that determine LODs and LOQs for analytical quantitation in different matrices and using different instruments.[110,111,112] LOD is the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit, and LOQ is the minimum concentration of an analyte in a specific matrix that can be reliably quantified. They

[110] US Environmental Protection Agency, Definition and Procedure for the Determination of the Method Detection Limit, Revision 2. https://www.epa.gov/cwa-methods. Accessed March 28, 2017.
[111] Alankar Shrivastava, Methods for the Determination of Limit of Detection and Limit of Quantitation of the Analytical Methods, Chronicles of Young Scientists, Vol. 2, Issue 1, Jan-Mar 2011.
[112] Association of Analytical Communities, AOAC Guidelines for Single Laboratory, Validation of Chemical Methods for Dietary, Supplements and Botanicals, 2002. https://www.aoac.org/aoac_prod_imis/AOAC_Docs/StandardsDevelopment/SLV_Guidelines_Dietary_Supplements.pdf. Accessed March 28, 2017.

are two important performance characteristics in method validation and help to make decisions based on the uncertainties and limitations associated with these reporting limits.[113,114]

Unfortunately, there are no universally accepted procedures for calculating LOD and LOQ, and different testing laboratories choose different approaches or even their own in-house methods to determine LOD or LOQ. To ensure the testing laboratories follow more-standardized approaches, the bureau listed three options in this proposed section to guide testing laboratories in the calculation of LODs and LOQs.

Among the three options, two options listed in subsections (a)(1) and (2) and subsections (b)(1) and (2), respectively, are the most developed and well-known approaches used in analytic laboratories and are described by the US Food and Drug Administration (FDA).[115] Cannabis goods are more close to food products than environmental samples (such as water or soil), and therefore CDPH and the bureau propose that testing laboratories determine LODs and LOQs based on FDA guidance.

Because in some situations there may be some technical difficulties with using the FDA calculations, the proposed regulation offers a third option, in subsections (a)(3) and (b)(3), that may provide less stringent guidelines. These subsections offer more options to include other methods published by the US FDA or the US EPA. Another reason for this third option is that some laboratories may already have procedures to determine LOD and LOQ based on reliable published methods.

It is proposed that all testing laboratories must choose one of these three options to produce valid testing results and avoid poor data quality and possible result fabrications.

§ 5355. Data Package

Proposed section 5355 specifies the requisite information that a laboratory must complete and include in a data package for each group of samples analyzed. Data packages, also referred to as laboratory reports, are meant to be clear and detailed documents that capture the workflow and results of samples tested. The purpose of this requirement is to systematically standardize data packages to include critical elements for all licensed testing laboratories.

Proposed subsections (a)(1) and (a)(2) specifically require the name and address of the testing laboratory as well as the names, functions (or titles), and signatures of the laboratory employees

[113] Alankar Shrivastava, Methods for the Determination of Limit of Detection and Limit of Quantitation of the Analytical Methods, Chronicles of Young Scientists, Vol. 2, Issue 1, Jan-Mar 2011.
[114] Wisconsin Department of Natural Resources Laboratory Certification Program, Analytical Detection Limit Guidance & Laboratory Guide for Determining Method Detection Limits, April 1996. http://dnr.wi.gov/regulations/labcert/documents/guidance/-LODguide.pdf. Accessed March 28, 2017.
[115] US Food and Drug Administration, Department of Health and Human Services, Guidance for Industry, Q2B Validation of Analytical Procedures: Methodology, November 1996. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073384.pdf. Accessed March 28, 2017.

involved in assembling the data package. This is necessary to be able to trace the integrity of the data and to hold laboratories accountable for testing. The integrity of analytical test results related to medical cannabis is very important because the consumer will rely on the truthfulness of the test results, and a significant public health safety risk would exist if analytical test results were altered.[116]

Proposed subsection (a)(3) specifically requires that the data package include sample results and quality-control sample results. It is necessary for the data package to include sample results because the sample result is the most desired, critical element of the data package. It is also necessary to include any and all quality-control sample data in the data package because quality control is an essential aspect of ensuring that data released is fit for the purpose determined by the quality objectives. Quality-control samples are used to measure accuracy, precision, contamination, and matrix effects.

Proposed subsections (a)(4) and (a)(5) specifically require that the data package include the raw data for each sample. Raw data can include, but are not limited to, analytical instrument printouts with analyte concentrations, sample preparation system printouts, handwritten calculations, and chromatograms. It is necessary to include these in the data package to deter testing laboratories from dry-labbing, which is the act of delivering fictional results in lieu of performing actual laboratory testing. The integrity of analytical test results related to medical cannabis is very important because the consumer will rely on the truthfulness of the test results and there could be a significant public health safety risk if analytical test results were altered.

Proposed subsections (a)(6) through (a)(8) enumerate requirements for data packages, if available. Instrument test method with parameters, instrument tune report, and instrument calibration data are included. It is necessary to include these in the data package to detour testing laboratories from dry-labbing.

Proposed subsections (a)(9) and (a)(10) specifically require that the data package include any worksheets or forms used for sample identification, characterization, and calculations and the quality-control report with worksheets, forms, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis. This is necessary because this is how the testing laboratories achieve measurement traceability for its testing measurements. ISO 17025:2005 covers the selection, identification, use, initial and continuing calibration checks, handling, transport and storage (control and maintenance), of the laboratory's certified and standard

[116] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 5.10.2, Test reports and calibration certificates. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

reference materials, calibration standards, and reference cultures in order to ensure their integrity.[117]

Proposed subsection (a)(11) would specifically require that the laboratory include the analytical batch sample sequence, also referred to as a run log. This is necessary to ensure that the testing laboratories are analyzing samples in the correct order and not randomly inserting samples without the proper associated quality-control samples. Both qualitative and quantitative testing methods must meet system suitability requirements that are needed for the verification of methods per ISO 17025:2005 subclause 5.4. Although the order in which the samples are analyzed is not specified, quality-control sample requirements are needed.[118] The laboratories will determine the order in which samples are analyzed according to their method-specific standard operation procedure (SOP). ISO 17025:2005 accreditation will help ensure that the testing laboratory's SOPs comply with these standards. It is necessary to comply with ISO standards because the integrity of analytical test results related to medical cannabis is integral to providing the consumer with accurate data.

Proposed subsection (a)(12) specifically requires that the sample field log and the chain-of-custody form be included in the data package. Chain-of-custody forms must account for the collection, storage, transfer or transport, and condition of the sample. It is necessary to include this because all sample movements should be traced and recorded to ensure the integrity of the sample and ultimately the integrity of the sample results. The integrity of analytical test results related to medical cannabis is very important because the consumer will rely on the truthfulness of the test results, and, if analytical test results are altered as a result of poor sample management or poor chain-of-custody procedures, a public health risk could be created.

Proposed subsection (a)(13) specifically requires that the certificate of analysis (COA) created as required under this proposed chapter by the testing laboratory be included in the data package. The COA created is the report prepared for the sample of a batch as required by Business and Professions Code section 19344. The COA includes information about the analytical testing performed and results obtained by the testing laboratory, which are then used to demonstrate that the product is fit for retail sale. This is necessary to include in the data package because this essentially completes the data package.

Proposed subsection (b) specifically requires that analytical results reported for dried flower samples be reported on a dry-weight basis with the percent moisture also reported in the COA. The initial contaminant concentration measured by a laboratory is considered an "as-is" or "wet"

[117] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 5.6, Measurement traceability. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

[118] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 5.9, Assuring the quality of test and calibration results. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

basis result, because no calculations have been made to compensate for the moisture content of the sample. When a "dry" value is reported, the laboratory has measured the moisture content of the sample and calculated the concentration based on the percent solids present in the sample. It is necessary to allow back calculation because the uncorrected contaminant concentration can be skewed because the result may also include contamination that was present in the moisture or other liquid phase of the sample and not just the solids portion.[119]

Proposed subsection (c) enumerates the duties and responsibilities of the laboratory director in regards to the data package. The purpose of the laboratory director's review is to verify that the method was properly performed and documented. General requirements for his or her data review include but not be limited to verifying calculations are correct, verifying the units reported are correct, verifying that the results listed on the COA are correct, verifying the acceptance criteria for quality-control samples are met, and verifying method-specific standard operating procedure requirements are met. The purpose of the laboratory director signing and dating the data package is that it makes the laboratory director accountable for the validity of the laboratory's test results. It is a final approval.

Proposed subsection (d) requires that the entire data package be kept for a minimum of seven years as required under the Act and be made available upon request by the bureau and the requester of the laboratory testing. It is necessary to keep the entire data package for a minimum of seven years because of the Act and because, in the event of a safety recall or a trace-back or trace-forward investigation, the data packages may need to be referenced.[120] To comply with ISO 17025:2005, the testing laboratory must make the data package available to the requester, as defined in section 5237(vv) of this division.

§ 5358. Required Proficiency Testing

This proposed section specifies the requirement for the testing laboratories to conduct regularly scheduled proficiency testing. The purpose of this requirement is to provide testing laboratories and the bureau with objective evidence of a laboratory's capability to produce data that are both accurate and repeatable for the tests that the laboratory routinely conducts. Proficiency testing data can be used to demonstrate a laboratory's competence to clients, potential customers, accreditation bodies, and regulatory bodies. Participation in proficiency-testing activities ensures that testing laboratories are consistently performing medical cannabis testing procedures properly. Through proficiency testing, a laboratory can verify its competence to perform the specific tasks that they are licensed to perform.

[119] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 5.9, Assuring the quality of test and calibration results. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

[120] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 4.4, Review of requests, tenders and contracts. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

Proposed subsection (a) specifies the frequency of a laboratory's participation in a proficiency test. The subsection states that a laboratory shall participate in a proficiency testing program at least once every six months. This can be a proficiency test for any one or multiple analytes. In addition, this section states that the proficiency test shall originate from an ISO-accredited proficiency test provider, or one that is run similarly to one, in order to increase confidence in the reliability of the data laboratories produce.

Proposed subsection (b) specifies that laboratories shall rotate the proficiency tests among their validated methods and among the staff in the laboratory so that all methods and all staff performing the methods have participated in a proficiency test over a reasonable time period, which shall be outlined in the quality-assurance manual required under these regulations. This is necessary to ensure that the methods used by the laboratory and the results produced by the tests are accurate and trustworthy. Also, it is necessary to routinely evaluate staff to verify that procedures are conducted competently.

Proposed subsection (c) specifies that the laboratory must participate in a proficiency testing program that requires the laboratory to analyze test samples using the same procedures with the same number of replicate analyses, standards, testing analysts, and equipment that is used for testing of medical cannabis goods. This requirement ensures that the proficiency test results are representative of the laboratory's routine analytical methods. This requirement ensures that the methods and equipment being evaluated during the proficiency testing are the same methods and equipment used in the laboratory's usual testing. By requiring this, this proposed subsection ensures that the proficiency testing is actually evaluating the methods and equipment used by the testing laboratory in testing medical cannabis.

Proposed subsection (d) specifies the requirement that laboratory employees who participated in a proficiency test sign the corresponding analytical report or attestation statement stating that the proficiency test was conducted in the same manner as the laboratory ordinarily conducts testing of medical cannabis goods. This requirement ensures that the proficiency test adequately represents the testing activities routinely done in the laboratory.

Proposed subsection (e) specifies that the laboratory director is responsible for reviewing all proficiency test samples analyzed and measurements reported. This requirement provides for an added layer of review of sample analysis and test-result reporting. This requirement also ensures that the laboratory director is involved and informed of proficiency testing occurring at the laboratory.

Proposed subsection (f) specifies the requirement that laboratories authorize the proficiency test provider to release the results of the proficiency test to the bureau at the same time that the results are submitted to the laboratory. It also specifies that the laboratory shall send the results of the proficiency test results to the bureau within three business days of the laboratory receiving

the results of the proficiency test. This requirement ensures that the bureau is well informed of the testing laboratory's proficiency in conducting routine testing of medical cannabis goods.

§ 5361. Successful Participation in a Proficiency Test

Proposed section 5361 specifies what is meant by "successful participation" in a proficiency test performed by the testing laboratory. It is necessary to have successful participation or "satisfactory" proficiency testing data because this is used to demonstrate a laboratory's competence to clients, potential customers, accreditation bodies, and regulatory agencies. Participation in proficiency test programs must have the aim of covering the entire scope of laboratory testing as it pertains to testing medical cannabis goods. "Covering the entire scope of laboratory testing" means that participation must consider not just methods, but also the analytes and matrices for which the method is used. Proficiency testing is a key means of obtaining evidence of laboratory competence.

Proposed subsection (a) would specifically require that, for a laboratory to be found to have successfully participated in a proficiency test, it must receive results that are considered "satisfactory" for an analyte tested in a specific method or results that reflect a positive identification for an analyte tested in a specific method. Each analyte is scored separately in proficiency tests; for example, a testing laboratory may receive "satisfactory" results for 8 out of 10 analytes tested in a specific method (80%), but the 2 analytes with results deemed to be "unacceptable," "questionable," or "unsatisfactory" should not be reported until corrective action is taken, and the laboratory must enroll in the next available round of proficiency testing for that analyte as detailed in section 5364 of this division.

This is necessary to protect the integrity of analytical test results. Incorrect or inaccurate test results could pose a significant public health safety risk. The bureau will consider the testing laboratory to have successfully participated in a proficiency test if test results demonstrate a positive identification of 80% of the analytes tested in a specific method, although additional action may need to be taken as referred to in subsection (b).

Proposed subsection (b) requires a testing laboratory to document and take remedial action when the laboratory participates in proficiency testing but does not obtain "satisfactory" results for an analyte tested in a specific method. Documenting (corrective action and root cause analysis) and taking action (controlling non-conforming work) against such results is necessary to protect the integrity of analytical test result and laboratory competency.[121] Additionally, this proposed subsection would prevent a testing laboratory from continuing to perform testing for analytes in which it received a proficiency test result that was deemed "unacceptable," "questionable," or "unsatisfactory." This is required because the reliability of test results are paramount and a

[121] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 4.11, Corrective action. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

testing laboratory should not be allowed to provide testing services for specific analytes if their methods have been deemed to not be up to the standard that is required.

§ 5364. No Participation or Unsatisfactory Participation in a Proficiency Test

Proposed section 5361 above specifies what is meant by "unsatisfactory participation" in a proficiency test performed by the testing laboratory. It is necessary to have successful participation or "satisfactory" proficiency testing data because this is used to demonstrate a laboratory's competence to the bureau, clients, potential customers, and ISO. Participation in a proficiency test program must be with the aim of covering the entire scope of laboratory testing to the extent that suitable and relevant programs are available. "Covering the entire scope of laboratory testing" means that participation must consider not just methods, but also the analytes and matrices for which the method is used. Proficiency testing is a key means of obtaining evidence of laboratory competence.

Proposed subsection (a) specifically requires that all licensed testing laboratories participate in proficiency test required in section 5358 and that failure to participate in proficiency testing may result in the bureau taking actions against the testing laboratory license. It is necessary to participate in proficiency testing to demonstrate laboratory competency and to sustain ISO 17025:2005 accreditation, which is mandated by statute. This subsection is necessary to inform licensees that participating in proficiency testing is required of all testing laboratory licensees and that failure to do so may result in actions against the license.

Proposed subsection (b) specifically refers to the repeated failures of proficiency tests and that the repeated failure may result in disciplinary action against of the testing laboratory license. Revocation or suspension in these cases may be necessary because the laboratory is not able to demonstrate the reliability of their testing methods. This will affect the reliability of test results that are relied on by clients, potential customers, accreditation bodies, and the bureau. The repeated failures will also affect their ability to sustain ISO 17025:2005 accreditation mandated by the statute. This subsection is necessary for adequately informing licensees of the potential effects of receiving two or more "failed" proficiency tests within three years.

Proposed subsection (c) requires that laboratories that receive an "unacceptable," "questionable," or "unsatisfactory" proficiency test result notify the bureau and provide to the bureau corrective action responses within 30 days. This subsection is necessary to ensure that the bureau is adequately informed of the activities of its licensees. The bureau has determined that 30 days is an appropriate amount of time to allow the testing laboratory to develop effective corrective action responses and provide them to the bureau. Corrective action plans should and usually do contain root-cause analysis and must contain remedial action plans. Therefore they are required here.

Proposed subsection (d) requires a testing laboratory who has received an unsatisfactory proficiency test result to provide the bureau and the accrediting body a written report indicating

whether the laboratory successfully implemented the corrective action. This is necessary to ensure that the licensed laboratories that have received unsatisfactory proficiency test results are taking the required action to correct the deficiencies. The bureau has determined that 180 days is an appropriate amount of time to allow the licensee to successfully implement the corrective action responses.

Proposed subsection (e) indicates that a testing laboratory who has received an unsatisfactory proficiency test result is not permitted to continue reporting analytes for which the laboratory received the unsatisfactory results until the laboratory satisfactorily remedies the cause of the unsatisfactory result. This section is required to maintain the integrity and reliability of the testing process. Laboratories that have received unsatisfactory results in proficiency testing should not be performing tests and reporting the results. The results of testing are relied on by the bureau, clients, potential customers, and accreditation bodies. An unsatisfactory result in proficiency testing is an indication that the test results from that particular test may not be reliable. Therefore, reporting results for testing should not occur until the laboratory is able to correct the deficiencies that led to the unsatisfactory proficiency test result.

Proposed subsection (f) indicates that a testing laboratory may only analyze analytes for which proficiency testing results were "satisfactory." This is the natural result of proposed subsection (e).

Proposed subsection (g) indicates that a testing laboratory that has received an unsatisfactory proficiency test result is not permitted to accept analytes for testing for which the laboratory received the unsatisfactory results until the laboratory satisfactorily remedies the cause of the unsatisfactory result. This subsection also requires the testing laboratory to enroll in the next round of available proficiency testing. This subsection is required to ensure that licensed testing laboratories that receive unsatisfactory proficiency test results are not continuing to test for analytes after receiving the unsatisfactory proficiency test result. Additionally, this subsection ensures that the licensee is taking the proper steps to remedy the deficiency, including enrolling in the next opportunity to participate in proficiency testing.

§ 5367. Internal Audit

Proposed section 5367 specifies the requirement for internal audit to be conducted by the testing laboratories. Internal audits are important in that they allow the laboratories to verify that its operations are conducted as planned and that laboratory operations continue to comply with the requirements of the laboratory's management system and ISO 17025 standard. Internal audit should be carried out by trained and qualified employees. When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory shall take timely corrective action. The areas of activities audited, the audit findings, and corrective actions that arise from them shall be recorded. Follow-up activities shall verify and record the implementation and effectiveness of the corrective action taken.

Proposed subsection (a) indicates that a laboratory is required to conduct an internal audit annually or as required by the ISO accrediting body. This subsection is necessary to specify the frequency in which internal audits must be performed. The bureau has determined that regular internal audits are important to the effective operation of a testing laboratory and the reliability of test results. The bureau has determined that one year is the longest amount of time that a testing laboratory should go in between conducting internal audits.

Proposed subsection (b) specifies that the requirements for internal audits performed by testing laboratories must comply with the ISO internal-audit standards. The bureau has determined that use of the ISO standards for internal audit is appropriate and necessary given the fact that ISO accreditation is required for licensure.

Proposed subsection (c) requires that a testing laboratory provide the results of internal audits to the bureau. The performance of regular internal audits is important to verify that the laboratory's operations continue to meet all of the requirements for licensure. This subsection is necessary to ensure that the bureau is informed of the licensee's activities.

Proposed subsection (d) clarifies that failure to perform internal audits as required by this section may result in action being taken against the laboratory's license. This section is necessary in order to notify licensees that regular internal audits are required for licensure and that there are consequences for failing to satisfy this requirement.

§ 5370. Additional Testing Laboratory Recordkeeping Requirements

Section 5370 proposes a list of records that a testing laboratory must retain and make available to the bureau upon request. The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records per ISO 17025:2005.[122] ISO 17025:2005 accreditation for cannabis testing laboratories is mandated by the MCRSA. These records will be used by the bureau to enforce these proposed regulations.

Proposed subsection (a) requires that the laboratory maintain analytical testing records and data packages as described in section 5355 of this division. This is necessary to be able to trace the integrity of the data and to hold laboratories accountable for testing, thus deterring testing laboratories from dry-labbing, which is the act of delivering fictional results in lieu of performing actual laboratory testing.[123] This section specifically requires that these records—electronic, hard copy, or in magnetic or optical media or both—be kept for a minimum of seven

[122] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 4.13, Control of records. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

[123] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 5.10.2, Test reports and calibration certificates. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

years and shall be made available upon request by the bureau. Seven years is the amount of time licensees are requested to keep records pursuant to MCRSA.

Proposed subsection (b) requires that testing laboratories maintain all documents, forms, records, archives, and standard operating procedures associated with the laboratory's methods as they relate to medical cannabis testing. It is necessary to keep these records in the event that the laboratories accreditation is in question and is also required by ISO 17025:2005.

Proposed subsection (c)(1) requires that testing laboratories retain and make available to the bureau records pertaining to employee qualification, training, and competency. The purpose of this is to ensure the aptitude of all laboratory employees who perform analyses, operate equipment, and conduct other duties related to laboratory functions. It is necessary that the employees are trained, qualified, and authorized to carry out their laboratory duties to ensure the integrity of analytical test results.

Proposed subsection (c)(2) requires that testing laboratories retain and make available to the bureau records pertaining to method verification and validation. The purpose of this is to assure that planning, conducting, evaluating, and approving the validation and verification of methods at the testing laboratories was suitable and correct.[124] This is necessary because the reliability of analytical test results is directly dependent on proper method verification and method validation. If analytical test results related to medical cannabis are skewed this could potentially pose a significant public health safety risk.

Proposed subsection (c)(3) requires that testing laboratories retain and make available to the bureau records pertaining to quality control and quality assurance. This is necessary because quality control is an essential aspect of ensuring that data released by the testing laboratory is fit for the purpose. Method accuracy is documented and controlled based on quality control. Quality assurance requires that is the laboratory's responsibility to ensure the accountability of all data and measurements.[125]

Proposed subsection (c)(4) would require chain-of-custody and sample field logs as well as sample-management records be made available to the bureau for inspection. These documents are necessary to ensure a sample has been properly handled through its lifecycle.

Proposed subsections (c)(5) and (c)(6) require that the testing laboratory retain and make available to the bureau records pertaining to purchase requisitions for equipment and supplies,

[124] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 5.4, Test and calibration methods and method validation. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.
[125] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 5.9, Assuring the quality of test and calibration results. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

equipment services, equipment installation, maintenance, and calibration.[126] ISO 17025:2005 requires this as well.[127,128]

Proposed subsection (c)(7) requires that all customer service records are kept and made available to the bureau upon request. The purpose of this is to ensure that the request met the customer's needs (including the methods used) and was adequately defined, documented, and understood by the laboratory.[129] ISO 17025:2005 describes the principles for review of customer requests, tenders, and contracts as well as service provided to the customer.[130] Testing laboratories should meet the standards described in ISO 17025:2005 in order to sustain their accreditation and these records should be made available to the bureau for enforcement purposes.

Proposed subsection (c)(8) requires that nonconforming work and corrective action records be kept and made available to the bureau. This is necessary for the identification and management of nonconformities. Corrective action is initiated when nonconformity is identified. The corrective action process includes but is not limited to the identification of a nonconformity, the selection of corrective actions, implementation and monitoring of corrective actions, and tracking the progress of corrective action. It is necessary to have the entire corrective action process be documented to confirm that the testing laboratory has remedied the cause of the issue. Documenting (corrective action and root cause analysis) and taking action (controlling non-conforming work) is also necessary to protect the integrity of analytical test result.

Proposed subsection (c)(9) requires that the testing laboratory retain and make available to the bureau records pertaining to internal and external audits. A testing laboratory's internal and external audits may consist of but are not limited to the auditing of all elements of the quality-management system, including the quality policies, quality objectives, procedures, testing activities, and work instructions. All aspects mentioned are vital to sustaining ISO 17025:2005

[126] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 5.6.2.1, calibration. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

[127] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 4.6, Purchasing services and supplies. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

[128] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 5.5, Equipment. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

[129] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 4.3, Document control. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

[130] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 4.7, Service to the customer. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

accreditation and should be assessed and documented during an internal or external audit.[131] These documents are necessary for the bureau to enforce these proposed regulations.

Proposed subsection (c)(10) requires that the testing laboratory retain and make available to the bureau records pertaining to management review; these records include technical data review reports and final management review reports. The purpose of the review is to verify that the method was properly performed and documented. General requirements for data review include but are not limited to verifying that calculations are correct, verifying the units reported are correct, verifying that the results listed in the certificate of analysis are correct, verifying that the acceptance criteria for quality-control samples are met, and verifying that method-specific standard operating procedures requirements are met. It is necessary that the records for the reviews are retained in the event that analytical test results are questioned, so the management review or final approval can be referenced.[132] This is also necessary to be able to trace the integrity of the data and to hold laboratories accountable for analytical testing results.

Proposed subsection (c)(11) requires that the laboratory maintain laboratory data reports, analytical testing records, and entire data packages and make them available upon request to the bureau. This is necessary to be able to trace the integrity of the data and to hold laboratories accountable for testing, thus deterring testing laboratories from dry-labbing.

Proposed subsection (c)(12) requires that the testing laboratory retain and make available to the bureau records pertaining to proficiency testing. Proficiency testing is used to demonstrate a laboratory's competence to the bureau, clients, potential customers, and accreditation bodies. Participation in proficiency test programs must have the aim of covering the entire scope of laboratory testing.

Proposed subsection (c)(13) requires that a testing laboratory retain and make available to the bureau records pertaining to electronic data, backed-up data, and laboratory security. Current law requires the safe and secure handling of medical cannabis goods but does not clearly enumerate all safety and security measures to be taken—including electronic data pertaining to the testing of medical cannabis goods. The purpose of retaining these records is to safeguard electronically stored data pertaining to medical cannabis testing is to protect all individual, identifiable information against intentional and negligent sharing, as well as to protect information regarding sample- or research-related materials. It is also necessary to protect the integrity of analytical test results from being altered, destroyed, or improperly shared. There could be a significant public health safety risk if analytical test results were altered, destroyed, or improperly shared.

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[131] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 4.14, Internal audits. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

[132] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 4.14, Internal audits. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

Proposed subsection (c)(14) requires that the testing laboratory retain and make available to the bureau records pertaining to traceability. The purpose of this is to demonstrate how the testing laboratories achieve measurement traceability for its testing measurements as described in the proposed "data package" section in these proposed regulations. This is necessary to be able to trace the integrity of the data and to hold laboratories accountable for testing, thus detouring testing laboratories from dry-labbing.[133]

Record retention pertaining to traceability is also required by ISO 17025:2005 and covers the selection, identification, use, initial and continuing calibration checks, handling, transport and storage (control and maintenance), the laboratory's certified and standard reference materials (CRMs and SRMs), calibration standards, and reference cultures.

Proposed subsection (c)(15) requires that the testing laboratory retain and make available to the bureau records pertaining to laboratory contamination and cleaning. Records for laboratory contamination and cleaning are needed to ensure the testing laboratory implements standards to prevent inadvertent contamination. It is essential to prevent contamination because this could skew analytical test results.

Proposed subsection (d) proposes that if records are missing or incomplete, or if a laboratory does not produce the records for the bureau upon request, the bureau may take disciplinary action against the licensee. Disciplinary action may be necessary to deter testing laboratories from altering records or keeping incomplete records and to hold laboratories accountable for the integrity of their testing.

ARTICLE 8. EMPLOYEE EDUCATION AND EXPERIENCE REQUIREMENTS

§ 5373. Personnel Qualifications

This proposed section specifies the education, training, and experience requirements for laboratory directors, supervisory analysis, and analysts. This section is necessary to clarify the acceptable level of education and experience possessed by each laboratory employee. This section is necessary to ensure that cannabis testing laboratory employees possess the requisite academic and professional qualifications necessary to perform the scientific duties and privileges associated with licensure.

Proposed subsection (a) specifies how an employee who attended a college or university outside of the United States or its territories may demonstrate that the institution is accredited. This requirement is satisfied if the employee meets the educational credentials equivalent to those of a

[133] International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories," Second edition 2005-05-15. Subclause 5.6, Measurement traceability. http://www.uobaghdad.edu.iq/uploads/pics13/q1684/iso17025_eng.pdf. Accessed March 28, 2017.

person who attended an accredited college or university within the United States. This section provides a means by which qualified laboratory applicants who gained their education outside of the United States or its territories to satisfactorily demonstrate that they completed the requisite educational standards. This section is necessary to allow laboratories to consider the most qualified applicants for work in the cannabis analytical laboratories regardless of where they earned their education.

Proposed subsection (b) specifies that persons responsible for analytical tasks must meet the experience and educational requirements of a testing analyst and be able to demonstrate proper performance of the analytical tasks. This section is necessary to clarify the minimum experience and education requirements for any laboratory employees involved in analysis of cannabis samples. This section further specifies that the analytical tasks performed by any laboratory employees must be performed properly. This provision is necessary to ensure integrity of all activities related to testing activity.

Proposed subsection (c) specifies that qualifications and work scopes of a cannabis testing laboratory director. This section is necessary to make clear the compliance standards for employing a director at a licensed cannabis testing laboratory.

Proposed subsection (c)(1) specifies the level of postsecondary education that must be completed by a candidate for employment as a laboratory director. This section further specifies that after completing the requisite postsecondary education, a person may be eligible for employment as a laboratory director upon completion of three years of full-time work performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body. This section is necessary to ensure that the highest-ranked laboratory employee—the laboratory director—possess the adequate knowledge of chemical or biological processes and has performed a sufficient degree of analytical work in a laboratory of the same caliber as one licensed by the bureau for medical cannabis testing. This section is also necessary to make clear one of the three ways in which an applicant for employment as a laboratory director may qualify for employment as such.

Proposed subsection (c)(2) specifies the level of postsecondary education that must be completed by a candidate for employment as a laboratory director. This section further specifies that after completing the requisite postsecondary education, a person may be eligible for employment as a laboratory director upon completion five years of full-time practical experience performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body. This section is necessary to ensure that the highest-ranked laboratory employee—the laboratory director—possess the adequate knowledge of chemical or biological processes and has performed a sufficient degree of analytical work in a laboratory of the same caliber as one licensed by the bureau for medical cannabis testing. This section is also necessary to make clear one of the three ways in which an applicant for employment as a laboratory director may qualify for employment as such.

Proposed subsection (c)(3) specifies the level of postsecondary education that must be completed by a candidate for employment as a laboratory director. This section further specifies that after completing the requisite postsecondary education, a person may be eligible for employment as a laboratory director upon completing seven years of full-time practical experience performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body. This section is necessary to ensure that the highest-ranked laboratory employee—the laboratory director—possess the adequate knowledge of chemical or biological processes and has performed a sufficient degree of analytical work in a laboratory of the same caliber as one licensed by the bureau for medical cannabis testing.

Proposed subsection (d) proposes that, in addition to meeting the educational and experience requirements, the laboratory director shall also be capable of satisfactorily fulfilling all of the following core responsibilities. This section ensures that the laboratory director relies on extensive experience and judgment to plan and accomplish tasks, including directing, establishing, and planning the overall policies and goals for a laboratory. These duties include:

(1) Overseeing and directing the scientific methods of the laboratory. The laboratory director must have a firm grasp of the methodologies used in the testing laboratory. (2) Ensuring that the testing laboratory achieves and maintains quality standards of practice. The laboratory director shall serve as a quality manager as well as having a laboratory director role. The laboratory director shall ensure quality of data created by the laboratory.
(3) Supervising all testing-laboratory personnel. The laboratory must be the head of the laboratory and ensure that his or her staff are properly carrying out their tasks and are trained appropriately. The laboratory director shall also ensure he or she hired qualified staff.

Proposed subsection (e) specifies that qualifications and work scopes of a medical cannabis testing laboratory supervisory analyst. This section is necessary to make clear the compliance standards for employing a supervisory analyst at a licensed cannabis testing laboratory.

Proposed subsection (e)(1) specifies that a candidate for employment as a supervisory analyst may satisfy the requisite education and experience standards by meeting the education and experience standards of a laboratory director as would be required by these proposed regulations. This section is necessary to make clear one of the four ways in which an applicant for employment as a supervisory analyst may qualify for employment as such.

Proposed subsection (e)(2) specifies the level of postsecondary education that must be completed by a candidate for employment as a supervisory analyst. This section further specifies that after completing the requisite postsecondary education under this subsection, a person may be eligible for employment as a laboratory director upon completion of one year of full-time practical experience performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body. This section is necessary to make clear one of the

four ways in which an applicant for employment as a supervisory analyst may qualify for employment as such.

Proposed subsection (e)(3) specifies the level of postsecondary education that must be completed by a candidate for employment as a supervisory analyst. This section further specifies that after completing the requisite postsecondary education under this subsection, a person may be eligible for employment as a laboratory director upon completion of at least two years of full-time practical experience performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body; This section is necessary to make clear one of the four ways in which an applicant for employment as a supervisory analyst may qualify for employment as such.

Proposed subsection (e)(4) specifies the level of postsecondary education that must be completed by a candidate for employment as a supervisory analyst. This section further specifies that after completing the requisite postsecondary education, a person may be eligible for employment as a laboratory director upon completion of three years of full-time practical experience performing analytical scientific testing in which the testing methods are or were recognized by a laboratory-accrediting body. This section is necessary to make clear one of the four ways in which an applicant for employment as a supervisory analyst may qualify for employment as such.

Proposed subsection (f) specifies that qualifications and work scopes of a cannabis testing laboratory testing analyst.

Proposed subsection (f)(1) specifies that a candidate for employment as a testing analyst may satisfy the requisite education and experience standards by meeting the education and experience standards of a laboratory director as would be required by these proposed regulations. This section is necessary to make clear one of the four ways in which an applicant for employment as a testing analyst may qualify for employment as such.

Proposed subsection (f)(2) specifies that a candidate for employment as a testing analyst may satisfy the requisite education and experience standards by meeting the education and experience standards of a supervisory analyst as would be required by these proposed regulations. This section is necessary to make clear one of the four ways in which an applicant for employment as a testing analyst may qualify for employment as such.

Proposed subsection (f)(3) specifies the postsecondary education that must be completed by a candidate for employment as a testing analyst. This section is necessary to make clear one of the four ways in which an applicant for employment as a testing analyst may qualify for employment as such.

Proposed subsection (f)(4) specifies the amount and type of education that a person must have completed to be a testing analyst. In addition to the education, a testing analyst must also have completed 1 year of full-time, non-education-related practical experience in a laboratory

performing analytical scientific testing in which the testing methods are or were recognized by an accrediting body.

Proposed subsection (g) specifies that qualifications and work scopes of a medical cannabis testing laboratory sampler. This section is necessary to make clear the compliance standards for employing a sampler at a licensed medical cannabis testing laboratory.

Proposed subsection (g)(1) specifies that a person aged 21 years or older is eligible for employment as a medical cannabis testing laboratory sampler. This section is necessary because, under California law, only people aged 21 years and older may possess nonmedical cannabis. Possession of medical cannabis by people younger than age 21 is permitted only if such person obtains a medical cannabis recommendation. The bureau recommends restricting the age of a sampler to 21 years old to prevent the unlawful possession of cannabis.

Proposed subsection (g)(2) specifies that a sampler must have completed at least two years of college coursework to satisfy the educational requirements of a sampler. This provision is necessary to ensure that laboratory samplers possess the level of responsibility and attention to detail that is commonly required of a person who has completed some amount of college coursework. The bureau recommends this standard to ensure the accuracy and reliability of the sampling conducted by laboratory employees.

Proposed subsection (g)(3) would require a sampler have completed the minimum training requirements set forth in section 5376(a) of this division.

§ 5376. Training Requirements for Samplers

Proposed subsection (a)(1) specifies that the testing laboratory must ensure that the sampler is trained in the scientific basis of medical cannabis sampling for chemical and microbiological tests. Such training may include, for example, topics of organic chemical characteristics of cannabinoids, inorganic properties, and inoculation or growth of a virus, bacterium, or mold that is beneficial to preventing change or deterioration of the sample. This provision is necessary to ensure that the sampler is adequately prepared to collect and store cannabis samples in a manner that minimizes exposure to contamination and degradation.

Proposed subsection (a)(2) specifies that the testing laboratory must ensure that the sampler is trained in the theory of sampling, including common sampling errors and how to identify and minimize errors. This provision is necessary to ensure that the sampler is performing the sampling procedure in a statistically valid manner. The most frequent cause of sampling error is bias introduced by the sampler during the sampling process. Thus, the bureau recommends adopting this provision as a means to minimize bias error by ensuring that the sampler is adequately trained in the topics of random sampling, representative sampling, sample size, and sample replication, among other critical training areas.

Proposed subsection (a)(3) specifies that the testing laboratory must ensure that the sampler is trained in methods for maintenance sample integrity. This provision is necessary to ensure that the sampler is adequately prepared to collect, store, and prepare for transport to the laboratory, the medical cannabis samples the sampler collects. Such training and knowledge is necessary to achieving compliance with these regulations.

Proposed subsection (a)(4) specifies that the testing laboratory must ensure that the sampler is trained to properly complete the chain-of-custody form. This provision is necessary to ensure that the sampler is capable of accurately recording environmental conditions at the distributor site (for example, temperature and the presence of contaminants), batch size, and sample unique identifiers, among other critical information required to be recorded on the chain-of-custody form. This training would also ensure that a sampler is able to properly complete the chain-of-custody form, which is a vital tool for tracking samples and providing assurance that samples collected by testing laboratory staff have been properly maintained and are representative of the batch they were taken from at the time of sampling. Such training and knowledge is necessary to achieving compliance with these regulations.

Proposed subsection (a)(5) specifies that the testing laboratory must ensure that the sampler is trained in sample-collection procedures for each medical cannabis goods matrix. This provision is necessary to ensure that the sampler is conducting the appropriate sampling method that is specific to the matrix and that comports with the laboratory's sampling standard operating procedure for the indicated matrix. There are different types of sample matrices, such as dried flowed, oil-type liquid, resin-type semi-solids, and solid types of medical cannabis goods. Understanding the physical properties of the matrices will increase the efficiency of the sampling and also help the sampler to choose the proper sampling tools and equipment.

Proposed subsection (a)(6) specifies that the testing laboratory must ensure that the sampler is trained on the relevant statutes and regulations pertaining to testing laboratories. This provision is necessary to ensure that the sampler is aware of the statutes and regulations that govern the process of collecting samples for laboratory testing. A better understanding of the relevant laws is likely to result in an increase in compliance with those laws.

Proposed subsection (a)(7) specifies that the testing laboratory must ensure that the sampler is trained in the selection, use, and maintenance of sampling tools and equipment. This provision is necessary to ensure that the sampler is familiarized with the appropriate sampling tools and equipment and how to properly use these supplies during the sampling of medical cannabis. The bureau recommends adopting this provision as a means of increasing sampling efficiency and, ultimately, the reliability of the analytical test results.

Proposed subsection (a)(8) specifies that the testing laboratory must ensure that the sampler is trained in the practical, hands-on application with representative samples. This provision is necessary to ensure that the sampler is capable of carrying out the requirements of these

regulations to collect samples that are representative of the batch from which the sample was collected. The bureau recommends adopting this provision as a means to ensure the reliability of the analytical test results.

Proposed subsection (a)(9) specifies that the testing laboratory must ensure that the sampler is trained in how to recognize observations regarding sampling that should be recorded and how to record those observations during sampling. This provision is necessary to ensure that during the sampling process, the sampler is able to identify and record any abnormalities with, among other things, the sample batch size, breaches in the sample packaging, or environmental factors that may impact the sample integrity. This information could impact test results, and, as such, it is vital that the sampler be trained in how to accurately capture such observations.

Proposed subsection (b) specifies that a laboratory must maintain documentation of training provided to and completed by samplers. This provision is necessary to allow the bureau to verify that the laboratory is in compliance with the required training provision for samplers and that all individuals who are working as samplers have an accurate record of their qualifications and training.

Proposed subsection (c) specifies that the records for samplers shall be kept by laboratories for seven years, whether or not the sampler is still employed by the laboratory. This provision is necessary to allow the bureau to audit the training activities of a laboratory even if a sampler has moved on to a different job. Under the MCRSA, all licensee records must be kept for a minimum of seven years.

§ 5379. Verification of Personnel Qualifications

Proposed Section 5379 establishes that the licensee is responsible for maintaining the documentation of qualifications of its employees. Proposed subsection (a) specifies the types of documentation that a testing laboratory must maintain under the proposed section.

Proposed subsection (a)(1) specifies that the laboratory is responsible for maintaining documents pertaining to the educational background of their personnel. This includes information such as the names and addresses of educational institutes attended by the personnel, including the date they attended and the degrees that they received. Retaining and maintaining this documentation is necessary because it is an effective method of exhibiting an individual's qualifications for a specific task. It is important that laboratory maintain these records as review of the records by the bureau may be required.

Proposed subsection (a)(2) requires that the testing laboratory maintain transcripts from educational institutions attended by laboratory personnel indicating courses completed and degrees received by laboratory personnel. Retaining and maintaining this documentation is necessary because it is an effective method of exhibiting an individual's qualifications for a specific task. It is important that laboratory maintain these records because review of the records by the bureau may be required.

Proposed subsection (a)(3) requires testing laboratories to maintain personnel records pertaining to credential evaluation services, including translations of transcripts from other languages. Retaining and maintaining this documentation is necessary because it is an effective method of exhibiting an individual's qualifications for a specific task.

Proposed subsection (b) clarifies the meaning of "documentation" of a person's experience. Proposed subsections (b)(1) and (2) indicate that information about laboratories that previously employed the employee, including the name and address of the laboratory, the dates in which the employee was employed at the laboratory, the number of hours a week the employee worked, and a description of the type of testing performed. Along with this documentation, the laboratory is required to maintain documentation of the laboratory employee's previous experience signed by the laboratory director or equivalent of the laboratory that previously employed the employee. Retaining and maintaining this documentation is necessary because it is an effective method of exhibiting an individual's qualifications for a specific task.

ARTICLE 9. LABORATORY SECURITY

§ 5382. Premises Security

Proposed subsections (a) and (b) establish the minimum measures required to ensure that the laboratory's development and implementation of security protocols are used to prevent diversion, theft, and loss of medical cannabis goods from the laboratory premises. This is necessary because the product could be used to contribute to unregulated sales or personal use. This could pose a significant public health safety risk because the untested medical cannabis goods could pose a risk to public health. It is also necessary to have the security protocol documented in writing and available to all laboratory personnel to make sure all staff are knowledgeable of and can readily access the protocol.

§ 5388. Access Control

Business and Professions Code section 19334, subsection (d)(3), requires laboratories to securely store all medical cannabis goods and to implement measures to prevent diversion of cannabis products. This section proposes that secure storage of cannabis products and prevention of diversion shall be achieved by requiring medical cannabis testing laboratories to establish limited-access areas that are accessible only to authorized personnel through the use of a badge (access-control card). This will increase the security of limited-access areas. The purpose of this section is to clarify the requirements needed for areas that should have limited access. Limited access is necessary to prevent diversion, theft, and loss of medical cannabis goods from the laboratory premises.

Proposed subsections (a)(1) and (a)(2) limit the access to certain personnel for the sole purpose of executing their specific job function. The purpose of having limited access and an access-control-card system that is capable of recording the transaction history of all entrants is to

maintain a record of all personnel entering limited access areas. Those records might be retrieved in the event of diversion, theft, or loss of medical cannabis goods from the laboratory premises.

Proposed subsection (a)(3) requires that the testing laboratories have a security alarm system. The purpose of having a security alarm system is to protect the laboratory from theft and loss of medical cannabis goods.

Proposed subsection (a)(4) specifically requires the testing laboratory to maintain a visitor arrival and departure log. When facility entrances are not secure, the testing laboratory is vulnerable. It is also important to maintain a log of all individuals who enter the laboratory premises. In the event of an investigation, the log of all visitors with the date and time of their visit may provide the laboratory and the bureau with valuable information.

