ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

"SUNRISE" REGULATORY REQUEST QUESTIONNAIRE

AS SUBMITTED BY

THE OFFICE OF ASSEMBLYMEMBER ROB BONTA

IN RESPONSE TO AB 34 OF 2015-16 SESSION

APRIL 16, 2015

STAFF CONTACTS:

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Section A: Applicant Group Identification

This section of the questionnaire is designed to help identify the group seeking regulation and to determine if the applicant group adequately represents the occupation.

1. WHAT OCCUPATIONAL GROUP IS SEEKING REGULATION? IDENTIFY BY NAME, ADDRESS AND ASSOCIATIONAL AFFILIATION THE INDIVIDUALS WHO SHOULD BE CONTACTED WHEN COMMUNICATING WITH THIS GROUP REGARDING THIS APPLICATION.

   There is no sponsor to the proposed legislation. However, there are a variety of occupational groups within the cannabis industry that seek regulation, including cannabis nurseries, cultivators, transporters, testing facilities, retail and dispensary operators, and manufacturers of cannabis products (e.g. edible cannabis products, cannabis-infused products, topical products, etc). There is also a request from those groups currently enforcing the limited existing state laws and local ordinances to regulate the cannabis industry, including local and state law enforcement, and the Department of Justice.

   The following individuals would be useful resources in gaining the industry's perspective on the importance of regulation:
   Nate Bradley, Executive Director, California Cannabis Industry Association (CCIA)
   916.671.4045 (cell); nate@cacannabisindustry.org
   Hezekiah Allen, Executive Director, Emerald Growers Association (EGA)
   916.879.5063 (cell); hezekiah@emeraldgrowers.org

   Nate will be able to direct you to his board members, who are owners of medical cannabis businesses, for more particular expertise within dispensaries and retail, testing, nurseries, and transportation. Hezekiah is a strong resource for cultivators, and his organization is a member of CCIA, so the following document will only reference the broader umbrella organization.

2. LIST ALL TITLES CURRENTLY USED BY CALIFORNIA PRACTITIONERS OF THIS OCCUPATION. ESTIMATE THE TOTAL NUMBER OF PRACTITIONERS NOW IN CALIFORNIA AND THE NUMBER USING EACH TITLE.

   The current cannabis industry within the state is virtually unregulated, thus there are no formal titles that are known to exist. The best way to answer this question is to describe the various activities involved: cultivators, retail dispensary operators, testing laboratories, manufacturers of cannabis edible and infused-products, and those involved in transport of the product.

   There is currently no feasible means available for quantifying the total number of practitioners in California involved in the above activities due greatly to the unregulated nature of the industry. In addition, although California has exercised its traditional power to regulate the practice of medicine and has determined that marijuana has medicinal properties that play a significant role in medicine, marijuana is currently listed as a Schedule 1 drug

under federal law; therefore it has been difficult for California practitioners within the field of medicinal cannabis to work under standard business practices without risking action from federal enforcement authorities. For these reasons, there is no single authoritative statewide or association-based registry to consult for such information. According to the Emerald Growers Association, there are an estimated 30,000 cultivation sites in the tri-county area of Humboldt-Mendocino-Trinity. According to numerous estimates, the California cannabis industry is in the billions of dollars.

3. IDENTIFY EACH OCCUPATIONAL ASSOCIATION OR SIMILAR ORGANIZATION REPRESENTING CURRENT PRACTITIONERS IN CALIFORNIA, AND ESTIMATE ITS MEMBERSHIP. FOR EACH, LIST THE NAME OF ANY ASSOCIATED NATIONAL GROUP.

   The California Cannabis Industry Association is a self-organized group which represents a large part of the cannabis industry and is comprised of a wide range of practitioners, including cultivators, dispensaries, manufacturers, testing facilities, nurseries, and other interest groups that are involved within the industry; its current membership includes over fifty organizations. The association has taken a leading role in the most recent discussions on legislation on establishing a regulatory framework for the cannabis