§ 5397. Storage Areas

Business and Professions Code section 19334, subsection (d)(3), requires laboratories to securely store all medical cannabis goods and to implement measures to prevent diversion of medical cannabis goods. This proposed section clarifies for the licensee the type and quality of locks permitted for use when storing medical cannabis goods. Secured storage areas using commercial-grade locks, whether in a room or cabinet, must be locked at all times except when managing or retrieving a secured item or items. It is necessary to maintain such limited access to prevent diversion, theft, and loss of medical cannabis goods from the laboratory premises. This is necessary because the goods could be used to contribute to unregulated sales or personal use and could pose a significant public health safety risk. This section specifies that medical cannabis goods should be stored apart and away (separately) from non-medical-cannabis samples or items. The purpose of this is to prevent contamination or inadvertently mixing incompatible chemicals. It is necessary to prevent contamination because this could potentially alter analytical test results. It is necessary to prevent the inadvertent mixing of incompatible chemicals because this could cause hazardous chemical reactions, which could result in fire, explosion, or a release of toxic gas.

Proposed subsection (a) enumerates the types of medical cannabis goods that are required to have secure, designated areas for storage. This is necessary to prevent diversion, theft, and loss of medical cannabis goods from the laboratory premises.

Proposed subsections (a)(1) through (4) specify specific items that a licensed testing laboratory must store in a secure place separate from other items. It is necessary to store these items in a secure place to prevent potential loss or theft. Additionally, these items should be kept separate to prevent potential contamination and maintain the integrity of the testing.

Proposed subsection (a)(5) also specifies that the laboratory shall designate secured areas for the storage of records of analytical tests, including certificates of analyses. The subsection requires that data packages be kept in a secured storage area to protect all information from unauthorized access to the information and to prevent loss. It is also necessary to protect the integrity of

analytical test results by preventing the result from being altered, destroyed, or improperly shared. There could be a significant public health safety risk if analytical test results were altered, destroyed, or improperly shared.

§ 5400. Electronic Data

This proposed section specifies the minimum requirements of a laboratory's computer system to maintain a security standard. The purpose of installing, managing, and maintaining password protection for electronically stored data pertaining to medical cannabis testing is to protect the information from unauthorized access. It is also necessary to prevent results from being altered, destroyed, or improperly shared. The integrity of analytical test results related to medical cannabis is very important because the consumer will rely on the test results in making decisions. There could be a significant public health safety risk if analytical test results were altered, destroyed, or improperly shared. Furthermore, it is necessary to protect the laboratories computer systems from the theft or damage to the hardware, software, or the information on them, as well as from disruption or misdirection of the services they provide.

§ 5403. Notification of Discrepancy

Business and Professions Code section 19334, subsection (d)(3), requires laboratories to securely store all medical cannabis goods and to implement measures to prevent diversion of cannabis products. This proposed section specifies that laboratories shall notify the bureau within 24 hours of discovering a breach in their security, per the MCRSA. It is very important that the bureau have the ability to track medical cannabis goods as they move through the system. To do this effectively, the bureau must have up-to-date information. In the event of an incident as described in this section, the bureau has determined that requiring notice within 24 hours is reasonable and appropriate given the bureau's need for timely information and the licensee's ability to provide such notice.

Proposed subsection (a)(1) would require reporting of any loss of 5% of the laboratory's medical cannabis goods inventory. Ideally, a laboratory would not lose any of the inventory, but the bureau realized that mistakes are made and has set the limit at 5%. This is a fairly small number, but the bureau took into account the small amount of loss of product that occurs during testing (for instance, medical cannabis adhering to equipment).

Similarly, in proposed subsection (a)(2), the bureau proposes that a loss of 1 unit of a packaged batch sample increment requires notifying the bureau. Whole packaged units should not be lost in a properly running laboratory.

Proposed subsection (a)(3) requires that the bureau be notified of any diversion or theft of medical cannabis goods or any other criminal activity pertaining to the operation of the laboratory. It is necessary to report such activities because the goods could be used to contribute to unregulated sales or personal use and could pose a significant public health safety risk due to the goods being untested.

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ALTERNATIVES CONSIDERED

In accordance with 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 the testing of harvest batches. 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 harvest-batch size 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 harvest-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 increased cost of testing is of concern because the higher the cost of compliance, the more likely some businesses will remain in the illegal market. The incremental increases 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.

Economic Costs and Benefits of Proposed Regulations for the Implementation of the Medical Cannabis Regulation and Safety Act (MCRSA)

Standardized Regulatory Impact Analysis

Prepared for the Bureau of Marijuana Control

by the University of California Agricultural Issues Center

April 7, 2017

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Medical Cannabis Regulation and Safety Act (MCRSA)

Economic Costs and Benefits of Proposed Regulations
Standardized Regulatory Impact Analysis (SRIA)

The Bureau of Marijuana Control (bureau), formerly named the Bureau of Medical Cannabis Regulation and the Bureau of Medical Marijuana Regulation, will be proposing regulations to implement the Medical Cannabis Regulation and Safety Act (MCRSA), which establishes the bureau as the state's licensing and enforcement authority for the distribution, transportation, testing, and dispensing of medical cannabis in California.

This Standardized Regulatory Impact Analysis is submitted for the purpose of evaluating the benefits and costs of the regulations proposed by the bureau, which will go into effect on January 1, 2018. The University of California Agricultural Issues Center (AIC) assessed the costs and benefits of the bureau's proposed regulations and two alternative sets of regulations.

For some issues, the MCRSA provided detailed regulatory specifications that the proposed regulations implement precisely. For other issues, the MCRSA provided broader guidance about the regulations. This SRIA considers the full package of proposed regulations, including those that implement precise statutory requirements. AIC gathered detailed cost, price, quantity, and other information to assess the impact of the proposed regulations on the industry and on the state. The results of this analysis are presented in this SRIA with background information and details provided in the Appendix.

AIC's analysis of the medical segment of the cannabis industry in California was conducted in the context of other cannabis segments in the state. Adult use of cannabis was legalized by Proposition 64 in the California general election of November 8, 2016, and is scheduled to be regulated alongside the medical segment beginning on January 1, 2018. In this document, we use the term "adult use" to refer to the segment of non-medical cannabis sales that will become legal and regulated starting in 2018. We use the term "illegal" to refer to the segment of unlicensed non-medical cannabis sales in California that is currently unlawful and will remain so in 2018.

After outlining statutory authority, this SRIA summarizes the scope of analysis and outlines AIC's approach to the calculations of economic impacts. A key feature of the approach is defining a baseline against which to measure the economic impacts of the proposed

regulations. These direct economic impacts are characterized in terms of effects on prices, quantities, revenues and taxes.

After measuring the economic effects within the medical cannabis segment, AIC used a standard economy-wide model (IMPLAN) to project ripple effects on the California economy more broadly. The SRIA outlines findings in terms of exployment, impacts on businesses, potential influence on broad indicators of benefits and costs, and government revenues. Finally, in addition to the benefits, costs and related impacts of the proposed regulations, AIC evaluated the benefits and costs of two alternatives: an alternative to represent a lower-cost package of regulations and an alternative to represent a higher-security package of regulations.

1. Statutory authority

The Medical Cannabis Safety and Regulation Act (MCSRA), which became effective in 2016, established the bureau within the California Department of Consumer Affairs and assigned to the bureau the responsibility of creating and administering a licensing and enforcement structure for the distribution, transportation, testing, and retail sale of medical cannabis in California.

Under Government Code section 11346.3, a California state agency proposing a “major regulation,” which Government Code section 11342.548 defines as “any proposed adoption, amendment, or repeal of a regulation subject to review by the Office of Administrative Law . . . that will have an economic impact on California business enterprises and individuals in an amount exceeding fifty million dollars ($50,000,000), as estimated by the agency,” is required to prepare a Standardized Regulatory Impact Analysis (SRIA) to be submitted to the state Department of Finance for review and comment before the regulations are noticed to the public.

The first requirement of a SRIA is that it must verify that the regulation under review meets the definition of “major regulation” under Government Code § 11342.548. The regulations adopted by the Department of Finance further define the threshold as $50 million in either costs or benefits occurring within one year of full implementation of the proposed regulations. The proposed regulations are scheduled to go into effect on January 1, 2018; therefore, the scope of consideration for the “major regulation” standard would be impact that occurs during the 2018 calendar year.

AIC calculations showed that these proposed regulations met the definition of "major regulation" in Section 7 below. In our approach to this and other determinations to be made in the SRIA, AIC relied on guidance from the 2015 joint report from the Office of Administrative Law and Department of Finance, which clarifies the interpretation of Government Code section 11346.3 with respect to SRIA content, purpose, and the "major regulation" determination.[134]

2. Nature and scope of regulatory impacts considered

In order to isolate the effect of the proposed regulations from intervening factors that may also have major effects on the California medical cannabis industry, the analysis must recognize that other factors operating over the same time period may also affect the California cannabis industry. The most important expected change to the cannabis industry in California is the legalization of non-medical use of cannabis by adults 21 and over, as per Proposition 64. The relevant statutes, collectively known as the Control, Tax and Regulate Adult Use of Marijuana Act (AUMA), added adult-use as a legal segment of the total cannabis market, establish a new tax structure for medical and adult-use cannabis, and assign the bureau responsibility for regulating both California's adult-use cannabis industry and medical cannabis industry.

The economic calculations and simulations reported below proceeded in three steps. First, we empirically assessed the November 2016 situation for medical cannabis in California. Second, in order to establish a relevant base for the regulatory analysis, we projected the impacts of legal sales of adult-use cannabis and taxation of all legal cannabis on the medical cannabis market segment. This step, which we call the "Taxation and Adult-Use Legalization," provides the baseline against which the proposed medical cannabis regulations may be measured. Evaluating this baseline before evaluating the impact of regulations allows analysts to consider each of these two sets of effects independently. The third step, and central focus of the SRIA, is to calculate and simulate the impact of the proposed regulations on the medical cannabis segment separately from the effects of taxation and adult-use legalization. We call this final market scenario "Proposed Regulation."

More precise definitions of each of these segments and simulated changes are set out in Appendix Chapter 5.

[134] November 1, 2015, report by the Directors of the Office of Administrative Law and Department of Finance to the Chair of the Senate Committee on Governmental Organization and the Chair of the Assembly Committee on Government al Organization, SB 617 and Finance Regulations appended.

3. Approach to economic modeling

Measuring the economic impact of a regulation is contingent on estimating relevant baseline market prices, quantities, revenues, taxes, and related aggregates that would occur in the absence of the regulation. The creation of such a baseline is often not as simple as assuming current conditions continue to apply in the absence of the regulations, even when data about market conditions are readily available.

The economic data and modeling underlying this SRIA are unusually complex for two reasons: (1) the unavailability of much relevant government or other public data and unavailability of much relevant banking, accounting, or other private data; and (2) the necessity of developing a counter-factual projected baseline that enabled the analysis to estimate the separate effects of taxation and adult-use legalization from the impacts of the proposed regulations.

First, there are no official government data sources on output, prices, jobs, or other economic aggregates for the industry to which the proposed regulations on medical cannabis apply, and official tax collections reflect a minority of operating businesses. Because much of the industry to which the proposed regulations apply has long been prohibited by Federal law, normal industry data have not been reported in standard authoritative Federal sources.

Moreover, businesses have not reported their financial results in standard ways. In many cases, businesses have been operating with cash, outside of the normal banking system, in a quasi-legal, quasi-regulated manner. Furthermore, the closely related adult-use segment has been illegal even under state law.

The lack of reliable authoritative public or private data required AIC to develop estimates of data that would have been readily available for most other industries. For instance, we collected data from more than 500 dispensaries in California. Estimates of economic aggregates and relationships provided below are approximations based on the best available information as of November 2016.

Second, as noted in Section 2, the bureau's MCRSA regulations are anticipated to take effect at the same time that AUMA legalizes adult-use cannabis, regulates sales of adult-use cannabis, and imposes taxes on both legal medical and legal adult-use cannabis. The joint launch of these two regulatory systems, which is expected to take place on January 1, 2018, creates legal sales in two cannabis segments—medical cannabis and adult-use cannabis. When in place, such a

system will enable many buyers who had previously been buying in the medical segment to shift purchases to the adult-use segment without any significant foreseeable switching costs. In addition, regulations related to the cultivation of cannabis, taxation of cannabis leaving the cultivation site, and regulation of the manufacturing of cannabis products will commence at the same time.

In order to isolate the impact of the proposed regulations in the relevant economic situation and context, AIC modeled and simulated the implications and effects of the emergence of a legal adult-use cannabis segment that is scheduled to exist side-by-side with the legal medical cannabis segment. This first simulation step also included the taxation of both legal cannabis segments (medical and adult-use) that are scheduled to accompany adult-use legalization.

These effects, created the baseline against which we simulated the impacts of regulations. We then analyzed the impacts of the proposed regulations on the medical cannabis segment in the context of the (hypothetical) cannabis industry with the baseline of taxation and adult-use legalization in place.

Let us illustrate the magnitude of the issue more concretely and foreshadow the estimates presented below. Based on our best assessment, the California medical cannabis segment, as of fall 2016, had aggregate revenue on an annualized basis of about $2 billion. After legalization of the cultivation and sale of adult-use cannabis and taxation of legal cannabis, but without yet considering the implications of the proposed regulations, economic calculations suggest that revenue in the medical cannabis segment will fall to about $600 million. Thus, the medical cannabis proposed regulations are likely to apply to a medical cannabis segment that is approximately 30% the size of the current medical cannabis segment.

Projecting the effects of market changes requires the specification of supply and demand response parameters. These are often expressed as elasticities. In this case, key estimates and assumptions include how responsive demand for cannabis overall is to prices and how responsive demand for cannabis in each segment is to relative prices in those segments. Simulation also requires evidence and assumptions about shifts in demand affecting each segment. On the supply side, we used assumptions about how responsive supply in each segment was to relative prices across segments. Evidence and assumptions about shifts in costs were required as well.

In summary, in order to isolate the impact of the proposed regulations, our procedure was to incorporate the changes to the marketplace step by step. Based on initial conditions for the November 2016 cannabis market, we first simulated the economic effects of taxation and adult-use legalization. Next, we incorporated the impact of the proposed regulations into the model and solved for economic aggregates. Finally, we assessed the impact of the proposed regulations by comparing the baseline taxation-and-adult-use-legalization scenario with a scenario that adds the effects of regulations on top of that baseline.

Finally, we assumed that the proposed regulations regarding the newly created legal adult-use cannabis segment (which are scheduled to be implemented at the same time as are the proposed regulations for medical cannabis) were expected to be similar to the proposed regulations for medical cannabis. Therefore, our analysis of regulatory impact assumes that both segments will become regulated with relatively small differences between the two.

4. Overview of data collection and initial market conditions

In constructing initial estimates of prices and quantities in the California cannabis market that applied in November 2016, AIC drew upon a variety of sources, including our own AIC retail cannabis price survey, which was conducted by several AIC researchers throughout the months of October and November, 2016 (details and results are in Appendix Chapter 4); third-party longitudinal retail and wholesale price surveys (Appendix Chapters 3 and 5); an AIC meta-analysis of published scientific journal articles, white papers, and government reports; and confidential AIC interviews with market experts and industry participants (Appendix Chapters 3 and 5). The appendix includes a complete list of references to documents cited and reviewed.

AIC started from estimates of the revenue of California medical cannabis dispensaries as of November 2016. There are no official or widely accepted industry estimates of the size of the medical cannabis industry in either revenue or quantity terms. AIC estimated that there is about $2 billion of total annual sales revenue (not including sales taxes collected) in the medical cannabis segment.

We developed that $2 billion revenue estimate as follows: The California Board of Equalization has estimated sales tax revenue from medical cannabis dispensaries was almost $60 million in 2015. No full year data were available for 2016. The statewide average tax rate is about 8.8% and that the rate of tax compliance was estimated at about one third. Using an effective tax rate of about 0.03 (0.088 times 0.34), $60 million in sales tax receipts implies industry revenue

of about $2 billion. Although an approximation, this estimate is in the range of other published estimates. (For more detail, see discussion and tables in Appendix Chapter 5).

Using data from the AIC survey, we observed the November 2016 market price of retail medical cannabis in California to be $3,453 per flower-equivalent pound. By flower-equivalent pound, we simply mean a unit of cannabis sold at retail that is equivalent to one pound of dried flowers for medical dispensary sales. More specifically, the data from the AIC survey (Appendix Chapter 4) provided information on a variety of prices from a sample of more than 500 dispensaries from many regions of the state. AIC collected data on prices of two package sizes for dried flowers and on prices of non-flower products. Unfortunately, no product quantities were available. AIC therefore used auxiliary information from interviews with industry participants and industry publications to develop weighted averages of product prices. AIC focused on the cannabis dried flower prices to create a flower-equivalent average price.

With the price of $3,453 per pound, the California medical dispensary sales revenue of about $2 billion implied a retail quantity of flower-equivalent units of approximately 583,000 pounds of medical cannabis sales on an annual basis.

AIC estimated that in November 2016, about 25% of total cannabis by volume (i.e. flower-equivalent pounds) that was sold in California was sold in the legal medical segment, and the remaining 75% was sold in the illegal segment. This estimate is based on the literature reviewed in Appendix Chapter 5 and interviews with industry participants. We estimate that as of November 2016, aggregate annual sales in the medical segment were $2 billion per year, sales in the illegal segment were $5.7 billion, and total cannabis industry sales were $7.7 billion.

5. Baseline market conditions after taxation and adult-use legalization

For about two decades, the only cannabis legally available for sale in California has been medical cannabis, which, according to the Brown Guidelines, can be sold only to California state residents over the age of 18 with doctors' recommendations and for the use of those between ages 12 and 18 with parental guidance. In 2016, a doctor's recommendation has been relatively easy to acquire, and receiving a recommendation has not required an in-person medical examination. Under the requirements of MCRSA, an in-person examination will be required. The general consensus of industry observers is that most consumers over the age of 21 in the medical cannabis segment could readily shift to the adult-use segment which would not require the added costly step of obtaining a doctor's recommendation.

In some other states, the recent institution of the adult-use system has altered the trajectory of the previously existing market for medical cannabis. Revenues for medical cannabis in Washington State, for instance, fell by one-third in the first year after the legal adult-use cannabis system took effect, and by more subsequently. See Appendix Chapter 10 for details and references to comparative literature.

In California, buying in the medical segment will have no clear advantage over buying in the adult-use segment, with a few exceptions. Remaining buyers in the medical segment include buyers who are under 21, buyers for whom a medical dispensary is more convenient, and buyers for whom a medical recommendation is important to their personal acceptance of cannabis use (say, for personal values, family relationships, or job rules). Some high-volume buyers may find the legislated sales-tax exemption to be cost effective; however, eligibility requires obtaining a state-authorized identification card, which we estimate will cost about $100 per year.[135] Current state records indicate that relatively few medical cannabis buyers (less than 7,000 annually for the past few years) have obtained a state-authorized identification card.[136] The AIC analysis suggested that consumers who do not fit into one of the above exceptions could realize cost savings by switching from the medical segment to the adult-use segment, and we identified no economic constraints that might limit most consumers from switching.

There are also no apparent supply-chain advantages for the medical cannabis segment that might translate to lower consumer prices for medical cannabis relative to adult-use cannabis. Based on these and other reasons that are explained in greater detail in Appendix Chapters 5, 6, and 7, the AIC review of the evidence concluded that in the environment of 2018, California's medical cannabis segment will be much smaller than it was at the end of 2016.

AIC analysis indicated that the opening of the market for adult-use cannabis and associated taxation will cause demand and supply in the existing cannabis market to change in several important ways that are relevant to the impact of medical cannabis regulations. First we specify three demand-side effects, and then we explain major supply-side effects.

[135] https://www.boe.ca.gov/pdf/l481.pdf
[136] https://www.cdph.ca.gov/programs/MMP/Documents/MMPCounty%20Card%20Count%2012-16.pdf

5.1 Demand-side effects resulting from taxation and adult-use legalization

Demand effect (A): We estimated that 60% of current demand in the legal medical cannabis segment (the initial medical cannabis is 25% of total quantity in pounds, by assumption) will shift to the newly legal adult-use segment due to the lower annual transaction costs. Adult-use cannabis purchase does not require an annual doctor's recommendation, which is costly for buyers of medical cannabis. Costs are likely to be $50 to $100 or more per year plus the cost of time and inconvenience. Relevant costs include an in-person doctor visit, which is mandated by MCRSA. In our models, demand effect A is represented as a reduction in the demand in the legal medical segment and an increase of the same magnitude in the legal adult-use segment. This demand effect is described in more depth in Appendix Chapters 5 and 7.

Demand effect (B): We projected that when legally allowed, slightly more than half of the demand currently in the illegal adult-use segment will quickly move to the legal adult-use segment to avoid the inconvenience, stigma, and legal risks of buying from an unlicensed seller. Of course, legal sales in the adult-use segment are not allowed until 2018. In our models, the demand effect B is represented as a reduction in demand of the current illegal segment counteracted by an increase in the newly-legal adult-use segment by the same magnitude. This demand effect is described in more depth in Appendix Chapters 5 and 7.

Demand effect (C): The third demand-side effect of taxation and adult-use legalization is a growth in the aggregate consumer demand for legal cannabis among consumers who were not previously in the California cannabis market at all. AIC modeled this as an increase in the demand for legal adult-use cannabis by about 9.4% of total cannabis sold in the period before taxation and adult-use legalization. This percentage was calculated by assuming an increase of 25% in the adult-use segment due to the demand of new buyers (i.e., 0.09375=0.75 x 0.5 x 0.25). (Recall that the initial illegal quantity was assumed to be 75% of total cannabis sales, by flower-equivalent pounds, before taxation and adult-use legalization. We estimated that about half of this illegal share would now shift to the newly legal adult-use segment.)

We expect this demand increase for two reasons. The first is new demand created by the opening of the cannabis market to consumers in the state who have interest in the product but have avoided it until now. Some of these potential consumers did not want to get a medical cannabis recommendation when they had no medical condition that warranted use. Moreover, many potential consumers may have avoided the illegal market because of inconvenience, legal

risk, or unwillingness to participate in illegal drug activity because of moral concerns or social stigma.

The second component of the outward demand shift resulting from adult-use legalization is new demand created by the opening of the cannabis market to California's out-of-state leisure and business visitors. There are more than 260 million visits to California from residents of other places per year. These visitors spend more than $122 billion in California.[137] A significant portion of this spending is on leisure goods and services. For instance, tourists have been estimated to spend $7.2 billion per year on wine in California.[138] Demand for new forms of leisure spending by tourists and other visitors to California is potentially large. Given that adult-use cannabis remains illegal in most other states, California's legalized adult-use industry may attract some new visitors whose primary reason for visiting the state is cannabis tourism, as has been observed in Colorado. This effect is discussed in the context of tourism survey data from Colorado in Appendix Chapter 10 and modeled in Appendix Chapter 7.

5.2 Cost reduction effects resulting from taxation and adult-use legalization

As cannabis is moved more into the mainstream of the economy through legalization of adult-use cannabis, suppliers have better access to capital, technology and management. With legalization of adult-use cannabis, sellers have a lower chance of loss from forfeiture and lower probabilities of criminal prosecution. Recent data have shown that the cannabis industry has unusually high costs compared production and marketing other agricultural products, and that many of these costs, including risk premiums, can be attributed to the illegality of adult-use cannabis sales prior to November 2016. This is reflected in the large differences (large compared with non-cannabis industry norms) that AIC and other industry observers have documented between costs per unit reported by businesses and receipts per unit at each stage in production, processing, distribution, and retailing of both medical and illegal cannabis.

AIC anticipates that adult-use legalization will result in a 35% reduction in the costs of supplying formerly illegal cannabis, which in this scenario now becomes legal adult-use cannabis without state regulation. We assume a smaller 20% reduction in the costs of the medical cannabis when adult-use legalization occurs. The costs in the medical cannabis segment fall as the cannabis industry as a whole becomes more mainstream and more investment, better management and

[137] http://industry.visitcalifornia.com/Find-Research/California-Statistics-Trends/
[138] Estimates of California wine tourism at http://www.discovercaliforniawines.com/media-trade/statistics/.

improved practices are adopted throughout the supply chain. More information on these assumptions is found in Appendix Chapters 3 and 6, and are modeled in Chapter 7.

Finally, a new system of taxes accompanies adult-use legalization. The excise tax of 15% on retail revenue was added to the existing sales tax. The sales tax is about 8.8% for cannabis sales (7.5% state sales tax and a 1.3% average of local sales taxes that vary across the state). We assumed that the new $9.25 per ounce tax on cultivation in the legal segments was incorporated into the cost of raw materials. We assumed full compliance after taxation and adult-use legalization.

The changes in demand, costs, and taxes, as included in our simulation of the California cannabis market, can be summarized as follows. Once these market changes are incorporated, the legal, adult-use segment will have about 61.5% of the overall market as measured in pounds. The unregulated illegal segment will have about 29.5% of the overall market, and the legal medical cannabis segment will have about 9% of the overall market.

Our regulatory impact analysis used this hypothetical taxation-and-adult-use-legalization scenario of prices, quantities, and taxes as the baseline. We evaluated the impact of regulations relative to this baseline.

6. Overall market impact of the proposed regulations

AIC simulated the impacts of taxation and adult-use legalization in order to identify the expected economic effects of the proposed medical cannabis regulations. Controlling for taxation and adult-use legalization before inputting the regulatory impact factors into our simulations was necessary to isolate the economic impact of the proposed regulations from the impact of taxation and legalization of adult-use cannabis.

6.1 Drivers of economic impacts of proposed regulations

The economic effects of the proposed regulations on market aggregates derive from two sources: (1) the costs imposed on the industry by the regulations compared with the situation without regulations but with taxation and adult-use legalization, and (2) an increase in consumer willingness to pay for the regulated product compared with the situation without regulations but with taxation and adult-use legalization.

First, the regulations impose costs on the cannabis industry. Details about components of the industry costs of complying with the proposed regulations are described below in Section 12. In that section, compliance costs of the proposed regulations are compared with compliance costs of two alternatives: an alternative package of lower-cost options and an alternative package of higher-security and higher-cost options. Recall that the proposed package of regulations includes those that were specified in detail in the MCSRA. The costs of compliance, and the data and calculations underlying them, are discussed in more detail in Appendix Chapter 6.

Overall, we found that the proposed regulations (compared to no regulations) add approximately $520 per pound of marketable dried-flower equivalent in direct operating costs. Most of the addition to costs, about $400 per pound, is due to the added costs of cannabis testing. In addition to regulations that have direct quantifiable costs, we model proposed regulations, which are based directly on the MCRSA, to restrict vertical integration of dispensaries into distribution or transport, which is required under MCRSA. AIC approximated the costs of restrictions on vertical integration as an added cost equivalent to a 1% increase in costs relative to the situation without regulation but with taxation and adult-use legalization.

In the simulation models, AIC specified that the cost increase in the medical segment caused by the proposed regulations was approximately 16% of the initial value of $3,453 per flower-equivalent pound. This was calculated as $520/$3,453 plus the 1% for the vertical integration restrictions.

The adult-use regulations are expected to be similar to the regulations regarding medical cannabis, thus AIC expected regulatory costs to be similar for the adult-use segment. Price in the adult-use segment is estimated to be about 5% lower than the price in the medical segment. Therefore, the direct cost of regulations as percentage of the base was calculated as: $520/$3,280 = 16%. This percentage was applied in the AIC simulations because the limits on vertical integration are less restrictive in the adult-use cannabis segment (a 20% vs. 5% limit on ownership across multiple tiers).

The second source of economic effects of the proposed regulations is an increase in consumer willingness to pay for legal cannabis that has more security, traceability, labeling information, and intensive product testing. In the AIC simulation the increase in willingness to pay modeled as equivalent to an increase of 6% in demand compared with the situation without regulation but with taxation and adult-use legalization. We discuss increased willingness to pay for

government regulations on product traceability, testing and labeling with reference to some of the relevant literature in Appendix Chapters 5, 7, and 8.

6.2 Economic impacts on price, quantity, revenue and tax

Summary results for the medical cannabis segment are reported in Table 1. (Detailed estimates of market prices, quantities, revenues and taxes are reported in Appendix Chapter 8.) Column 1 lists variables of interest: cannabis price per pound, tax rate per pound, quantity in pounds, segment revenue and segment sales and excise taxes paid to governments. Column 2 presents simulated values for estimates of prices, quantities, revenues, and taxes for medical cannabis with adult-use legalization but without regulations. Note that the industry revenue (without including sales and excise taxes) is about $601 million and tax revenue is $143 million. Column 3 reports prices, quantities, revenues, and taxes with the proposed regulations imposed. In this column the market price is higher (because costs per unit rise with regulations) and the quantity is slightly lower than the corresponding estimates in column 2. In column 3, the revenue of the medical cannabis segment is $714 million and tax revenue is $170 million. Column 4 reports the effects of the regulations on the medical cannabis segment by subtracting column 2 from column 3. In column 3, price is higher by $551 per pound, quantity is lower by about 5,000 pounds, revenue is higher by $113 million and tax receipts are higher by $27 million than the baseline figures in column 2 which depict the scenario of taxation and adult-use legalization with no regulation.

Table 1. Impact of proposed regulations on prices, quantities, revenues, and taxes per pound for medical cannabis in California

Variable	*Baseline with taxation and adult-use legalization*	*After regulation imposed on the baseline*	*Difference: after regulation from the baseline*
Price per pound without tax	$2,556	$3,107	$551
Tax rate per pound	$608	$739	$131
Quantity, pounds	235,000	230,000	-5,000
Revenue without tax	$601 million	$714 million	$113 million

Tax revenue	$143 million	$170 million	$27 million

Source: Results derived from simulations of effects of taxation and adult-use legalization in the first step and then regulations imposed on that baseline. Pounds are dried-flower equivalent.

6.3 Summary of economy wide impacts of proposed regulations on the medical cannabis segment

The medical cannabis-specific effects summarized in Table 1 were introduced into a modified IMPLAN model in order to determine AIC estimates of economy-wide impacts. These economy-wide impacts are summarized in this section, with more discussion and comparisons provided in Appendix Chapter 9.

The IMPLAN database, which uses U.S. industry classifications, does not have cannabis industry categories. Therefore, to approximate the economy-wide impacts, AIC first specified industries that were as close a match as possible to the medical cannabis sectors required for the analysis. Then the economic ratios in these matching industries were modified based on available data for the corresponding cannabis sectors. For medical dispensaries, AIC modified some of the ratios in the retail drug store industry (IMPLAN industry 401) to better reflect shares of costs of goods sold. The allocation of industry revenue minus costs of goods sold to taxes and other costs was modified using data that were available from the AIC review of medical cannabis dispensary accounting costs, a process that is detailed in Appendix Chapter 3.

For medical cannabis distribution businesses, the IMPLAN wholesale trade industry was the closest match (industry 395). The main adjustment was for the ratio of price to distributors minus costs of goods sold to better fit AIC data on medical cannabis costs. Note that the dollar value of output for retail and wholesale industries in IMPLAN is based on the difference of price minus cost of goods sold times quantity in the sector. That is, these companies are assumed to provide output in terms of wholesale or retail services added to the cost of goods that pass through the industry.

The information on the IMPLAN courier services industry was the closest match to the medical cannabis transport sector. No data were available to modify the IMPLAN ratios for this sector. The closest IMPLAN match for laboratory testing of medical cannabis was medical and diagnostic laboratories. No data were available to adjust the economic ratios for that sector.

As noted, AIC calculations in the IMPLAN analysis were based on the simulation model results for market prices and quantities (presented in Table 1). The model input included detailed data on costs of regulations, which were especially important for the testing sector. The IMPLAN results are presented at the change in the value of output, value added, and jobs compared to the baseline situation with adult-use cannabis legalization but without the proposed regulations.

Based on the IMPLAN simulations, in the dispensary sector, the output in the sector (measured by revenue above costs of goods sold) rises compared to the no-regulations baseline by $43 million, value added rises by $34 million, labor income rises by $18.5 million, and direct jobs rises by 456 jobs. After considering multiplier impacts, the California economy-wide value added rises by $54 million, and 655 added jobs may be attributed to the increase in dispensary value of output. In the distribution sector, margin rises by $12.5 million and number of direct jobs rises by 60. The total number of jobs in California attributable to distribution rise by 136. Transport revenue changes very little, because quantity shipped falls slightly, but value of shipments rises. Jobs change very little in the transport sector.

Under the regulations, the expanded laboratory testing sector is subject to significant new economic activity. Revenue rises by $90 million; direct value added rises by $61 million; and the number of jobs in the sector rises by 713. Economy-wide value added attributable to the testing expansion rises by $119 million, and the number of jobs economy-wide rises by 1,290. Overall, the economy adds 1,223 jobs in the medical cannabis sectors. Overall, jobs in California rises by 2,071 jobs.

These impacts are expected to be distributed geographically across California roughly in proportion with populations. Some evidence (discussed in Appendix Section 5.4) suggests that cannabis use is particularly prevalent among young adults. Thus there may be some concentration of dispensaries and resulting multiplier effects in locations with more young people, including urban centers.

6.4 Comparison of regulated scenario with 2016 scenario

Based on our comprehensive review of industry information and especially data and assessments from California tax authorities that we detailed in the appendix to the SRIA, we estimated that medical cannabis sales were about $2 billion (retail value) in the fall of 2016 (on an annual basis). The AIC survey of medical cannabis dispensaries across a wide range of

locations in California found a representative retail price of about $3,450 per pound. Hence, the implied quantity of medical cannabis is about 580,000 pounds on an annual basis before taxation and legalization.

The regulation scenario presented in Table 1 of this SRIA indicates 230,000 pounds at a price without tax of about $3107 per pound and tax of about $739 per pound.

When regulations are placed on top of taxation and legalization of adult-use, the quantity of medical cannabis is projected to be about 60% smaller than the quantity in the fall of 2016. The price including state taxes is projected to be about 11.4% higher than the price in the fall of 2016 and the price excluding taxes is projected to be about 10% lower than the price in the fall of 2016.

The economy-wide impacts of the proposed regulations summarized in this SRIA are largely based on the increased revenues from higher prices under the regulated scenario compared to the baseline that included taxation and legalization of adult use cannabis. However, annual revenue under the proposed regulation is projected to be about $883 million or about 56% lower than the annual revenue of $2 billion in the 2016 situation. We expect the economy-wide contributions of medical cannabis to be commensurately lower compared to the earlier economic situation of the industry. As noted in this SRIA, we expect most of the shift of consumption away from medical cannabis to be associated with a shift into adult use cannabis as sales in that segment become legal and regulated.

7. Assessment of whether the proposed regulations meet the "major regulation" standard in Government Code § 11342.548

After performing the analyses described above, we have determined that the total economic impact of the proposed regulations exceeds the one-year $50 million minimum economic impact threshold, as measured by costs or benefits, that is required for the proposed regulations to meet the standard for a "major regulation" for the purposes of Government Code § 11342.548.

As noted, this SRIA calculated the impact of a package of regulations by comparing the economic outcome in the market situation without regulations in place against the economic outcome in the situation with the proposed regulations in place, all other things being equal (here, including, especially, the assumption that taxation and adult-use legalization applies

either way). Using this definition of impact, we calculated the effect on medical cannabis segment revenue as $113 million per year. We calculated that consumer expenditure rose by $140 million (because of the tax component); see Table 1 above for details.[139] We also note that the impact applies to the market after some initial short-term dislocations in the market are settled. The short period just after implementation of taxation and adult-use legalization and the proposed regulations may have even more economic impact on the industry if the cannabis market is in a state of flux temporarily.

Measured benefits of the proposed regulations to buyers are reflected in their higher willingness to pay per pound of medical cannabis with the proposed regulations in place. Note that quantity falls very little with substantially higher prices, and therefore consumer expenditures (dispensary revenue) rise significantly when industry per-unit costs rise.

The direct economic impacts on the medical cannabis segment do not include multiplier impacts, as changes in the medical cannabis segment ripple through the rest of the economy. Once the ripple effects are taken into account, the economy-wide economic impact would be even greater. Either way, the estimates of costs or benefits are sufficient to meet the "major regulation" standard in Government Code § 11342.548.

8. Determination of the impact of the regulatory proposal on the state economy, businesses, and the public welfare (Government Code § 11346.3(c))

In Government Code § 11346.3(c), the markers to be used in assessing the economic impact of the proposed regulations in a SRIA are the following:

(1) The creation or elimination of jobs in the state;

(2) The creation of new businesses or the elimination of existing businesses in the state;

(3) The competitive advantages or disadvantages for businesses currently doing business in the state;

(4) The increase or decrease of investment in the state;

[139] An alternative, narrower method of calculating the impact of the proposed regulations in isolation would be to compare the economic outcome in the situation with a set of minimum statutory requirements against the economic outcome in the situation with the proposed regulations. That would require determining precisely the statutory minimum package of regulations and conducting a simulation of costs and benefits under a counter-factual baseline assuming those regulations applied.

(5) The incentives for innovation in products, materials, or processes; and

(6) The benefits of the proposed regulations, including, but not limited to, benefits to the health, safety, and welfare of California residents, worker safety, environment and quality of life, and any other benefits identified by the agency.

Quantitative estimates in this section were based where possible on the IMPLAN projections of economy-wide impacts presented in Section 6.

Assessment 8.1. ***The creation or elimination of jobs in the state***

As noted in Section 6, the proposed regulations will increase jobs by an estimated 456 jobs in California's medical cannabis dispensaries. The total effect on jobs in the dispensary sector, including ripple effects, is an increase of 655 jobs.

The other major increase in jobs is in the medical cannabis laboratory testing sector. The IMPLAN results based on the AIC simulations project that the proposed regulations will create 713 new jobs directly and 1,290 new jobs when multiplier impacts are included. In the distribution sector of the medical cannabis segment, the IMPLAN results based on the AIC simulations project that the proposed regulations will create 60 new jobs directly and 136 new jobs in total when multiplier impacts are included. In the transport sector of the medical cannabis segment, the IMPLAN results based on the AIC simulations project that the proposed regulations will cause a loss of 6 jobs directly and a loss of 10 jobs when multiplier impacts are included.

Overall, we found 1,223 more jobs in the medical cannabis segment due to the proposed regulations, and 2,071 jobs added in California after including multiplier effects.

We expect these jobs to move, likely to urban areas, especially for laboratory testing, and in places where cannabis consumption is more prevalent.

Assessment 8.2. ***The creation of new businesses or the elimination of existing businesses in the state***

AIC analysis of available data indicates that, on average, medical dispensaries sell about 600 pounds of cannabis each. If the total number of pounds sold declines by about 5,000 pounds as indicated in Table 1, this would imply about eight fewer medical dispensaries state-wide due to

the proposed regulations if average size of dispensaries did not change. Of course, with significant new regulations there may be existing businesses that find their operations less suited to the regulatory environment and other businesses that may enter to replace some existing businesses that exit.

Both creation and elimination of businesses is a natural occurrence for any significant change to the business conditions. Regulations related to license holder characteristics may cause some business to leave the segment because the current business owners find it difficult to meet requirements. Exits from the industry will generally be accompanied by other business entering or current businesses expanding.

Table 1 and the discussion in Section 6 indicate a large increase in the size of the medical cannabis laboratory testing sector. Table 1 reported that about 230,000 pounds per year were projected to be sold in the medical segment after taxation and adult-use legalization, and testing costs (and associated revenue for testing businesses) in the medical segment alone were projected to be about $92 million. Assuming that each laboratory tests almost 12,000 pounds annually, and thus has revenue of almost $5 million, these figures imply about 20 laboratory testing businesses in the medical segment.

Information from industry sources indicates that as of November 2016, there are two to four medical cannabis testing laboratories currently operating in California that are equipped with the type of wet-lab facilities that would be necessary to conduct the required pesticide tests. Therefore, most testing businesses will be new businesses generated by the proposed regulations. These businesses are expected to be located near distribution centers and spread across the state in major centers of medical dispensary sales.

MCRSA requires that the distribution function be separated from the cultivation and dispensary functions, and the proposed regulations reflect this requirement. There is a large geographic spread of urban centers and rural areas with significant numbers of dispensaries around the state. We assumed that distribution businesses could realize cost advantages by locating near clusters of dispensaries. We therefore estimated that the proposed regulations will create about 40 medical cannabis distribution businesses across the state, assuming about 5,800 pounds distributed per distribution business per year. No data were available to estimate the number of distribution businesses that would be created with adult-use legalization, but without a regulatory requirement for separate distribution businesses. We therefore assume that most of the new distribution businesses will be generated by the proposed regulations, and not by adult-use legalization.

We anticipate that most transporter license holders will be affiliated with other licensed businesses. These may be cultivators, manufacturers or distributors for transport to distributors and may be distributors for transport to dispensaries. With an economically efficient system, we assumed that the full cost of distribution through the system would be no higher and might be lower under the new regulations relative to the pre-regulation system. There will be efficiencies from using a hub and spoke system that goes through the required distribution businesses in a market with many small cultivators and many small retailers. There will be an additional step in the system with the addition of the distributor level. However, if the distributor is also the transporter, the distributor should experience lower transportation costs because of the distributor's increased volume, the ability to transport numerous products from different cultivators to the same dispensary, and the ability to transport to many dispensaries on the same delivery route.

Based on the reasoning and evidence, we project few, if any, separate transport businesses. The distributor license holders can easily subsume the transportation function. However, a few specialized transport businesses, separate from the distribution businesses could develop. This would result in the creation of new businesses. These businesses would coordinate with, but be distinct businesses from the distributor business. Such transportation companies could specialize, for example, in moving cannabis from cultivators to manufacturers or distributors, or moving samples to the testing laboratories. Additionally, a few small, local, or specialized transport businesses could be created in local areas or for specific products not well served by transporters who also hold distribution licenses. These smaller businesses may not transport high volumes or handle a large share of total value, there may be the creation of new transport businesses.

Assessment 8.3. ***The competitive advantages or disadvantages for businesses currently doing business in the state***

AIC analysis indicates some advantages for businesses currently doing business in California. Recall that this SRIA shows estimates of the impacts of medical cannabis regulations imposed upon the cannabis industry relative to the baseline with taxation and adult-use legalization in effect. To be relevant, this sub-section therefore discusses competitive advantages and disadvantages relative to the counter-factual baseline, not relative to the current situation. Here, as elsewhere, we considered only the impact of the proposed regulations, with the baseline assumption that taxation and adult-use legalization are already in place.

The MCRSA limits vertical integration, and the proposed regulations of the medical cannabis

segment provide more detailed direction to implement those restrictions. Since many existing medical cannabis dispensaries are vertically integrated with upstream operations, this part of the proposed regulations will impose adjustments on the organizational structure of existing businesses. Such adjustments may affect the competitive advantage of some current dispensaries.

AIC simulations did not include any results about the characteristics of businesses that may benefit or not from restrictions on vertical integration, and specifically, we have no quantitative information on how such restrictions may affect businesses currently in the industry relative to new entrants. Vertical restrictions will weaken the competitiveness of businesses that now rely on integration upstream or downstream. For example, dispensaries with business linkages with cultivators that would have to change under the proposed regulations may lose that competitive advantage. In general, the requirement that medical cannabis be transported to a distribution business before it is sent to a dispensary changes current practices and may adversely impact the competitive advantages of some current businesses.

The MCRSA requires that current companies that own or operate both dispensaries and testing labs either divest of one of the operations or set up new legal structures. This reduces the competitive advantages to some businesses currently doing business in the state.

We expect that some businesses will adjust to the proposed regulations relatively easily, and that others will find adjustment too costly and will leave the industry. (Recall that during the time of the initial implementation of these rules, volume in the medical cannabis segment is likely to fall substantially, so significant exit from the industry is likely in any case.) Given the nature of the adjustment costs, we expect larger businesses with strong management personnel and access to the capital and legal services necessary to meet the new regulatory standards, to adjust more readily, and thus to have a competitive advantage over new entrants. We expect that the existing businesses without these qualities, however, will be placed at a competitive disadvantage.

Sections 6 and 8 documented a large increase in economic activity including revenue and jobs in medical cannabis laboratory testing. Subsection 8.2 projected several new laboratory testing businesses. AIC discussions with industry sources indicated that medical cannabis testing laboratories as they currently operate in California would not be fully compliant with the proposed regulations. The existing business would need to make adjustments to comply.

Current medical cannabis laboratory testing businesses have two competitive advantages. First,

they already operate in what is likely to be an expanding sector. Second, their applications for licenses have priority under the statutory requirements of MCRSA. Existing labs' main disadvantage is that their services will require upgrading to meet proposed regulations, which is costly and time-consuming. (See Appendix Chapter 6 for details, and see Appendix Chapter 10 for a discussion of laboratory testing concerns and dislocations experienced in other states.)

Most medical cannabis distribution and transportation operations are currently integrated with upstream or downstream businesses. Thus, there are few current distinct businesses in these sectors that are advantaged or disadvantaged.

Assessment 8.4. ***The increase or decrease of investment in the state***

We estimated that the regulations will increase investment in California medical cannabis businesses relative to the baseline. As noted, medical cannabis revenue will rise by about $113 million from the adult-use-legalization base, and this added revenue would be accompanied by investment. Some additional investment (for example in security equipment) in the distribution business sector would likely follow from proposed regulations. Most dispensaries would make additional investments to comply with the proposed regulations in that industry sector as well. Additional transport investment will likely be made mostly by business in the other business sectors that we anticipate would conduct most of the transporting.

As documented in Sections 6 and 8, many of the added costs of the proposed regulations are associated with laboratory testing. In order to generate about $92 million in annual revenue, the laboratory testing sector will require a substantial increase in investment in equipment.

Assessment 8.5. ***The incentives for innovation in products, materials, or processes***

MCRSA mandates that the proposed regulations include substantial new medical cannabis testing requirements. Information provided by government laboratory testing specialists and industry sources indicated that proposed regulations are likely to create incentives for innovations in testing procedures. For example, the proposed regulations create incentives for innovation to reduce costs for wet-lab testing machinery, perhaps including mobile testing laboratories. (More information on the testing requirements, incentives and potential innovations are provided in Appendix Chapter 6.) The proposed regulations create few direct incentives for innovations in the other business sectors, transport, distribution and dispensaries in the medical cannabis segment.

Assessment 8.6. ***The benefits of the proposed regulations, including, but not limited to,***

benefits to the health, safety, and welfare of California residents, worker safety, environment and quality of life, and any other benefits identified by the agency

8.6.1 Public safety benefits. The proposed regulations include a number of specific items related to public safety. These are discussed more fully in Section 12 and described in more detail in Appendix Chapters 6 and 12. In summary, video surveillance and archival requirements benefit public safety by improving the ability of licensing agencies to investigate bad actors, and by improving the ability of the bureau and other agencies to document violations, collect penalties, and enforce sanctions on unlawful operations. They may also benefit public safety insofar as they are able to help law enforcement apprehend criminals who are outside the jurisdiction of the bureau. These security measures apply to transport, testing, distribution, and dispensary sectors of the medical cannabis segment.

The proposed track-and-trace and other regulations that guard the integrity of the product as it makes its way through the supply chain benefit public safety by preventing the diversion of cannabis into the illegal market and becoming a source of income for criminal enterprises. We expect general safety benefits from careful regulation of an enterprise that has historically been linked with violent and harmful activity. In addition, we expect some deterrence of criminal activity due to the enhanced security measures from the proposed regulations. These benefits apply to security measures in the proposed regulations in all four industry sectors of the medical cannabis segment, including transport, distribution, testing and dispensing. AIC has not quantified these benefits.

8.6.2 Public health benefits. As noted, the MCRSA and the proposed regulations include requirements for laboratory testing of medical cannabis. The proposed regulations may benefit the public by protecting consumers against the possibility of purchasing contaminated cannabis that many consumers wish to avoid. As noted above, our simulation model assumed an increased willingness to pay for cannabis that has been regulated and tested. The assumption was that this willingness to pay for testing offsets the cost of the proposed regulations such that quantity sold in the medical market is little affected by regulatory costs.

By comparison, relevant examples are abundant in agriculture. USDA's regulation of meat and poultry production and FDA's regulation of American food manufacturers have been shown to increase willingness to pay in food markets. However, we do not anticipate a major shift of consumers from adult-use cannabis toward medical cannabis to result from consumers' higher valuation of cannabis that meets health and safety standards, because we anticipate that adult-use cannabis will be similarly regulated in ways that are relevant to consumer safety and the

protection of public health.

In addition to testing, proposed regulation concerning the track-and-trace system may provide additional security against contamination and therefore public health benefits. These proposed regulations apply to transporters, distribution businesses and dispensaries.

Appendix Chapter 6 provide more information on proposed regulations in this area. Appendix Chapter 8 contains discussion and references on demand effects of food safety and traceability regulations. Cannabis-specific scientific evidence on safe levels of potential contaminants is, however, incomplete.

8.6.3 Worker safety. The proposed regulations include measures that reduce the risk of crime, thereby enhancing worker safety while improving public safety.

8.6.4 Environmental and other quality-of-life benefits. AIC analysis did not quantify specific environmental or other quality of life benefits of the proposed regulations for the medical cannabis segment. Recall that the proposed regulations under consideration have very small impacts on the total quantity of cannabis produced or consumed in California. General quality of life benefits may occur in locations near to the regulated dispensaries because these licensed businesses will have more incentives to operate in ways conducive to good neighbor practices. With respect to environmental issues, some small additions to transport fuel use may follow from required transport to and from distribution businesses and to testing facilities. There may also be environmental or quality of life benefits in neighborhoods where licensed dispensaries are located as they comply with security and related regulations and have an incentive to minimize environmental impacts that might be attributable to them. We expect that any such environmental impacts are likely to be relatively small. More significant environmental impacts may follow from regulations of the cultivation industry, which have been investigated in the context of those proposed regulations.

9. Benefits of the proposed regulations, expressed in monetary terms to the extent feasible and appropriate

Section 6 above described the overall economic impact of the regulations and highlighted perceived benefits of regulations to consumers in terms of higher willingness to pay per flower-equivalent pound of cannabis. As shown in Table 1 in Section 6, with only a 2% reduction in aggregate quantity, medical cannabis consumers are willing to pay approximately $113 million per year ($551 per pound) for benefits derived from the proposed regulations. This monetary

value indicates that consumers draw quantifiable benefits from the regulations.

These figures state the impacts within a single year after the proposed regulations take effect. For a longer time horizon—for example for the lifetime of the regulation—the impact would be far larger. Using a discount rate of 5% and assuming these benefits continue indefinitely, the present value of the sum of discounted benefits accrued into future years is given by: $113 million/0.05 = $2.23 billion.

10. Types of costs considered for implementation of the proposed regulations

The costs to the industry necessary to comply with the proposed regulations comprise the most immediate, first-order costs. These costs are provided in detail below where we discuss regulatory alternatives in Section 12. Added costs include additional product testing, safety, and security measures that are discussed in Sections 6, 8 and 12. Fees to support the regulatory program compose a relatively small share of the whole.

AIC projected that the proposed regulations would have very small effects on the quantity of medical cannabis consumed (Table 1). Therefore, any social costs associated with the changes in the use of cannabis from proposed regulations would be small.

11. Effects on the General Fund, special state funds, and affected local government agencies attributable to the proposed regulations

As shown in Section 6, the proposed regulations increase sales revenue of dispensaries. Since tax receipts are calculated as about 23.8% of dispensary sales revenue, the proposed regulations indirectly cause tax receipts to rise. AIC simulations project that the proposed regulations will increase sales tax and excise tax receipts by about $27 million. Most of the projected additional tax receipts ($17 million) was derived from the 15% excise tax that is scheduled to apply to medical cannabis starting in 2018. The existing 7.5% state sales tax would generate an additional $8.5 million in tax receipts for the state. The final $1.5 million in sales tax receipts is attributable to local sales taxes.

Local jurisdictions may also levy taxes or fees on medical cannabis. No data were available on local taxes and fees for medical cannabis, or on whether tax or fee rates are expected to change in response to state regulations. If these fees are based on cannabis quantities transacted or on the number of dispensaries, the additional receipts would be expected to decline slightly

because AIC simulation projected a slight 2% decline in quantities of medical cannabis sold. If local taxes or fees are based on medical cannabis revenue, then local tax receipts would be expected to rise in proportion to medical cannabis revenue, which AIC simulations projected to rise by about 19% due to the proposed medical cannabis regulations.

To estimate economic and fiscal impacts of proposed regulations requires estimates of costs licenses caused by proposed regulations. We develop an estimated licensing cost per pound was calculated because the economic modeling was developed on a per pound basis. The licensing fees discussed in this paragraph are calculated as an average of full license fees on a per pound basis. These total costs do not represent the actual licensing fees per business operation that will be required by the bureau. Fees for licenses were calculated to match the bureau's expected total operating costs including costs associated with the medical cannabis segment and the adult-use cannabis segment. These cost estimates also include the cost to the licensee of operating the track and trace system. The license fees (including all license types) were calculated to be about $20 per pound. Applying this rate of fees per pound to the quantity of 230,000 pounds of medical cannabis (estimated as the market size in the situation with regulations applied) yields the total fee receipts of $4.6 million.

Many cities and counties in California are in various stages of developing and implementing regulations, taxes and fees for medical cannabis and adult use cannabis sold in their jurisdictions. The taxes and fees will generate local revenue and expenditures. We note that developing local regulations and fees are quite different around the state, not available in summarized form and have yet to be determined for 2018. These range from a straightforward 15% tax on both medical and adult use cannabis sales (Hayward and Alameda Counties) to licenses fees and taxes that are higher for adult use cannabis that for medical cannabis. For example, we have seen proposed retail taxes that range from zero to 15% for medical cannabis. For the purposes of this SRIA, there is an assumption that local regulatory costs will be low enough that companies will choose to comply.

An average local tax rate of 5% would generate $44 million in local revenue based on our estimated total industry size of $884 million (inclusive of state taxes). License fees for dispensaries would add additional revenues as they do under some current local laws. Local revenues and expenses may be affected by the proposed state medical cannabis regulations. Relative to taxation and legalization baseline without the effects of the proposed regulations, the regulations are expected to increase local tax revenue by $7 million statewide, using an assumed 5% average local tax rate.

Local regulations, taxes and fees may also affect the balance between medical, adult use and illegal sales of cannabis and thus interact with the proposed state regulations. Some jurisdictions are considering permitting local sales of medical cannabis, but not adult use. If large local impediments or costs are imposed on legal cannabis, there may be a reduction in the overall legal sales relative to illegal sales. Similarly, if medical cannabis sales receive favorable local treatment relative to adult use cannabis, medical sales could remain larger than our model anticipates. An important caveat to the importance of local impediments for statewide aggregate impacts is that consumers could as they do now; avoid purchasing in unfavorable local areas. For example, areas of the state that do not allow local medical cannabis dispensaries are served by delivery dispensaries located nearby. Thus, statewide impacts are likely to be significantly smaller than without such adjustments. Overall, for medical cannabis sales, we see relatively little impact on aggregate measures from local impediments some of which may increase (from what they would otherwise be) the size of medical sales relative to adult use sales.

12. Evaluation of two reasonable alternatives to the proposed regulations

This section introduces and provides analysis of two alternative regulations: a lower-cost package and a higher-security package of regulations. This section compares these alternatives relative to the proposed regulations. Summary description is provided in Table 2. Next, we assess the costs for each alternative and provide the summary costs in Table 3 for each of these alternatives and the proposed regulations. (Detailed calculations of the costs of the package of proposed regulations and the two alternative packages of regulations can be found in the Appendix Chapter 6.) Finally, simulations of economic impacts with the two alternative packages of regulations are compared to the proposed regulations.

12.1 Alternatives summarized

The two alternative sets of regulations can be compared to the proposed regulations in terms of three features of the packages, which are summarized in Table 2.

Table 2. Proposed regulations and two alternative regulatory packages			
Category	***Lower-cost alternative***	***Proposed regulations***	***Higher-security alternative***
1. Testing regulations	• No maximum batch size	• 10-lb maximum batch size	• 5-lb maximum batch size
2. Delivery methods	• E-bikes allowed • one employee can make deliveries alone	• Cars only • one employee can make deliveries alone	• Cars only • Deliveries must be made by two or more
3. Security-video archival requirements	• No requirements	• 1280 x 1024, 20 fps*, 30 days archive	• 1280 x 1024, 20 fps, 90 days archive

* The term "1280x1024" indicates pixel resolution; the term "20 fps" indicates frames per second of recorded video; term "30 days archive" indicates length of time the business is required to store video, as calculated according to Seagate.com surveillance video storage guidelines and Amazon.com cloud storage rates; see Appendix Chapter 6 for detailed cost calculations.

12.1.1 Testing. The lower-cost alternative assumes an array of contaminant, pesticide, and other tests that together is estimated to cost $1,000 per test, according to California Department of Public Health (CDPH) estimates. The proposed regulations impose contamination and pesticide tests that raise the cost to approximately $1,200 to $1,500 per test, according to CDPH. We used $1,350 per test, the midpoint in this range.

Maximum testing batch size also affects the cost of testing per pound of medical cannabis sold, especially for businesses capable of producing large batches for testing. There is no requirement in MCRSA regarding batch size. Therefore, the batch size for the lower-cost alternative is no maximum batch size. We estimate that the cost impact of the lower-cost regulations would be approximately $177 per pound.

The proposed testing regulations institute a more stringent set of pesticide tests than those in the lower-cost alternative and establish a 10-pound maximum batch size for testing. These requirements raise the cost of medical cannabis by $407 per pound, or $230 more per pound than the lower-cost alternative.

The higher-security alternative, which keeps the same set of tests in place but lowers the maximum batch size to five pounds, raises the estimated testing cost per pound of medical cannabis to $624. This is approximately $217 per pound more than the proposed regulations (10-lb maximum batch size). A smaller batch size may allow for more accurate testing. (More on testing and background on cost estimates is included in the Appendix Chapter 6.)

12.1.2 Delivery methods. Retail medical cannabis deliveries are typically done by car. However, some urban dispensaries make deliveries on foot, bicycle, electronic bicycle (e-bike), or scooter at a significant cost savings. The proposed regulations prohibit on-foot, bicycle, e-bike, or scooter deliveries.

The lower-cost alternative places no regulatory restrictions on delivery methods. Delivery costs currently add approximately $150 per pound to the average cost of medical cannabis. This estimate relies on the AIC price survey data that 40% of medical cannabis is transferred to consumers via delivery services. (See Appendix Chapter 4 for details on that estimation.) Allowing the lower-cost delivery methods lowers the average cost of medical cannabis in the state by approximately $25 per pound compared with the proposed regulations.

Unenclosed vehicles do not allow as much security as enclosed vehicles. Attaching a lock-box to a person would be impossible, and attaching a lock-box to a bicycle, e-bike, or scooter would likely be impractical. With these delivery vehicles allowed, the security objectives of the proposed lock-box regulatory provisions would be ineffective at the delivery stage, increasing the potential for criminal activity in neighborhoods surrounding dispensaries.

A higher-security alternative is to require two employees to be in each delivery vehicle (one driver and one delivery representative), which would enable one employee to be with the medical cannabis inventory at all times. This would provide an additional level of security. The additional labor costs that would result from the higher-security alternative would increase the cost of medical cannabis by approximately $105 per pound relative to the proposed regulations. (Appendix Chapter 6 provides details on the calculations of delivery costs with lower-cost and higher-security alternatives.)

12.1.3 Security video archival requirements. The MCRSA does not contain specific security video or archival requirements. The proposed regulation includes the requirement that licensees other than transporters maintain security cameras with high enough quality for facial recognition (proposed to be 1280 x 1024 pixels at 20 frames per second) covering many areas of the inside of and entrances to the building, and to maintain 30-day video archive of footage from these cameras. The 30-day video archival requirement achieves the bureau's enforcement objectives as well as law enforcement objectives not directly related to the bureau's activities, but which have benefits to the public safety as discussed above.

We estimated that the average dispensary will require either five or six cameras to achieve coverage. We estimated the cost per pound of retail medical cannabis to rise by approximately $40 per pound compared with the lower-cost alternative, which requires no surveillance archive storage. A higher-security alternative would be to require footage to be maintained for 90 days. This would raise costs by $25 per pound above the proposed regulations. (Appendix Chapter 6 provides our interpretation of the video requirements.)

12.2 Simulation results for alternatives

We introduced the two alternative regulation packages into the simulation model that we used to analyze impacts of the proposed regulations. Recall that the proposed regulations were assumed to shift out demand by 6% compared to the baseline with taxation and adult-use legalization but without regulation. Likewise, each of the alternative regulations were also assumed to raise demand relative to the baseline. The lower-cost alternative was assumed to shift out demand by 4% relative to the baseline. The higher-security alternative was assumed to shift out demand by 6% relative to the baseline.

Next, we introduce the increase in costs. Recall that the proposed regulations raised costs by 16% relative to the baseline. The lower-cost alternative was calculated to raise costs by 6% compared with the baseline with taxation and adult-use legalization but without regulation. The high cost alternative was assumed to raise costs by 26% compared with the baseline with taxation and adult-use legalization but without regulation.

Table 3. Estimated compliance costs per pound of alternative regulatory packages			
Cost per pound dried-flower equivalent	***Lower- cost alternative***	***Proposed regulations***	***Higher-security alternative***
License fees[1]	$20	$20	$20
Distribution & transport compliance[2]	$3	$7	$9
Retail-delivery-method restrictions[3]	None	$25	$130
Dispensary compliance[2]	$25	$65	$90
Testing compliance[4]	$177	$407	$624
Total compliance costs per pound	**$225**	**$524**	**$873**

Notes: Numbers below $20 were rounded to the nearest $1. See Appendix Chapter 6 for details. Cost components do not add up exactly to total costs, because of rounding.

1. License fees per pound are calculated to cover the bureau's annual operating budget, which includes license fees for and costs of regulation of adult-use cannabis.

2. Not including dispensary delivery, which is covered in the row above, "retail-delivery-method restrictions." Proposed regulations require a 30-day surveillance video archive, quarantine, and laminated badges for employees. Higher-security alternative extends video archive requirement to 90 days.

3. Proposed regulations prohibit on-foot, bicycle, e-bike, or scooter deliveries. Higher-security alternative requires two employees to make a delivery.

4. The lower-cost testing regime is estimated to cost $1,000 per test, with no maximum batch size; we assume 10% failure rate and 15-pound average batch (equivalent to current market average). Testing in proposed regulations is estimated to cost $1,350 per test (to which we add $25 in additional handling costs), with a 10-pound maximum batch size; we assume 20% failure rate and 8-pound average batch. Higher-security alternative sets a 5-pound maximum batch size and assumes a 4-pound average batch.

The key results of simulations in the two alternative regulation packages are as follows. With the lower-cost alternative regulations, industry revenue is higher than the baseline by $71 million, and quantity sold is higher than the baseline by about 8,000 pounds.

With the higher-security alternative regulations, industry revenue is higher than the baseline by $105 million, but quantity is lower than the baseline by 30,000 pounds, or about 10%. The higher security option provides relatively little benefit as assessed by businesses and their customers, but imposes substantial extra costs. The implication is substantially smaller sales of medical cannabis (and more sales in the illegal markets) because the price is substantially higher. These results can be compared with AIC simulation results for the proposed regulations that were presented in Table 1. Industry revenue is higher than the baseline by $113 million, and quantity sold is lower than the baseline by 5,000 pounds. Note that under both alternative sets of regulations, the increase in industry revenue relative to the baseline is less than the increase in revenue under the proposed regulations. Detailed calculations underlying these conclusions are reported in Appendix Chapter 8.

13. Final remarks

This SRIA summarized the AIC economic analysis of proposed regulation of the medical cannabis segment in California. Specifically, the SRIA considered proposed regulations of transport, distribution, testing and dispensing in the medical cannabis segment. The proposed regulations were projected to impact economic costs or benefits to industry participants by more than $50 million within the first year after taking effect, compared with the baseline relevant to proposed implementation in January 2018. As discussed in some detail, the relevant baseline assumes taxation and adult-use legalization, but not the proposed regulations.

Among the most costly aspects of the proposed regulations is laboratory testing. However, the assessment presented in this SRIA was that such testing also is likely to raise willingness to pay for medical cannabis, and that benefits thus offset costs. The proposed regulations increase economic activity and jobs in the medical cannabis segment—especially in the laboratory testing part of that segment. The analysis also used a standard approach to assess economywide “multiplier” effects, and found that the added economic activity in the medical cannabis segment raises economic activity broadly in the state.

Economic Costs and Benefits of Proposed Regulations for the Implementation of the Medical Cannabis Regulation and Safety Act (MCRSA)

Report prepared as an appendix to a

Standardized Regulatory Impact Analysis

Prepared for the Bureau of Marijuana Control

in the California Department of Consumer Affairs

by the University of California Agricultural Issues Center

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Economic Costs and Benefits of Proposed Regulations for the Implementation

of the Medical Cannabis Regulation and Safety Act (MCRSA)

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Introduction

This report provides background research and documentation for a Standardized Regulatory Impact Analysis (SRIA) of proposed regulations related to medical cannabis. This report functions as an appendix to the SRIA, which provides an executive summary of methodology and results.

We begin by laying out the legal background related to the regulations under consideration and the requirements for a SRIA. This provides the specific context for the economic analysis to follow. Chapter 1 presents the context and authority, and Chapter 2 presents the statutory and regulatory history and situation.

Because cannabis is illegal under federal law, official data are scarce and incomplete. In Chapters 3 through 5, we provide data that provide a snapshot of the industry as it stood in November 2016. We provide background on costs (Chapter 3), prices (Chapter 4), quantities (Chapter 5), and demand characteristics (Chapter 5) from a variety of sources, including a survey of medical dispensaries. In Chapter 6, we provide data and analysis on the compliance costs of the proposed regulations and of two alternative packages of regulations: a lower-cost alternative and a higher-security alternative.

Chapter 7 is more technical and mathematical than the previous chapters. It lays out in detail the economics underlying the model we developed to simulate the impact of proposed regulations on the medical cannabis segment of the overall cannabis industry in California. The model proceeds in steps. We did not directly compare the impacts of the regulations with the November 2016 situation, because the legalization, regulation, and taxation of non-medical adult-use cannabis will be implemented alongside the regulation and taxation of medical cannabis in January 2018. Simply comparing the November 2016 situation with the January 2018 situation would yield impact calculations that included the effects of taxation and adult-use legalization, which are outside the scope of this SRIA. We thus used a taxation and adult-use legalization scenario as the baseline against which we analyzed the impacts of the proposed regulation. The construction of the baseline is explained in the SRIA itself, and Appendix Chapter 7 lists assumptions and parameters in detail.

Chapter 8 provides the detailed background assumptions for our simulation model and reports our simulation model results for the proposed regulations and the two alternatives. The impact is measured as the difference between the results with regulations in place and the results with

only taxation and adult-use legalization in place. Those results are presented in Table 8.2. Chapter 9 uses the results of Table 8.2 to derive economy-wide impacts of the proposed medical cannabis regulations. Again, the impacts on value added, labor income, and jobs are measured as differences from a taxation and adult-use legalization baseline.

The final sections of the report provide useful background information that helps document our modeling and parameter choices and data used in the analysis.

In sum, this report serves as a background appendix to the main SRIA. It contains material useful in understanding and interpreting the regulatory impact analysis provided in the SRIA.

1. Context and authority

1.1 Background legal setting

For the two decades since the 1996 passage of the Compassionate Use Act (Proposition 215), the ballot initiative that made California the first state in the United States to decriminalize the use of medical cannabis, California's medical cannabis industry has been operating under an inconsistently enforced patchwork of local ordinances, with little state-level oversight.

The Medical Cannabis Regulation and Safety Act (MCRSA), passed in 2015 as Assembly Bill 266, Assembly Bill 243, and Senate Bill 643, establishes a Bureau of Medical Cannabis Regulation, (Bureau), now known as the Bureau of Marijuana Control, within the California Department of Consumer Affairs (DCA). The Bureau is tasked with setting up and administering a licensing and enforcement system governing the distribution, transportation, testing, and retail sale of medical cannabis in California.

This Specialized Regulatory Impact Analysis (SRIA) was commissioned by the Bureau for the purpose of calculating the costs and benefits of the MCRSA-implementing regulations proposed by the Bureau, which are aimed at going into effect on January 1, 2018. This SRIA was prepared by the University of California Agricultural Issues Center (AIC).

In the California general election of November 8, 2016, California voters passed the ballot initiative known as Proposition 64, the Control, Tax and Regulate Adult Use of Marijuana Act (AUMA), which legalized adult-use cannabis in California. AUMA immediately eliminated criminal penalties for personal use, re-named the Bureau the Bureau of Marijuana Control,

established a new tax structure for medical and adult-use cannabis, and assigned the Bureau responsibility for also regulating California's adult-use cannabis industry.

The task of calculating the economic impact of the Bureau's proposed implementation of the medical cannabis regulations required by MCRSA now requires us to account for the economic implications of the legalization, regulation, and taxation of adult-use cannabis that will begin on January 1, 2018, the same date as the new regulations governing medical cannabis take effect.

This SRIA thus incorporates the expected impact of AUMA on the economic costs and benefits of the regulations proposed by the Bureau to implement MCRSA, but it does not include any specific analysis of the proposed regulations pertaining to AUMA.

1.2 Nature and scope of regulatory impacts considered

We analyze the medical segment of the cannabis industry in California in the context of the adult-use cannabis segment. The medical segment is so closely related to the adult-use segment that impacts of regulations must be considered in the broader context of all cannabis sold in California. After estimating economic effects within the medical cannabis segment, we use a standard economy-wide model to project ripple effects on the California economy more broadly.

At the heart of our analysis is an evaluation of the costs and benefits to (1) California businesses, (2) California consumers, and (3) the California state government of three possible sets of medical cannabis regulations, which we call "regulatory packages": (A) the regulations currently proposed by the Bureau; (B) an alternative package of regulations that would be less costly than the proposed regulations while still fulfilling the minimum statutory requirements of MCRSA; (C) an alternative package of regulations that would impose higher security standards than the proposed regulations.

To isolate the effects of the proposed regulations and alternatives from intervening factors that may also have major effects, we took into account other factors operating over the same time period that are also affecting the California market for cannabis. In this case, the major change to the California medical cannabis segment is the passage of the adult-use legalization ballot question (Proposition 64) in the California general election of November 8, 2016. That set of statutes, known as the Control, Tax and Regulate Adult Use of Marijuana Act (AUMA), established a new tax structure for medical and adult-use cannabis and assigned the Bureau

responsibility for regulating California's adult-use cannabis industry, as well as its medical cannabis industry.

To arrive at the economic calculations and simulations reported below, we proceeded in three steps. First, we assessed the current (fall 2016) situation for medical cannabis in California. Second, to establish a relevant baseline for the regulatory analysis, we assessed the impacts of legal sales of adult-use cannabis and taxation of all cannabis on the medical cannabis segment. This step provided us with the baseline upon which medical cannabis regulations were analyzed, and it allowed us to separately observe the effects of the two major changes to the medical cannabis segment that will occur. The third step was to calculate and simulate the impact of the proposed regulations and alternatives on the medical cannabis segment separately from the effects of taxation and adult-use legalization.

2. Statutory and regulatory background

2.1 Compassionate Use Act (1996)

The ballot initiative known as Proposition 215 made California the first state to decriminalize medical cannabis. In the 20 years since then, the state has played an extremely limited role in regulating medical cannabis. Legal guidelines coming from the state that has exerted influence on the behavior of medical cannabis businesses and patients have been largely limited to Senate Bill 420 (see Section 2.2) and the non-binding Brown Guidelines (see Section 2.3).

2.2 Senate Bill 420 (2003)

In 2003, the California Legislature passed Senate Bill 420, which added (section 11362.7 *et seq.* to the California Health and Safety Code relating to controlled substances. SB 420 established a basic framework for the legal operation of medical cannabis entities.

2.3 Brown Guidelines (2008)

In 2008, the laws regarding medical cannabis were clarified for operators of medical cannabis entities in an opinion issued by then-Attorney General Jerry Brown, an opinion many of the industry operators we spoke with cite as their canonical reference document on how to comply with California state law in the pre-regulation environment. Municipal and county ordinances generally concur with the Brown Guidelines but otherwise vary widely in their local regulation

and licensing approach, ranging from a total prohibition on the medical cannabis industry in some areas to robust ordinances in others (Mendocino, San Francisco, and Oakland, for instance) to a total lack of regulation in some rural areas.

2.4 Compliance with SB 420 and Brown Guidelines to date

Operators' degrees of compliance to SB 420 and the Brown Guidelines have been widely divergent. In the absence of an agency to supervise the state's medical cannabis businesses, these documents have generally served more as loose behavioral guidelines than as functioning rules.

Nonetheless, operators seem to have been consistent in their observance of the Brown Guidelines standards. Most currently operating dispensary storefronts require patients to submit the original hard copy of their physician's recommendation (which is checked against a database maintained by the prescribing physician's office), an original document verifying California residency, and a completed medical intake form before they can purchase medical cannabis or even enter the area of the store in which products are displayed.

In many cases, dispensary operators have cited local (rather than state) enforcement as their primary incentive to follow the Brown Guidelines. In other segments within the medical cannabis industry, on the other hand, the Brown Guidelines appear to have been less consistently observed amongst delivery services without fixed retail locations, and private, low-profile medical collectives who do not advertise their services to their public. Such businesses may not observe the medical recommendation or California state residency requirements, for instance, in spite of their participation in the legal medical cannabis segment.

2.5 Medical Cannabis Regulation and Safety Act (2015)

The MCRSA, which added Business and Professions Code sections 19300 through 19355 and Labor Code section 147.5, and Health and Safety Code sections 11357 through 11362,[140] introduced a new state-wide structure for the governance of the California medical cannabis industry as well as a system by which the state may collect licensing and enforcement fees and penalties from cannabis businesses.

[140] This is not intended to be a comprehensive list of all MCRSA provisions.

The Bureau shares responsibility for promulgating and enforcing regulations implementing MCRSA with the California Department of Public Health (CDPH), and the California Department of Food and Agriculture (CDFA) The responsibilities assigned to the Bureau include the issuance of licenses to and the collection of license and penalty fees from medical cannabis distributors, retail and delivery dispensaries, testing laboratories, and transporters.

The Bureau was initially funded with a $10,000,000 startup loan from the state General Fund, which is to be paid back with proceeds from licensing fees collected by the Bureau.

2.6 Adult Use of Marijuana Act (2016)

Although the scope of this SRIA is limited to evaluating the economic impact of the proposed regulations governing medical cannabis, the legalization of adult-use cannabis in California in November 2016 by Proposition 64 is likely to have a considerable material impact on the state's medical cannabis market.

This impact is likely to arise due to consumer substitution. In this SRIA, we rely on the working assumption that medical cannabis and adult-use cannabis[141] are to a large extent substitutable. This implies that businesses in these two parallel systems will thus compete for customer demand, and that the systems themselves will compete with each other for new entrants in the sense that entrants will weigh the pros and cons of each. That is, in the short run, prices in the adult-use cannabis segment will be likely to affect quantities transacted in the medical cannabis segment. If the price of adult-use cannabis is significantly lower than the price of medical cannabis, then consumers will be likely to demand less medical cannabis and more adult-use cannabis; if the price of medical cannabis is significantly lower, then consumers will be likely to do the opposite.

We must now make assumptions about economic behavior that are informed by the knowledge that regulations implementing AUMA and MCRSA will take effect simultaneously on January 1, 2018, and that the issuance of new licenses under both systems are also set to begin simultaneously.

The MCRSA framework imposes certain costs not found in the AUMA framework. For example, under MCRSA, a testing laboratory must contract with a third-party transport licensee to move

[141] In much of the literature, medical cannabis is referred to as "medical marijuana" and adult-use cannabis is referred to as "recreational marijuana."

product samples between licensees' premises and their own testing labs. This requirement is not in AUMA.

3. Background on operating costs for medical cannabis dispensaries

In fall 2016, through a series of confidential informal interviews and information requests guaranteeing respondents' anonymity, AIC assembled a set of hypothetical income statements from California medical cannabis dispensaries in four broad size categories constructed for the purpose of roughly representing the distribution of dispensaries of various sizes across the state.

We developed idealized estimates of itemized dispensary cost and revenue line-item averages for four different idealized representative dispensary sizes. Dispensaries were sorted into these four idealized categories based on their annual revenues. The model dispensary in the first category, which we call "micro," received approximately $1,000,000 in annual revenue from selling 290 flower-equivalent pounds (defined in Section 5.3.1), at the assumed retail price of $3,453 per pound (derived from AIC calculations from the AIC dispensary survey, whose details are found in Section 4).

The second idealized dispensary category, "small," averages $2.4 million in annual revenue and 695 flower-equivalent pounds sold per location. The third idealized category, "medium," averages $6 million in annual revenue and 1,738 flower-equivalent pounds sold per location. The fourth and largest idealized category, "large," averages $24 million in annual revenue and 6,950 flower-equivalent pounds sold per location.

Separating dispensaries into four categories was necessary to account for the considerable economies of scale in larger operations and arrive at a reasonable approximation of the business landscape in order to calculate the effects of regulations on costs per flower-equivalent pound of dispensing cannabis. In the interest of simplicity, we did not account for any possible retail price differences between dispensaries of different sizes.

3.1 Raw material costs

The single largest component of dispensary costs is the cost of raw materials (in this case, dried cannabis flower). Raw material costs are not the subject of our analysis but are important for understanding the industry cost structure. As of November 2016, US wholesale prices for dried

cannabis flower hovered with relative stability around 35% to 40% of retail price, based on the Cannabis Benchmarks data described and cited in Tables 3.1 and 3.2 and Figure 3.1. As of the end of November 2016, Cannabis Benchmarks set the weekly US spot wholesale price at $1,465 per pound of dried flower. This Cannabis Benchmarks index was down 28% for the year (in January 2016, it had stood at $2,032).[142]

At the end of November 2016, the Cannabis Benchmarks spot price for California dried flower was $1,332 per pound, or 38.6% of AIC's estimated retail price (calculated based on the results of our survey, as described in Section 4). Data-collection methodology employed by Cannabis Benchmarks favors more highly compliant and therefore slightly-more-expensive-than-average suppliers of raw material.

We also note that wholesale prices were falling throughout 2016, and that such surveys may be slightly delayed in tracking these changes. We assume that the true wholesale price per pound is $1,199, 10% lower than Cannabis Benchmarks' estimate of $1,332. Rounding this result, we used $1,200 as the raw material input price for our economic models. This wholesale price is 34.7% of our estimated retail price of $3,453, which is consistent with the observed national range of wholesale-to-retail price ratios.

Table 3.1. California wholesale price snapshot, November 2016

Cultivation method	***Low price***	***High price***	***Weighted average***
Outdoor	$1,150	$1,750	$1,423
Greenhouse	$1,275	$1,900	$1,437
Indoor	$949	$2,200	$1,447
Weighted average			**$1,439**

Source: Cannabis Benchmarks archive. December 16, 2016 data used to observe end-of-November prices, assuming two-week lag between market prices and Cannabis Benchmarks price data.

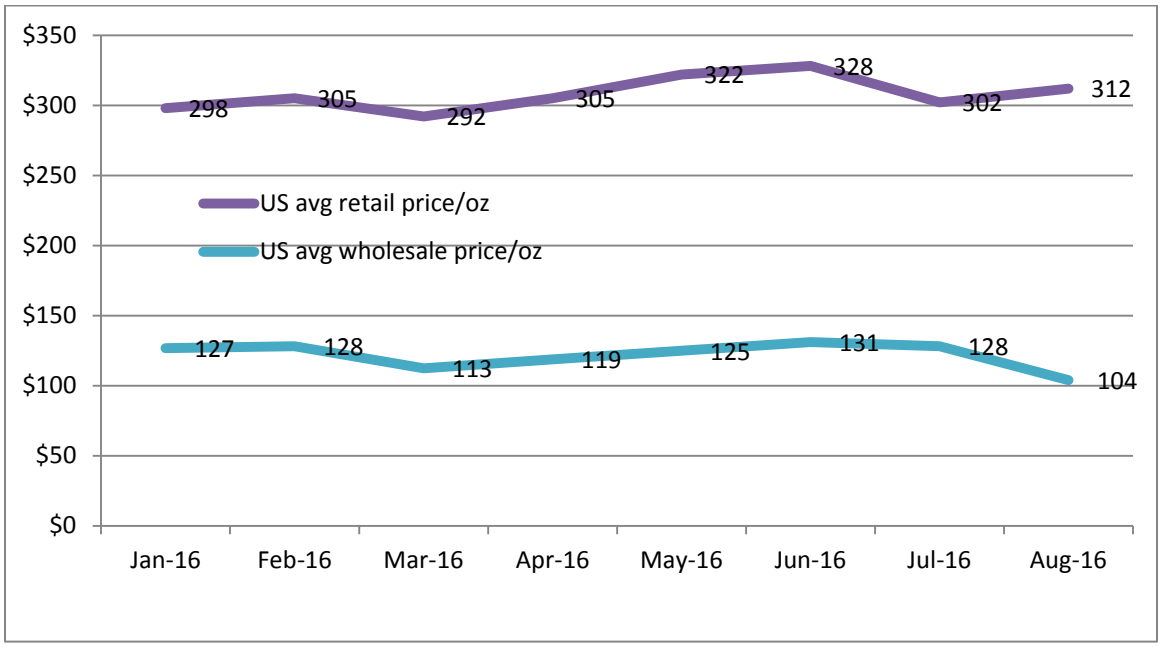
Table 3.2. Avg wholesale cost as percentage of retail price, first 8 months of 2016

	Jan-16	**Feb-16**	**Mar-16**	**Apr-16**	**May-16**	**Jun-16**	**Jul-16**	**Aug-16**
Wholesale costs	42%	42%	39%	39%	39%	40%	43%	33%

Source: Cannabis Benchmarks (2016); PerfectPrice.

[142] Throughout this SRIA, we assume a two-week lag between market prices and Cannabis Benchmarks price data. End-of-November prices are thus taken from the Cannabis Benchmarks reports of December 16, 2016.

Figure 3.1. Avg US retail and wholesale prices, one ounce dried flower, first 8 months of 2016



Source: Cannabis Benchmarks (2016); PerfectPrice.

Fluctuations of prices after November 2016 seem to have to been affected by the legalization of personal adult-use possession and reductions in penalties for non-medical sale.

3.2 Dispensary margins and risk-premium (illegal-operation) effects

The sale and possession of cannabis remains illegal under Federal law. Therefore, all owners and operators of cannabis businesses in California risk violating Federal law.

An economic situation in which industry participants are operating legally or partially legally with respect to state law and still fully illegal on a federal level presents many cost-related concerns. Atypical business risks (e.g., arrest, seizure of property) as well as atypical business challenges (e.g., the vagaries of local municipal law, denial of access to the banking system) face cannabis cultivators, intermediaries, and retailers compared with the farmers, intermediaries, and retailers of other agricultural products. Such risks drive up business costs across the board, especially labor costs. For example, workers willing to risk arrest expect to be rewarded with

premium wages. According to Krissman (2016), cannabis trimmers in California command a 200% wage premium over the market for agricultural labor.

Such extra business costs have a direct effect on consumer prices. The extra price paid by consumers for the products of industries with significant probability of losses is sometimes known in economics as the "risk premium." Sifaneck et al. (2007), for example, observed a street price of $50 to $80 for a one-eighth ounce of cannabis from a New York City delivery service in the mid-2000s in New York, where criminal restrictions for cannabis sale and possession were tightly enforced. Before adjusting for inflation, this is approximately double the median price for generic delivery-service medical cannabis in California.

Comparing the price of non-medical adult-use cannabis between countries demonstrates the workings of risk premiums more clearly. For instance, in Uruguay, where adult-use cannabis is decriminalized, the street price an ounce for medium-quality dried flower is about US$172. (Marijuana Travels, 2016). In Germany, where adult-use cannabis is illegal but possession laws are generally not enforced, and where medical cannabis is legal, the street price for medium-quality dried flower is about US$239 per ounce (Williams, 2016; Marijuana Travels, 2016). In China, where personal possession can land a first offender in prison for six months, the illegal-market price for one ounce of medium-quality dried flower is about $696 per ounce (Hill, 2015; Marijuana Travels, 2016). (We recognize that there are other legal and economic differences influencing relative prices in these locations.)

A more controlled way of observing risk premium effects is by comparing current prices between US states. When cannabis prices in US states are compared, the five states with the highest average prices are the states with some of the harshest state-level penalties in the United States for cannabis offenses, as is illustrated in Table 3.3.

Table 3.3 Cannabis prices and penalties: most expensive and least expensive states, 2015

Five most expensive US states for retail cannabis, avg market price of 1 lb dried flower

State	Street price (source: Forbes)	Adult use cannabis	Medical cannabis	Min penalty for possession of 1 oz cannabis
North Dakota	$6,192[1]	Illegal	Illegal	30 days incarceration[4]
Virginia	$5,808[1]	Illegal	Illegal	1 yr incarceration[4] (mandatory minimum)

South Dakota	$5,760[1]	Illegal	Illegal	1 yr incarceration[4]
Maryland	$5,760[1]	Illegal	Illegal	1 yr incarceration[4]
Louisiana	$5,744[1]	Illegal	Illegal	6 mo incarceration[4]

Five least expensive US states for retail cannabis, avg market price of 1 lb dried flower

State	Street price (source: Forbes)	Adult use cannabis	Medical cannabis	Current penalty for possession of 1 oz cannabis[4]
Oregon	$3,264[1,2]	Legal	Legal	None[4]
California	$3,453[3]	Legal, not yet regulated	Legal, not yet regulated	$100 fine[4]
Washington	$3,712[1]	Legal	Legal	None[4]
Colorado	$3,888[1]	Legal	Legal	None[4]
Nevada	$4,240[1]	Legal, not yet regulated	Legal	$600 fine[4]

[1] Source: Bi (2015), collecting and analyzing May 2015 data set from priceofweed.com for *Forbes.* Prices reported for 1 oz purchase; we multiplied by 16 to arrive at price per pound.

[2] Does not account for fall 2016 retail price increases observed in the Whitney report caused by the testing-laboratory supply shortage.

[3] Source: SRIA estimate of $3,453/lb based on AIC retail price survey. Priceofweed.com's California estimate as quoted by *Forbes* is $3,872/lb, which would move it below Washington on the rank list of states with the lowest retail prices.

[4] Source: NORML website.

Taking the national and international comparative data into account, we conclude that the differences between retail prices are not fully explained by differences in production costs, but must also integrate risk premiums, which translate into higher retail margins over the cost of production as a reward for operators who are willing to assume a certain set of business and legal risks that arise out of regulatory uncertainty, conflicts of law, and social stigma.

When illegal-market prices are observed, the price differences between heavy-penalty states and light-penalty states become even more exaggerated. A survey of 6,000 dispensaries (PerfectPrice, 2016) found that the states with the cheapest medical cannabis had illegal-market street prices that were cheaper, proportionally, than the illegal-market street prices in more expensive (high-security) states.

3.3 Summary of costs

The data used to construct Tables 3.4 through 3.6 come from an aggregation of the informal AIC survey, fall 2016. To use these data to model baseline industry costs and regulatory variation, we then convert these business costs into per-pound units. These per-pound cost estimates inform our other modeling efforts necessary to assess the impacts of regulations.

For our calculations of California dispensary costs, we assume a risk premium of $420.00, as shown in Table 3.4, which accounts for the discrepancy between our retail price estimate ($3,453) and the sum total of direct costs ($2,569.68) and net income ($464.00) reported by dispensaries.

These data are averages of the more detailed costs estimates that are provided by size category in Table 3.5. Note that labor is the largest direct cost after raw materials.

Table 3.4 Average dispensary operating costs per pound, AIC estimates, November 2016

Average dispensary operating costs per lb	
Raw material supply cost[1]	$1,200.00
Sales, general, and admin costs[2]	
Labor costs (including benefits & HR)	$777.00
Rent, supplies, and overhead	$265.00
Community giving, education programs	$40.00
Legal, accounting, and local compliance costs	$57.00
Local permit fees, and application preparation	$22.00
Public relations	$57.00
Delivery costs[3]	$152.00
Total dispensary operating costs per lb	**$2,570.00**
Average dispensary margins	
Risk & non-mainstream premium (16%)[4]	$420.00
Net income (18%)[5]	$464.00

Total dispensary revenue per lb	**$3,453.00**

Note: All data averaged across a group of anonymous businesses from which AIC collected approximate current accounting information. See Table 3.5 for more detailed calculations of averages. Numbers rounded to the nearest dollar and may not add up exactly due to rounding error.

[1] Source: AIC estimate. See Section 3.1 for details.

[2] Source: Anonymized dispensary internal accounting data collected by AIC.

[3] Source: AIC vehicle delivery cost analysis. Dispensaries to customers only; does not include transportation between other licensees.

[4] Source: AIC economic analysis.

[5] Source: AIC anonymized dispensary accounting cost survey.

Table 3.5. Detailed operating costs per pound for four different representative dispensary sizes

November 2016 estimates, current snapshot without regulations in place.

Averages across a group of anonymous businesses.

Dispensary size categories: aggregates	**Micro**	**Small**	**Medium**	**Large**	**All locations**
Total number of locations in category[1]	471	378	47	15	911
Category's share of total locations[1]	51.7%	41.5%	5.2%	1.6%	100%
Aggregate volume in category (lb)	137,000	260,000	82,000	104,000	583,000
Aggregate revenue in category	$471 million	$898 million	$282 million	$360 million	$2.01 billion

Raw material margin per location	**Micro**	**Small**	**Medium**	**Large**	**All locations**	**Averages**
Volume per location (flower-equivalent pounds)[3]	290 lb	695 lb	1,738 lb	6,950 lb	583,000 lb	**640 lb**
Revenue per location[2]	$1,000,000	$2,400,000	$6 million	$24 million	$2.01 billion	**$3,453/lb**
Raw material costs per location[3]	$345,000	$800,000	$2,100,000	$8.3 million	$700 million	**$1,200/lb**

Total raw material margin per location	$655,000	$1,600,000	$3,900,000	$15.7 million	$1.31 billion	**$2,253/lb**
Fixed, labor, and administrative costs per location[2]	**Micro**	**Small**	**Medium**	**Large**	**All locations**	**Averages**
Labor costs (including benefits and human resources)	$296,000	$540,000	$1,260,000	$5,550,000	$453 million	**$834/lb**
Rent, supplies and other ops expenses	$58,000	$139,000	$619,000	$3,053,000	$155 million	**$265/lb**
Community giving, education programs	$15,000	$35,000	$52,000	$71,000	$23.6 million	**$40/lb**
Legal, tax, and regulatory compliance	$16,000	$38,000	$110,000	$398,000	$33 million	**$57/lb**
Permit fees and application preparation	$8,000	$18,000	$35,000	$63,000	$12.9 million	**$22/lb**
Public relations	$18,000	$45,000	$84,000	$225,000	$33.2 million	**$57/lb**
Total fixed, labor, and administrative costs per location	$411,000	$815,000	$2,160,000	$9,360,000	$710 million	**$1,275/lb**

Estimates between $500,000 and $5 million rounded to nearest $10,000. Estimates between $5 million and $100 million rounded to nearest $100,000. Estimates above $100 million rounded to nearest $1,000,000.

[1] Represents number of discrete retail business premises. A single firm may operate several locations.

[2] Source: Anonymized dispensary internal accounting data collected via AIC interviews and surveys. Does not include delivery costs or delivery employees.

[3] Source: AIC estimates based on fall 2016 Cannabis Benchmarks wholesale price data and estimates from Era Economics.

Labor costs. Table 3.6 uses aggregate AIC accounting cost survey information to break down labor costs into categories. Wages average approximately $18 per hour for non-manager employees and $75 per hour for managers. Costs of labor are integrated into the dispensary accounting costs used in our simulation model in Chapter 7, the results of Chapter 8 and the IMPLAN analysis reported in Chapter 9.

Table 3.6 Detailed dispensary labor cost breakdowns for four different representative dispensary sizes, November 2016, without regulations in place

Dispensary size categories:

aggregates	**Micro**	**Small**	**Medium**	**Large**	**All locations**
Total number of locations in category	471	378	47	15	911
Category's share of total locations	51.7%	41.5%	5.2%	1.6%	100%
Aggregate volume in category (lb)	137,000	260,000	82,000	104,000	583,000
Aggregate revenue in category	$471 million	$898 million	$282 million	$360 million	$2.01 billion

Labor costs per location	**Micro**	**Small**	**Medium**	**Large**	**Avg location**
Avg employees per dispensary[1]	6	10	20	60	9.22
Revenue per location[1]	$1,000,000	$2,400,000	$6 million	$24 million	$2.01 billion
Avg employees per $1M revenues[1] (incl managers + non-managers)	6.00	4.17	3.33	2.50	4.20
Avg revenue per employee[1]	$166,667	$240,000	$300,000	$400,000	$238,202
Managers per dispensary[1]	1	2	4	10	1.71
Annual salary per manager[1] (incl benefits & HR costs)	$116,000	$126,500	$171,000	$355,000	$149,485
Avg hourly wage per manager[1]	$58	$63	$86	$178	$74.74

(assuming 2000 hrs per yr)					
Non-manager employees per dispensary[1]	5	8	16	50	7.51
Non-manager annual salary[1]	$36,000	$36,000	$36,000	$40,000	$36,414
Avg hourly wage per non-mgr[1]	$18	$18	$18	$20	$18.21

Total labor costs	**Micro**	**Small**	**Medium**	**Large**	**Avg location**
Avg total annual labor costs	$296,000	$541,000	$1,260,000	$5,550,000	$533,901
Avg annual salary per employee	$49,333	$54,100	$63,000	$92,500	$57,889

Note: All numbers averaged across a group of anonymous businesses from which AIC collected approximate current accounting information. Estimates between $500,000 and $5M rounded to nearest $10,000. Estimates between $5M and $100M rounded to nearest $100,000. Estimates above $100 million rounded to nearest $1M.

[1] Source: Anonymized dispensary internal accounting data collected via AIC surveys and interviews.

[2] Does not include delivery employees, who are accounted for under "delivery costs."

4. Retail cannabis prices and price patterns in California

Public information on cannabis is scarce. Official data sources on current and historical prices, such as those published Federally by the Bureau of Labor Statistics for most other common agricultural products, are unavailable. Estimates of prices are complicated because there are many different types of cannabis products sold in dispenaries. Furthermore, as with other consumer products, prices vary geographically and depend on the unit of quanity sold (for example, one-eighth-ounce sized packages versus one-ounce-sized packages). These complications mean that price data need to be handled carefully.

This section reports on a variety of information used to develop the representative price that is used in modeling and estimation. As an important component of this effort, AIC surveyed dispensaries in California from September through November 2016. The AIC survey collected price ranges (as highs and lows) by cannabis product, location, and by unit of quantity. We recorded whether the dispensary was delivery only and its customer rating. The majority of this section is devoted to discussing data-collection methods, data descriptions, and patterns. We also compare our survey information with price data available from other sources.

4.1 Product overview

Dried flower from the cannabis plant, which is generally inhaled through joints or pipes, is the dominant cannabis product at retail. Dried flower is sold in one-gram, eighth-ounce, quarter-ounce, half-ounce, and one-ounce packages and generally labeled by strain (e.g. “Sour Diesel,” “Blue Dream,” “Jack Herer”). Other information sometimes included on labels includes species (sativa, indica, or “hybrid,” indicating a sativa-indica cross-breed), outdoor-grown (“OG”), strength (in active-ingredient concentration as measured by THC and CBD percentages), and occasionally branded quality or origin certifications.

According to informal industry sources and industry press reports, the fastest-growing portion of the California retail cannabis market is concentrated cannabis oil cartridges, which is vaporized and inhaled using battery-powered “vape pens” (hand-held devices similar to e-cigarettes). Cartridges contain oil concentrate (also known as “extract”) that is generally extracted to THC levels between 50% and 75% and packaged in 500-milligram cartridges. Other popular forms of concentrate include wax and shatter. Concentrates can also be consumed by “dabbing” or can be used in making edible cannabis products. Some concentrates at the top end of the market are now advertised in terms of aromatic compounds known as “terpenes,” whose clinical effects are unclear.

Concentrates have been claiming increasing share in the cannabis market, especially for those willing to pay high prices. If the prices of the various products mentioned above are converted into prices per gram of THC in the package, edible cannabis products are the most expensive way of purchasing cannabis, followed by concentrates, and dried flower is the cheapest (Orens et al. 2015).

The AIC retail price survey, which is presented below, does not measure edible prices, but it confirms the Orens et al. finding that THC in cartridge form sells for more than twice the price of THC in dried flower form. This reflects the additional costs of manufacturing and packaging, and in some cases it also reflects the margins of an additional business in the supply chain (the manufacturer who buys dried flower or oil and produces packaged cartridges or edibles).

See Section 5.3.1 for an explanation of the “flower equivalent” methodology we used to combine various forms of cannabis and estimate aggregate market prices and quantities.

4.2 Survey methods

AIC conducted a survey of medical cannabis dispensaries in California during the fall of 2016. The main purpose of the survey was to learn about current distributions and other patterns of prices for medical cannabis.

Dispensaries are collectively representative of the varied demographics of California. We selected counties and cities to approximate the distribution of the medical cannabis retail outlets in the state and arrived at approximations of state-wide retail prices.

By using internet sources including WeedMaps, Leafly, Yelp!, Google Local, and dispensaries' own websites, we collected prices and other related information from each dispensary. We called dispensaries when web information was unclear or insufficient. Data were collected during the 60-day span between September 25 and November 23, 2016. Our data set consists of information collected from 565 dispensaries, including both physical storefronts and delivery-only, in eight counties across California.

4.3 Information collected

Our data set consists of several types of information for each retailer, including the retail location, characteristic (shop and/or delivery), cannabis retail prices, and the online ratings of the retailer. Retail location was categorized by county and city, and for storefront shops, we recorded the address. We also recorded website and phone number for most dispensaries.

Retailer characteristic: Some retailers operate their businesses without having a physical storefront with a physical address. In these cases, transactions are conducted online or via phone and the product is delivered to the consumer's home. For each retailer, we recorded whether the business is based out of a storefront dispensary, whether the retailer delivers the products to consumers, or both.

Retail medical cannabis prices: Among the differentiated cannabis-based products sold, we chose three leading products that we judged to be most representative and comparable across different retail environments. In an initial pre-survey, we determined that one gram, one-eighth ounce, and one ounce are the three most common dried flower packages for sale at California dispensaries, and that the 500-milligram cartridge was the most common concentrate or extract package. We chose not to collect one-gram package prices due to their higher degree of variability within and between locations. We thus collected prices for one-eighth-ounce and one-ounce dried flower and 500-milligram catridges. As expected, we observed substantial

quantity discounts per ounce for buying dried flower in one-ounce portions vs. one-eighth-ounce portions.

We collected maximum and minimum prices in each of these three product categories at each dispensary. We chose this approach in part because many dispensaries have a price schedule with just two levels for eighth-ounce and one-ounce packages: low (which we call "generic"), and high ("top-shelf," which we call "premium") prices. Some dispensaries had three to four price levels, but we rarely observed more than five. In the interest of simplicity, we collected two prices from each dispensary: one "generic" price, representing the lowest product in the price range for the given product, and one "premium" price, representing the highest. Thus, the low and high prices for each of the three products generate six different prices in our data set.

As observed by Sifaneck et al. (2007) and discussed above, prices vary by characteristics and the quality level as perceived by consumers. It is important to note that perceived quality does not necessarily correspond to objective quality in terms of hedonic preferences. In the US wine market, a wide price spread between generic and premium prices appears to be stable even though the difference between generic-priced and premium-priced products are not readily distinguishable by wine consumers in blind taste tests (Goldstein et al. 2008), and beer consumers pay price spreads for premium brands whose physical properties they cannot readily differentiate (other than the label and branding; Almenberg et al. 2014). For the cannabis marketplace, we collected data on both generic and premium prices to better understand the retail market, and we are thus able to observe consumer willingness to pay in two different perceived-quality categories.

4.4 Data overview

Table 4.1 reports the summary statistics of our survey data. Out of 565 retailers, 57% conduct business from a storefront (with a physical address of the dispensary), and 47% conduct business using a delivery service. Only 4% of surveyed retailers sell through both storefront retail and a delivery service. We believe that this 4% is likely to be an underestimate due to reporting bias (some delivery services are not fully compliant with the Brown Guidelines or local municipal ordinances, and would prefer not to disclose their existence to non-customers).

Even though not all retailers report all six prices considered here, almost all retailers (561 out of 565) list the price of one-eighth ounce dried flower, which interviews consistently cite as the most frequently purchased item at dispensaries (we do not yet have reliable data on the

distribution of package sizes within dried flower purchases, however). Comparing the high and low prices of dried flower for one-eighth ounce and one ounce, two observations emerge. First, the high price is, on average, almost twice the low price. The price differential between high and low for cartridges is much smaller than dried flower, perhaps because (1) quality difference in raw material after distillation may be less critical than in manufactured products, and (2) the product is already premium-positioned, so the low price is not for a truly "generic" product.

Second, there are considerable discounts for larger quantity. Our data indicate that the quantity discounts are as much as 25% for both high and low categories. The low and high prices for one-eighth ounce dried flower are $28.28 ($226 per ounce) and $54.58 ($436 per ounce), respectively. These prices are 25% and 27% higher for low and high than the equivalent prices for dried flower sold in one-ounce packages.

Our data on ratings indicate that most retailers were rated highly. The reported rating means in Table 4.1 come from individual rating averages specific to review site. For each retailer, we used a considerable number of reviews to construct individual rating averages.

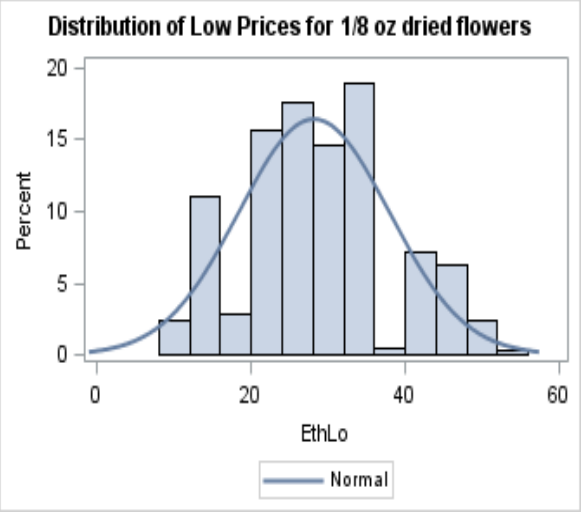
The distributions of dried flower and cartridge prices are presented in the panels of Figure 4.1. Comparing the distributions of low and high prices for dried flower indicates that low prices tend to be more clearly multi-modal than high prices for both 1/8 ounce and one ounce dried flower. We may infer some market structure information from these price distributions. The multi-modality of generic markets may indicate more variability in the quality of products even within the generic category, or may suggest the influence of other key factors relative to the single-modal premium market products. Unlike dried flower, the distribution of low prices of cartridges has a single mode and resembles a normal distribution.

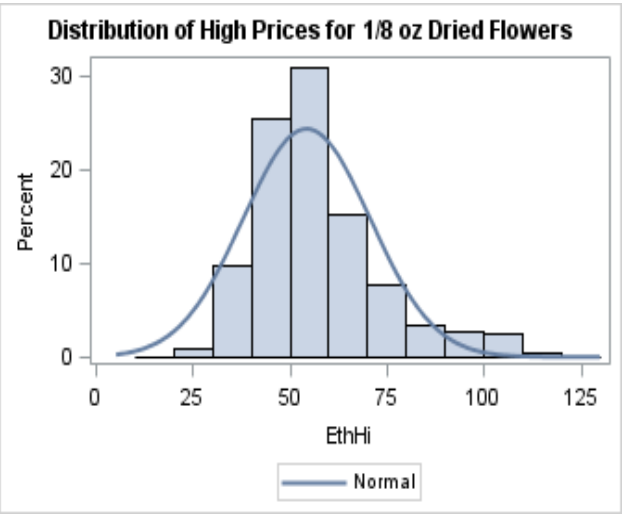
Table 4.1. Summary statistics of AIC survey of cannabis dispensaries in California

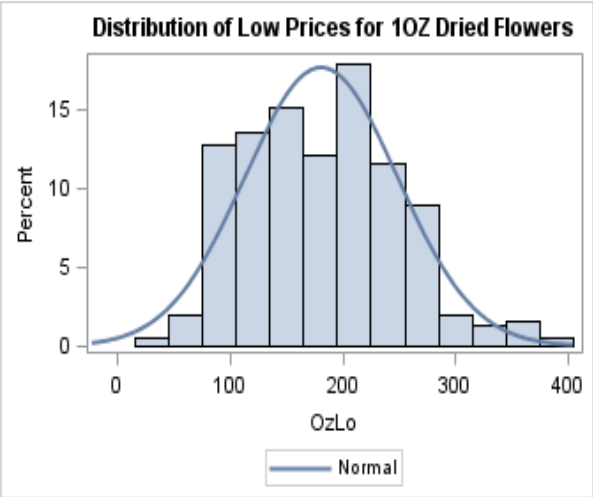
Variable	*Obs.*	*Mean*	*Std Dev*	*Minimum*	*Maximum*
Retail and/or delivery					
Retail (yes=1)	565	57%		0	1
Delivery (yes=1)	265	47%		0	1
Retail price					
1/8 oz dried flower					
Low price	561	$28.20	$9.70	$8.00	$55.00
High price	561	$54.50	$16.40	$13.00	$125.00
1 oz dried flower					
Low price	503	$181.30	$68.0	$20.0	$400.00
High price	503	$341.70	$111.5	$70.0	$1,000.00
0.5g Cartridge					
Low price	327	$30.30	$7.80	$10.00	$70.00
High price	328	$41.50	$13.10	$15.00	$120.00
Rating					
Google Local	89	4.4	0.6	0.0	5.0
Yelp!	127	4.2	0.9	0.0	5.0
Weedmaps	556	4.7	0.4	0.0	5.0
Leafly	105	4.6	0.6	0.0	5.0

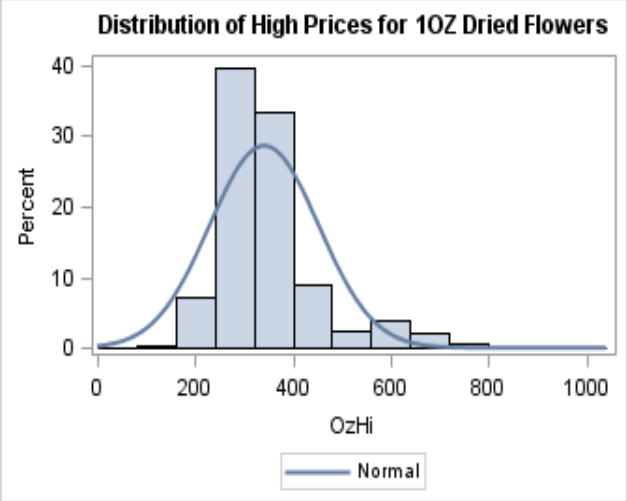
Source: AIC cannabis price survey conducted in fall 2016.

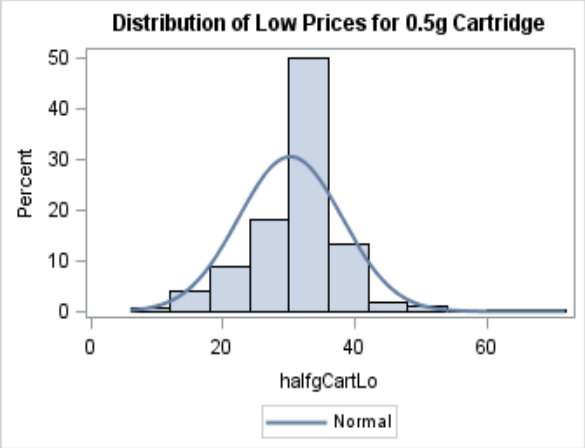
Figure 4.1. Distribution of low and high prices for dried flower and cartridges

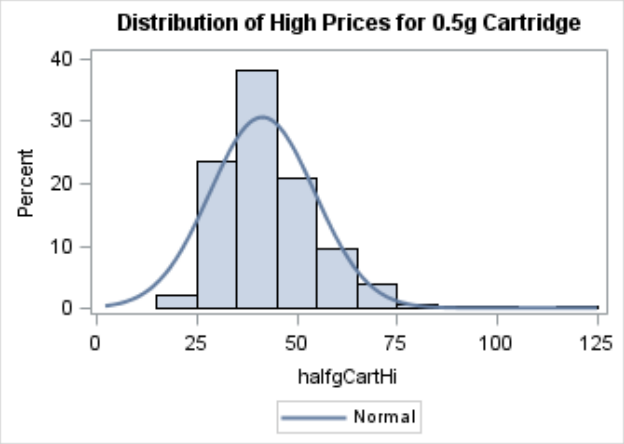










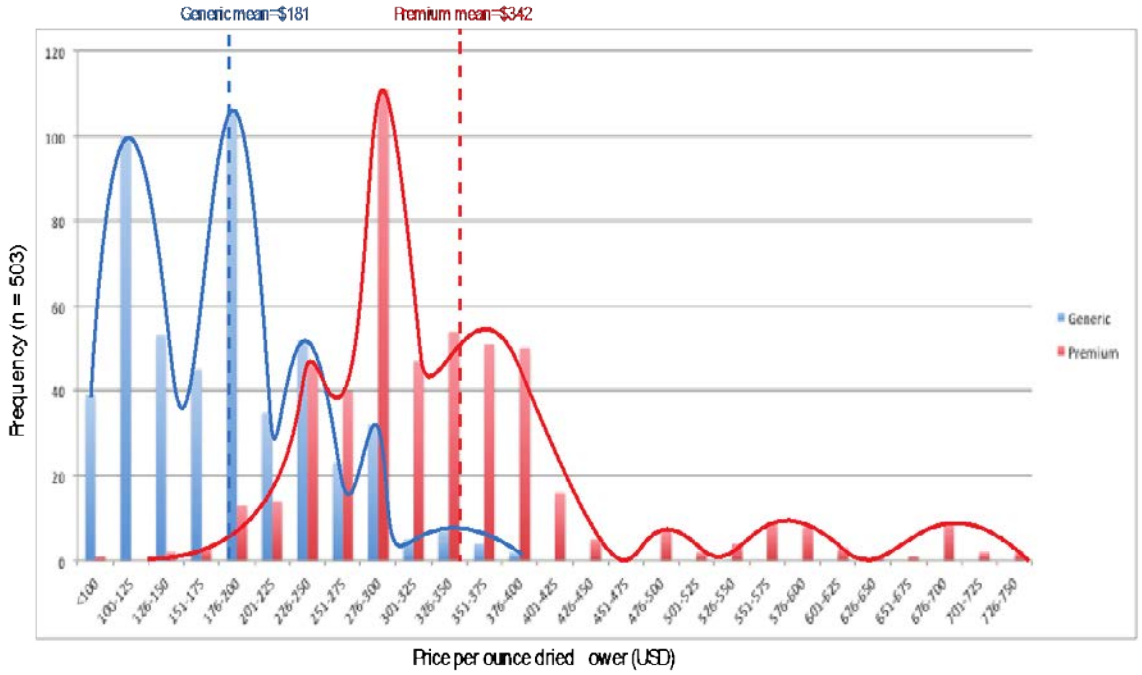


Source: AIC cannabis price survey conducted in fall 2016.

4.5 Complexities in price distributions

Here we examine complexity in price distributions using one-ounce dried flower prices. The analysis below begins by censoring the data into price categories with a range of $25 each, which yields a multi-modal frequency distribution of prices that is not easily described by conventional distribution forms.

Figure 4.2. Distribution of one ounce retail dried flower prices, California



Source: AIC cannabis price survey conducted in fall 2016.

For the low-priced category, we see two modes, local modes of $175 to $200 per ounce and $100 to $125. What we are likely seeing at the $100 and $200 levels is quality differentiation: normal-potency dried flower at the higher primary mode versus lower-potency “shake” or “schwag” at the lower secondary mode. The mean price per ounce across dispensaries for the low prices is $181, and the mass of the distribution is skewed to the left of center.

For the high-price observations, the frequency distribution has a modal price of $276 to $300. The mean of the high prices per ounce is $342, and the mass of the distribution is skewed to the left of center with a long, stretched tail on the right side of the distribution. One interpretation of the price distributions is that neither consumers nor sellers know quality. Another is that there are many quality classes of cannabis products, which have not been standardized.

4.6 County- and region-specific analyses

Table 4.2 presents the summary statistics of various prices by county, where the mean is the average of the midpoints between the high and low prices. The table includes the coefficient of variation (CV) for each price (the standard deviation divided by the mean) to represent the

dispersion of prices around the mean. The higher CV represents the greater dispersion of prices.

Cannabis prices, especially of dried flower, tend to be lowest in the counties of Fresno, Kern, and Butte. Price differences across counties tend to be smaller for cartridges than for dried flower. High prices of dried flower tend to be considerably higher in Santa Clara and San Diego counties. It is plausible that consumers have a general higher willingness to pay in coastal areas, where quality is higher or costs are higher for dispensaries.

Table 4.2. Summary Statistics of Prices, by County

Alameda County	***Obs.***	***Mean***	***Std Dev***	***CV***	***Minimum***	***Maximum***
1/8 oz dried flower, low price	15	$31.3	$10.0	0.32	$15.0	$50.0
high price	15	$55.0	$10.0	0.18	$35.0	$75.0
1 oz dried flower, low price	13	$215.1	$72.4	0.34	$100.0	$325.0
high price	13	$355.8	$52.2	0.15	$280.0	$440.0
500-mg cartridge, low price	14	$29.0	$8.7	0.30	$10.0	$40.0
high price	14	$52.1	$25.2	0.48	$15.0	$120.0
Butte County	***Obs.***	***Mean***	***Std Dev***	***CV***	***Minimum***	***Maximum***
1/8 oz dried flower, low price	22	$29.3	$8.5	0.29	$20.0	$45.0
high price	22	$47.3	$11.6	0.25	$30.0	$90.0
1 oz dried flower, low price	17	$162.1	$53.0	0.33	$100.0	$275.0
high price	17	$291.8	$58.5	0.20	$190.0	$390.0
500-mg cartridge, low price	11	$35.9	$6.6	0.18	$20.0	$45.0
high price	11	$47.3	$10.6	0.22	$30.0	$60.0
Fresno County	***Obs.***	***Mean***	***Std Dev***	***CV***	***Minimum***	***Maximum***
1/8 oz dried flower, low price	46	$33.1	$8.5	0.26	$15.0	$50.0
high price	46	$53.4	$17.5	0.33	$30.0	$100.0
1 oz dried flower, low price	39	$189.1	$67.8	0.36	$100.0	$375.0
high price	39	$302.2	$91.4	0.30	$180.0	$650.0
500-mg cartridge, low price	22	$31.8	$6.5	0.20	$20.0	$45.0
high price	22	$38.6	$9.8	0.25	$25.0	$60.0
Kern County	***Obs.***	***Mean***	***Std Dev***	***CV***	***Minimum***	***Maximum***
1/8 oz dried flower, low price	43	$21.1	$8.1	0.39	$10.0	$40.0
high price	43	$52.1	$17.5	0.34	$25.0	$100.0
1 oz dried flower, low price	32	$160.1	$61.6	0.38	$80.0	$285.0
high price	32	$340.3	$143.0	0.42	$180.0	$840.0
500-mg cartridge, low price	23	$29.6	$5.8	0.20	$20.0	$45.0
high price	23	$35.4	$7.2	0.20	$30.0	$60.0
Los Angeles County	***Obs.***	***Mean***	***Std Dev***	***CV***	***Minimum***	***Maximum***
1/8 oz dried flower, low price	243	$25.9	$9.2	0.36	$8.0	$55.0
high price	243	$53.3	$16.9	0.32	$13.0	$110.0
1 oz dried flower, low price	223	$176.1	$63.2	0.36	$40.0	$380.0
high price	223	$328.0	$103.1	0.31	$140.0	$720.0

500-mg cartridge, low price	120	$30.3	$7.1	0.23	$10.0	$50.0
high price	121	$37.1	$10.5	0.28	$20.0	$80.0
Sacramento County	***Obs.***	***Mean***	***Std Dev***	***CV***	***Minimum***	***Maximum***
1/8 oz dried flower, low price	66	$28.2	$8.4	0.30	$15.0	$50.0
high price	66	$50.7	$10.3	0.20	$30.0	$85.0
1 oz dried flower, low price	62	$169.8	$60.6	0.36	$40.0	$320.0
high price	62	$326.4	$77.1	0.24	$150.0	$680.0
500-mg cartridge, low price	36	$28.8	$10.3	0.36	$15.0	$70.0
high price	36	$46.1	$12.3	0.27	$20.0	$70.0
San Diego County	***Obs.***	***Mean***	***Std Dev***	***CV***	***Minimum***	***Maximum***
1/8 oz dried flower, low price	109	$33.8	$9.6	0.28	$10.0	$55.0
high price	109	$61.9	$17.5	0.28	$35.0	$125.0
1 oz dried flower, low price	101	$197.9	$80.5	0.41	$20.0	$400.0
high price	101	$397.2	$138.0	0.35	$70.0	$1000.0
500-mg cartridge, low price	84	$31.2	$8.0	0.26	$10.0	$60.0
high price	84	$45.1	$13.6	0.30	$25.0	$100.0
Santa Clara County	***Obs.***	***Mean***	***Std Dev***	***CV***	***Minimum***	***Maximum***
1/8 oz dried flower, low price	17	$26.4	$7.6	0.29	$15.0	$40.0
high price	17	$56.0	$8.1	0.15	$35.0	$73.7
1 oz dried flower, low price	16	$209.7	$66.4	0.32	$100.0	$360.0
high price	16	$381.9	$73.8	0.19	$280.0	$589.4
500-mg cartridge, low price	17	$26.1	$8.4	0.32	$12.0	$40.0
high price	17	$45.6	$10.8	0.24	$30.0	$70.0

Source: AIC cannabis price survey conducted in fall 2016.

Table 4.3 presents the statistics aggregated by region, where “Northern California” includes Alameda, Sacramento, Butte, and Santa Clara counties; “San Joaquin Valley” includes Fresno and Kern counties; and “Southern California” includes Los Angeles and San Diego counties. Our regional statistics suggest that Southern California prices are highest. The relatively high overall prices in Southern California (versus the rest of California) are driven more by high prices for premium dried flower than by high prices for generic dried flower.

Table 4.3. Summary Statistics of Prices, by Region

	Northern California			***Central California***			***Southern California***		
Variable	Obs	Mean	Std Dev	Obs	Mean	Std Dev	Obs	Mean	Std Dev
1/8oz, low	120	$28.5	$8.5	89	$27.3	$10.2	352	$28.4	$10.0
1/8oz, high	120	$51.4	$10.5	89	$52.7	$17.4	352	$56.0	$17.5
1oz, low	108	$180.0	$64.1	71	$176.0	$66.2	324	$182.9	$69.7
1oz, high	108	$332.7	$75.4	71	$319.4	$118.1	324	$349.5	$119.3
500mg cart, low	78	$29.2	$9.5	45	$30.7	$6.2	204	$30.7	$7.5
500mg cart, high	78	$47.3	$14.8	45	$37.0	$8.6	205	$40.4	$12.5

Source: AIC cannabis price survey conducted in fall 2016.

Table 4.4 reports the share of physical storefront retailers and delivery-service retailers, by county. These shares differ considerably across counties. For example, none of the retailers in Butte County has a storefront location. Also, while few of the retailers in our survey report both a physical storefront and deliveries, Alameda County is an exception. Our data indicate that over half of retailers we surveyed (53%) in Alameda County report a physical storefront and delivery service.

Table 4.4. Dispensary characteristics, by county, storefront vs. delivery

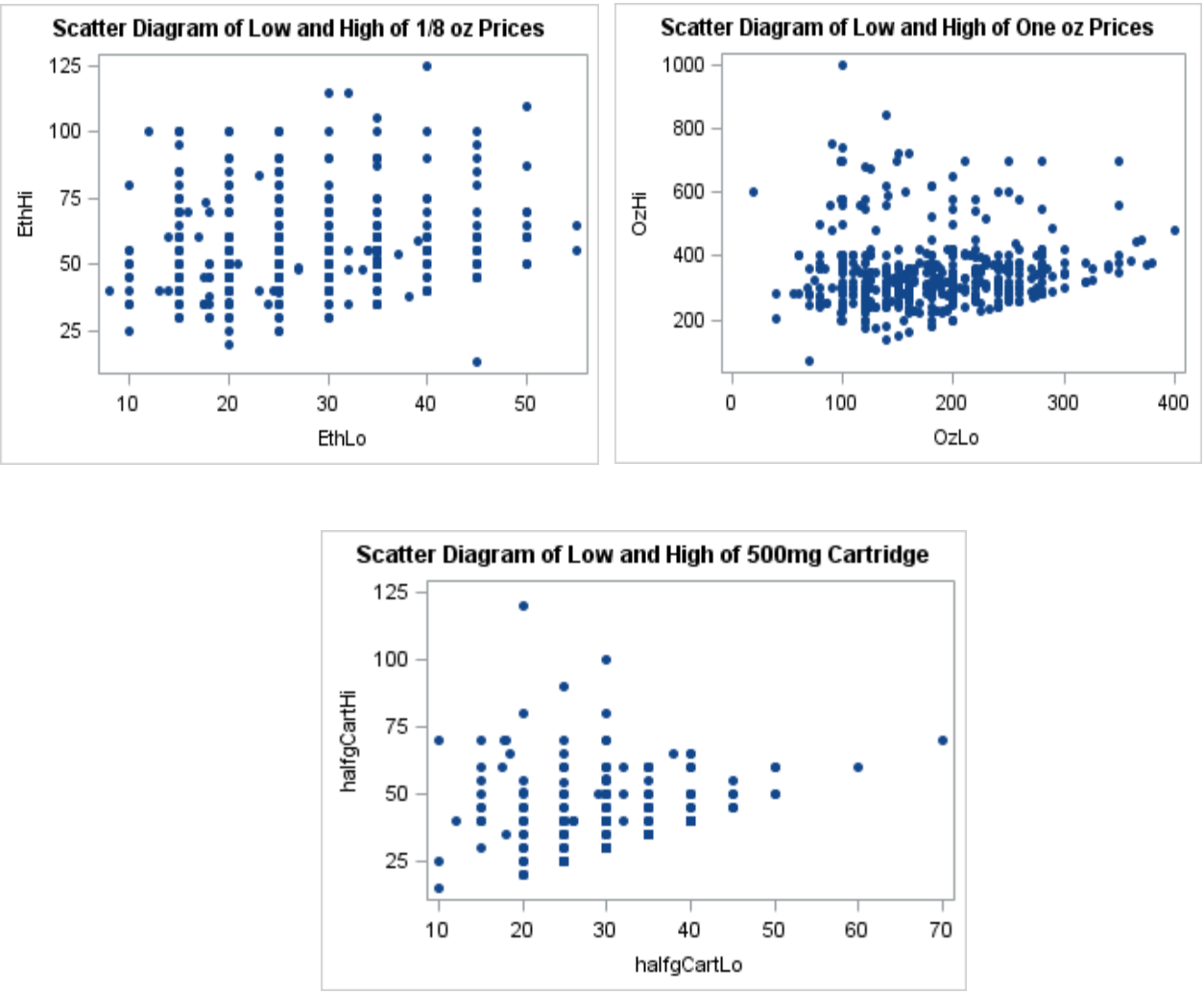
County	*Obs.*	*Retail*	*Delivery*
Alameda	15	73%	80%
Butte	22	0%	100%
Fresno	47	17%	89%
Kern	43	81%	21%
Los Angeles	245	75%	26%
Sacramento	67	42%	58%
San Diego	109	39%	67%
Santa Clara	17	94%	12%
California	**565**	**57%**	**47%**

Source: AIC cannabis price survey conducted in fall 2016.

4.7 Relationships Between High and Low Prices and Product Characteristics

4.7.1 Scatter diagrams of the price relationships. In Figure 4.3, we plot the high (premium) price against respective low (generic) price for the sample. For all three categories of products, we found a positive correlation between low and high prices. Among the three categories of products, the positive price relationship seems stronger for one-ounce dried flower.

Figure 4.3. Scatter diagrams for 1/8-ounce and one ounce dried flower and 500 mg cartridges



Source: AIC cannabis price survey conducted in fall 2016.

4.7.2 Concentration premium effects in the California retail cannabis market. To get a broad picture of the relationship between prices and product THC levels, we solicited a separate sample of 106 price-THC pairs from a stratified sub-sample of 8 dispensaries scattered across the state. We then partitioned the data into nine price categories and created an ordinal "price category" variable. We then calculated the mean THC measurements of products falling into each of these nine categories, which allowed us to observe a smoothed version of the price-THC relation in the sub-sample for which THC was reported. We note a tendency for price to rise with THC.

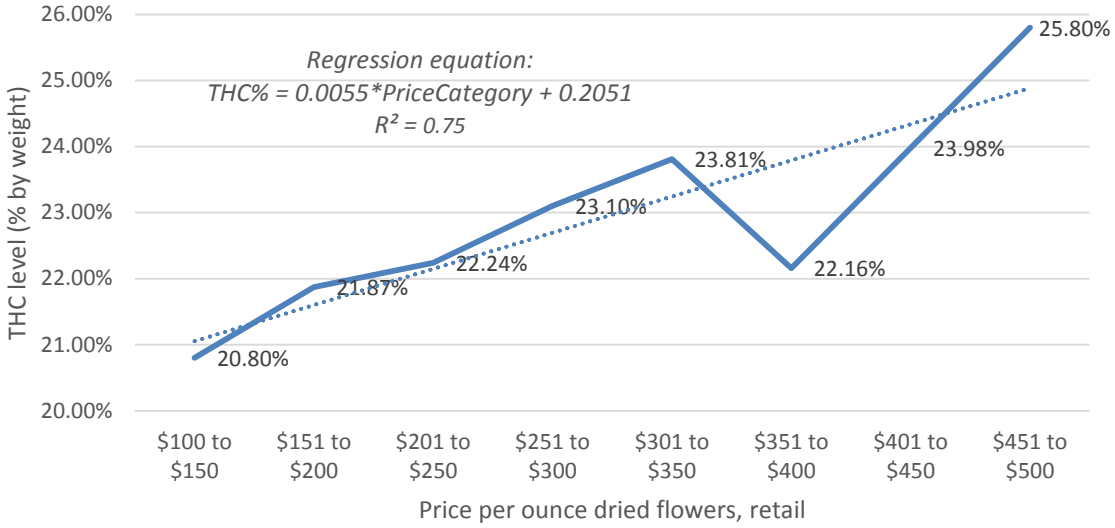
Table 4.6. Summary statistics, sub-sample

Price range	*Products*	*Mean THC level*
$100 to $150	2	20.80%
$151 to $200	7	21.87%
$201 to $250	14	22.24%
$251 to $300	38	23.10%
$301 to $350	27	23.81%
$351 to $400	10	22.16%
$401 to $450	0	N/A
$451 to $500	5	25.80%
$501 to $550	1	48.30%

Source: AIC cannabis price survey conducted in fall 2016.

Next, we considered a price-category linear regression that turns each of these nine price categories into an ordinal variable from 1 to 9 (i.e., we predicted average THC level given a price category, coding price category as an ordinal variable from 1 to 9). This regression yields a coefficient. In this model, the price-category coefficient (0.0055) means that moving up 1 unit on the 1-to-9 price-category scale, which corresponds to an increase in price of $50 per ounce of dried flower, the expected average THC level of all products in the price category rose by approximately 0.5%. We have not weighted this regression by sample size in each category, and we ignore one outlying category with only one observation of a single product that had almost double the THC of any other product in the sample.

Figure 4.7. Price category-THC relationship, sub-sample



Source: Sub-sample from AIC cannabis price survey conducted in fall 2016.

Table 4.7 displays the low and high prices for each of the 8 sub-sample dispensaries.

Table 4.7. Low and high prices and THC levels

Dispensary	*Low Price*	*THC Level*	*High Price*	*THC %*	*Price spread*	*THC spread*
#1	$360	19.00%	$480	25.80%	$120	6.80%
#2	$250	21.10%	$380	30.50%	$130	9.40%
#3	$199	22.80%	$350	28.46%	$151	5.66%
#4	$240	21.40%	$330	23.72%	$90	2.32%
#5	$120	21.50%	$400	22.67%	$280	1.17%
#6	$285	15.65%	$360	17.70%	$75	2.05%
#7	$200	15.90%	$340	23.70%	$140	7.80%
#8	$140	20.10%	$280	26.48%	$140	6.38%
Means	**$224**	**19.70%**	**$365**	**24.90%**		

Source: Sub-sample from AIC cannabis price survey conducted in fall 2016.

4.8 Determination of a representative California retail price

The representative price of $3,453 per pound dried flower that we used as an initial situation in our simulation analysis was derived with the following procedure. Our initial data consist of high and low prices in each sampled dispensary for 1/8-ounce packages and full one-ounce packages. We did not include the manufactured products in this calculation because those products contain additional processing and packaging costs that add to the complexity of deriving the cannabis equivalent prices.

To calculate a representative high and low price per pound of flower-equivalent product, we used the statewide averages for each. The first step was to assign a volume share for the low prices and high prices. We noted that for most consumer products, the highest-priced product has a much lower market share (by volume) than the low-priced product, meaning that the volume-weighted average market price falls below the mid-point between the generic and premium prices (See Section 4.9 for an example from the beer market).

In many dispensaries, there are other packages available at prices between the two extremes. As a broad simplifying assumption, relying on other industries for guidance, we assumed that about the low price represents 90% of the volume transacted and the high price (which tends to be extreme) represents 10% of the volume.

We used the statewide average by package size for high prices and low prices that we present in Table 4.1 to generate flower-equivalent-pound volume averages. The state average low price for 1/8-ounce packages is $3,584 per pound. The state average high price for 1/8-ounce packages is $6,912 per pound. The volume-weighted average is $3,917. For one-ounce packages, the flower-equivalent pound (as defined in Section 5.3.1) averages for the low and high prices are $2,896 and $5,472 per pound, respectively, for a volume-weighted average of $3,154 per pound. Finally, guided by evidence from the beer industry as explained in Section 4.9, we used the weighted average of these prices using the aggregate quantity shares of about 61% for 1/8-ounce products and 39% for one-ounce products.

Using these shares, the weighted average price, which will be used as an aggregate representative retail price in our analysis, is calculated as $3,453.

4.9 Quantity-weighted average prices tend to be well below midpoints and medians

We examined the price distribution of beer and wine to help confirm that market volumes tend to be higher for products that sell in the lower price categories, such that average market prices tend to below midpoint or median prices.

Most product categories are composed of goods with varying attributes that sell for different prices and in different volumes. To determine the weighted average price of a good in a particular category, we must know both the volume and price of the good. Beer and wine sales in the United States are examples of price diversity within a broad category.

Below is a chart of retail beer sales in the United States by volume and total dollar for the first 11 months of 2016. These data are from based on the market surveys conducted by IRI (a firm specialized in retail surveys including scanner data). The unpublished summary in Table 4.8 was supplied to us courtesy of the National Brewers Association. Volume units are in cases (24 cans of 12 ounces per container, or 288 ounces per case).

Table 4.8 Distribution of beer prices and volumes by price category

Beer segment	***Retail sales*** ($ millions)	***Share of Category***	***Volume Sales*** (millions of cases, 24 x 12 ox)	***Volume Share of Category***	***Retail Price*** ($/case)
Domestic sub-premium	$4,788	16%	299	24%	$16
Domestic premium	$11,699	40%	567	45%	$21
Import	$5,192	18%	173	14%	$30
Craft	$3,224	11%	89	7%	$36
All and Average	**$29,248**	**100%**	**1,272**	**100%**	**$23**

Source: National Brewers Association, 2016.

The average of the lowest price per case ($16.00) and the highest price per case ($36.08) is $26.04. However, the actual weighted average case price is $22.99, approximately 13% below the average of the high and low prices.

Table 4.9 is from the 2013 Gomberg-Fredrikson Report of *wholesale* wine shipments from California wineries to wholesalers in the United States. Retail wine prices differ by category more than do beer prices. Some wines retail under $3 per bottle, while others retail at well over $100 per bottle. This price diversity is reflected in the Gomberg-Fredrikson data, which show an average wholesale case price of $51 but a range of $20 to $128 per case.

Table 4.9 Distribution of wine prices and volumes by price category, 2013

Wine segment (750-mL bottle price)	***Wholesale Dollar Sales*** ($ millions)	***Share of Category***	***Volume Sales*** (millions of cases, 12 x 750 ml)	***Volume Share of Category***	***Wholesale Price*** ($/case)
<= $3	$958	9%	47	22%	$20
>$3-$7	$2,309	21%	71	34%	$33
>$7-$14	$3,961	37%	64	31%	$62
>$14	$3,573	33%	28	13%	$128
Totals/averages	**$10,801**	**100%**	**210**	**100%**	**$51**

Source: Gomberg-Fredrikson Report (2013), reporting data from wholesale wine shipments from California wineries to wholesalers in the United States. Data provided by courtesy *https://www.gfawine.com/products/gfr/*

5. The California cannabis market

In this chapter we evaluate the California retail cannabis market. We first clarify our framework for constructing and modeling the cannabis market and its segments. We then draw on data and market research, which is presented in Sections 5.3 and 5.4 below, to construct estimates of prices and quantities in the November 2016 California cannabis market as it stood before Proposition 64 was passed, and before any state cannabis regulations went into effect.

5.1 Market segments

Until November 2016, the sale of medical cannabis was legal under state law, but the sale of non-medical cannabis was not. We look at a snapshot of the early November 2016 market prior to any form of adult-use legalization. This early November 2016 cannabis market was divided into two parts, which we call "segments": the legal medical cannabis segment, which in November 2016 was regulated only at the county and municipal level and not at the state level (hereafter denoted as "medical," or "m" in the notation used in Appendix Chapter 7); and the illegal non-medical cannabis segment, which, by construction, was unregulated (hereafter denoted as "illegal," or "i" in the notation used in Appendix Chapter 7).

The terms "legal" and "illegal" can be confusing, especially in the context of cannabis, which is illegal under Federal law is likely to remain so in 2018 and beyond. In the present discussion, by "legal," we mean to refer only to the status of sales in the segment under California state law at the specific time to which the discussion applies. Even this determination can be unclear, as for example some cannabis sellers in November 2016 were operating in observance of some parts of SB 420 and the Brown Guidelines and others were not.

We handle such confusion simply by constructing our "medical" cannabis segment broadly to include all cannabis that is sold upon the presentation and verification of a medical recommendation, including but not limited to sales at storefront dispensaries, delivery services, and patients' collectives. We use the term "illegal" segment to refer to the rest of cannabis sales at that time. This segment includes all cannabis that was sold during that period to any consumers (whether medical patients or non-patients) via non-medical channels, including street dealers, non-medical delivery services, and direct grower-to-consumer sales.

In Section 5.3, we survey a range of available data describing the market through November 2016. We state our assumptions and make estimates of prices and quantities in the legal medical cannabis segment, the illegal non-medical cannabis segment, and the total California cannabis market in the November 2016 situation, which we assume to be a snapshot of the market as measured prior to the California election of November 8, 2016. Because many of our data sources are monthly indicators, and assuming that market prices will take more than three weeks to reflect the effects of partial adult-use decriminalization due to Proposition 64, we collected measurements (including our AIC retail price survey) through the end of November 2016.

As is detailed in Section 5.3, we agree with other industry analysts in estimating that the majority of cannabis sold in the marketplace as of November 2016 went through illegal channels. Specifically, we estimate that the illegal segment comprises 75% by weight (in flower equivalent; see Section 5.3.1 for explanation of units and conversion methodology) of the November 2016 cannabis market, and that the medical segment comprises 25% by weight.

5.2 Effects of changes to market segments

Before proceeding to describe some data of the situation in November 2016, we briefly explain how these estimates will be used in the simulation model that is detailed Chapter 7. The situation in 2018 will be different from the November 2016 situation in three major ways: sale of all legal cannabis will be taxed, the sale of adult-use cannabis will be legalized, and the sale of all legal cannabis will be regulated. In order to separate out the respective economic impacts of taxation and legalization of adult use cannabis (taken together) from the economic impacts of proposed regulations, we apply the changes to our model in two separate steps, estimating at each step the new prices and quantities generated by the model.

We also must make a number of additional assumptions to simulate impacts, including estimates of price elasticities of demand for each segment, supply elasticities and the expected cost (supply) and demand shifts that are assumed to be caused by the two major changes. With these assumptions we are then able to make projections effects of each of the major changes on prices and quantities in the medical ("m") segment, in the illegal ("i") segment, and in a new legal adult-use segment ("a"), which is created by adult-use legalization and thereby competes with the other two segments.

The two major changes and their resulting cost (supply) and demand shifts are described next. The magnitudes of the estimated shifts, along with elasticities and other assumptions, are reported in Chapter 7 and Chapter 8.

5.2.1 Change 1: Taxation and adult-use legalization. The first major change, which we call "taxation and adult-use legalization," results in a new hypothetical scenario (understood to be after November 2016, but not pegged to any specific date, as it is a counter-factual scenario) in which the sale of adult-use cannabis becomes legal and the cultivation and excise taxes on cannabis are imposed, but the California cannabis industry remains otherwise unregulated by the state. Note that this is a purely counter-factual scenario, constructed for the purposes of separately isolating the impacts of proposed regulations. It does not correspond to the passage

or implementation of AUMA or to any other real-life market environment that is expected to arise now or in the future. So as to cleanly separate our starting market snapshot from the changes whose effects we estimate, the market data in this chapter are meant to describe the California cannabis market up to the point in November 2016, when Proposition 64 passed.

In the actual California cannabis situation, we recognize that the AUMA framework is taking effect in two temporal stages. First, in November 2016, immediately upon the passage of Proposition 64, several cannabis activities were decriminalized for all adults 21 and over, including adult possession of up to one ounce, the cultivation of up to six plants for personal consumption, and the distribution of free cannabis. Also in November 2016, the sale of cannabis and possession of larger quantities of cannabis was reclassified from a felony to a misdemeanor under state law. Second, in January 2018, the state will implement regulations that legalize adult-use sales and begin collecting new taxes for legal sales of cannabis.

We continued to survey data for our November 2016 market snapshot through the end of the month of November, under the assumption that it would take at least several weeks, if not months, for the effects of the decriminalization of personal adult-use possession (but not sale) due to Proposition 64 to begin to have significant effect on market prices or quantities. Data we collected in December 2016 and January 2017, however, were not used to construct the November 2016 market snapshot.

The unregulated “taxation and adult-use legalization” scenario which we use for the counter-factual baseline to assess impacts of regulations does not correspond to the real-life partially decriminalized 2017 situation (which does not include taxation or legal adult use dispensary sales) or to the real-life 2018 marketplace (in which state regulations will be in effect as well as adult-use sales). Rather, the “adult-use legalization and taxation” hypothetical is understood to be a situation in which adult-use cannabis is legally sold at retail and all legal cannabis sales are fully taxed, but in which the regulations are not implemented.

The supply and demand shifts we project from adult-use legalization may first begin to partially manifest during 2017, as the information that adult-use cannabis has been legalized may already begin to lower risk premiums, open capital markets, attract new consumers, and so on. However, since a retail adult-use storefront industry is not likely to exist before 2018, so the shifts in supply in demand attributable to taxation and adult-use legalization will not manifest fully until after that.

Thus the “taxation and adult-use legalization without regulation” scenario will remain a counter-factual hypothetical and never materialize in the actual California marketplace.

Supply effects of Change 1: First, adult-use legalization legitimizes the industry in the eyes of trading partners and the potential labor market, and it opens up new mainstream sources of risk-averse capital, enabling investment in more efficient technology and expansion to enable scale economies. The removal of taboos and social stigma may also expand the labor market to include a new pool of potential managers and other employees.

Second, adult-use legalization lowers the “risk premium” for supplying cannabis, which, as explained in Appendix Section 3.2, is a significant cost of doing business in the November 2018 pre-legalization market. This reduction of risk premium costs is greatest in the newly legal adult-use segment, as formerly illegal sellers whose business activities that had formerly been punishable by lengthy imprisonment terms open legal adult-use operations with little fear of state criminal prosecution. This lowers the premium wages that illegal cannabis businesses would previously have had to pay employees in exchange for assuming such risks, as well as lowering security costs, costs of concealment, and other costs of doing illegal business. This results in a shift downward of costs for supplying adult-use cannabis (shift right in the supply curve).

Risk premium costs are also lowered in the medical segment. Although their prior risk premium costs had not been as high as they were in the illegal market, the opening of mainstream capital labor markets that results from de-stigmatization also lowers the costs of doing business for medical cannabis businesses. These effects combine to lower the total cost of supplying cannabis in the adult-use and medical segments, with shifts downward (right) in their respective supply curves.

Finally, cultivation and excise taxes are applied to legal cannabis at two different points along the supply chain, resulting in an additional percentage cost increase for supplying all legal cannabis and an additional shift upward (left) of the supply curves in the medical and adult-use segments.

Demand effects of Change 1: Adult-use legalization is expected to have four main effects on demand for cannabis. The first demand effect is the migration of consumers from the illegal market to the adult-use market due to the lower perceived risks of punishment, unsatisfactory product quality, or fraudulent seller activity. This results in a shift outward (right) of the

demand curve for adult-use cannabis and a shift inward (left) of the demand curve for illegal cannabis. Note that consumers under 21 must stay in the medical market if they wish to purchase legally; for more on the under-21 portion of the market, see Section 5.4.

The second demand effect is the migration of consumers from the medical market to the adult-use market due to adult-use dispensaries' competitive advantage of not requiring a medical recommendation, which we currently estimate at $50 per year per consumer plus the inconvenience of obtaining the recommendation. This results in a shift inward (left) of demand for medical cannabis and a shift outward (right) of demand for adult-use cannabis.

The third demand effect is the emergence of new cannabis demand from risk-averse non-medical consumers who had previously been unwilling to buy cannabis illegally due to the risks of punishment, social stigma, or moral disutility. This results in a shift outward (right) of demand for adult-use cannabis.

The fourth demand effect is the expansion of the cannabis market to include tourists and other out-of-state visitors, who are prohibited from buying in the medical segment but can participate in a legalized adult-use market (see Section 5.2.2 for details on this effect). This results in a shift outward (right) of demand for adult-use cannabis.

5.2.2 Expected demand shift from out-of-state consumers. There are more than 260 million visits to California from residents of other places per year. These visitors spend more than $122 billion in California.[143] A significant portion of this spending is on leisure goods and services. For instance, tourists have been estimated to spend $7.2 billion per year on wine in California.[144] Demand for new forms of leisure spending by tourists and other visitors to California potentially large.

Given that adult-use cannabis remains illegal in most other states, California's legalized adult-use industry may attract some new visitors whose primary reason for visiting the state is cannabis tourism, as has been observed in Colorado (Miller, 2015), where adult-use cannabis was legalized in 2014. Colorado, whose tourism industry, like California's, is a significant contributor to GDP, may be the most relevant available comparison with respect to the potential impact of an adult-use cannabis industry on tourism.

[143] http://industry.visitcalifornia.com/Find-Research/California-Statistics-Trends/
[144] Estimates of California wine tourism at http://www.discovercaliforniawines.com/media-trade/statistics/.

A survey by Strategic Marketing and Research Insights (Miller, 2015), commissioned by the Colorado Tourism Office and reported in the Denver Post (Blevins, 2015), conducted 33-question surveys of approximately 3,250 tourists from Chicago, Dallas, Houston, San Diego, and several other cities, of which about 10% had vacationed in Colorado between April and September, 2015, the year after adult-use legalization first took effect in Colorado.

8% of the Miller (2015) respondents reported visiting an adult-use cannabis dispensary, of which 85% said cannabis was a "primary motivator" of their visit to Colorado.

5.2.3 Change 2: Regulation. The second major change, which we call "regulation," is then applied to the "taxation and adult-use legalization" scenario, resulting in a scenario that corresponds to the actual situation expected in California in 2018, with state regulation established under the proposed regulations governing medical cannabis plus a set of hypothetical regulations governing adult-use cannabis that are assumed to be substantially similar to the medical regulations.

Supply effects of Change 2: The costs of licensing and compliance with testing, surveillance, transportation, and other new regulations, which are calculated and explained in Chapter 6, add an increase to the cost of supplying all legal cannabis, but not to the illegal segment. This results in a shift upward (left) of the supply curve in the medical and adult-use segments.

Demand effects of Change 2: The contaminant and pesticide testing, labeling, and track-and-trace requirements established by the regulations communicate higher quality, consistency, and product safety to consumers, adding value to the product sold in the two regulated cannabis segments. This results in a shift outward (right) of the demand curve in the medical and adult-use segments.

A summary of the scenarios and supply and demand effects described above is presented in Table 5.1. Following this, we proceed to our estimates of the magnitude cannabis quantity sold to consumers in California, a summary of published market size estimates, and finally a discussion of the under-21 and under-18 portions of the market.

Table 5.1. Summary of baseline market scenarios, changes, and supply and demand effects

Scenario	*Supply effects*	*Demand effects*
November 2016 Medical legal Adult use illegal No cannabis taxes No state regulations	Starting situation	Starting situation
Change 1 Medical legal ***+Adult-use legal*** ***+New taxes applied*** No state regulations	1. Sale, cultivation, and possession decriminalized for 21+; threat of criminal prosecution eliminated: greater efficiency and reduced operating costs translate to cost savings for legal cannabis sellers 2. Risk premium costs decrease amongst the portion of formerly illegal sellers who switch to running legal adult-use operations 3. Risk premium costs also decrease for medical sellers 4. Cultivation and excise taxes increase costs for medical and adult-use sellers	1. Migration from illegal to adult-use due to lower risk and greater convenience reduces illegal demand and increases adult-use demand 2. Migration from medical to adult-use due to lack of need for medical recommendation reduces medical demand and increases adult-use demand 3. New use from California buyers previously deterred by illegal market increases adult-use demand 4. New use from out-of-state visitors increases adult-use demand
Change 2 Medical legal Adult-use legal New taxes applied ***+New state regulations***	1. Costs of compliance increase medical cannabis supply costs 2. Costs of compliance increase adult-use cannabis supply costs	1. Higher perceived safety and quality increases demand for both medical and adult-use

5.3 Quantity estimation methodology

Due to the high level of measurement error inherent to the analysis of markets that have historically been largely illegal, current estimates of the size of the California and US medical and adult-use cannabis markets vary widely.

The market size estimates that would be imputed by taking tax collection information or voluntary patient registration information at face value are not reliable. They vary dramatically

compared with the market projections of industry analysts, informal estimates by industry insiders, and our own estimates.

We begin by explaining the methodology with which we size the market in flower equivalent pound units, and then we report our own AIC market size estimates in Table 5.2. We follow this by reporting and annotating the estimates of other researchers and industry analysts in Tables 5.3a through 5.8.

For cultivation and manufacturing estimates, we rely on projections and calculations made by the economic teams carrying out research for CDPH and DFA.

As indicated in Table 5.2, we estimate the size of the California medical cannabis market in November 2016 at approximately $2 billion of total annual sales revenue (not including sales taxes collected) in the medical cannabis segment. Tax revenue is estimated by the California Board of Equalization leadership to be about $60 million.[145]

Based on Board of Equalization estimates and our calculations, we estimate tax revenue to be about 33% of taxes that would be owed if dispensaries were reporting full revenues.[146] That is we used data from the AIC survey to create an index for the price of medical cannabis, stated as a flower-equivalent price, of $3,453 per pound, which implies a retail quantity of flower-equivalent units of 583,333 pounds on an annual basis.

5.3.1 Flower equivalent units and THC content. An additional challenge in estimating market quantities and prices was accounting for quantities transacted within the various sub-divisions of the existing market, which, as described above, is characterized by a mix of different forms of cannabis as well as different routes from producer to end consumer. The way we confront this challenge is by stating our quantity estimates in terms of "dried flower equivalent," which we derive as follows, benchmarking according to THC levels.

At dispensaries, THC content is the dominant measurement used to test and communicate the strength of a portion of dried cannabis flowers or cannabis oil. THC is also the dominant means of measuring the number of portions of cannabis contained within an edible product. Converting grams of cannabis products into grams of THC is thus the only straightforward

[145] These data are from https://www.boe.ca.gov/news/marijuana.htm

[146] The calculation is based on estimates of how much cannabis sales revenue is generated and how much sales tax receipts are collected. http://www.latimes.com/politics/la-pol-sac-pot-taxes-20160830-snap-story.html

conversion between different categories of cannabis products using information currently provided on product labels. Measuring the grams of THC in a given end-consumer product also corresponds approximately to the amount of raw cannabis that was harvested and processed in order to generate such product.

In a sub-sample of 106 price-THC level pairs for dried flower that we solicited as part of the AIC retail price survey, we observed a mean THC level in dried flower of 23.29%, with a standard deviation of 5.46%. Median THC level was 23.30%, almost identical to the mean, suggesting that the distribution is not significantly skewed. (A more sophisticated analysis of this sub-sample is presented in Appendix Section 4.7.2.)

In our sub-sample, we observe average high prices of $28.00 per 1/8 oz of generic dried flower with an average THC level of 19.7%, or 0.698 g THC, which is equivalent to $40.11 per gram pure THC. For premium dried flowers the price is $45.63 per 1/8 oz of premium dried flower with an average THC level of 24.9%, or 0.882 g THC, which is equivalent to $51.73/g pure THC. The price increase per unit THC for premium vs. generic dried flower is $11. 62 or 29%.

By comparison, a report on cannabis portion equivalency by Orens et al. (2015) for the Colorado Department of Revenue observes an average THC level of 17.1% THC for dried flower, and THC equivalent prices of $55.50/g pure THC equivalent for “discounted” dried flower and $69.40/g for “most common” dried flower, representing a price premium per unit THC of 25.0% for premium vs. generic dried flower.

Although we rely on our own sub-sample for the THC-price regression analysis presented in Section 4.7.2, we rely on the Orens et al. (2015) averages, rather than the averages from our own retail price survey, in obtaining the ratios necessary to convert between different products and estimate total volume, as the AIC survey does not include THC levels of concentrate cartridges or edibles at dispensaries. Due to the large variety of edible products available and the lack of standardization of such products across the marketplace, the AIC survey does not include data on retail prices of edibles.

One-eighth ounce of dried cannabis flower with 17.1% THC (the Orens et al. average) contains 0.61 grams of pure THC equivalent, whereas a 0.5 g cartridge with 62.1% THC (the Orens et al. average) contains 0.31 grams of pure THC equivalent. Using the Colorado retail prices observed in Orens et al. for conversion, THC purchased in vape-cartridge form sells for an average of 2.28

times the price of THC purchased in 1/8-oz dried flower form, and that THC in edible form sells for an average of 3.00 times the price of THC purchased in 1/8-oz dried flower form.

In the AIC survey, cartridge prices averaged $30.30 and $41.50 for high-end. Assuming that the THC concentration ratio for premium vs. generic cartridges is the same (24.9% / 19.7% =) 1.264 as it is for premium vs. generic dried flowers, and taking the Orens et al. (2015) estimate of 62.1% to represent the generic market, we arrive at a generic cartridge THC price of $97.74/g pure THC equivalent, and a premium price of $105.91/g pure THC equivalent. This represents a generic-cartridge-to-generic-dried-flower THC-equivalent price ratio of ($97.74 / $40.15) = 2.43, and a premium-cartridge-to-premium-dried-flower THC-equivalent price ratio of ($105.91 / $51.70) = 2.05. The midpoint between these two ratios is 2.24, which is close to the Orens et al. (2015) observed ratio of 2.28, which gives us confidence in the applicability of Orens et al. (2015) to the California market.

We further assume that the additional markups on THC when sold in the “high-end” forms of concentrates, cartridges, or edibles reflect the additional costs of processing cannabis into other forms, such as concentrates (which require the use of solvents or other processing agents, as well as processing machinery) or edibles (which require even more processing, starting with concentrates and then adding other food ingredients to the mix).

On the low end, meanwhile, some consumers are currently buying dried cannabis flower at prices barely above wholesale. According to anonymized AIC interviews with industry participants at the BMCR pre-regulatory meetings, some non-profit cooperatives with few operating expenses (none, in some cases) are operating in compliance with the Brown Guidelines (at least to an equivalent extent as currently operating dispensaries), and thus form part of the legal medical market while also displaying systematic price heterogeneity unobserved by our retail price survey. If cannabis purchased by consumers through these co-operatives were incorporated into our retail price averages, it would exert a downward pressure on the low end of the price distribution.

As these price anomalies at the high end and the low end are difficult to measure and affect only their respective tails of the price distribution, we assume that the integrity of mean and median prices estimated by our retail price survey are reasonable approximations of the market mean and median prices.

We convert the physical quantity of cannabis transacted in a given market into "flower-equivalent" pounds, wherein one flower-equivalent pound equals the THC-content equivalent of one pound marketable dried cannabis flower containing our retail price survey average of 23.30% THC. The estimates of average prices and quantities that are found throughout the SRIA and Appendix are thus stated in flower-equivalent units.

5.4 AIC quantity estimates

We estimate that 25% of total cannabis by weight, in flower-equivalent units, is currently sold in the medical (legal) segment and 75% is in the illegal segment, which translates to an overall cannabis industry of approximately $7.7 billion in November 2016. These estimates are within the range of other estimates in the industry press.

Table 5.2. AIC estimates of current California cannabis market segments, November 2016

Segment	Share	Lbs flower equivalent	Retail price	Total value
Legal medical cannabis	25%	583,333	$3,453/lb = $216/oz	$2.0 billion
Illegal cannabis	75%	1,750,000	$3,194/lb = $200/oz	$5.7 billion
Total cannabis market	**100%**	**2,333,333**	**$3,259/lb = $204/oz**	**$7.7 billion**

Sources: AIC retail price survey; Board of Equalization tax data; AIC market size meta-study, taking into account credible industry, and analyst estimates as detailed in Tables 5.3a–5.8.

5.5 Other quantity estimates

ArcView estimates are presented in Table 5.3a, and Table 5.3b summarizes a large variety of estimates that provide context to the size of the California market.

Table 5.3a. California cannabis market size, 2014–2016, ArcView estimates

	Segment		
	Legal medical cannabis	***Illegal cannabis***	***Total***
2014 market size	$2.69B	$4.2B	$6.9 billion
2015 market size	$2.76B (61% of US medical market, 48% of total US legal market)	$4.5B	$7.3 billion
2016 market size *Projected to end of year from 6-month data*	$2.81B (56% of US medical market, 40% of total US legal market)	$5.0B	$7.8 billion

Source: ArcView Group annual market capsule reports, 2014, 2015, and 2016.

Table 5.3b. Industry, and analyst estimates of current California legal cannabis market size

Market size	*Relevant market*	*Specific market projection*	*Publication reference*	*Source of value data*	*Publication date*
$2.0 billion	California legal, medical	2016 revenue from CA medical market	"Five More States Could Legalize Adult-use Cannabis On Election Day." Debra Borchardt, *Forbes*	David Dinenberg, CEO, KIND (cannabis software firm)	10/10/2016
$2.7 billion	California legal, medical	2016 revenue from CA medical market	"In California, Cannabis is Smelling Like Big Business." Ian Lovett, *New York Times*	ArcView Group; New Frontier (industry analysts)	4/11/2016
$2.83 billion	California legal, medical	2016 revenue from CA medical market	"How California's Cannabis Legalization Vote Could Impact the Entire Country". Debra Borchardt. Forbes	Adam Bierman, CEO, MedMen (cannabis investment firm)	11/07/2016

Table 5.4 summarizes a variety of estimates about the likely size of the California market in 2018 after implementation of adult-use cannabis statutes (AUMA), including an October 2016 report prepared for Truth Enterprises (University of the Pacific, 2016), which estimates total 2018 legal market quantities at 1.4 million to 1.7 million pounds.

Table 5.4. Media, industry, and analyst estimates of future size of California legal cannabis market with regulation

Market size	*Relevant market*	*Specific market projection*	*Publication reference*	*Source of value data*	*Publication date*
$4.3 billion	California legal, all segments, 2018	2018 total revenue from CA legal market	"How Will Cannabis Legalization Affect California's Black-Market Exports?" Madison Margolin, *LA Weekly*	New Frontier analysis (Cannabist website)	12/05/2016

$5 billion	California legal, all segments	"Future" revenue from CA medical and adult-use markets	"Five More States Could Legalize Adult-use Cannabis On Election Day." Debra Borchardt, *Forbes*	David Dinenberg, CEO, KIND (cannabis software firm)	10/10/2016
$6.5 billion	California legal, all segments, 2020	Projected size of CA legal market	"Report: Legalizing cannabis in California could create $6.5 billion market by 2020." Alicia Wallace, *The Cannabist*	ArcView Group; New Frontier	8/23/2016; cited again 11/04/2016
$7 billion	California legal, all segments	Projected size of CA legal market	"California Treasurer Asks Trump for Guidance on Pot, Banking." Associated Press, quoted in *New York Times.*	John Chiang, California State Treasurer	12/02/2016
$8.38 billion	California legal, all segments	"Prop 64 could add $8.38 billion in annual sales to an already robust medical market worth an estimated $2.83 billion."	"How California's Cannabis Legalization Vote Could Impact The Entire Country." Debra Borchardt, *Forbes*	Adam Bierman, CEO, MedMen (cannabis investment firm)	11/07/2016
$11 billion	California legal, all segments, 2017	"Cannabis consumables expected to grow to $11 billion by the end of 2017."	"OutCo Announces Key Findings from New Report on Cannabis Industry In California" (Outco 2016)	OutCo (industry analyst), quoted in PR Newswire	12/07/2016
1.4 million lbs; 1.55 million lbs	California legal, all segments, 2018	Estimates 1.4 million lbs 2018 baseline, 1.55 ("low growth")–1.69 million lbs ("high growth") with adult-use legalization	"Economic Impact Study of the Cannabis Sector in the Greater Sacramento Area" (University of the Pacific 2016)	Center for Business & Policy Research, University of the Pacific; prepared for Truth Enterprises Inc.	12/07/2016

Table 5.5 provides a summary of the size of the US market, and Table 5.6 looks toward adult-use legalization in more states.

Table 5.5. Media, industry, and analysts estimates of size of current US legal cannabis market

Market size	***Relevant market***	***Specific estimate***	***Publication reference***	***Source of value data***	***Publication date***
$5.7 billion	US legal, all segments, 2015	2015 revenue in US legal market	"Report: Legalizing cannabis in California could create $6.5 billion market by 2020" Alicia Wallace, *The Cannabist*	New Frontier (industry analyst)	8/23/2016
$6 billion	USA legal, all segments, 2016	2016 revenue in US legal market	"The Number of Cannabis Jobs Could Triple in the Years to Come." Sean Williams, *The Motley Fool*	Cowen & Co. (investment firm)	12/11/2016
$7 billion	USA legal, all segments, 2016	2016 revenue in US legal market	"Election May Be a Turning Point for Legal Cannabis". Thomas Fuller, *New York Times*	ArcView Group (industry analyst)	10/24/2016

Table 5.6. Media, industry, and analyst estimates of future size of US legal cannabis market

Market size	***Relevant market***	***Specific estimate***	***Publication reference***	***Source of value data***	***Publication date***
$22 billion	USA legal, all segments, 2020	"The market for both adult-use and medicinal cannabis is projected to grow to $22 billion in 4 years."	"Election May Be a Turning Point for Legal Cannabis". Thomas Fuller, *New York Times*	ArcView Group (industry analyst)	10/24/2016
$23 billion	USA legal, all segments,	2020 revenue from US legal market	"The nation's legal cannabis industry is expected to climb to $23 billion in 2020, up from	New Frontier (industry analyst)	8/23/2016

	2020		$5.7 billion in 2015."		
$50 billion	USA legal, all segments, 2026	"Investment firm Cowen & Co. believes legal cannabis sales could soar…to $50 billion by 2026."	"The Number of Cannabis Jobs Could Triple in the Years to Come." Sean Williams, *The Motley Fool*	Cowen & Co. (investment firm)	12/11/2016

Table 5.7 provides summary statistics on these estimates from a variety of sources.

Table 5.7. Summary statistics from Tables 5.2 – 5.3 compared with AIC estimates

Note: The calculation of means and medians for future projections group together market-size projections for different years, as well as undated market size projections, into a single statistic. Such estimates vary widely and do not appear to correlate with time scale, but in any case the summary statistics should not be interpreted as externally valid meta-statistics. We do not rely on any of the above estimates or projections for our AIC estimates or projections, but we include them in this report by way of comparison and context for our findings.

Current (Fall 2016) California legal cannabis market

Range: $2.0 billion—$2.83 billion

Mean: $2.51 billion / Median: $2.7 billion

Standard deviation: $0.45 billion

AIC estimate: $2.0 billion

Future California legal cannabis market with adult-use legalization and regulation

Number of estimates: 6

Range: $4.3 billion—$11 billion

Mean: $7.03 billion / Median: $6.75 billion

Standard deviation: $2.43 billion

Current US legal cannabis market

Number of estimates: 3

Range: $5.6 billion—$7 billion

Mean: $6.2 billion / Median: $6.0 billion

Standard deviation: $0.72 billion

Future US legal cannabis market

Number of estimates: 3

Range: $22 billion—$50 billion

Mean: $31.7 billion / Median: $23 billion

Standard deviation: $15.9 billion

Table 5.8 summarizes a number of estimates of current and potential tax revenues from cannabis in California.

Table 5.8. Estimates of current and future California tax collections by mainstream, business, and industry media and analysts

Tax Receipts	Relevant market	Specific estimate	Source of media citation	Source of value data	Publication date
$40 million	California current sales tax revenue	Current annual California state sales tax revenue collected from medical segment	"California regulators will be swamped by $1 billion in pot taxes." David Downs, *San Francisco Chronicle*	Fiona Ma, Chairwoman, California BOE	11/4/2016
$777 million	California future annual tax revenue	Projected 2018 California tax revenue from all legal cannabis	"Cannabis Industry Entrepreneurs Want Donald Trump To See Them As Job Creators". Julie Weed, *Forbes*	Matt Karnes, Managing Partner, GreenWave Advisors, LLC	12/5/2016
$1 billion	California future annual tax revenue	Annual tax revenue from legal medical and adult-use MJ sales in California (beginning in 2018).	"California Treasurer Asks Trump for Guidance on Pot, Banking." Associated Press, quoted in *New York Times*	John Chiang, California State Treasurer	12/2/2016

$1 billion	California future annual tax revenue	"Future" annual tax revenue from legal cannabis production	"Former California Mayor Connects Cities With Cannabis Companies." Julie Weed, *Forbes*	No specific source of data given	10/1/2016
$1 billion	California future annual sales tax revenue	"Future" annual sales tax revenue from legal cannabis sales	"California regulators will be swamped by $1 billion in pot taxes." David Downs, *San Francisco Chronicle*	Fiona Ma, Chairwoman, California BOE	11/4/2016; 12/4/2016

5.6 Younger consumers in the market

Under AUMA, adult-use cannabis can be sold only to adults 21 or older, whereas under MCRSA, adults between 18 and 20 are permitted to obtain a physician's recommendation for medical cannabis and to enter a medical cannabis dispensary unaccompanied by a guardian. Therefore, consumers between 18 and 20 will not legally be able to substitute adult-use cannabis for medical cannabis (although they can illegally obtain adult-use cannabis from friends who are 21 or older, as under-21 alcohol consumers do). In terms of economic impact, this disparity in age is the single most substantive distinction between the adult-use and medical regulatory systems.

Cannabis sales to the 18- to 20-year-old consumer group make up a significant portion of the overall consumer cannabis market. According to Johnston et al. (2016), nearly 40% of 19- and-20-year-old Americans consume cannabis at least once per year, and this percentage grew from 2010 to 2015 (Johnston et al. 2016). In 2010, 5.1% of 19- to-20-year-old consumers surveyed reported having consumed cannabis during the prior day, 18.0% had consumed during the prior 30 days, and 30.6% had consumed during the prior year.

By 2014, those numbers had all risen sharply: 7.9% of 19-to-20-year-old consumers surveyed had consumed during the previous day (a 55% increase over the five-year period), 24.3% had consumed during the previous 30 days (a 35% increase), and 38.0% had consumed during the previous year (a 24% increase). Whether measured by frequent or infrequent consumption, Americans between the ages of 19 and 20 are more likely to be cannabis consumers than people of any other age (Johnston et al. 2016).

A 2012 California Behavioral Risk Factor Surveillance System (BRFSS) survey of 7,525 Californians observes that 9.3% of 18-to-24-year-olds—the youngest age group surveyed in the study—report being medical cannabis patients, the highest prevalence of any age group; 25-to-34-year-olds are in a distant second place, with a prevalence of just 5.5% (Ryan-Ibarra 2012).

Our own analysis of data from the National Survey on Drug Use and Health (NSDUH), adding in several simplifying assumptions, suggests that as of 2013, 14.4% of all cannabis consumed in the United States was consumed by people between 18 and 20, and an additional 8.1% was consumed by the 12-17 age group; in total, thus, 22.5% of total cannabis consumed in 2013 was consumed by people under 21 (NSDUH 2013).

Taking all of the above evidence into consideration, we estimate that users between 18 and 20 currently make up approximately 15% of the $2 billion medical retail cannabis market, or $350 million, and 15% of the $6 billion illegal cannabis market, or $800 million. Whereas consumers over 21 will likely shift away from medical cannabis when legal adult-use cannabis becomes more convenient, some and perhaps many consumers under 21 will remain in the legal medical market and pay for its additional barriers to consumer entry.

A SAMHSA study of 2013 to2014 data found a 30-day use prevalence of 8.74% amongst youths aged 12 to 17 (Hughes et al. 2015), and data from NSDUH suggested that approximately 5% of all cannabis is consumed by 12-to-17-year-olds (NSDUH 2013). Under the expected MCRSA and AUMA regulations, medical cannabis patients under 18 will only be able to obtain medical cannabis at a dispensary if accompanied by primary caregivers 18-years-old or older.

Data on the whole California consumer market are summarized in Tables 5.9 and 5.10. Overall, about 14% of California residents 12 and over report cannabis use in the past year and 9% report use within the past month. The age decomposition of use is summarized in Table 5.11, which shows the peak use is in the age 18 to 24, with about 21% consuming within the prior month. Use in the age group 12 to 17 is almost 10% higher than those 25 and over.

Table 5.9. Percentage[1] of individuals aged 12 or older in California that report cannabis use in the past year, by county

Region	Small Area Estimate[2]	95% CI (Lower)[3]	95% CI (Upper)[3]
Sacramento County	15.70%	12.99%	18.86%
San Francisco County	22.56%	17.94%	27.96%
Santa Clara County	12.31%	10.08%	14.96%
Contra Costa County	14.90%	12.12%	18.19%
Alameda County	14.77%	12.19%	17.79%
San Mateo County	13.61%	10.69%	17.17%
Los Angeles County	13.55%	12.40%	14.78%
Orange County	12.76%	10.83%	14.97%
Fresno County	13.20%	10.69%	16.20%
San Diego County	15.81%	13.65%	18.24%
San Bernardino County	12.45%	10.42%	14.82%
California Statewide	**14.32%**	**13.51%**	**15.18%**

[1] Source: percentages are annual averages based on SAMHSA, Center for Behavioral Health Statistics and Quality, and National Survey on Drug Use and Health (NSDUH) 2012, 2013, and 2014.

[2] Source: estimates are based on a small area estimation (SAE) methodology in which sub-state-level NSDUH data are combined with county and census block group and tract-level data from California.

[3] The 95% confidence (credible) intervals are based on a survey-weighted hierarchical Bayes estimation approach and are generated by Markov Chain Monte Carlo techniques.

Table 5.10. Percentage[1] of individuals aged 12 or older in California that report cannabis use in the prior month, by county

Region	Small Area Estimate[2]	95% CI (Lower)[3]	95% CI (Upper)[3]
Sacramento County	10.19%	8.04%	12.83%
San Francisco County	15.46%	11.52%	20.44%
Santa Clara County	7.78%	6.10%	9.89%
Contra Costa County	9.55%	7.32%	12.36%
Alameda County	10.67%	8.41%	13.44%
San Mateo County	9.07%	6.72%	12.13%
Los Angeles County	8.44%	7.55%	9.43%
Orange County	8.09%	6.58%	9.89%
Fresno County	8.10%	6.17%	10.58%
San Diego County	9.42%	7.70%	11.47%
San Bernardino County	7.62%	6.03%	9.59%
California Statewide	**14.32%**	**13.51%**	**15.18%**

[1] Source: percentages are annual averages based on SAMHSA, Center for Behavioral Health Statistics and Quality, and National Survey on Drug Use and Health (NSDUH) 2012, 2013, and 2014.

[2] Source: estimates are based on a small area estimation (SAE) methodology in which sub-state-level NSDUH data are combined with county and census block group and tract-level data from California.

[3] The 95% confidence (credible) intervals are based on a survey-weighted hierarchical Bayes estimation approach and are generated by Markov Chain Monte Carlo techniques.

Table 5.11 Measures of Cannabis Use in California[1], by Age Group: Estimated Numbers and Share of Age Group Population, Annual Averages Based on 2013-2014 NSDUHs

			Age		
Measure	***12 and over***	***12-17***	***18-25***	***26 and over***	***18 and over***
		Number of cannabis users (in thousands)			
Past Year Use	4,633	463	1,506	2,664	4,170
Past Month Use	2,942	269	941	1,733	2,673
		Share of age group population			
Past Year Use	14.49%	15.03%	33.69%	10.91%	14.44%
Past Month Use	9.20%	8.74%	21.05%	7.09%	9.25%

Sources: SAMHSA, Center for Behavioral Health Statistics and Quality; National Survey on Drug Use and Health, 2013 and 2014.

[1] Measures are estimated using a survey-weighted hierarchical Bayes estimation approach.

6. Compliance costs of proposed regulations and alternatives

Regulations generally add to costs. The proposed regulations for medical cannabis add new compliance costs for medical cannabis businesses that are not part of their current costs of doing business without regulation (as reported in Chapter 3) nor part of the costs that are generated by the hypothetical taxation and adult-use legalization baseline scenario (as explained in Chapter 5). Potential benefits of proposed regulations are discussed in Chapter 5 and Chapters 7 and 8 in terms of increased willingness to pay by consumers for additional security and safety.

This chapter will estimate three different sets of compliance costs: costs generated by the proposed regulations; costs generated by an alternative regulatory package that are less costly than the proposed regulations; and costs generated by a second alternative package that imposes higher security than the proposed regulations, but at higher costs. We present and discuss these alternative packages in Section 6.1 and Table 6.1, and the remainder of Chapter 6 estimates and compares their respective compliance costs.

In all three cases, compliance costs are applied and analyzed in the context of a business environment with taxation and adult-use legalization already in place. Compliance costs are thus calculated as costs generated by each new scenario (with taxation, adult-use legalization, and the given regulation package in place) minus costs generated by the hypothetical baseline scenario (taxation and adult-use legalization in place but no regulations).

6.1 Evaluation of compliance costs and selection of regulatory alternatives

In the following sections, we describe and estimate compliance costs under the package of proposed regulations and compare them with compliance costs under two other hypothetical packages of regulations: a lower-cost alternative package and a higher-security alternative package. From the universe of all possible alternative regulatory packages that would meet the statutory requirements of MCRSA, we selected the lower-cost and higher-security alternative packages by varying particularly significant elements of the proposed regulations in terms of direct costs of compliance for cannabis businesses. We set out the chosen regulatory alternatives and axes of variation in Table 6.1.

Table 6.1 Major differences between the proposed regulatory package and two alternative regulatory packages with implications for direct costs of compliance

Impact Variable	*Lower-cost alternative*	*Proposed regulations*	*Higher-security Alternative*
1. Maximum batch size for mandatory testing	• No maximum batch size	• 10 lb maximum batch size	• 5 lb maximum batch size
2. Dispensary-to-consumer delivery restrictions	• No restrictions on vehicle type • No lockboxes required • No restrictions on number of employees	• Cars only • Lockboxes required • No restrictions on number of employees	• Cars only • Lockboxes required • Deliveries must be made by 2 or more employees
3. Security video archival requirements	• No requirements	• 1280x1024, 20fps • 30 days archive	• 1280x1024, 20fps • 90 days archive
4. Cannabis waste disposal and quarantine requirements	• No requirements	• Before disposal, all cannabis waste must be:	• None chosen

	1. Disguised by blending with solid waste or soil 2. Weighed and labeled with bill of lading with product info 3. Quarantined in a dedicated area on camera for 72 hrs

Source: AIC analysis of proposed regulations, MCRSA statutes, and AIC interviews with Bureau and CDPH.

In Sections 6.2 through 6.4, we itemize and break down the compliance costs for each of the business activities that is regulated by the Bureau. We sort costs into three groups by business function along the vertical supply chain: distribution and transportation (Section 6.2 and Table 6.2), testing (Section 6.3 and Table 6.3), and dispensing (Section 6.4 and Tables 6.4–6.6). For each of these functions, we list the compliance costs under the proposed regulations and under the hypothetical lower-cost and higher-security alternatives and compare them with the baseline without regulation. In Table 6.5, we provide a more detailed breakdown of video surveillance and archival costs, which is component of compliance costs for all functions except transport. Finally, in Section 6.5 and Table 6.7, we summarize all of the above costs and derive total compliance costs for the proposed regulations and alternatives.

6.2 Compliance costs for distribution and transportation

Table 6.2 shows our cost estimates for the distribution and transportation functions. The proposed regulations add about $6.51 per pound, whereas the lower-cost alternative adds $2.51 per pound and the higher-security alternative adds $8.92 per pound.

Table 6.2. Itemized compliance cost estimates for distribution and transportation

All costs stated per pound flower equivalent

Compliance costs	*Unregulated Baseline*[2]	*Lower-cost alternative*	*Proposed regulations*	*Higher-security alternative*
Video surveillance and archival[1]	-	-	$1.45	$3.86
Disposal and quarantine[1]	-	-	$2.48	$2.48
Laminated employee badges[1]	-	-	$0.08	$0.08
Other compliance[2]	-	$2.51	$2.51	$2.51
Total compliance costs	-	$2.51	$6.51	$8.92
Difference vs. unregulated baseline		**$2.51**	**$6.51**	**$8.92**

Source: AIC estimates based on industry data.

[1] Video, disposal, and badge costs calculated based on dispensary estimates. See Sections 6.4.1–6.4.3 for details.

[2] Includes track-and-trace.

[3] Taxation and adult-use legalization baseline without regulations applied.

6.3 Compliance costs for testing

AIC estimates that testing is the category of regulations causing the largest compliance costs, with the proposed regulations adding approximately $407 per pound to the cost of cannabis. Table 6.3 presents our estimates of testing costs with the proposed or alternative regulations in effect vs. testing costs in the unregulated taxation-and-adult-use legalization baseline.

Table 6.3. Itemized compliance cost estimates for testing

All costs stated per pound flower equivalent

Compliance variables and costs	*Unregulated baseline*[6]	*Lower-cost alternative*	*Proposed regulations*	*Higher-security alternative*
Assumed average batch size[1]	-	15 lbs	10 lbs	5 lbs
Basic lab cost per test[1]	$200.00	$1,000.00	$1,350.00	$1,350.00
Handling restrictions per test[1]	-	-	$25.00	$25.00
Percent of total cannabis tested[1]	10%	100%	100%	100%
Testing costs per pound[1]	$2.67	$66.67	$171.88	$343.75
Video surveillance and archival[2]	-	-	$0.72	$1.93
Disposal and quarantine[2]	-	-	$1.24	$1.24
Laminated employee badges[2]	-	-	$0.04	$0.04
Other compliance[3]	-	$1.25	$1.25	$1.25
Testing laboratory margin[4]	$0.67	$16.98	$43.78	$87.05
Inventory loss due to failed tests[5]	-	$95.80	$191.60	$191.60
Total testing compliance costs	$3.33	$180.70	$410.51	$626.87
Difference vs. unregulated baseline		**$177.37**	**$407.18**	**$623.53**

Source: AIC calculations based on industry data.

[1] Baseline testing cost of $250 (assumed to be 25% margin) from informal AIC survey of two testing labs. Regulation scenario testing costs are based on CDPH and DPR estimates, assuming $1,000 per test in lower-cost alternative, $1,350 per test + $25 per test handling cost in the proposed regulations and higher-security alternative. Higher-security alternative varies only batch size, not lab or handling cost. Higher-security alternative assumes same cost per test as proposed regulations, and varies only maximum batch size.

[2] Video, disposal, and badge costs calculated based on dispensary estimates. See Sections 6.4.1–6.4.3 for details.

[3] Includes track & trace compliance.

[4] Assumes 25% margin; calculated against pre-inventory-loss testing costs.

[5] Assumes 10% loss in lower-cost alternative, 20% loss in proposer regulations and higher-security alternative. Assumes $150/lb resale value of failed inventory for distillation (source: interview with Era Economics).

[6] Taxation and adult-use legalization baseline without regulations applied.

6.3.1 Testing costs without regulation. We do not expect that the addition of taxation and adult-use legalization would add any extra testing costs to the pre-legalization November 2016 scenario that we observed empirically, so we construct our estimate for testing costs in the taxation and adult-use legalization baseline by analyzing data from AIC's fall 2016 survey (see Chapter 4 for details). In that survey, we observed that 6% of retail product is tested, and that virtually all businesses who test are only testing and labeling for THC and CBD content, and not testing for pesticide residues or other contaminants that require wet-lab technology.

We adjust the percentage of product tested from 6% to 10% based on our estimate that only 60% of dispensaries who test for THC report the results in their online product descriptions. As testing is currently voluntary, there is obviously no maximum batch size, so we use the industry average batch size of 7.5 pounds per batch (Cannabis Benchmarks 2016; we also use this average in our calculations of distribution and transportation costs).

Based on estimates from two leading testing laboratories in the state, SB Labs in Santa Barbara and Steep Hill Labs in Oakland, we estimate that the types of tests currently being obtained voluntarily by cannabis business are priced between $150 and $350, with $250 as a rough average. We thus obtain a net testing cost per pound of ($250 / 7.5) x 10% = $3.33 per pound, of which $2.67 is testing cost and $0.67 is testing lab margin.[147]

6.3.2 Testing costs under the proposed regulations. Testing for only THC and CBD concentration, as is currently done in the industry, is relatively quick and inexpensive, and can be done with portable technology because it uses light-based techniques. (However, there are reports of widely variable and inaccurate testing results.) Testing for pesticides and other compounds requires wet-lab procedures that are relatively immobile and require the use of costly chemical reagents and the employment of skilled lab technicians with master's-degree-level educations.

[147] We assume all testing costs to include a 25% testing lab margin (in this case, $160 costs + $40 margin), which is chosen based on AIC interviews with two anonymous lab operators. Note that we do not assume margins for the distribution or transportation functions: unlike testing labs, those functions are not currently set up as independent businesses with observable margins.

The proposed testing regulations include DPR's current proposed set of pesticide tests as of December 2016, which are more stringent than those specifically required by the MCRSA statute. These proposed pesticide tests are the largest source of added costs per pound in the proposed regulations. The information provided by DPR and CDPH suggests that the lab costs of the tests in the proposed regulations, will cost between $1,200 and $1,500 per test. We assume the midpoint of $1,350 per test for the proposed regulations.

The proposed regulations also add certain restrictions on the collection, storage, labeling, and disposal of samples that are relatively minor compared with the cost of pesticide testing. We estimate that these costs will add approximately $0.27 per five-gram sample, or $25 per pound tested, which we call "handling costs." These handling costs are separate from the compliance costs for the track-and-trace requirements mandated by the MCRSA statutes, which are included as costs in all three regulatory scenarios as part of "other compliance costs." We thus use $1,375 as our total cost per test for the proposed regulations.

The proposed regulations also establish a 10-pound maximum batch size for testing. Batch-size regulations may allow for more-precise testing and are tied to homogeneity of a batch to assure that the sample reflects the characteristics of the batch. A lower batch size allows for a more-representative sample and therefore more-accurate testing, which in turn allows for cleaner cannabis. It also dissuades people from mixing clean harvest batches with tainted batches and assuming that there is a low probability that the tainted product will be sampled for testing.

Maximum-batch-size regulations add costs to testing, as they require distributors to divide up larger cannabis lots into multiple batches for testing, thus increasing the average cost per pound of testing. For example, while a 10-pound maximum batch size rule would not affect the price per pound of testing a five-pound lot, it would double the price per pound of testing a 20-pound lot, which would have to be tested in two 10-pound batches. According to Cannabis Benchmarks (2016), the average lot size in the California wholesale market is currently about 15 pounds. We estimate that imposing a 10-pound maximum would lower the average tested batch size from 15 pounds (if each batch represented a full lot) to eight pounds, which almost doubles the number of cannabis tests that must be performed in the state.[148] Assuming $1,375 per test and eight pounds per batch, we estimate that the proposed regulations will raise the

[148] This figure is lower than 10 pounds due to the fact that as long as many small lots exist, as we expect they will in the foreseeable future, the average batch size will always be lower than the maximum batch size).

cost of medical cannabis by approximately $407 per pound from the taxation and adult-use legalization baseline described in Section 6.3.1.

6.3.3 Testing costs under the lower-cost alternative regulations. An earlier October 2016 analysis by CDPH chemists and estimates from laboratories, conducted before the latest more costly set of pesticide testing standards were proposed by DPR, estimated the lab cost per test at $1,000. In the absence of more complete information from CDPH and DPR, we use $1,000 per test in our lower-cost alternative package. In the lower-cost alternative, we also leave out the restrictions regarding collection, storage, labeling, and disposal of samples that are not part of the MCRSA statutory requirements, so we do not add the $25 per pound in additional sample handling costs.

There is no statutory guidance from the MCRSA on maximum batch sizes, so a less costly alternative would be to specify no maximum batch size for testing. We thus assume no maximum batch size in the lower-cost alternative package of regulations. We estimate that the lower-cost alternative will raise the cost of medical cannabis by approximately $177 per pound compared with the taxation and adult-use legalization baseline described in Section 6.3.1. This is $230 per pound less than the cost of the proposed regulations described in Section 6.3.2.

6.3.4 Testing costs under the higher-security alternative regulations. The higher-security alternative varies batch size, imposing a five-pound maximum batch (as in Washington State), but otherwise assumes the same set of pesticide residue minimums, handling requirements, etc. The cost per test in the higher-security package is thus held constant at $1,375.

With a maximum batch size of five pounds, we assume an average tested batch size of four pounds (following the same logic as in Section 6.3.2 footnote 4). This raises the testing cost per pound of medical cannabis by $624 above the taxation-and-adult-use-legalization baseline. This is $217 per pound more than the proposed regulations.

6.4 Compliance costs for dispensing

The proposed regulations have a multi-faceted impact on the cost of selling cannabis at retail. Table 6.4 reports summary compliance costs for dispensing, not including dispensary delivery.

Table 6.4 Itemized compliance cost estimates for dispensing, not including delivery
All costs stated per pound flower equivalent

Compliance costs	*Unregulated baseline*[5]	*Lower-cost alternative*	*Proposed regulations*	*Higher-security alternative*
Video surveillance and archival[1]	-	-	$14.47	$38.63
Disposal and quarantine[2]	-	-	$24.81	$24.81
Laminated employee badges[3]	-	-	$0.75	$0.75
Other compliance[4]	-	$25.05	$25.05	$25.05
Total dispensing compliance costs per lb, not including delivery	-	$25.05	$65.08	$89.24
Difference vs. unregulated baseline		**$25.05**	**$65.08**	**$89.24**

Source: AIC calculations based on industry data.

[1] For assumptions, explanations, and cost detail for video surveillance, see Table 6.5.

[2] Assumes 60 sq ft, $265/sq ft/yr costs, $15,880/yr/dispensary, 640 lbs/yr/dispensary.

[3] Assumes $53/employee/year, 9.1 employees/dispensary, 640 lbs/yr/dispensary.

[4] Includes track-and-trace compliance. Assumes $1,060/yr/employee, 9.1 employees/dispensary, 640 lbs/yr/dispensary, plus AIC estimate of $10 per pound for track-and-trace compliance.

[5] Taxation and adult-use legalization baseline without regulations applied.

6.4.1 Surveillance and video archival compliance costs. The proposed regulations require license holders to maintain security cameras with 1280 x 1024 resolution at 20 frames per second, and to maintain a 30-day video archive of footage from these cameras. We estimate that the average dispensary will require five or six cameras to achieve compliant coverage. Detailed calculations are shown in Table 6.5.

Table 6.5. Itemized compliance cost estimates for dispensary video surveillance and archive

Compliance variables and costs	*Unregulated Baseline*[4]	*Lower-cost alternative*	*Proposed regulations*	*Higher-security alternative*
Number of cameras	-	-	6	6
Resolution	-	-	1280x1024	1280x1024
Frames per second	-	-	20 fps	20 fps
Days of storage	-	-	30	90
Amount of storage required[1]	-	-	18 TB	54 TB
Storage cost per month[2]	-	-	$608.00	$1,825.00
Equip, maintenance & power cost per month[3]	-	-	$120.00	$120.00
Total cost per month	-	-	$728.00	$1,945.00
Total cost per year	-	-	$8,736.00	$23,340.00
Total cost per lb	-	-	$728.00	$1,945.00
Difference per lb vs. unregulated baseline		**-**	**$14.47**	**$38.63**

Source: AIC estimates based on industry data.

[1] TB = terabytes. Surveillance video storage requirement estimates from Seagate.com.

[2] Based on Amazon Cloud storage price quote of $0.033/GB.

[3] Assumes $20/camera/month equipment, software, maintenance, and power costs.

[4] Taxation and adult-use legalization baseline without regulations applied.

Because MCRSA does not state any security video or archival rules and there is no current mandatory cost of video surveillance archival in the unregulated state, the taxation and adult-use legalization baseline and the lower-cost alternative for mandatory security video costs are both set to zero. Under the proposed regulations, we estimate the cost per pound of retail medical cannabis to rise by about $14 per pound compared with the lower-cost alternative.

A higher-security alternative would be to require footage to be maintained for 90 days. This would raise costs to $39 per pound above the lower-cost alternative, which is $27 per pound above the cost of the proposed regulations. The 30-day video archival requirement achieves Bureau regulatory enforcement and non-Bureau-related law enforcement objectives which have benefits to the public safety discussed above.

Other additions to dispensary costs are labeling and track-and-trace requirements, for which the proposed regulations are not substantially more costly than what would be required by the lower-cost alternative, as MCRSA requires a track-and-trace system. For all functions, these costs are included in the "other compliance" category in all scenarios with regulations, including the lower-cost alternative, and thus do not impact the differences between the costs of proposed regulations and the costs of lower-cost or higher-cost alternatives.

6.4.2 Disposal, quarantine, and badge compliance costs. The proposed regulations specify that licensees must follow certain procedures in order to dispose of cannabis waste. Licensees must maintain a dedicated quarantine area, take precautions to secure the area, and make cannabis waste "unusable and unrecognizable" before removing it from the premises. This must be done by "grinding and incorporating the cannabis waste with non-consumable solid waste such that the resulting mixture is at least 50% non-cannabis waste." Permitted types of non-consumable solid waste for these purposes include paper, plastic, cardboard, food waste, grease or other compostable oil waste, a compost activator, or soil.

Cannabis waste must then be labeled with a bill of lading or shipping manifest that indicates product information and weight. Finally, it must be held in the quarantine location for at least 72 hours before being removed from the premises. All of this must be done on camera, and a separate surveillance camera with 30-day archive is required for the quarantine area. As quarantining is not currently practiced by dispensing, distribution, transport, or testing businesses in the state, it is difficult to estimate the costs of the new quarantine requirements with any degree of confidence.

We estimate that these quarantine requirements will add approximately $25 to total cost per pound for dispensaries. We base this on the assumption that the average quarantine area will be 60 square feet (assuming a 6-foot-by-10-foot space) and cost $265 per square foot per year to rent, maintain, and operate, including security, surveillance video maintenance, labor and training costs. This is a total of $15,900 per year per location.

Assuming that the average dispensary will sell 640 pounds flower equivalent per year (an estimation developed in based on data collected from currently operating cannabis businesses, as detailed in Chapter 3), we arrive at an added cost of disposal and quarantine approximately $25 per pound cannabis for dispensaries. We do not vary this standard in the higher-security alternative, as the proposed disposal and quarantine standards appear to be comprehensive.

Finally, we estimate the cost of producing compliant badges for all employees at dispensaries at $53 per employee per year, based on equipment and materials costs. Assuming 9.1 employees per dispensary and 640 pounds produced per dispensary, this converts to an overall cost of $0.75 per pound.

6.4.3 Estimation of video surveillance and archive, disposal and quarantine, and badge compliance costs for the distribution and testing functions. The video surveillance and archive, cannabis waste disposal and quarantine, and laminated badge cost calculations described in Sections 6.4.1 and 6.4.2 apply not just to dispensaries, but also to the distribution and testing functions described in Sections 6.2 and 6.3. (We do not consider transporters separately because we anticipate that almost all licensed transporters will also hold other licenses and thus already need to comply.)

In order to obtain estimates for these compliance cost inputs for the distribution and testing functions, as shown in Tables 6.2 and 6.3, we note that the costs of compliance in these categories are substantially (though not strictly) fixed per location. For instance, the construction and maintenance of a quarantine area is unlikely to vary much between an average dispensary and an average distributor, even if the distributor has a larger facility and handles 10 times the amount of cannabis as the dispensary.

To estimate video surveillance costs, disposal costs, quarantine costs, and laminated badge costs for the distribution and testing functions, we thus made the broad assumption that these per-location costs were the same per location as for dispensaries.

We thus calculate costs per pound of compliance with disposal, quarantine, and badge regulations for distribution and testing as follows: we assume that 640 pounds per year are handled by the average dispensary and that there is one distributor for every 10 dispensaries, with the average distributor thus handling 6,400 pounds per year. Video, disposal, quarantine, and badge compliance costs per pound for distributors are therefore estimated at 10% of those costs for dispensaries. We assume that there is one testing lab for every 2 distributors, or

12,800 pounds per year handled by the average testing lab. Thus, video, disposal, quarantine, and badge compliance costs per pound for testing labs are estimated at 5% of those costs for dispensaries.

6.4.4 Dispensary delivery compliance costs. Medical cannabis deliveries are now typically done by car. However, some urban dispensaries make deliveries on foot, bicycle, electronic bicycle (e-bike), or scooter at a significant cost savings to the firm.

Delivery costs currently add approximately $150 per pound to the retail cost of medical cannabis. This calculation relies on an AIC estimate that 40% of product is delivered. We derived this estimate as follows: the AIC retail price survey, as detailed in Appendix Chapter 4 and summarized in Table 4.1, found that 53% of dispensaries offered in-store sales only, 43% of dispensaries offered delivery sales only, and 4% of dispensaries offered both in-store and delivery sales. Accounting for the fact that retail dispensaries tend to have larger annual sales volume than delivery services, we estimated that approximately 40% of cannabis in California is sold via delivery, and 60% is sold via in-store sales.

MCRSA statutes do not specify any delivery-method restrictions, and there are none currently in place, so neither taxation and adult-use legalization baseline nor our lower-cost alternative generate any additional costs above the basic $150 per pound delivery cost.

The proposed regulations do not allow any of the lower-cost alternative delivery methods, which, due to their energy efficiency, we would otherwise expect to become more common business practices as the industry moves into the mainstream. As shown in Table 6.6, this restriction would raise the average cost of delivering medical cannabis in the state to $160 per pound, and would raise the cost of cannabis delivery by approximately $10 per pound compared with the unregulated baseline delivery cost. However, unenclosed vehicles do not allow as much security as enclosed vehicles. Attaching a lock-box to a person would be impossible, and attaching one to a bicycle or e-bike, or scooter would likely be impractical. With these delivery vehicles allowed, the security objectives of the proposed lock-box regulatory provisions would be ineffective at the delivery stage increasing potential for criminal activity in neighborhoods surrounding dispensaries.

A higher-security alternative is to require two employees to be in each delivery vehicle (one driver and one delivery representative), which would enable one employee to be with the medical cannabis inventory at all times. This would provide an additional level of security. The

additional labor costs that would result from the higher-security alternative would increase the cost of medical cannabis by an additional $148 per pound compared with the proposed regulations.

Table 6.6 breaks down the calculations and assumptions we use to estimate dispensaries' delivery compliance costs. Note that these compliance costs apply only to the dispensing function and not to other functions.

Table 6.6 Itemized compliance cost estimates for dispensary delivery

Compliance cost variables	*Unregulated baseline*[4]	*Lower-cost alternative*	*Proposed regulations*	*Higher-security alternative*
Total lbs sold	230,000	230,000	230,000	230,000
Total lbs delivered (assuming 1/2 oz)[1]	92,000	92,000	92,000	92,000
Avg lbs per delivery[2]	0.03125	0.03125	0.03125	0.03125
Avg distance per on-foot delivery, miles	1	1		
Avg time per on-foot delivery, hours	0.5	0.5	-	-
Total cost per on-foot delivery, including equip & labor[3]	$10.80	$10.80	-	-
Avg distance per e-bike delivery, miles	3	3	-	-
Avg time per e-bike delivery, hrs	0.5	0.5	-	-
Total cost per e-bike delivery, including equip & labor[3]	$10.83	$10.83	-	-
Avg distance per car delivery, miles	5	5	3	3
Avg time per e-bike delivery, hrs	0.5	0.5	0.5	0.5
Total cost per car delivery, including equip & labor[3]	$13.63	$13.63	$12.50	$23.30
Overall avg cost per delivery	$11.75	$11.75	$12.50	$23.30
Avg cost of delivery per lb delivered	$376.00	$379.18	$400.00	$745.60
Total cost of delivery per lb sold	$150.40	$150.40	$160.00	$298.24

Difference vs. unregulated baseline	**-**	**$9.60**	**$147.84**

Source: AIC calculations based on industry data.

[1] Assumes 40% of product delivered based on AIC fall 2016 survey and analysis; see Section 6.4.4 for methodology.

[2] Assumes average delivery of 1/2 oz = 0.03125 lbs per trip.

[3] Assumes $18/hour labor (see Chapter 3) plus 20% administrative time. We assume $0.01/mile e-bike operating costs and $0.565/mile car operating costs (the Federal reimbursement rate). Assumes that one-third of deliveries average 1 mile and could be made on foot, one-third of deliveries average 3 miles and could be made by e-bike, and one-third of deliveries average 5 miles and would be made by car.

[4] Taxation and adult-use legalization baseline without regulations applied.

6.5 License fees and summary compliance costs

A summary of the costs of the package of proposed regulations and the two alternative packages of regulations are provided in Table 6.7. Testing is by far the most costly component of the proposed regulations, accounting for 80% of added costs. Surveillance video archive, cannabis waste disposal, and quarantine expenses also add significantly to compliance costs. License fees are a small share of additional costs, and would account for about 4% of added costs of compliance and well below 1% of likely consumer prices, which include substantial sales and excise taxes.

Table 6.7 Summary of license fees and compliance costs

All costs stated per pound flower equivalent

Additional compliance costs	***Lower-cost alternative***	***Proposed regulations***	***Higher-security alternative***	***Assumptions & references***
License fees[1]	None	$20.00	$20.00	Fees set to cover Bureau budget
Distribution & transport[2]	$2.51	$6.51	$8.92	See Tables 6.2, 6.5
Testing[4]	$177.37	$407.18	$623.53	See Tables 6.3, 6.5
Dispensing[2]	$25.05	$65.08	$89.24	See Tables 6.4, 6.5
Dispensary delivery[3]	None	$9.60	$147.84	See Table 6.6
Total compliance costs per lb	**$204.93**	**$508.37**	**$889.53**	

Source: AIC calculation based on industry data. Cost components do not add exactly to total costs due to rounding.

[1] License fees calculated to cover the Bureau's approximate operating budget.

[2] The proposed regulations add 30-day surveillance video archive, quarantine, and laminated badge requirements. Higher-security alternative extends video archive requirement to 90 days.

[3] The proposed regulations prohibit on-foot, bicycle, e-bike, or scooter deliveries. Higher-security alternative requires two employees to make a delivery.

7. Modeling the Effects of Shifts in Cannabis Demand and Supply on Prices and Quantities

The model outlined below first characterizes demand for cannabis in a form amenable to simulation. Next, we explain a simplified supply side of cannabis sales to consumers. We then discuss the solution for effects of changes in statutes and regulations. This chapter is necessarily more technical and contains more mathematical notation than other chapters.

7.1 Demand

The model of consumer demand for cannabis is based on a two-stage budgeting process developed in Deaton and Muellbauer (1980a, 1980b). The first stage generates a system of individual demand functions for the allocation of total expenditure among commodity categories. The second stage of the two-stage allocation generates a system of individual segment-specific demand functions within the cannabis commodity group. A comprehensive review of the literature on two-stage budgeting can be found in Deaton (1986). The first stage models of demand for cannabis as a whole. In the second stage, demand for segment-specific cannabis is modeled conditional on the total cannabis expenditure across all segments determined in the first stage.

The two-stage budgeting approach is widely used in demand simulations. Since the number of own-price and cross-price elasticities of demand increases with the square of the number of commodities, the complexity of the simulation and requirement for estimated or assumed parameters expands similarly. Under the two-stage budgeting and accompanying assumptions, the number of products can be kept relatively small. This approach offers considerable empirical convenience. The key assumption here is that cannabis (the group of the individual cannabis segments) has demand relationships with other goods as an aggregate. Theoretical consistency of the model requires developing an aggregate cannabis group price index and some conditions on consumer demand behavior between cannabis and all other goods.

Following the suggestion in Deaton and Muellbauer (1980b), we developed the aggregate cannabis price index using the Stone (1954) price index method. To derive segment-specific elasticities, we specify demand substitution parameter values. These values are developed based on data, previous studies and researcher judgments described below.

To focus on the application at hand we first note that the medical cannabis segment is distinct in access from what has been the illegal cannabis segment. The prices and quantities in this segment are designated with subscript "m." Second, we note that the non-medical part of the market will soon separate into two segments. The prices and quantities in the newly legal adult-use segment will be designated with the subscript "a". Finally, in the segment that remains illegal, prices and quantities will be designated with the subscript "i."

Let us begin with the utility function expressed as (1), with notation shown in Table 11.1 for easy reference:

Total utility function: $u = U(Q^c, Q^o)$ (1)

Equation (2) defines the price of aggregate cannabis in terms of three cannabis segments' prices, lnP_j, and market shares, w_j:

Stone's price index: $lnP^* = \sum_{\{j=i\}}^{\{i,a,m\}} w_j lnP_j$ (2)

Equation (3) defines the aggregate quantity in terms of the quantity of each segment (illegal, legal adult-use and legal medical):

Aggregate quantity demanded for cannabis: $Q_c = Q_i + Q_a + Q_m$ (3)

The following assumptions are used:

a) Demand for cannabis is weakly separable from other goods in the demand system. The weak separability assumption can be represented by $U(Q^c, Q^o) = F\big(u_c(Q^c), u_o(Q^o)\big)$, where U is the utility

function of consuming all goods, Q^c is the quantity vector for cannabis group, $u_c(Q^c)$ is the sub-utility function associated with cannabis consumption, and Q^o is the quantity vector for any other products, $u_o(Q^o)$ is the sub-utility function associated with consumption of products other than cannabis, and F is an increasing function in all its arguments.

b) The total cost of living (TCOL) is independent to sub-utility level (Edgerton 1997; Carpentier and Guyomard 2001), i.e. that the empirical variation of $P^I(\boldsymbol{p}^I, \overline{\boldsymbol{p}^I}, u_I) \cong P^I(\boldsymbol{p}^I, \overline{\boldsymbol{p}^I})$, $\forall\, I = c, o$, where I is the product group index, P^I is the index for total cost of living, $\boldsymbol{p}^I$ is the price vector for group I, $\overline{\boldsymbol{p}^I}$ is the base period prices for group I, u_I is the sub-utility of consumption for group I. The product group indices include cannabis (c) and non-cannabis products (o). This capital I is not related to lower case I which represents the illegal cannabis segment within c.

Given the weak separability assumption, the group allocation problem can be defined as

$$Max_{\{u_c, u_o\}} F(u_c, u_o)$$

$$s.t. M = \sum_{I=c}^{c,o} c_I(\boldsymbol{p}^I, u_I),$$

where u_I is the value of the sub-utility function for group I, M is the total expenditure, $\boldsymbol{p}^I$ is the price vector for group I, $c_I(\boldsymbol{p}^I, u_I)$ is the cost function associated to the sub-utility function $u_I(\boldsymbol{q}^I)$.

The cost of consuming group I at price $\boldsymbol{p}^I$ can be rewritten as

$$c_I(\boldsymbol{p}^I, u_I) = c_I(\overline{\boldsymbol{p}^I}, u_I)\frac{c_I(\boldsymbol{p}^I, u_I)}{c_I(\boldsymbol{p}^I, u_I)} = c_I(\overline{\boldsymbol{p}^I}, u_I)P^I(\boldsymbol{p}^I, \overline{\boldsymbol{p}^I}, u_I), \forall I = c, o,$$

where $P^I(\boldsymbol{p}^I, \overline{\boldsymbol{p}^I}, u^I)$ is the true cost of living price index (TCOL price index) and $c^I(\overline{\boldsymbol{p}^I}, u^I)$ can be thought of as a quantity index (Carpentier and Guyomard, 2001). By assuming the TCOL price index is approximately independent with subutility u^c and u^o, i.e. $P^I(\boldsymbol{p}^I, \overline{\boldsymbol{p}^I}, u_I) \cong P^I(\boldsymbol{p}^I, \overline{\boldsymbol{p}^I})$, we can rewrite the utility maximization problem as

$$Max_{\{c_c,c_o\}}\Phi\left(c_c(\overline{\boldsymbol{p}^c},u_c),c_o(\overline{\boldsymbol{p}^o},u_o)\right)$$

$$s.t.M=\sum_{I=c}^{c,o}c_I\left(\overline{\boldsymbol{p}^I},u_I\right)P^I(P^I,\overline{P^I}),$$

where the Φ is the modified utility function in terms of quantity indices for cannabis and other goods, $c_I\left(\overline{P^I},u_I\right)$ is the quantity index for group I, and $P^I(P^I,\overline{P^I})$ is the total cost of living.

For example, based on Carpentier and Guyomard's (2001) result, the unconditional elasticity of demand for medical cannabis and the cross-price demand elasticity between medical and illegal cannabis, using an approximation to the Slutsky substitution term, could be approximated in general forms as follows, where we illustrate the expressions with the own elasticities for medical cannabis and the cross effects between medical and illegal cannabis.

The unconditional expenditure elasticity for medical use cannabis is: $\eta_{mY}=\eta_{mY}^c\eta_{cM}$.

The unconditional Hicksian demand elasticity for medical use cannabis is:

$$\eta_{mm}^*=\eta_{mm}^{*c}+w_m\eta_c^*\eta_{mY}^c\eta_{mY}^c.$$

The unconditional cross-price Hicksian demand elasticity between medical and illegal use cannabis is:

$\eta_{mi}^*=\eta_{mi}^{*c}+w_i\eta_c^*\eta_{mY}^c\eta_{mY}^c$.

The unconditional Marshallian demand elasticity for medical use cannabis is:

$\eta_{mm}=\eta_{mm}^c+w_m\left(\frac{1}{\eta_{mY}^c}+\epsilon^*\right)\eta_{mY}^c\eta_{mY}^c+w_m s_c\eta_{cM}\eta_m^c(\eta_{mY}^c-1)$.

And, the unconditional cross-price Hicksian demand elasticity between medical and illegal use is:

$\eta_{mi}=\eta_{mi}^c+w_i\left(\frac{1}{\eta_{iY}^c}+\epsilon^*\right)\eta_{mY}^c\eta_{iY}^c+w_i s_c\eta_{cM}\eta_m^c(\eta_{iY}^c-1)$,

where the subscripts m, i, and a represent cannabis segments, medical, illegal and adult-use. η_{jk} with $j,k=m,i,a$, represents the cross-price Marshalian demand elasticity between group j and k. η_{jk}^* with $j,k=m,i,a$, represents the cross-price Hicksian demand elasticity between group j and k. The subscript Y represents the cannabis group expenditure. η_{jY} with $j=m,i,a$, represents the expenditure elasticity for group j. The subscript c represents the whole cannabis group. Elasticity η_c^* represents the Hicksian demand elasticity for cannabis group. The elasticity ϵ^* represents the Marshalian demand elasticity for

cannabis group. The superscript c means the parameter is conditional on the group expenditure and s_c is the expenditure share of cannabis of the total income.

If we assume homothetic preferences and a unit conditional expenditure elasticity (Edgerton, 1997), we could rewrite the above equation as follows.

The unconditional expenditure elasticity for medical cannabis:

$\eta_{mY} = \eta_{cM}$.

The unconditional Hicksian demand elasticity for medicinal use cannabis:

$\eta^*_{mm} = \eta^{*c}_{mm} + w_m\eta^*_c$.

The unconditional cross-price Hicksian demand elasticity between medicinal and illegal use cannabis:

$\eta^*_{mi} = \eta^{*c}_{mi} + w_i\eta^*_c$.

The unconditional Marshallian demand elasticity for medical use cannabis:

$\eta_{mm} = \eta^c_{mm} + w_m(1 + \epsilon^*)$. (4)

The unconditional cross-price Marshallian demand elasticity between medical and illegal use cannabis:

$\eta_{mi} = \eta^c_{mi} + w_i(1 + \epsilon^*)$. (5)

We can rewrite equations (4) and (5), using conditional Slutsky equation under unit conditional expenditure elasticity, $\eta^c_{mm} = \eta^{*c}_{mm} - w_m$, and $\eta^c_{mi} = \eta^{*c}_{mi} - w_i$, and the conditional Hicksian cross-elasticity of demand, $\eta^{*c}_{kj} = w_j\sigma^c_{kj}$, where σ^c_{kj} is the conditional elasticity of substitution of group j and k, with the homogeneity condition, which implies in the three factor case, $\eta^{*c}_{mm} = -\eta^{*c}_{mi} - \eta^{*c}_{ma}$, and the symmetry condition, $\sigma_{im} = \sigma_{mi}$, as:

$\eta_{mm} = -w_i\sigma^c_{mi} - w_a\sigma^c_{ma} + w_m\epsilon^*$ and (6)

$\eta_{mi} = w_i\sigma^c_{mi} + w_i\epsilon^*$. (7)

7.2 The supply side and simulation model of the changes in quantities and prices in the market

We begin with a set of assumed prices and quantities in the three segments to which proportional changes to the demand function and parameters and the supply function and parameters applied. The medical segment initial prices and quantities were developed from recent data as described in detail in later sections of this report. As an initial starting point for the prices and quantities of the newly legal

adult-use cannabis segment, we assume that the current illegal market is separated into two equal sized segments: segment a, which includes that quantity demanded and supplied that is most readily transferred to the legal adult-use segment, and segment i, which includes that quantity that is less readily shifted to legal sales.

We assume initially that these two segments have equal quantities. We set the initial price in the newly legal adult-use segment as 5% below the medical dispensary price and the price in the continuing illegal segment as 10% below the medical dispensary price. These initial situation choices are not crucial to the results and could be adjusted with appropriate adjustment to other parameters.

For the initial situation we explore proportional changes from the demand side and supply side on each segment. On the demand side, the quantity demanded for segment-specific cannabis changes α which is a vector of quantity changes in percentage terms, when holding the prices and total expenditure constant.

Based on the unconditional own-price and cross-price elasticity, we can approximate the changes in quantity and total revenue for segment-specific cannabis, as

$$dlnQ_m^d = \eta_{mm}\, dlnP_m^d + \eta_{ma}\, dlnP_a^d + \eta_{mi}\, dlnP_i^d + \alpha_m \quad (8)$$

$$dlnQ_a^d = \eta_{am}\, dlnP_m^d + \eta_{aa}\, dlnP_a^d + \eta_{ai}\, dlnP_i^d + \alpha_a \quad (9)$$

$$dlnQ_i^d = \eta_{im}\, dlnP_m^d + \eta_{ia}\, dlnP_a^d + \eta_{ii}\, dlnP_i^d + \alpha_i \quad (10)$$

where the supersript d represents the variables on the demand side. For example, $dlnQ_m^d$ represents the change of quantity demanded for medicinal cannabis.

As with the demand side of the market, the supply side of the model focuses on the retail prices and quantities. This application of the model for the impact analysis includes shifts in costs that apply to wholesale and retail functions, including product transportation and testing. Thus we take any changes

at the farm and processing level of the production process as exogenous, and we do not explore those changes in any detail.

On the supply side, the cost of production changes by β, which is a vector of cost shifts for segment-specific cannabis. Ad valorem taxes t apply to retail revenue in two segments. Among parameters required are the supply elasticities for the three segment-specific cannabis marginal cost functions.

We then approximate the change in prices facing suppliers with tax included, as

$$dlnP_m^S = \frac{dlnQ_m^S}{\xi_m} + \beta_m + t_m \quad (11)$$

$$dlnP_a^S = \frac{dlnQ_a^S}{\xi_a} + \beta_a + t_r \quad (12)$$

$$dlnP_i^S = \frac{dlnQ_i^S}{\xi_i} + \beta_i + t_i \quad (13)$$

where the superscript s represents the variables on the supply side. For example, $dlnP_m^S$ represents the price change of medicinal cannabis for suppliers. ξ_j with $j = m, a, i$ represents the supply elasticity for group j.

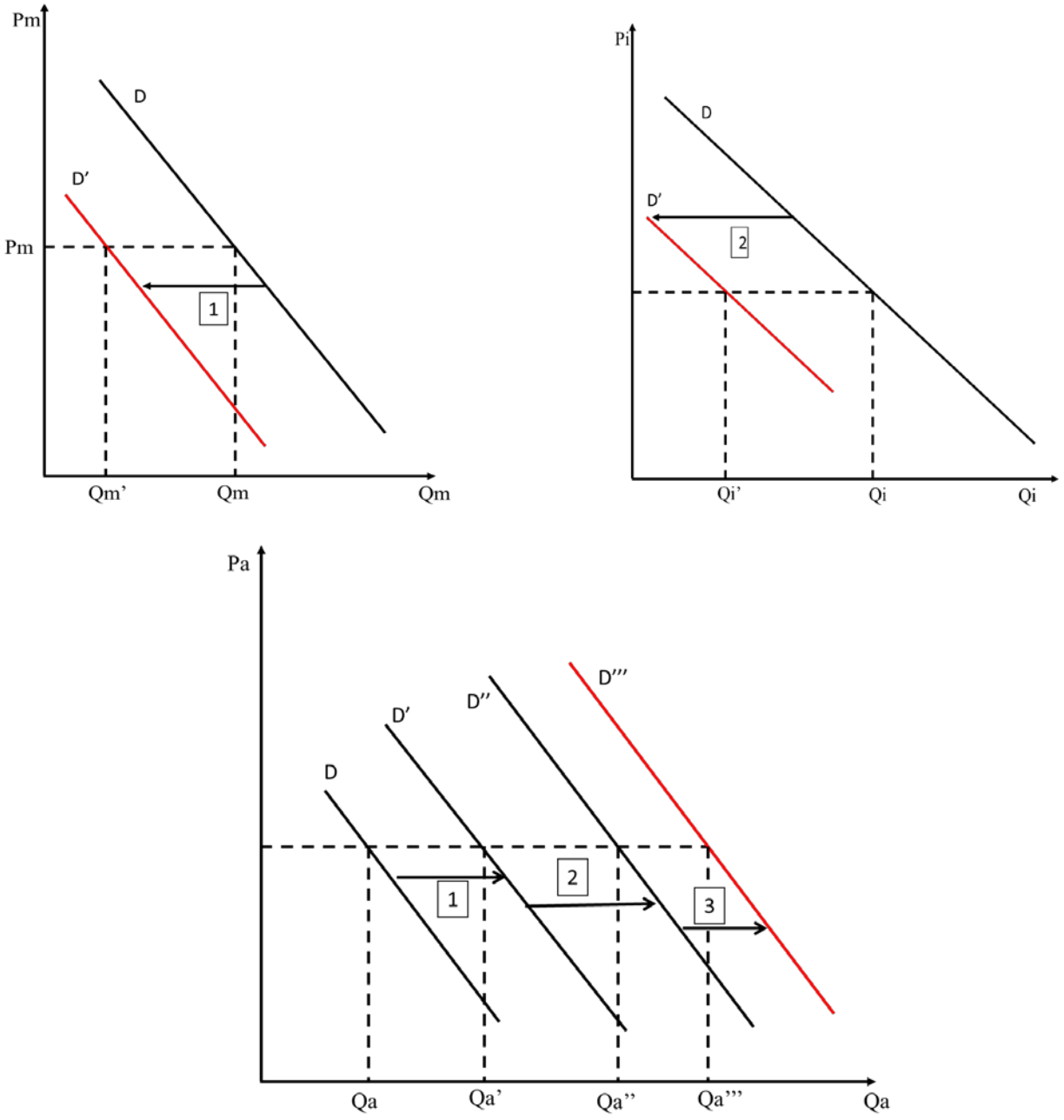
Notice that these marginal cost specifications already incorporate the price equals marginal cost equilibrium condition and are specified as vertical shifts in the supply function reflecting per unit costs. Equations (8) to (13) and the market equilibrium conditions are used in simulations to investigate how shifts in costs and demand affect prices and quantities of cannabis and prices and quantities of medical, legal adult-use and illegal cannabis. Parameters include shares, own-price and cross-price demand elasticities and supply elasticities.

7.3 Illustration of demand shifts in the cannabis market due to adult-use legalization

This section illustrates the shifts in Cannabis demand discussed above. The top left panel of Figure 7.1 shows a shift back in the demand from D to D' in the medical segment that accompanies the taxation and legalization of adult-use cannabis. This occurs because previous medical cannabis buyers can avoid the added costs of acquiring a medical recommendation by now buying in the adult-use segment. The top right panel of Figure 7.1 shows a shift back from D to D' in the quantity of cannabis sold in the illegal segment as some buyers leave the illegal segment for the newly legal non-medical adult-use segment.

The bottom panel of Figure 7.1 shows the initial position of demand for adult use cannabis that accompanies taxation and adult-use legalization represented by demand D and quantity Q_a. This initial situation represents a portion of the previous demand for cannabis in the illegal segment that readily shifted to the adult-use segment. The reduction in demand shown in the top left panel is represented in the bottom panel by the shift out in demand for adult-use cannabis from D to D'. The further reduction in illegal cannabis illustrated in the upper right panel of Figure 7.1 is shown in the bottom panel as a further increase in demand for adult-use cannabis from D' to D''. Finally, an increase in demand from buyers who previously avoided the medical or illegal segments for personal reasons and are now entering the adult-use market due to an increase of exposure of cannabis to mainstream consumers and visitors to California who now have access to legal cannabis is shown in the shift from D'' to D'''.

Figure 7.1. Demand shifts in medical, illegal, and adult-use cannabis markets that accompany adult-use legalization



7.4 Solving for implied tax rate for the simulation model

The law that set out legalization of adult-use cannabis included a percentage tax rate t_t on the retail revenue of medical and adult-use cannabis. In order to solve for the impact of that percentage tax rate on prices, quantities and implied revenue, we solve for the equivalent initial (pre-change) tax rate as a percentage of prices that would occur without adult-use legalization. The tax rate equivalent is used in equations (11) to (13) to simulate impacts.

Let us begin with the total revenue for medical cannabis after the legalization of adult-use cannabis as shown in equation (14). The medical cannabis faces a tax rate t_b before adult-use legalization. Adult-use legalization imposes t_m tax rate on top of the initial price, P_0 as follows:

Total tax revenue: $R_t = Q_1 P_0 \cdot (t_m + t_b)$. (14)

The revenue excluding tax and target tax rate can be written as a function of the new price P_1:

Revenue without tax: $R_{-t} = \mathrm{Q_1 P_1} - Q_1 P_0 \cdot (t_m + t_b)$. (15)

Target tax rate: $t_t = \frac{Q_1 P_0 (t_m + t_b)}{Q_1 P_0 (1 + dlnP - t_m - t_b)}$ (16)

By rearranging equation (16), we obtain equation (17) indicating the relationship of the target adult-use legalization tax rate, t_t, and the imposed tax rate, t_m, in terms of initial price.

$(1 + t_t)t_m - t_t dlnP = t_t(1 - t_b) - t_b$ (17)

We could extend the approach for adult-use cannabis. Because of adult-use legalization, adult-use cannabis faces an increase in tax rate from zero to t_t at the outcome. In terms of the initial prices before adult-use legalization, the tax rate is t_a. Equation (18) represents the relationship between the target tax rate and the tax rate in terms of initial price.

$(1 + t_t)t_a - t_t dlnP = t_t$ (18)

The illegal cannabis faces no tax. Together with (17) and (18), we have the following equations:

$$(1 + t_t)t_m - t_t dlnP_m = t_t(1 - t_b) - t_b \quad (19)$$

$$(1 + t_t)t_a - t_t dlnP_a = t_t \quad (20)$$

$$t_i = 0 \quad (21)$$

7.5 Solution matrix

We now have a system of equations including equations (8) to (13), equations (19) to (21), and market equilibrium conditions. We will use this system of equations to solve for the price and quantity changes for each specific cannabis segment. A simplified matrix is shown below and the solution could be solved as the product of the inverse of matrix M and vector b, where matrix M is the coefficient matrix on the left hand side and b is the dependent matrix on the right hand side. The solution is in terms of supply and demand elasticities, the target tax rate, and the demand function and parameter changes and supply function and parameter changes.

$$\underbrace{\begin{bmatrix} \eta_{mm} - \xi_m & \eta_{ma} & \eta_{mi} & \xi_m & 0 & 0 \\ \eta_{am} & \eta_{aa} - \xi_a & \eta_{ai} & 0 & \xi_a & 0 \\ \eta_{im} & \eta_{ia} & \eta_{ii} - \xi_i & 0 & 0 & \xi_i \\ -t_t & 0 & 0 & 1 + t_t & 0 & 0 \\ 0 & -t_t & 0 & 0 & 1 + t_t & 0 \\ 0 & 0 & 0 & 0 & 0 & 1 \end{bmatrix}}_{M} \underbrace{\begin{bmatrix} dlnP_m^d \\ dlnP_a^d \\ dlnP_i^d \\ t_m \\ t_a \\ t_i \end{bmatrix}}_{x} = \underbrace{\begin{bmatrix} -\alpha_m - \xi_m\beta_m \\ -\alpha_a - \xi_a\beta_a \\ -\alpha_i - \xi_i\beta_i \\ t_t(1 - t_b) - t_b \\ t_t \\ 0 \end{bmatrix}}_{b}$$

Solution: $x = M^{-1}b$

The quantity change $dlnQ_{j=m,a,i}$ for segment-specific cannabis could be obtained from equations (8) to (10). The aggregate quantity change $dlnQ_c$ is the weighted sum of the three segment-specific cannabis

quantity changes. As an alternative, we could also derive the aggregate quantity change, $dlnQ_c = \epsilon^* dlnP^* + \alpha^*$, where $dlnP^* = \sum_{j=i}^{i,m,a} w_j dlnP_j$, and $\alpha^* = \sum_{j=i}^{i,m,a} w_j \alpha_j$.

7.6 Individual segments and the change in revenue in the medical market

We consider supply-side shifts (the change in marginal cost) and demand-side shifts (the change in the quantity purchased at a given price the medical, legal adult-use and illegal cannabis). We must also include the cross effects between the different segments. Shifts affect the relative prices in cannabis segments, and this impact shifts each segment's demand because of substitution effect over cannabis segments.

Based on the quantity and price changes of cannabis, we can approximate the total revenue change. Here we will illustrate the total revenue change and consumer surplus change in the medical segment as an example. The change of the total revenue for the medical segment is the sum of the proportional changes in medical price and the quantity and their product, based on $dlnTR_m = dln(P_m \cdot Q_m)$, as, $dlnTR_m = dlnP_m + dlnQ_m + dlnP_m \cdot dlnQ_m$

7.7 Change in the aggregate total revenue

Based on the aggregate quantity of demand effects and the price-index change for cannabis, we can write the change of total revenue in cannabis segment as the sum of the change in total quantity and price index:

$dlnTR_c = (1 + \epsilon^*) dlnP^* + \alpha^*$, where $dlnP^* = \sum_{j=i}^{i,m,a} w_j dlnP_j$, and $\alpha^* = \sum_{j=i}^{i,m,a} w_j \alpha_j$.

As an alternative, the aggregated revenue change is just the weighted sum of the individual weighted sum, as $dlnTR_c = \sum_{j=i}^{i,m,a} w_j \, dlnTR_j$.

Table 7.1. Notation used in derivation and discussion of simulation

Notion	Description
$Q^I\ (I = c, o)$	The quantity vector for cannabis group and other goods.
$u_I\ (I = c, o)$	The sub-utility function of consuming cannabis and other goods.
$\boldsymbol{p}^I\ (I = c, o)$	The price vector for cannabis and other goods.
$\overline{\boldsymbol{p}^I}\ (I = c, o)$	The base-period price vector for cannabis and other goods.
$\boldsymbol{c}_I\ (I = c, o)$	The cost function for cannabis and other goods.
Q_c	Quantity of cannabis.
P^*	The Stones' price index of cannabis group.
P^o	The price of composite goods which includes all other products in the demand system.
M	Total income.
$P_j\ (j = i, a, m)$	The prices of illegal (i), adult-use legal adult-use (a), and medical (m) cannabis.
$w_j (j = i, a, m)$	The within-group expenditure share of illegal, adult-use, and medical cannabis. They sum to 1.
$Q_j (j = i, a, m)$	The quantities of illegal, adult-use, and medical cannabis.
Y^c	Total expenditure on cannabis.
ϵ^*	The total own-price elasticity of demand for cannabis.
$\xi_j\ (j = i, a, m)$	The supply elasticity for illegal, adult-use, and medical cannabis.
η_{jj} $(jj = ii, aa, mm)$	The unconditional own-price Marshallian elasticity of demand for illegal, adult-use, and medical cannabis.
η_{jj}^{c} $(jj = ii, aa, mm)$	The conditional own-price Marshallian elasticity of demand for illegal, adult-use, and medical cannabis.
η_{jj}^{*} $(jj = ii, aa, mm)$	The unconditional own-price Hicksian elasticity of demand for illegal, adult-use, and medical cannabis.
η_{jj}^{c*} $(jj = ii, aa, mm)$	The conditional own-price Hicksian elasticity of demand for illegal, adult-use, and medical cannabis.

η_{jk} $(jk = ma, mi, ai, am, ia, im)$	The unconditional cross-price Marshallian elasticity of demand within the group of medical, adult-use, and illegal cannabis.
η_{jk}^{c} $(jk = ma, mi, ai, am, ia, im)$	The conditional cross-price Marshallian elasticity of demand within the group of medical, adult-use, and illegal cannabis.
η_{jk}^{*} $(jk = ma, mi, ai, am, ia, im)$	The unconditional cross-price Hicksian elasticity of demand within the group of medical, adult-use, and illegal cannabis.
η_{jk}^{c*} $(jk = ma, mi, ai, am, ia, im)$	The conditional cross-price Hicksian elasticity of demand within the group of medical, adult-use, and illegal cannabis.
η_{jY}^{c} $(j = i, a, m)$	The conditional expenditure elasticity of demand for illegal, adult-use and medical cannabis.
σ_{jk}^{c} $(jk = ma, mi, \mathrm{a}i, am, ia, im)$	The conditional elasticity of substitution within the group of medical, adult-use, and illegal cannabis.
η_{cM}	The unconditional income elasticity of demand for cannabis.
η_{c}	The Marshallian demand elasticity for cannabis group
η_{c}^{*}	The Hicksian demand elasticity for cannabis group
α_j $(j = i, a, m)$	The demand shift for illegal, adult-use, and medical cannabis.
β_j $(j = i, a, m)$	The marginal cost shift for illegal, adult-use, and medical cannabis.
t_t	The target tax rate after adult-use legalization.
t_j $(j = i, a, m)$	The imposed tax rate in terms of the pre-adult-use-legalization price.

7.8 Further demand considerations: additive behavior and the Becker approach to drug demand

We refer here to the addictive behavior approach introduced by Becker and Murphy (1988) regarding drug consumption, which is also discussed in Grossman and Chaloupka (1998) and Becker et al. (2006). This approach assumes that addicts behave rationally and emphasizes the interdependency of past,

current, and future consumption of an addictive good. This indicates that consumers incorporate the effects of current consumption on future utility. This approach is generally consistent with our modeling, but we make no particular assumption about addition of habits.

For any illegal activity, a component in determining substitution between the uses is the level of enforcement for the remaining illegal production, sale and use. Becker et al. (2006) modeled the linkage between the elasticity of demand for an illegal good and the effects of enforcement against illegal goods, and thus the overall size of the illegal market. We recognize this relationship. However, although changes in enforcement of the remaining illegal market may shift marginal cost, we do not model them as changing elasticities of supply or demand in this study.

7.9 Literature on empirical estimates of the own-price elasticity of demand for cannabis

The empirical literature on the effects of price on the use of additive drugs such as cocaine, cannabis, and heroin is sparse. Nisbet and Vakil (1972) estimated a price elasticity of demand for cannabis ranging from −0.36 to −1.51 using an anonymous mail survey of students at the University of California at Los Angeles. Lkhdar et al. (2016) also estimated a cannabis price elasticity for demand using 250 French users in 2005. Their elasticity estimates were between -1.7 and -2.1, which were relatively high compared to those found in other studies.

The price elasticity estimates by Pacula et al. (2001) using high school seniors ranged between -0.002 to -0.69. Van Ours and Williams (2007) examined cannabis use by young Australians, and their elasticity estimates ranged between -0.31 and -0.70. Most recently, Jacobi and Sovinski (2016) conducted an empirical cannabis study using the Australian National Drug Household Survey, which was published in American Economic Review. Their estimate for price elasticity was -0.2, and we adopt this value in our study to derive cross-price elasticities.

Unlike other studies, Jacobi and Sovinski (2016) used data from the broad population of cannabis users, which is one reason we adopt this value.

7.10 Assumptions about the elasticities of demand for cannabis and categories of cannabis

To project the changes in consumer demand for the three uses of cannabis, it is critical to assess consumer substitution between these uses. To evaluate the substitution possibility and ultimately the quantity changes, we rely on previous studies, empirical data, and economic theory. To consistently derive the cross-price elasticities (which measure the extent of product substitution), we first developed an economic model that describes consumers' consumption behavior under reasonable assumptions, and applied empirical data and some behavioral parameters from previous studies to our demand model. These elasticities play a critical role in projecting demand and in evaluating aggregate economic impact.

8. Numerical Simulation of Changes in Cannabis Prices, Quantities, Revenues, and Taxes in Response to Changes in Proposed Regulations

8.1 Simulation parameters

The simulation model described above is characterized numerically by specifying values for the parameters listed. We begin by characterizing the baseline without regulation. The price and quantity for all cannabis and shares in each category are based on the medical revenue of about $2.0 billion, a medical share of 25% and an initial retail price of $3,453 per pound of flowers. The prices for adult-use cannabis and illegal-use cannabis are assumed to be 5% and 10% cheaper, respectively, than the medical price for a standard dried follower equivalent product.

Parameters are shown in Table 8.1. Some key parameter values assumed are the aggregate cannabis price elasticity equal to -0.2, as explained in Section 7.9. The budget share of aggregate cannabis consumption is calculated to be 0.03 based on annual expenditure of about $200 per capita. The income elasticity for cannabis is assumed to be 1.0.

The substitution elasticity between medical use and adult-use cannabis is 4.0; the substitution elasticity between medical and illegal cannabis use is 0.5; and the substitution elasticity between adult-use and

illegal cannabis use is 7.0. The substitution matrix is symmetric. The conditional expenditure elasticities of each category are 1.0.

We initialize the model with equal share between the segment of suppliers who initially find it most cost effective to remain in the illegal segment and the segment of suppliers who are more prone to shift to the legal adult-use segment. The underlying parameters and initial shares lead to the matrix of own- and cross-price elasticities of demand as shown, with large elasticities within the group. Own-price elasticities are -1.74, -3.64 and -2.85 at the initial expenditure shares.

On the supply side, we assume a very elastic supply elasticity for medical cannabis (20), as the conditions between that segment and the adult-use segment are very similar and suppliers would find it easy to move between the two. We consider a high supply elasticity of 10.0 for adult-use cannabis because these suppliers can expand or contract with little effect on input costs. These elasticities apply after any bottlenecks caused by regulations (for example testing capacity) are removed. These high supply elasticities also imply that there is very small producer surplus after producers pay for the services of managers and the returns to capital, which already reflect remaining risk premiums.

The supply elasticity of illegal cannabis is 1.0, which assumes that these suppliers face some restrictions in contracting supply. In particular, these suppliers may have difficulty moving into legal supply because of operator human capital. They may also be well suited to the illegal market and earn producer surplus relative to other occupations open to them.

8.2 Shifts in demand and costs associated with adult-use legalization

With this baseline set of parameters, including shares of the three segments, we considered some demand shifts associated with adult-use legalization to establish the adult-use legalization baseline quantities and prices. We then consider some supply side cost shifts also associated with adult-use legalization.

First, we introduce a 60% percent shift from medical to adult-use cannabis to reflect the lower costs of accessing the adult-use segment, given that to be in the adult-use segment does not require an annual cost of acquiring a medical recommendation.

Second, we introduce a further 10% shift from illegal to adult-use cannabis to reflect drawing more demand from buyers who find the adult-use segment easy to access relative to the illegal segment. This shift is in addition to the initial split of the previously illegal portion of cannabis sales into equal sized segments (by quantity). Finally, we assume a 25% additional demand increase into the adult-use segment, where each of these shifts are percentages based on the initial quantity shares.

The shifts on the supply side include cost reductions from taxation and adult-use legalization as described in Chapter 5. These cost reductions relate to reduced risk premiums from conducting illegal activities or dealing with suppliers and others engaged in illegal activities. For the newly legal adult-use cannabis segment, the marginal cost decline is 35%. For the medical segment the cost reduction is 20%—lower because dispensary businesses have been decriminalized under state law for many years, unlike the adult-use segment. There is still some marginal cost reduction because many retailers have dealt with illegal cultivation supply and distribution of raw materials even under the decriminalized environment for medical dispensaries. We assume the continuing illegal segment will face higher costs because of increased enforcement and isolation from the legal segments because of enforced track-and-trace measures. We have relatively little data to document these cost shifts, but they are consistent with the broad magnitudes of current risk premiums estimated by the differences between market prices and measured accounting costs at both wholesale and retail.

The second component on the supply side is increased enforcement of the current sales tax and new introduced cannabis specific taxes. The sales tax is about 8.8% on cannabis. The state tax rate is 7.5% and the average of county tax rates, which we assume is 1.3%, depends on how cannabis sales are distributed among local tax jurisdictions. Compliance in 2016 suggests about an effective 3% tax rate for medical cannabis. The tax at the cultivator stage is a $148 per pound on a flower equivalent product affect raw material costs and are assumed to be subsumed in the marginal cost shifts on a per pound basis. The new ad valorem excise tax is 15% on retail sales.

In the previous section, we derived the impact of such taxes on shifts on the cost side of the model. The net effect is a lower cost curve for adult-use cannabis (inclusive of tax), a slightly higher cost curve for medical cannabis, and a higher cost for illegal cannabis. The equilibrium prices depend on the interactions of supply and demand in each segment and the solution for a new equilibrium.

Table 8.1 Baseline prices and quantities and model parameters for simulations of the impacts of regulations

Cannabis group as a whole

Share of income spent on cannabis	*Total quantity (1000s of lb)*	*Price/lb*	*Own demand elasticity*	*Income elasticity*
0.3%	2,333	3,262	-0.2	1.0

Within-group parameters

	Quantity share	*Price/lb*	*Elasticity of substitution between uses*		*Conditional expenditure elasticity*	
Medical	25%	$3,453	Med and Rec.	4.0	Medical	1.0
Adult-use	37.5%	$3,280	Med and Illegal	0.5	Adult-use	1.0
Illegal	37.5%	$3,108	Rec. and Illegal	7.0	Illegal	1.0

Implied demand elasticities matrix derived from basic parameters

Demand elasticities matrix derived from baseline parameters

	Medical	*Adult-use*	*Illegal*
Medical	-1.74	1.43	0.11
Adult-use	1.01	-3.64	2.43
Illegal	0.08	2.57	-2.85

Supply elasticities	*Medical*	*Adult-use*	*Illegal*

of medical cannabis regulations	20.0	10.0	1.0

8.3 Simulated results for the adult-use legalization baseline

Results provided in Table 8.2, 8.3, and 8.4 include in the first column the baseline for prices, quantities, revenues, and taxes for the adult-use legalization baseline for medical cannabis. The top row shows the new market price facing consumers ($3,164), which includes taxes of $608 per pound (23.8%). Adult-use legalization results in a market of 235,000 pounds. Revenue with taxes (that paid by consumers) is $743 million, but the revenue of retailers is $601 million. These values are the baseline to which the situation with regulation is compared.

8.4 Simulated regulation impacts on prices, quantities, and related variables

In Section 6, we provide estimates of the costs of regulation per pound that apply for the four license types under consideration. Overall, we find that the proposed regulations add approximately $520 per pound of marketable dried flower equivalent in direct operating costs. Most of the addition to costs, about $400 per pound, is due to the added costs of required testing. In addition to these direct costs, we assume that regulations in the medical cannabis segment that restrict vertical integration of retail firms into wholesale distribution or transport have costs on the industry. We approximate those costs as about 1% of retail revenue.

We therefore assume that the cost increase due to regulations is approximately 16% of the initial value of $3,453 per pound. Since newly legal adult-use cannabis regulations are expected to be similar to the regulations on medical cannabis, we also expect regulatory costs to be similar for the adult-use market. The adult-use segment does not face limits on vertical integration and has a lower base price by 5%. We assume that the costs in that segment also rise by 16%.

The second source of economic effects is an increase in consumer willingness to pay for legal cannabis that has more wholesale security, retail security, and transport security, full traceability, and intensive product testing. We assume the increase in willingness to pay is equivalent to a 6% increase in demand (as represented by a shift out in the demand curve). Such a willingness to pay increase is consistent with USDA certification in food markets such as eggs and meats and with increased government-mandated

testing, for example as introduced in pistachios (Gray et al. 2005). It is also consistent with improved traceability as modeled in Pouliot and Sumner (2008 and 2011) and the literature they cite.

The prices, quantities, revenues, and taxes change in expected ways upon introducing the proposed regulations. Column 2 of Table 8.2 reports prices, quantities, revenues, and taxes with regulations imposed. In this column, the market prices (both with and without taxes) rise (because costs rise with regulations and the ad valorem tax is applied to the price with regulations imposed) and quantity falls slightly. The revenue of the medical cannabis segment (without taxes) is $714 million. Tax revenue itself with regulations is $170 million. Column 3 of Table 8.2 reports the effects of the regulations on the medical cannabis segment by subtracting column 1 from column 2. Price rises by $551 per pound, quantity falls by about 5,000 pounds, revenue rises by $113 million and tax receipts rise by $27 million. The share of the medical cannabis segment is down slightly in quantity terms relative to the entire cannabis industry. However, the share of the medical cannabis segment is slightly higher in revenue terms because regulations raise prices of medical cannabis relative to other segments, especially the illegal segment.

Under these parameters, Tables 8.3 and 8.4 show effects of the lower-cost regulations and higher-security regulations. They are structured like Table 8.2. The results are as expected: less-costly regulations raise price by less than more-costly (higher-security) regulations. The lower-cost regulations are estimated to shift up costs by 6% and shift out demand by 4%.

The higher-security regulations are estimated to shift up costs by 26% and shift out demand by the same 6% as the proposed regulations. Because higher costs affect the supply and demand balance, the higher-security regulations reduce quantity by 30,000 pounds or about 13% from the baseline. Price rises because of higher costs, but total revenue generated by the medical cannabis segment is lower because quantity falls by more in percentage terms than price rises. Much of the reduction in quantity shifts to the illegal market, because the higher-security regulations would apply as well to the adult-use segment.

Table 8.2 Impact of proposed regulations on the medical cannabis segment, given the baseline with taxation and adult-use legalization

Variables	***Baseline with taxation and adult-use legalization***	***After regulations imposed on baseline***	***Difference: After regulations imposed on baseline***
	Values of variables for medical cannabis		
Price per lb, with tax	$3,164	$3,846	$682
Price per lb, without tax	$2,556	$3,107	$551
Tax rate per lb	$608	$739	$131
Quantity (lbs)	235,000	230,000	-5,000
Share of total cannabis quantity	9.1%	8.97%	-0.13%
Revenue, with tax	$743 million	$883 million	$140 million
Revenue, without tax	$601 million	$714 million	$113 million
Tax revenue	$143 million	$170 million	$27 million
Share of total cannabis revenue, with tax	9.7%	9.8%	0.1%
Share of total cannabis revenue, without tax	9.1%	9.2%	0.1%

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

For details on the proposed package of regulations, see section 6.1.

Table 8.3 Impact of lower cost regulations on the medical cannabis segment, given the baseline with taxation and adult-use legalization

Variables	***Baseline with taxation and adult-use legalization***	***After regulations imposed on baseline***	***Difference: After regulations imposed on baseline***
	Values of variables for medical cannabis		
Price per lb, with tax	$3,164	$3,423	$259
Price per lb, without tax	$2,556	$2,765	$209
Tax rate per lb	$608	$658	$50
Quantity (lbs)	235,000	243,000	8,000
Share of total cannabis quantity	9.1%	9.38%	0.28%
Revenue, with tax	$743 million	$832 million	$89 million
Revenue, without tax	$601 million	$672 million	$71 million
Tax revenue	$143 million	$160 million	$17 million
Share of total cannabis revenue, with tax	9.7%	10.1%	0.4%
Share of total cannabis revenue, without tax	9.1%	9.5%	0.4%

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

For details on the lower-cost package of regulations, see section 6.1.

Table 8.4 Impact of higher-security regulations on the medical cannabis segment, given the baseline

	Baseline with taxation and adult-use legalization	***After regulations imposed baseline***	***Difference: After regulations imposed on baseline***
	Values of variables for medical cannabis		
Price per lb, with tax	$3,164	$4,264	$1,100
Price per lb, without tax	$2,556	$3,445	$889

with taxation and adult-use legalization

Tax rate per lb	$608	$819	$211
Quantity	235,000	205,000	-30,000
Share of total cannabis quantity	9.1%	8.15%	-0.95%
Revenue, with tax	$743 million	$874 million	$131 million
Revenue, without tax	$601 million	$706 million	$105 million
Tax revenue	$143 million	$168 million	$25 million
Share of total cannabis revenue, with tax	9.7%	9.1%	-0.6%
Share of total cannabis revenue, without tax	9.1%	8.4%	-0.7%

Source: Simulation model results based on parameters discussed in the text and in Table 8.1.

For details on the higher-security package of regulations, see Section 6.1.

9. Economy-wide impacts of proposed medical cannabis regulations

This chapter reports on the impacts of the proposed regulations on the broader economy outside of the cannabis industry. The impact estimates build directly on the results presented in Table 8.2 and focus on how changes in medical cannabis costs and revenues ripple through the economy. We use a modified version of the IMPLAN input/output model and data set to develop the economy-wide impacts. For readers unfamiliar with this approach a brief discussion of IMPLAN and similar models is provided as background in Chapter 13.

The IMPLAN version 2014 data set was adjusted to incorporate information about medical cannabis, which is not a separate covered industry in the IMPLAN data set. In particular, we adjusted the ratio of value added to intermediate purchases and the shares within value added to reflect tax payments among other modifications. The IMPLAN analysis was conducted using four sectors in medical cannabis. These are treated as “industries” in the IMPLAN nomenclature.

The four sectors correspond to the four sets of services and licenses that are the subject of proposed regulations. These are distribution, testing, transporting, and dispensing. Farm cultivation and manufacturing of medical cannabis are not a part of this analysis. We note that for wholesale and retail industries the IMPLAN framework treats "output" (in dollar value terms) as the difference between gross sales revenues collected by the wholesale or retail business sector minus the dollar value of the costs of goods sold by the wholesale or retail business sector. Therefore, IMPLAN analysis of wholesale and retail businesses does not include backward linkages from the wholesale (distribution) industry back to the raw and manufactured materials that represent costs of goods sold for distributors. Similarly, the IMPLAN linkages analyzed for the retail (dispensing) industry do not include the cost of goods that are acquired from the distributors. This means there is no double counting when we include both distribution businesses and dispensaries in the IMPLAN modeling.

For dispensing, we considered IMPLAN industry number 401 (drug stores and related retailers) as the best match from which to make adjustments. For distribution, we considered IMPLAN industry number 395 (wholesalers) as the best match from which to make adjustments. For testing, we considered IMPLAN industry number 479 (medical and diagnostic laboratories) as the best match from which to make adjustments. For transporting, we considered IMPLAN industry number 415 (couriers and messengers) as the best match from which to make adjustments.

We do not describe implications of regulations of medical cannabis for the illegal and adult-use segments of the cannabis market. Such analysis would require using simulations of the segments for illegal cannabis and adult-use cannabis. While these segments are affected by the proposed regulations, it is beyond the scope of this report to analyze those implications. A more complete analysis would consider how proposed regulations that will apply to the whole cannabis market will impact consumers and suppliers in the cannabis market as a whole.

9.1 Multipliers

Table 9.1 provides the detailed multipliers for the four "industries" that compose the portions of the medical cannabis industry that are licensed and overseen by the Bureau, from its wholesale transfer from cultivator to distributor or dispensary to its retail transfer to the consumer. These multipliers are used to calculate impacts of the "value of output" of the

industry changes. In each case, multipliers are presented as dollars per dollar of output. Recall that for distribution and dispensing, “value of output” is defined as sales revenue minus costs of goods sold. Thus, for example, the value of the output of dispensaries is their revenue minus the cost they paid for the products that they sell. Dispensary output is valued by their provision of retail services, not by their gross sales revenue. For testing and transporting, output is the value of the services provided, which is the revenue of the sector.

Value added is defined as the contribution to gross state product of the sector (output minus the value of indirect inputs purchased from other sectors). For example, for a dispensary, these indirect input purchases include normal retail-level purchases by the dispensary such as display labels, electricity services, cleaning supplies, costs of equipment such as fans or added lights, and cash registers. Labor income associated with the business is a part of value added and includes proprietor income as well as hired employee wages and salaries. Value added includes business taxes and other returns to the operation.

The final panel of Table 9.1 includes jobs per million dollars of output. This is calculated as the number of employees and managers employed in the industry divided by total value of output as defined above for each industry sector. For each industry sector, the multipliers are provided for indirect effects. These multipliers represent the ripple effects of purchases by the medical cannabis industry from other industries outside the medical cannabis segment. First-level purchases and subsequent ripples are both considered. This effect is described more fully in Section 13. The induced effects are the ripples associated with purchases made by those that earn the value added of the industry. So, for example, employee wages are spent on goods and services from other industries ripple through the economy creating additional value added, labor income and employment. The total effect adds the direct effect to indirect and induced effects.

9.2 Economy-wide contributions under the adult-use legalization baseline

Table 9.2 builds off the results presented in column 1 of Table 8.2. The top row of Table 9.2 lists the direct value of output expected under taxation and adult-use legalization, but without proposed regulations. In this case, IMPLAN shows output of $78 million for distribution, minimal output of $1.8 million for testing, about $30 million for transport of medical cannabis, and output of about $375 million for dispensing.

We note that these outputs include taxes. Recall that taxes are about 24% of revenue for the dispensaries. Labor income is more than half of the value of output for dispensaries. Recall that this includes returns to proprietors. The reason it is not a higher share is because taxes are such a large share of value added.

Table 9.1. Statewide Impact Multipliers for the Medical Cannabis Industry Sectors of Distribution, Testing, Transporting and Dispensing

Multiplier	*Distribution*	*Testing*	*Transporting*	*Dispensing*
Value of Output	*Output for economy per $1.00 output by cannabis sector (US $)*			
Direct Effect	1.000	1.000	1.000	1.000
Indirect Effect	0.402	0.349	0.509	0.285
Induced Effect	0.569	0.711	0.486	0.470
Total Effect	1.971	2.060	1.994	1.756
Value Added	*GDP per $1.00 of output (US $)*			
Direct Effect	0.681	0.674	0.559	0.778
Indirect Effect	0.249	0.218	0.294	0.179
Induced Effect	0.340	0.425	0.290	0.281
Total Effect	1.269	1.317	1.143	1.238
Labor Income	*Labor income per $1.00 output by sector (US $)*			
Direct Effect	0.475	0.661	0.352	0.426
Indirect Effect	0.164	0.140	0.195	0.104
Induced Effect	0.197	0.247	0.169	0.163
Total Effect	0.837	1.048	0.716	0.693
Employment	*Jobs per $1 million of output*			
Direct Effect	4.8	7.9	9.1	10.5

Indirect Effect	2.4	2.0	2.9	1.6
Induced Effect	3.6	4.5	3.1	3.0
Total Effect	10.8	14.3	15.0	15.1

Source: Multipliers were generated in IMPLAN using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

Table 9.2. Economic impacts of the California medical cannabis industry by sector, with taxation and adult-use legalization baseline, without regulation

	Distribution	***Testing***	***Transporting***	***Dispensing***
Impact Measure				
Value of Sector Output		*Millions of US $*		
Direct Output	78.0	1.8	30.2	374.5
Indirect Output	31.4	0.6	15.4	106.9
Induced Output	44.4	1.3	14.7	176.1
Total Output	153.7	3.7	60.3	657.5
Value Added				
Direct Value Added	53.1	1.2	16.9	291.3
Indirect Value Added	19.4	0.4	8.9	67.1
Induced Value Added	26.5	0.8	8.8	105.1
Total Value Added	99.0	2.4	34.6	463.5
Labor Income				

Direct Labor Income	37.1	1.2	10.6	159.6
Indirect Labor Income	12.8	0.3	5.9	38.9
Induced Labor Income	15.4	0.4	5.1	61.0
Total Labor Income	65.2	1.9	21.7	259.4
Impact Measure	***Distribution***	***Testing***	***Transporting***	***Dispensing***
Employment		*Number of Jobs*		
Direct Employment	374	14	275	3,932
Indirect Employment	187	4	88	599
Induced Employment	281	8	94	1,123
Total Employment	842	26	453	5,654

Source: Values were estimated by UC AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

9.3 Economy-wide contributions under the proposed regulations

Table 9.3 builds on the results presented in column 2 of Table 8.2. The top row of Table 9.3 is the direct value of output expected under adult-use legalization but before regulations are applied. In this case we expect output of $90.5 million for distribution and output of $92 million for testing. Recall that testing costs rise to about $400 per pound with the proposed regulations. The transport industry continues to have about $30 million of output for medical cannabis. Finally the output is about $417.9 million for dispensing. Much of the increase of the value of output is due to costs of regulations that add to costs at the dispensary.

Recall that taxes are about 24% of revenue for the dispensaries, and that these taxes apply to the higher market prices caused by regulations. Further, recall that because consumer willingness to pay rises with more security and product safety, the quantity sold falls little. Also recall that we assume that similar regulations, including testing, apply to adult-use cannabis.

With regulation, 4,388 direct jobs are in the dispensing sector, and these contribute 6,310 jobs to the economy overall. The testing sector is next with 727 direct jobs and 1,316 jobs to the economy overall. Distribution and transporting have few direct and total employment impacts consistent with their smaller outputs.

9.4 Economy-wide impacts of proposed regulations

Table 9.4 builds economy-wide impacts of the proposed regulations by subtracting the results in Table 9.2 from those in Table 9.3. These differences in value of output effects, value added effects, labor income effects, and jobs comprise the results presented in Table 9.4. The total dollar values in Table 9.4 are reported in millions and are relatively small for distribution and transporting where regulations add little to costs. The regulatory impacts are much more significant in testing and dispensing.

Table 9.3. Economic impacts of the California medical cannabis industry by sector, with taxation and adult-use legalization, with proposed regulations

Impact Measure	*Distribution*	*Testing*	*Transporting*	*Dispensing*
Value of Sector Output		*Millions of US $*		
Direct Output	90.5	92.0	29.6	417.9
Indirect Output	36.4	32.1	15.0	119.3
Induced Output	51.5	65.4	14.4	196.6
Total Output	178.5	189.6	59.0	733.7
Value Added				
Direct Value Added	61.7	62.0	16.5	325.1
Indirect Value Added	22.5	20.0	8.7	74.9
Induced Value Added	30.7	39.1	8.6	117.3
Total Value Added	114.9	121.1	33.8	517.3
Labor Income				
Direct Labor Income	43.0	60.8	10.4	178.1
Indirect Labor Income	14.9	12.9	5.8	43.4
Induced Labor Income	17.8	22.8	5.0	68.0
Total Labor Income	75.7	96.4	21.2	289.5
Employment		*Number of Jobs*		
Direct Employment	435	727	269	4,388
Indirect Employment	217	184	86	669
Induced Employment	326	414	92	1,254
Total Employment	978	1,316	444	6,310

Source: Values were estimated by UC AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

In the dispensary sector, the output measured by margin rises by $43.4 million, value added rises by $33.8 million, direct labor income rises by $18.5 million and direct employment rises by 456 jobs. For the dispensary sector, the California economy-wide impacts of the proposed regulations are as follows: value added rises by $53.7 million, and the increase in number of jobs attributable to the increase in dispensary output is 655 jobs. In the distribution sector, output rises by $12.5 million and direct jobs rise by 60. For the distribution sector, the California economy-wide impacts of the proposed regulations are as follows: value added rises by $15.9 million, and the increase in number of jobs attributable to the increase in distribution output is 136 jobs.

Transport revenue falls by only $0.6 million because quantity shipped falls slightly and number of shipments may increase slightly direct employment falls by 6 jobs. For the transport sector, the California economy-wide impacts of the proposed regulations are as follows: value added falls by $0.7 million, and the fall in number of jobs attributable to the fall in transport is 10 jobs.

The expanded testing sector is subject to significant new economic activity. Output measured by revenue rises by $90.2 million, direct value added by $60.8 million and direct jobs rise by 713. Economy-wide value added attributable to testing rises by $118.8 million, $94.5 million more in total economy-wide labor income, and economy wide jobs rise by 1,290 jobs.

These impacts are additive in the economy-wide calculations because the retail and wholesale sectors within IMPLAN are measured on a margin basis. Adding the sector specific impacts, the economy-wide impacts of the proposed regulations are substantial. Within the sector the increase in due to the proposed regulations of direct value added is $102.7 million. Economywide the value added rises by $187.7 million and economywide labor income (including proprietor income) rises by $134.6 million. Overall, the economy adds 1,223 jobs within the medical cannabis sector and overall California employment rises by 2,071 jobs.

These economy-wide implications are derived from and consistent with the results in Table 8.3, which shows the direct impacts of regulations in the medical cannabis segment in terms of prices, outputs, revenues, and taxes.

Table 9.4. Differences between economic impacts of the California medical cannabis industry by sector, adult-use legalization baseline from the proposed regulations

Impact Measure	*Distribution*	*Testing*	*Transporting*	*Dispensing*
Value of Sector Output		*Millions of US $*		
Direct Output	12.5	90.2	-0.6	43.4
Indirect Output	5.0	31.5	-0.3	12.4
Induced Output	7.1	64.2	-0.3	20.4
Total Output	24.7	185.8	-1.3	76.2
Value Added				
Direct Value Added	8.5	60.8	-0.4	33.8
Indirect Value Added	3.1	19.6	-0.2	7.8
Induced Value Added	4.3	38.4	-0.2	12.2
Total Value Added	15.9	118.8	-0.7	53.7
Labor Income				
Direct Labor Income	6.0	59.6	-0.2	18.5
Indirect Labor Income	2.1	12.6	-0.1	4.5
Induced Labor Income	2.5	22.3	-0.1	7.1
Total Labor Income	10.5	94.5	-0.5	30.1
Employment		*Number of Jobs*		
Direct Employment	60	713	-6	456
Indirect Employment	30	180	-2	69
Induced Employment	45	406	-2	130
Total Employment	136	1,290	-10	655

Source: Values were estimated by UC AIC staff by applying input-output multipliers generated in IMPLAN and using revenue and costs data provided by industry respondents to project questionnaire.

Note: Labor income includes employees and proprietor income.

10. Legal cannabis policy and markets: A comparative review of west coast states

The western states have long formed the core of the US cannabis market. All three states on the west coast of the continental US (Washington, Oregon, and California), as well as Colorado and (as of 2016) Alaska and Nevada, have now legalized both medical and adult-use cannabis.

Although California was the first state to decriminalize medical cannabis (in 1996), it will be the last of the three west-coast states to regulate cannabis on a state level when taxation and adult-use legalization and the proposed regulations for adult-use and medical cannabis take effect in 2018. California can therefore look to the other western markets for comparative evidence on the different forms of regulation that have come into effect in its neighboring states.

First, we summarize the comparative situation in Table 10.1, which lists the key similarities and differences in regulatory systems and timelines between California, Oregon, and Washington. We provide relevant details on the regulatory environments, economic indicators, and data sources used for each state.

This is followed by Table 10.2, which summarizes wholesale price differences and trends in six western states.

10.1 California and Colorado

Until now, the medical cannabis market has been the only legal cannabis market in California. Its retail sales have been taxed at a rate of approximately 3%, accounting for widespread non-compliance. In 2018, the legalization of adult-use cannabis and implementation of the proposed regulations will result in a new tax rate (not including cultivation taxes) of approximately 23.8% and a package of testing regulations and other regulations that will add a total cost of approximately $500 per pound.

The statutory and regulatory history, our economic calculations, and expected economic effects with respect to California are detailed in other portions of this report. In this section, we focus on the comparative analysis with Washington and Oregon. Colorado's situation is not readily comparable to California's because in Colorado, the adult-use cannabis regulations are significantly more costly than the ones imposed on medical cannabis, resulting in higher relative prices of adult-use cannabis. (In section 5.2.2, however, we do consider Colorado data in the context of estimating the outward demand shift that we expect to result in the California adult-use market from tourists and other visitors to the state.)

Among California's neighboring states, Washington and Oregon are the focus of this comparative analysis because of the unique regulatory similarities between the proposed regulations in California and the ones currently in place in Washington and Oregon, particularly with respect to testing regulations, track-and-trace, labeling, security regulations, and the relationship between medical and adult-use regulations.

Table 10.1 Comparison of major regulatory changes and subsequent economic effects in regulated U.S. states

	Washington	***Oregon***	***California***
1. Medical legalization changes	1998: Medical use legalized.[1]	1998: Medical use legalized.[1] 2013: Dispensaries legalized.[1]	1996: Medical use decriminalized.[2] 2015: MCRSA establishes Bureau to regulate medical use.[2]
Subsequent unregulated period	1998–2012: Industry remains unregulated except by local municipalities.[1]	1998–2015: Industry remains unregulated except by local municipalities.[1]	1996–Nov 2016: Industry remains unregulated except by local municipalities.[1] Total market size grows to $7.7 billion ($2 billion medical cannabis, $5.7 billion illegal cannabis).[5]
2. Adult-use legalization changes	Nov 2012: Initiative 502 legalizes and rolls out adult use regulation in 2013; cultivators, manufacturers, and retailers pay excise tax of 25%; medical remains untaxed and unregulated.[1]	Nov 2014: Ballot Measure 91 legalizes adult use starting Jul 1, 2015.[1]	Nov 2016: Proposition 64 decriminalizes personal adult-use possession and cultivation immediately and reduces penalty for sale from felony to misdemeanor. Prop 64 also legalizes and regulates adult use starting Jan 1, 2018.[2]
Subsequent economic	Unregulated medical market, with cost advantages over	After adult-use legalization, adult use segment claims	Reliable data are not yet available for changes to the

effects observed	adult-use market, continues to grow modestly. Adult-use market grows much faster, surpassing medical in late 2014 and doubling size of medical market by mid-2015.[3]	50% of legal cannabis market.[4] Market size estimated as $750M in fall 2016 ($375M = 50% legal; $375M = 50% illegal).[4] As of Sept 2016, there were 1,300 applicants but only 200 businesses licensed.[4]	marketplace between Nov 2016 and Jan 2017.
3. Latest regulatory changes	Jul 2015: regulations of medical and adult-use segments roughly equalized. Similar compliance costs imposed in both segments. Effective tax rate of 37% imposed on all medical and adult-use cannabis. Registered medical patients will be exempt only from state sales tax, a small component of overall tax rate.	Oct 2016: stringent new testing standards imposed on entire legal market. Nov 2016: batch size limitations lifted due to standstill in testing process.	Jan 2018: regulations of medical and adult-use segments will be roughly equivalent. Similar compliance costs are imposed in both segments. Effective tax rate of 15% imposed on all medical and adult-use cannabis (excise). Registered medical patients will be exempt only from state sales tax, a small component of overall tax rate.
Subsequent economic effects observed	With compliance costs equalized, medical segment loses price and other advantages, and consumers rapidly migrate from medical segment to adult-use segment. By June 2016, 1 year after the removal of tax and regulatory incentives for consumers to remain in the medical market, adult use revenues have grown to 89% of the $630 million legal cannabis market[3] and medical revenues have fallen to 11% of the legal market. If current trends continue, the Washington medical cannabis segment appears unlikely to survive in the long run.	Legal cannabis prices rise by 27%–39% in the two-month span after testing rules take effect.[6,7] Revenue falls by $23,500 per dispensary due to supply constraints.[8] half of legal segment ($187.5 million) shifts back to illegal market.[4] The illegal market grows from 50% to 75% while the legal market falls from 50% to 25%.[4]	With compliance costs equalized, medical segment has no price or other advantages, and consumers rapidly migrate from medical segment to adult-use segment. Our simulation model projects that the CA medical market will hold about 10% of the overall cannabis market, which agrees with the rates of consumer migration observed in WA under similar conditions. Short-term supply shortages may cause temporary flight to CA's illegal market and spike prices; but SRIA analysis's scope of prediction is one year after implementation, by which point we project that testing will impose an additional cost of approximately 12% on cannabis in the post-regulation equilibrium.[5]

[1] Source: NORML legal history, norml.com; Washington, Oregon, and California state laws.
[2] For a timeline of California statutory history, please see Chapters 1 and 2.
[3] Source: Washington Department of Revenue data. Full data set shown in Tables 10.3 through 10.6. For market sizing, revenues are calculated simply as 12 times June 2016 reported revenues. Sales are growing so rapidly in this market that to construct the annualized estimate on a more sophisticated seasonal spreading basis would fail to observe the dominance of this growth in the pattern.
[4] Source: Whitney Economics November 30, 2016 white paper.
[5] Source: AIC estimates. For detailed analysis of AIC market size calculations, see Chapter 5, with supporting empirical background material in Chapters 3 and 4.
[6] Source: the 27% two-month price increase estimate comes from an AIC re-analysis of the distribution of the "price increases due to the lack of available supply" responses in Whitney Economics November 30, 2016 survey data (69 responses of 683 businesses surveyed).
[7] Source: the 39% two-month price increase estimate comes from Cannabis Benchmarks' Oregon spot prices of $1,500 on 10/28/2016 and $2,082 on 12/23/2016. The Oregon spot price peaked at $2,300 on 12/9/2016 (a 53% increase in the first six weeks after the testing regulations took effect).
[8] Source: Whitney Economics, November 30, 2016 white paper and AIC re-analysis of the distribution of "lost revenue per month as a result of supply constraint" responses in Whitney survey data (72 responses of 683 businesses surveyed).

Table 10.2. Retail and wholesale spot prices for cannabis in six western states

State (ranked from least to most expensive)	**Retail price per lb**[1]	**Wholesale spot price per lb**[2]	**Marketing multiple**[3]	**Average deal size**[4]
Oregon	$2,921 *n=2,735*[5]	$2,082	1.40	2.5 lbs
Washington	$3,024 *n=4,496*	$1,329	2.28	7.4 lbs
Colorado	$3,190 *n=3,722*	$1,430	2.23	3.0 lbs
California	$3,453 *(AIC est.)*	$1,495	2.31	12.9 lbs
Arizona	$3,614 *n=3,144*	$2,404	1.50	7.1 lbs
Nevada	$3,695 *n=1,850*	$2,425	1.52	6.6 lbs

[1] Source: Priceofweed.com retail user survey, data current as of 23 December 2016. Medium quality assumed. AIC's own assumptions used for California.

[2] Source: Cannabis Benchmarks Premium Report, 23 December 2016. Weighted averages.

[3] Ratio of retail price to the cost of raw goods.

[4] Weighted averages.

[5] "n=" refers to number of observations in each state.

10.2 Washington State

Washington State's history of cannabis regulation has much in common with California's, beginning with medical legalization in 1998 (vs. 1996 in California) and 14 years (vs. 22 in California) of state-unregulated operation of the medical cannabis industry. The history of legal cannabis policy in Washington can be partitioned by the following three changes: the initial legalization of medical cannabis in 1998, the legalization and regulation of adult-use cannabis in 2012, and the restructuring of the cannabis tax system in 2015 so as to regulate medical cannabis similarly to adult-use cannabis. At each stage, the treatment of medical cannabis was impacted, and each will be examined in turn.

Medical cannabis possession and use was decriminalized by ballot initiative in 1998. The policies in the initiative failed to establish any regulatory structure, and the medical cannabis industry functioned as a gray market similar to the one that has been in place in California to date, with only local regulations governing firm behavior. There were no state regulations to govern the establishment of dispensaries or to regulate providers of medical cannabis cards. In 2000, legislation was passed that would have established a regulatory system, but the majority of the law was vetoed by the governor.[149]

Initiative 502 legalized adult-use cannabis use in 2012, but ignored the established medical cannabis system. This meant that adult-use cannabis and medical cannabis existed in parallel. The initiative included a three-tiered tax structure for adult-use cannabis, but medical cannabis was exempted from any taxation. This created competition between the regulated adult-use system and the unregulated medical system, and because of the tax advantages in and ease of access to the medical system, some consumers continued to purchase medical cannabis. In March of 2015, there were 123 licensed adult-use dispensaries and approximately 1,100 state-unregulated medical dispensaries (Washington Office of Financial Management 2016).

[149] In Washington, the governor may line-item veto, and in this case, the law was still enacted, but most of the legislation pertaining to cannabis regulation did not actually go into effect.

To address the disparity in the regulatory system, and to simplify the tax structure, Washington SB 5052 was passed in 2015 to restructure both the adult-use and medical cannabis systems into one regulatory structure.[150] The medical system was not phased out, but the same licensing system now governs adult-use and medical dispensaries. Medical cannabis products can be purchased by any consumer now, whether a medical cardholder or not, but there is also an additional medical endorsement that dispensaries may obtain.

Despite this, there are still key differences between adult-use consumers and medical consumers. Medical cardholders may possess larger quantities of cannabis, may purchase higher-THC products, may grow cannabis at home or participate in a growing cooperative, and are exempted from any taxation on cannabis. (This tax break is only offered to cardholders.) Under the new regulatory structure, medical cards are now issued by the state, with a voluntary registration database similar to California's.

Following is a review of specific characteristics of the Washington medical and adult-use regulations, so that economic results in Washington can be interpreted in consideration of those factors, especially insofar as they differ from the proposed regulations in California.

Cannabis products in Washington are labeled in three ways: General Use, High-CBD, and High-THC. The definitions and limitations are as follows:

- General Use
    - Any approved cannabis product may be packaged in servings containing up to 10 mg of THC, but may not exceed 10 servings or 100 mg of THC
    - May be purchased by anyone over 21 or anyone holding a recognition card
    - May be sold by any licensed retail outlet

- High-CBD cannabis
    - May be any approved cannabis product except usable cannabis intended for smoking
    - Servings must contain no more than 2 percent THC concentration by weight and at least 25 times more CBD concentration
    - May be purchased by anyone over 21 or anyone holding a recognition card and may be sold by any licensed retail outlet

- High-THC cannabis

[150] All of the specific information in Section 10.2 is drawn from the Washington Governor's Office (2016) website: "Frequently Asked Questions - Cannabis Patient Protection Act (SB 5052)."

- A cannabis product containing more than 10, but no more than 50, mg of THC per serving
- The only products that qualify as High THC are capsules, tinctures, transdermal patches, and suppositories
- May only be purchased by patients holding a recognition card, and may only be sold by medically endorsed licensed retail establishments

A consumer must obtain a state-registered medical card in order to participate in the Washington medical cannabis system, which enables the consumer to buy medical cannabis under a set of rules that have certain advantages over the adult-use rules: including a lower minimum age of legal purchase and consumption (18), and order-of-magnitude-higher concentration and quantity allowances.

Participation in the medical segment requires completion of two-page authorization form by healthcare practitioner. The healthcare practitioner may be a medical doctor, physician assistant, osteopathic physician or assistant, naturopathic physician, or an advanced registered nurse practitioner. Provider may recommend that the patient be allowed to grow more than the number of plants allowed by law, up to 15. The form allows for identification of a designated provider (a person whom the patient authorizes to purchase their cannabis product or grow their cannabis plants).

A medical card can be acquired by a person of any age, but a patient under 18 must be registered in the authorization database. The authorization form requires the patient or designated provider's name and address, and the name, license number, and contact information of the medical practitioner listed. The healthcare practitioner must also indicate the diagnosis that allows for the authorization. The authorization form expires after one year.

Once the authorization form is completed, the patient may join the medical cannabis authorization database and receive a medical cannabis recognition card. This requires the patient to visit a licensed and medically endorsed cannabis store and contact the medical cannabis consultant on staff. The consultant will then enter the patient's information into the database and create the new medical cannabis recognition card.

The patient must pay a one-dollar fee for the creation of the card (the fee is transferred to the Washington Department of Health). As of December 5, 2016, a total of 15,536 recognition cards have been created, with 47 issued to minors under 18.

- Benefits of a medical recognition card:
    - Buy products at medically endorsed retail stores sales tax free;
    - Buy up to three times the current limits (see below for these levels) at medically endorsed retail stores;
    - Buy High-THC products;
    - Grow in their home or as a member of a cooperative:
        - 6 plants for personal medical use; and
    - Possess up to 8 oz usable cannabis produced from their plants.
    - Protection against arrest (if not registered in the database, patients only have an affirmative defense).

- Current purchase limitations:
    - Authorized medical patients entered into the state database are permitted to possess exactly three times the amounts permitted for adult-use consumers, plus the right to cultivate small amounts of cannabis:
        - 3 oz usable cannabis;
        - 48 oz cannabis-infused product in solid form;
        - 216 oz cannabis-infused product in liquid form;
        - 21 g cannabis concentrate;
    - Grow in one's home or as a member of a cooperative:
        - 6 plants for personal medical use; and
        - Possess up to 8 oz usable cannabis produced from their plants.

Medical-cannabis-endorsed stores must have a certified medical cannabis consultant on hand. Consultant may enter authorization form information into authorization database. There are currently 161 active medically endorsed retail stores (out of a total of 467 licensed retail locations in Washington). A medically endorsed retail store is defined as a store that has at least one certified medical cannabis consultant on staff.

Prior to July 2015, adult-use and medical producers, processors, and retailers paid an excise tax of 25%. This tax was in addition to state and local sales taxes and business and operation taxes. After July 2015, only retailers have paid excise tax, which was raised to 37%. The excise tax is collected by the Washington Liquor and Cannabis Board, while the Department of Revenue collects sales and B&O taxes.

- Adult-use cannabis is available to all individuals over the age of 21.

- Adult-use consumers are permitted to buy and possess:
    - 1 oz usable cannabis;
    - 16 oz cannabis-infused product in solid form;
    - 72 oz cannabis-infused product in liquid form;
    - 7 g cannabis concentrate.

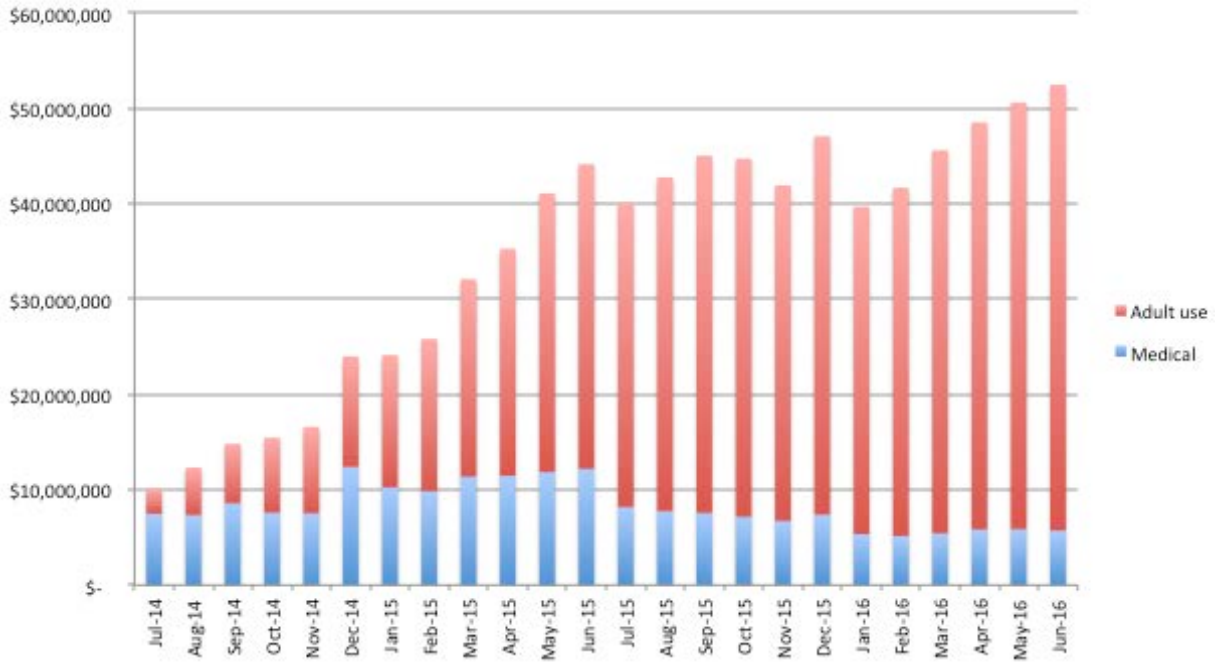
- Adult-use consumers are permitted to buy and possess high-CBD cannabis products.

- Adult-use consumers are not permitted to buy or possess high-THC cannabis products.

Information from the Washington Department of Revenue tax collection data are summarized graphically in Figure 10.1, and the data are reported in Tables 10.3–10.5. Figure 10.1 paints a stark picture of the medical cannabis segment losing 89% of the legal market after the introduction of adult-use cannabis in 2013, as detailed in Table 10.1. In October 2014, medical cannabis loses its majority share, and medical revenues begin to fall precipitously in July 2015.

Figure 10.1. Monthly sales of medical and adult-use cannabis,

Washington State, July 2014–June 2016



Source: Washington Department of Revenue data.

Table 10.3. Washington medical cannabis taxes for fiscal years 2015 and 2016[1,2]

Month of Sales Activity[3]	*Taxable Retail Sales*	*State Retail Sales Tax Due*	*State Business & Occupation Tax Due[4]*	*Local Retail Sales Tax Due*	*Implied Tax Rate*
Jul-2014	7,478,171	486,081	38,953	199,188	0.070
Aug-2014	7,346,693	477,535	38,298	192,169	0.070
Sep-2014	8,597,641	558,847	50,291	244,816	0.070
Oct-2014	7,597,259	493,822	39,986	235,881	0.070
Nov-2014	7,526,287	489,209	39,182	190,601	0.070
Dec-2014	12,405,007	806,326	87,933	324,655	0.070
Jan-2015	10,237,454	665,435	62,151	266,680	0.070
Feb-2015	9,868,715	641,467	58,817	254,938	0.070
Mar-2015	11,366,900	741,985	70,441	371,598	0.070
Apr-2015	11,451,376	744,340	69,432	298,760	0.070
May-2015	11,844,387	769,885	72,394	307,258	0.070
Jun-2015	12,181,480	791,568	75,506	336,761	0.069
FY 2015 Totals	**117,901,369**	**7,666,500**	**703,383**	**3,223,303**	**0.070**
Jul-2015	8,184,880	532,017	78,955	208,521	0.070
Aug-2015	7,755,748	504,124	76,926	197,800	0.070
Sep-2015	7,553,969	491,008	100,731	244,654	0.070
Oct-2015	7,155,186	465,087	78,412	179,608	0.070
Nov-2015	6,725,384	437,150	72,884	171,567	0.070
Dec-2015	7,388,484	553,995	72,912	196,490	0.081

Jan-2016	5,337,565	346,942	54,557	140,740	0.070
Feb-2016	5,146,542	336,236	52,242	135,477	0.070
Mar-2016	5,420,006	438,338	57,585	146,974	0.088
Apr-2016	5,825,874	378,682	52,022	154,723	0.070
May-2016	5,862,166	381,041	48,947	155,382	0.070
June-2016	5,721,786	371,916	46,734	152,387	0.070
FY 2016 Totals	**78,077,590**	**5,236,536**	**792,906**	**2,084,323**	**0.072**

Source: Washington Department of Revenue data.

[1] Data contain adjusted amounts as of August 12, 2016. This includes adjusted data for the most current month, as well as any adjustment made to previous months. These figures do not include assessments.

[2] These data come from 269 registered medical cannabis retailers who have reported retail sales, retail sales taxes and other excise taxes. There may be other medical cannabis sellers who have also properly remitted excise taxes, but who have not been identified as such by the Washington Department of Revenue.

[3] Month of Sales Activity represents the month purchased from a retailer.

[4] The retail sales tax and the state business and occupation tax (B&O tax) represent the major taxes paid by these taxpayers with other taxes being trivial.

Table 10.4. Washington adult-use cannabis taxes for fiscal years 2015 and 2016[1,2]

Month of Sales Activity[3]	*Taxable Retail Sales*	*State Retail Sales Tax Due*	*State Business & Occupation Tax Due[4]*	*Local Retail Sales Tax Due*	*Implied Tax Rate*
Jul-2014	2,578,241	167,586	31,125	52,679	0.070
Aug-2014	4,954,243	322,026	46,673	108,469	0.070
Sep-2014	6,208,687	403,565	62,140	139,183	0.070
Oct-2014	7,838,338	509,492	81,054	182,596	0.070
Nov-2014	9,053,929	588,505	94,701	212,475	0.070
Dec-2014	11,560,057	751,404	97,899	271,983	0.070

Jan-2015	13,864,329	901,181	103,626	324,943	0.070
Feb-2015	15,915,997	1,034,540	119,232	371,655	0.070
Mar-2015	20,699,013	1,372,534	157,671	483,891	0.071
Apr-2015	23,790,464	1,546,380	185,190	561,581	0.070
May-2015	29,210,099	1,898,656	216,663	688,782	0.070
Jun-2015	31,931,700	2,075,561	243,550	751,860	0.070
FY 2015 Totals	**177,605,098**	**11,571,430**	**1,439,523**	**4,150,099**	0.070
Jul-2015	31,822,630	2,068,471	260,069	747,756	0.070
Aug-2015	34,976,812	2,273,493	287,489	824,443	0.070
Sep-2015	37,443,163	2,433,806	321,116	887,877	0.070
Oct-2015	37,533,721	2,439,692	321,989	904,438	0.070
Nov-2015	35,178,194	2,286,583	299,310	861,753	0.070
Dec-2015	39,657,987	2,587,874	336,215	972,630	0.070
Jan-2016	34,316,151	2,230,550	322,273	865,698	0.070
Feb-2016	36,490,730	2,371,897	327,316	882,626	0.070
Mar-2016	40,156,970	2,610,203	367,116	973,085	0.070
Apr-2016	42,666,562	2,773,327	386,681	1,051,718	0.070
May-2016	44,704,504	2,905,793	396,306	1,101,269	0.070
June-2016	46,709,764	3,036,135	424,332	1,155,568	0.070
FY 2016 Totals	**461,657,187**	**30,017,823**	**4,050,212**	**11,228,861**	0.070

Source: Washington Department of Revenue.

[1] Includes taxes paid by producers, processors, and retailers.

[2] Data contain adjusted amounts as of August 12, 2016. This includes adjusted data for the most current month, as well as any adjustments made to previous months.

[3] Month of Activity represents the month in which a producer and/or processor sold product to a retailer or a consumer purchased from a retailer.

[4] The retail sales tax and the state business and occupation tax (B&O tax) represent the major taxes paid by these taxpayers with other taxes being trivial.

Table 10.5. Washington adult-use cannabis sales revenue and excise tax for calendar year 2016

Month	Sales (Shelf Price)[1]	Excise Tax Due	Implied Tax Rate
Jan-2016	77,962,150	14,643,661	0.2313
Feb-2016	81,081,943	15,659,135	0.2394
Mar-2016	91,340,974	17,356,284	0.2346
Apr-2016	95,063,638	18,156,968	0.2361
May-2016	95,171,114	18,149,800	0.2356
Jun-2016	106,762,250	20,012,239	0.2307
Jul-2016	121,494,961	23,547,274	0.2404
Aug-2016	134,635,800	25,003,323	0.2281
Sep-2016	139,621,291	26,002,289	0.2289
Oct-2016	141,031,391	25,623,780	0.2220
Nov-2016	136,778,617	24,828,041	0.2218
Dec-2016[2]	21,960,275	4,397,984	0.2504
Calendar Year 2016 Totals	**1,242,904,404**	**233,380,778**	**0.2312**

Source: Washington Department of Revenue.

[1] Shelf price = sales price + tax

[2] December 2016 includes sales as of December 12, 2016.

10.4 Testing and the Oregon market

On November 30, 2016, Whitney Economics LLC released a white paper on the two-month impact of new state testing standards on the Oregon cannabis market, whose results were

widely reported in the Oregon and cannabis media. This is the most up-to-date empirical data set currently available on the economic effects of testing standards similar to those in the proposed regulation.

As for the results we quote earlier from ArcView and other private industry research firms and think-tanks that have published white papers or research reports, we must approach these data with caution due to the fact that it they are compiled by analysts who have vested interests in the success of certain types of startup ventures over others.

Due to this and a wide array of other biases inherent to the questionnaire and response bias effects, we cannot rely on the Whitney survey to make economic estimates. Instead, we use it for rough comparison purposes only; and when we do reference the survey, we make additional qualifications about internal and external validity as necessary.

Legislative changes in Oregon may be poised to lessen some of these burdens through a dramatic policy shift. This situation has continued to develop as we have been compiling the SRIA, and in the last three months of 2016, policies have been fluctuating on a weekly or monthly basis. The following material is quoted from a report in the *Oregonian* report from December 15, 2016 (Harbarger, 2016):

> Oregon this week continued to tweak its cannabis testing rules, hoping to ease a backlog and get flowers, oils and cannabis-infused snacks and treats into the medical and adult-use markets. The Oregon Health Authority issued yet another set of revised rules Wednesday that in essence reduce the number of required tests for potency, solvents and pesticides. The rules don't change the type of tests required, though Jeff Rhoades, a senior adviser to Gov. Kate Brown, told a panel of lawmakers this week that the state is considering replacing the pesticide testing system in favor of a looser approach used in agricultural crops. Apples, grapes and hops, for instance, undergo random sampling for pesticides before they land on grocery store shelves.
>
> "That is the approach we are looking to take eventually with cannabis," said Andre Ourso, manager of the medical cannabis program at the health authority. Under Oregon's standards now, cannabis is subjected to frequent and comprehensive testing at multiple stages, from flower to oils. The state will re-examine its testing requirements early next year, Ourso said.
>
> Norris Monson, CEO of Cultivated Industries, a Portland-based cannabis producer, processor and retailer, said he's experienced long delays getting his products back from labs. He said he's begun to spend more for expedited testing so he can move his flower and extracts more quickly. He figures he gets three to four calls a day from shops desperate for products. "A lot of them have nothing on their shelves anymore," he said.

11. Brief historical review of alcohol control in the United States, with potential lessons for the impact of cannabis regulations

The United States has a long history of legislation designed to control alcohol consumption. From 1919 through 1934, the commercial production and distribution of beverage alcohol was illegal, and alcohol control is the subject of both the 18th and 21st Constitutional amendments (Pinney, 2005). Issues surrounding how to incorporate alcohol into society are not dissimilar to those facing state and local governments as they move to license, regulate and label medical cannabis in California (Mendelson, 2009). Beverage alcohol and medical cannabis are, of course, very different products, but issues of licensing, taxation, separation of producer from retailer, local control of production and sales and labeling are similar for beverage alcohol and medicinal cannabis. Alcohol is a heavily regulated product and such regulation adds costs that in turn effect both demand and supply. A review of alcohol regulation in the United States, and particularly in California, may have lessons for the regulation of medical cannabis.

11.1 Prohibition

National prohibition of alcohol was quite different from the criminalization of cannabis. The Eighteenth Amendment prohibited the production, distribution, and sale of most alcoholic beverages. However, it did not criminalize the possession or consumption of alcohol. Individuals with private cellars stocked with pre-Prohibition alcohol could legally consume those beverages at home and serve them to guests, although they could not legally transport the beverages to another location.

Nor were all forms of alcohol illegal to produce. The Volstead Act, which was the Congressional legislation designed to enforce the 18th Amendment, allowed for the production of “non-intoxicating” fruit juices produced from apples and grapes. Up to 200 gallons of wine per family could legally be produced each year and consumed on-site and shared with guests. Unlike wine and hard cider, the production of beer and distilled spirits was illegal, and it was these two forms of beverage alcohol that were produced or smuggled into the country and sold.

Some of the legally-produced wine for home consumption was likely diverted into the illegal distribution system, just as some medical cannabis is probably resold to individuals without

medical cannabis cards, but the volume is unknown and wine was not the focus of government enforcement, which centered on distilled spirits (Mendelson, 2009; Pinney, 2005).

The legality of home wine production had a curious effect that may have parallels with medical cannabis, in that it spurred grape production. Because wine was the major legal form of alcohol during Prohibition, demand for wine, and for wine grapes, increased. Grapes that had sold for $30 per ton in 1919 were sold for $100 per ton the following year. The high prices sparked a winegrape planting boom, and winegrape acreage in California almost doubled from 98,500 acres in 1920 to 188,000 acres in 1930. The high prices only lasted for a few years, until quantity produced from the new plantings met quantity demanded, at which point winegrape prices fell to pre-Prohibition levels.

However, as is often the case in agricultural booms, the actual acreage of new vineyards exceeded the acreage needed to meet demand, and prices fell to $18 per ton by the late 1920s (USDA, 2014). Even after the repeal of Prohibition, low grape prices caused low profitability among growers, although not so low as to cause vineyard removals.

By 1938, low prices led the winegrape industry to mandate the distillation of 45% of the 1938 crop in an effort to stabilize winegrape prices (Pinney, 2005). Of course, winegrapes are perennial crops and, once planted, will produce for many years, whereas cannabis is an annual crop and growers can more quickly adjust supply relative to demand. However, investments in indoor growing facilities or land represent real costs that will only be recouped if used. Such investment may cause growers to continue to produce crop even at low prices. As growers respond to an increased demand that may follow the regularization of medical cannabis, limitations on the size of cannabis farms may result in an increased number of individual firms entering the industry, rather than the expansion of existing firms.

11.2 Repeal and taxation

Although by 1930 many Americans had concluded that Prohibition was a failure, more than a quarter of the states wished to continue some form of alcohol business ban and could thus block the Constitutional amendment that was necessary in order to repeal the 18th Amendment. The political compromise that was reached in the form of the 21st amendment

was that each state was given the right to control production and distribution of alcoholic beverages.

As a consequence, the United States effectively became 50 countries, each controlling alcohol in different ways and taxing at different rates. Some states, such as Oklahoma and Mississippi, maintained Prohibition for many years. Others, such as Utah and Pennsylvania, became what is termed "control states" and created a system in which the state was the importer, wholesaler and retailer of alcoholic beverages. Most states created a system in which private firms were licensed by the state to perform specific functions, such as production, wholesaling or retailing, generally separating retailing from other activities. This system, often referred to as the "three-tier" system, is addressed in greater detail later in this report (Mendelson, 2009).

One key point of State control was and is taxation. Each state taxes various alcoholic beverages at differing rates, often based on the concentration of the alcoholic beverage. In California, for example, distilled spirits under 100 proof (50% concentration) pay an excise tax of $3.30 per gallon; beer, wine and hard cider, on the other hand, pay $0.20 per gallon. The economic Law of Demand stipulates that all other things being equal, price increases will decrease the quantity consumed of a good. If price decreases, on the other hand, consumption will go up. In 1890, the Federal government eliminated the $0.90 a gallon excise tax on brandy used in fortifying wine for the production of dessert wines. Prior to 1890, fortified wine constituted about 5% of California's total wine production. Without excise taxes, fortified wine prices fell and fortified wine quickly became the least expensive form of beverage alcohol available to consumers. By the early 20th century, fortified wine accounted for over 40% of California's total wine production (West, 1935).

Taxes do change consumer behavior. There are numerous examples of consumers crossing state borders to purchase goods in a low-tax state. A 2011 study of consumer behavior in West Virginia concluded that consumers close to Kentucky and Ohio, whose tax rates on alcohol were lower than those of West Virginia, sometimes traveled out of state to purchase alcohol, resulting in lower sales and tax revenue for West Virginia counties adjoining Kentucky or Ohio (Nesbitt and King-Adzima, 2011). Conversely, the West Virginia counties bordering Virginia, whose alcohol tax rates are higher than those of West Virginia, benefited from Virginia consumers crossing the border into West Virginia to purchase alcohol.

Anecdotal examples of consumers crossing borders to purchase alcohol and illegally smuggling their purchases back into their home state abound. In 2009 a Massachusetts legislator who had voted for a tax increase on alcohol was arrested smuggling alcohol purchased in New Hampshire, where alcohol taxes were lower (Henchman, 2009). Pennsylvania, which has a state monopoly on alcohol sales, and thus higher prices for similar products than in New Jersey or Delaware, has actively enforced searches of cars entering the state in an attempt to reduce liquor smuggling (Patch Staff, 2013).

Given observed behavior of consumers of alcohol, some cannabis consumers may travel from a high-cost area to a low-cost area for cannabis. Since this would occur intra-state, it would be legal from a state perspective, but it would reduce the volume of sales in the high-cost area. These effects may be considered by municipalities and counties when setting local requirements for cannabis licensing, but it is of course impossible for us or for the Bureau to predict the future actions of local municipalities with respect to the taxation of cannabis.

11.3 Three-tier distribution

Prior to Prohibition, a major concern of temperance advocates was the so-called “tied house” where a producer or supplier also owned the retail establishment, generally a saloon. The concerns were that vertical integration reduced alcohol prices, thus encouraging consumption, and that vertical integration tended to create large-scale enterprises that dominated independent retailers. Mendelson (2009) reports that by 1900, perhaps 80 percent of saloons in the United States were owned by brewers or distillers. Following the repeal of Prohibition, the Federal government and most states adopted what were called “tied-house” laws, which prohibited a supplier or wholesaler from also being a retailer. Although the original issue had been with on-sale establishments such as saloons or bars, most tied-house laws enacted after Prohibition included off-sale retail stores as well.

States differ in how rigorously they apply separation of licenses. Some states separate each tier and restrict the number of licenses that can be owned by a single entity. Colorado, for example, only allows one license per individual or company. Colorado requires an importer’s license for companies bringing alcohol into the state. The importer pays state excise taxes and can only sell to a wholesaler. The wholesaler buys product from in-state producers or from importers and can only sell to retailers. Colorado retailers may only buy from wholesalers, can sell only to

consumers and can only hold a retail license for one location—thus Whole Foods can sell wine and beer at only one of its supermarkets in the state. Colorado's restrictions on license ownership are unusually severe, but most other states attempt to separate production from distribution and retail (Lapsley, Alston and Sambucci, 2016).

Other states use pricing mechanisms in addition to the three-tier system to control prices and availability of alcoholic beverages. Some use "price posting" in which the producer or importer posts with the state agency minimum prices at which the product can be sold at wholesale, thus eliminating volume discounts to retailers.

Ohio, for example, requires that suppliers publicly "post" their price to wholesalers in a document filed with the Ohio Division of Liquor Control. Under Ohio law, wholesalers and retailers must use minimum markups, thus assuring that no discounts for volume purchases by retailers are allowed and that retailers will sell the same good for the same price across the state. The general rationale for such systems is that no single retailer or wholesaler can dominate or control the marketplace (Mendelson, 2009). The practical result is that Ohio consumers pay higher prices than in neighboring states (Conlon and Rao, 2015).

Until 1980, California had a similar system of price posting for wine, which was overturned by the California Court of Appeals in the Midcal-Aluminum decision (Mendelson, 2009). Alcoholic beverage retailing changed dramatically in California following the 1980 decision as firms such as Liquor Barn appeared on the California retail scene, offering lower prices and wider selections.

California generally uses the three-tier system, but, as the dominant U.S. producer of wine, has allowed wineries special privileges under the California Winegrower license since Repeal. The Winegrower license combines the rights found in several different licenses. A holder of a Winegrower license can crush and ferment grapes, produce wine, buy and sell bulk wine, import and export bulk and bottled wine, sell wine to wholesalers and retailers in state, sell its produced wine directly to consumers either at the licensed facility or via direct shipping, pour wine for consumers, and charge for the pour—but cannot own a retail establishment that sells alcoholic beverages produced by other manufacturers. Thus the holder of a California Winegrower license can act as a producer, importer, wholesaler, retailer, and bar, but is limited to only being able to sell its own products.

One of the stated goals of the three-tier system and tied-house laws was to prevent a single firm from dominating alcohol sales. In 2014, there were 4,286 licensed wineries in California. But most production and California sales was made by the three largest wine firms: Gallo, Constellation, and the Wine Group, which collectively account for approximately 50% of U.S. sales. The top ten U.S. producers account for approximately 80% of all production and imports. Similar consolidation has occurred at the wholesale level, where the top 5 national wholesalers accounted for more than 50% of all sales by value in 2014.

The average small winery is quite small, producing perhaps 5,000 gallons of wine (Lapsley, Alston and Sambucci, 2016). Small wineries generally have difficulty in acquiring three-tier distribution, and many survive partly on the strength of direct sales to consumers who visit their winery or join their wine clubs. For these firms, the provision in the California Winegrower's license that allows direct sales to consumers is key to business success. In retrospect, there seems to be little data to indicate that tied-house laws and three-tier distribution have limited producer or retail consolidation. One consistent pattern is that in states in which retailers cannot purchase directly from producers or where price posting is maintained, consumers do pay higher prices (Conlon and Rao, 2015).

11.4 Local option and licensing

Although some states allow so-called "local option" at the county or city level for the retailing of alcoholic beverages, local option for alcohol retailing has not been allowed in California since Repeal. However, California has, in a sense, allowed de facto local option for medical cannabis, as the proposed regulations do not allow applicants to obtain state licenses until they have first been granted the permission to operate by their local counties or municipalities. Local option allows individual communities to decide whether or not they wish to allow cannabis cultivation and retailing in their county or city, but it also creates additional regulations and costs for firms, which should result in higher prices than if statewide regulations only are applied.

For a medical cannabis user located in a "dry" city or county, local option may also add cost in time and travel expense for the individual to visit a dispensary in a community where sales are allowed. 34 states currently allow local option at the county level for alcohol control, and it is estimated that approximately ten percent of counties, mostly in the Midwest and the South, ban the sale of alcohol. However, the general trend seems to be toward allowing alcohol sales.

A 2014 study of 152 dry counties in the South and Midwest showed 40 changes in local option elections during the period from 1994- 2001, all moving toward allowing sale of alcoholic beverages (Billings, 2014).

Given the local option for medical cannabis sales, the lack of clear state-wide guidelines for issuing cultivation and dispensary permits may create complexities for firms. The California Department of Alcoholic Beverage Control was created by a State Amendment in 1954, taking control of licensing from the State Board of Equalization, members of which had engaged in "selling" of licenses (California, 2005). The California Alcoholic Beverage Control Board's system of retail licensing linked to population density and type of license offers an objective and fair way to license retailers, while still considering local opinions.

11.5 Testing and labeling

Testing for alcohol concentration in wine is straightforward, relatively inexpensive, and easily performed in a winery laboratory. Federal law requires that wineries have some means to determine alcohol concentration, and the typical instrument is an ebulliometer, a device that calculates alcohol concentration of a liquid by measuring the liquid's boiling point relative to the boiling point of water. Ebulliometers cost about $1,000 and the test takes perhaps 10 minutes.

Two of the main reasons that the Federal government requires producers to test alcohol concentration in wine are that (1) wine is taxed differently depending upon alcohol concentration; and (2) wine labels must state alcohol concentration within the range of plus or minus 1.5% of observed alcohol. The testing does not need to be performed by an accredited third-party laboratory, and the process does not add appreciably to producer cost. The only check on label accuracy is performed by the Federal Tax and Trade Bureau (TTB) of the Department of Treasury, which conducts random product integrity audits that include testing of alcohol concentration.

Generally speaking, the incidence of label fraud with regard to state alcohol seems quite low for wine. Alston (2015) compared more than 91,000 alcohol label claims with alcohol levels analyzed by the Liquor Control Board of Ontario and found that the average actual alcohol concentration was 13.30% while the average alcohol content reported on the label was 13.16%.

Wine labels have evolved significantly from 1934, when a wine label might simply bear the name of the bottler, a semi-generic description of type such as “California Burgundy” or “New York Champagne,” and a statement of alcoholic content. Today, most wines are labeled with the name of the grape variety and the location of where the grapes were grown. Such labeling was made possible by the TTB, which issued new labeling regulations in response to consumer demand for more information.

Under the 1978 regulations, wines can carry a varietal designation if at least 75% of the wine was produced from the named grape variety. Wines may carry a geo-political designation, such as “Napa County,” if 75% of the grapes came from the named geo-political region. The 1978 regulations also allowed the creation of “American Vineyard Appellations” (AVAs). AVAs can be large, covering several states, or very small, nestled within a county. “Napa Valley” is probably the best known AVA (Lapsley, 1996). For a wine to bear an AVA on its label, 85% of the grapes must come from the named AVA.

Appellation has become an important factor in price and profitability for wine grapes, with the location of production being more important economically than the variety. Using Cabernet Sauvignon as an example, the average price for Cabernet from Fresno was under $500 per ton, while the average price of the same variety grown in Napa was over $5,000 a ton—an order-of-magnitude difference. Such factors should be considered in greater depth if the proposed regulations are eventually extended to include rules governing location-of-origin labeling.

11.6 Conclusions

The commercial production of alcohol was been banned from 1919 to 1934, and it has taken decades since Repeal to determine how alcohol should be assimilated into American society and what levels of control are necessary. Indeed, the discussion of the place of alcohol is still debated and the types and levels of control and taxation vary from state to state, and within state. The regulation of medical cannabis is still very much in its infancy, but lessons may be learned by examining how alcohol production, distribution, and sales have evolved in California and other states.

12. Health, safety, community, and environmental benefits

12.1 Potential medical benefits of medical cannabis

Clinical trials on the benefits of medical cannabis find mixed results (Grant et al. 2012; Crippa et al. 2009; Wang et al. 2008). Medical cannabis may be an option for treating certain conditions,

such as pain or nausea. Part of the reason cannabis works to relieve pain and quell nausea is that, in some people, it is reported to improve mood and/or act as a sedative. Grant et al. (2012) observes that medical cannabis may be effective in the treatment of psychiatric disorders or neuropathic pain.

*Some findings in the medical literature suggest that using cannabis carries p*sychiatric risks including addiction, anxiety, and psychosis, while other findings suggest that cannabis is an effective treatment for those same conditions. In general, the literature is sparse, especially in top-tier scientific journals. In this SRIA, we do not attempt to evaluate or compare the relative technical merits of conflicting medical opinions in an area of neuropsychiatric research that is still in its early stages of development.

12.2 Product safety for medical users

Product safety may be one of the most important benefits of legalizing and regulating medical cannabis. Pesticide use in agriculture is common, but pesticides and pesticide residues are regulated. Allowable pesticides and residue levels on food crops are restricted by the U.S. Environmental Protection Agency, and the monitoring of the levels of residues are carried out by the Federal Drug Agency and U.S. Department of Agriculture. However, pesticide use in medical cannabis cultivation is not regulated. There are no approved pesticides or application limits established for use on cannabis crops.

Cannabis cigarettes and other common smoking devices often do not include filtration mechanisms, which may be likely to increase the intake of pesticide residues compared with tobacco smoking. Sullivan et al. (2013) investigated the presence of chemical residues on cannabis and the transmission of those residues into the user, and evaluated the presence and extent of 10 different chemical residues using three different smoking devices. Sullivan et al.

observed differences between the smoking devices, but they found that the portion of pesticide recovery was generally high enough to be a serious concern (over 50% of residues except in a water pipe with filters).

Given that medical cannabis is intended for consumption by medical patients, the intake of toxic substances may cause further health complications for medical users. Sullivan et al. (2013) also suggests that chemical residues found in cannabis may be the result of obtaining the cannabis products from unregulated product supply chains.

Under the legalization and regulation of the medical cannabis market, product testing is an important part of the governance system. A well-executed regulatory approach will help reduce the public health and safety risks that may arise from pesticide exposure or other forms of contamination.

12.3 Benefits to community residents

As is detailed in Chapters 7 and 8, our simulations predict that a regulated medical cannabis market is likely to reduce the size of the illegal market. A diminished illegal market will benefit California residents and improve their overall quality of life. The benefits from a reduction in illegal cannabis transactions will be potentially more explicit for California residents residing in urban low-income areas where drug dealing is more widespread. However, the magnitude of potential effects depends on the substitution effects between medicinal and illegal cannabis, which in part also depends on how the actual regulations are administered. The greater the extent to which regulations are able to incite previously illegal medical buyers to migrate into the legal medical market, the greater the reduction in the size of the illegal market and the greater the benefits to California residents.

12.4 Environmental effects

The potential environmental impacts of regulated cannabis can be discussed relative to the possible environmental impacts of unregulated cannabis.

It has been reported that unregulated cannabis has been cultivated in national parks and forests and associated with illegal deforestation (Caulkins 2010; National Drug Intelligence

Center 2009). Unfortunately, there are no hard data on the extent of cannabis cultivation on public land. However, it is logical to expect that the current level of encroachment and resulting environmental damage on public lands could be greatly diminished or eliminated if regulation shifted cultivation to privately owned land. Private ownership of land used for cannabis cultivation acts as an incentive to preserve the land quality and maintain the long-term productivity.

Illegal outdoor cannabis cultivation sites may have harmful impacts on the environment. Illegal cannabis cultivation is associated with illegally diverted water, soil contamination, the presence of hazardous wastes, and the use of banned fertilizers and pesticides (Drug Enforcement Administration 2016; Wilkey 2013). The Drug Enforcement Administration (DEA) reports that rodenticide and insecticide toxicants that are detrimental to wildlife are frequently discovered on unregulated cannabis cultivation sites (DEA 2016). The DEA also reports that over 110,000 acres of land in California have been destroyed since 2006 due to fires associated with unregulated cannabis cultivation, costing taxpayers more than $55 million.

A significant share of cannabis is cultivated indoors. Indoor cultivation is a carbon-intensive endeavor that consumes huge amounts of energy. Mills (2012) finds that cannabis energy use costs about $6 billion annually and that indoor cannabis production may account for 1% of the entire country's electricity consumption.

Specific energy uses by indoor cultivation operations include high-intensity lighting, dehumidification to remove water vapor, space heating during non-illuminated periods and drying, preheating of irrigation water and ventilation and air-conditioning to remove waste heat (Mills 2012). Substantial energy inefficiencies arise from air cleaning, noise and odor suppression, and use of inefficient electric generators to avoid conspicuous utility bills. One-third of the energy used by indoor growing operations comes from the lighting; the rest is devoted to ventilation, heating, dehumidification, and air conditioning (Mills 2012; Bullis 2014).

One reason for the current proliferation of indoor cultivation operations is also that they are the more inconspicuous to authorities. Insofar as state regulation enables and compels cultivators to be openly licensed and monitored by state authorities, the risk-reduction incentives to run warehouse growing operations in situations where they are less efficient are eliminated. Thus regulation may further push investment in legal cannabis production toward

more efficient greenhouse operations that use less energy inputs. This effect will likely by amplified by the increased availability of investors willing to participate in capital-intensive projects like greenhouse construction. Of course, these cultivation impacts are not the direct focus of the analysis in this appendix.

The nexus of movement toward greenhouse cultivation resulting from the proposed regulations is likely to reduce the negative environmental impact of indoor artificial-light cultivation, as well as reducing carbon emissions and more efficiently allocating and thus conserving public resources such as water and farmland.

13. A primer on IMPLAN methodology

13.1 Introduction

The most common and widely accepted methodology for measuring the economic impacts of specific industries is input-output (I-O) analysis, a subset of a family of methods called social accounting models (Shaffer, et al. 2004; Hewings 1986).

Input-output models are helpful to describe an array of economic transactions between various sectors in a defined economy for a given period, typically one year. These models not only provide researchers with estimates of the scalar multipliers but also support a detailed decomposition of the multipliers.

Like any economic model, the one presented in this SRIA is an abstraction of the real world and depends on assumptions that may be imperfect. Studies that document the economic impact of industries or changes in industries seldom discuss these limitations.

Input-output models are used descriptively and analytically to demonstrate the relative importance of a business, industry, or sector, such as the California almond industry (Sumner et al. 2014, Sumner et. al. 2015), and to estimate the economic responses from alternative actions such as the establishment of a new regulatory structure for the California medical cannabis industry.

Input-output analysis is attractive in part because it provides fairly straightforward results. Another appeal of I-O analysis is that it uses multiplier effect to calculate the total impact, which is broader than simple direct effects.

13.2 Using IMPLAN to project economy-wide impacts from wholesale and retail industries

In I-O analysis, one common source of misleading impact estimation is the inclusion of the value of goods sold in sectors that serve as intermediaries between the producer and the consumer. Wholesale and retail are examples of sectors that work with margins, which are calculated as sales receipts less the cost of the goods sold, plus sales taxes and excise taxes that are collected by the trade establishment (Day et al., 2012).

To account for economic impacts of wholesale and retail properly, it is necessary to conduct the analysis considering only the margins of these sectors, and to model the value of goods sold as part of their production processes. In correctly applied margins, the direct effect is distributed among all contributing sectors to reflect each sector's proportion of the total sales value. This not only correctly distributes the sales value, but also ensures the appropriate total effects on the region. Under this approach, separate impacts from production, transportation, wholesale, and retail can be added up, avoiding double counting of the value of the vertical chain between farm and end consumer.

Running impact analysis using margins is often applied for various settings including vineyards and wine (Michaud et al. 2016), retail sales (Sullivan et al. 2012), and food (Jablonski et al. 2016). Crompton et al. (2015) discusses double counting and other issues involved in conducting impact analyses.

13.3 Input-output methodology

An I-O model offers a "snapshot" of the economy, detailing the sales and purchases of goods and services between all sectors of the economy for a given period of time within a conceptual framework derived from economic theory. The activities of all economic agents (industry, government, households) are divided into a specified number of production sectors.

The transactions between the sectors are measured in terms of dollars and segmented into two broad categories: non-basic, which includes transactions between local industries, households and other institutions; and basic, which includes transactions between industries, households, and other institutions outside the economy being modeled (i.e., imports and exports). One can think of an I-O model as a large "spreadsheet" of the economy where columns represents buying agents in the economy.

These agents include industries within the economy buying inputs into their production processes; households and governments purchasing goods and services; and industries, households, and governments that are located outside the region of analysis. The last group represents imports into the economy.

Economic agents can import goods and services into the regional economy for two reasons. First, the good or service might not be available and must be imported. Second, local firms might produce or supply the imported good or service, but the local prices or specifications might not meet the needs of the purchasing economic agents. The columns represent economic demand. The rows of the “spreadsheet” represent selling agents in the economy or supply. These agents include industries selling goods and services to other industries; and households, governments, and consumers outside the region of analysis. The latter group represents exports out of the economy. Households that sell labor to firms are also included as sellers in the economy.

A key assumption in the construction and application of input-output modeling is that supply equals demand. In the framework of the “spreadsheet of the economy” outlined above, the row total (supply or industry revenue) for any particular industry equals the column total (demand or expenditures): the “spreadsheet of the economy” must be balanced. This framework enables analysis of how changes in one part of the economy affect the whole of the economy.

In this analysis, for example, the introduction of regulations to the medical cannabis industry might increase demand for cannabis products. To meet this new, higher level of demand, cannabis supply must increase. Increasing production requires the purchase of additional flowers, the purchase of additional equipment from manufacturing, purchase of additional professional services, and/or more use of labor.

These other sectors must also increase production, and their corresponding inputs, to meet the new level of demand created by an increase in manufactured cannabis products. The new labor hired has higher levels of income, part of which is in turn spent in the regional economy. The increased demand for cannabis products creates a ripple or “multiplier” effect that can thus be measured across the whole economy and applied to the impact assessment.

13.4 Input-output multipliers

In the input-output model “spreadsheet of the economy,” any change ripples across the entire economy. By manipulating the empirical I-O model, it is possible to compute a unique multiplier for each sector in the economy.

These multipliers provide insight in the analysis of policy regulations of the California medical cannabis industry and are used to estimate the economic impact of alternative regulatory policies to the economy. In addition, the multipliers can identify the degree of structural interdependence between the medical cannabis industry and the rest of the economy. The sector output multiplier described here is among the simplest input-output multipliers available. By employing a series of fixed ratios from the input-output model, researchers can create a set of multipliers ranging from output to employment multipliers, as shown in Table 13.1.

The income multiplier represents a change in total income (employee compensation plus proprietary income) for every dollar change in output in any given sector. The value-added multiplier measures change in total income and profit minus business taxes for every dollar in additional output by the sector. The employment multiplier represents the total change in employment resulting from the change in output in any given sector. Thus, changes in economic activity can be estimated in four ways.

Table 13.1. Understanding multipliers

Type	*Definition*
Output multiplier	The output multiplier for an industry measures the sum of direct and indirect requirements from all sectors needed to deliver an additional dollar-unit of output of that industry to final demand.
Income multiplier	The income multiplier measures the total change in income throughout the economy from a dollar-unit change in final demand for any given sector.
Value added multiplier	The value added multiplier measures the total change in labor income and profit minus business taxes throughout the economy from a dollar-unit change in final demand for any given sector.
Employment multiplier	The employment multiplier measures the total change in employment due to a one-unit change in the employed labor force of a particular sector.

13.5 Initial, indirect, and induced effects

Construction of the multipliers allows us to decompose the multiplier effect into three parts: (1) the direct effects; (2) the indirect effects; and (3) the induced effects. Direct effects represent the initial change in the industry in question (e.g., in the industry itself). Indirect effects are changes in inter-industry transactions when supplying industries respond to increased demands from the directly affected industries (e.g., impacts from non-wage expenditures). Induced effects reflect changes in local spending that result from income changes in the directly and indirectly affected industry sectors (e.g., impacts from wage expenditures).

The initial effect is associated with the scenario that creates the impact on the economy. In the medical cannabis example, this is the increase in medical cannabis sales. To produce the additional output, the firm or industry must purchase additional inputs.

The inputs take two forms: purchases from other businesses, and labor. Purchases from other businesses creates the indirect effect. Labor creates the induced effect. For a particular

producing industry, multipliers estimate the three components of total change within the region of interest.

Comparing and contrasting the indirect and induced effects can offer important insights. Under the input-output framework assumptions, industries that are more labor-intensive will tend to have larger induced effects and smaller indirect effects. Industries that tend to pay higher wages and salaries will also tend to have larger induced effects. Decomposing the multiplier into its induced and indirect effects can provide a better understanding of the industry under examination and its relationship to the larger economy.

Although input-output analysis is a useful economic tool for examining the impacts on an economy from changes in a particular industry, it does have some limitations in its assumptions. For example, I-O analysis assumes that production technology and returns to scale are constant. In other words, production technology does not vary across industries and does not evolve. These assumptions lead to the model being static. There is no allowing for adjustments due to advancements in technology or industry practices.

13.6 Modeling system

The input-output modeling system used in this study is IMPLAN (Impact M for Planning), originally developed by the USDA Forest Service. A product of the Rural Development Act of 1972, IMPLAN is a system of county-level secondary data input-output models designed to meet the mandated need for accurate, timely economic impact projections of alternative uses of U.S. public forest resources. IMPLAN is now operated by the Minnesota IMPLAN Group (MIG).

At the heart of the IMPLAN model is a national input-output dollar flow table called the Social Accounting Matrix (SAM). Unlike other static input-output models, which only measure the purchasing relationships between industry and household sectors, a SAM is an organized matrix representation of all transactions and transfers between different production activities, factors of production, and institutions (households, corporate sector, and government) within the economy and with respect to the rest of the world.

A SAM is thus a comprehensive accounting framework within which the full circular flow of income—from production to factor incomes to household income to household consumption and back to production—is captured. All the transactions in the economy are presented in the form of a matrix in a SAM. Each row of the SAM gives receipts of an account, and the column gives the expenditure. Using the SAM allows IMPLAN to model transfer payments such as unemployment insurance.

Another advantage of the IMPLAN system is its design allows users the ability to alter the underlying structure of the data, the model, or means of assessing impact. The combination of the detailed database, flexibility in application, and open-access philosophy has made IMPLAN one of the most widely used and accepted economic impact modeling systems in the United States. To assess the economic impact of medical cannabis segments, we employed IMPLAN 2014 at the county level using the most recently available IMPLAN database.

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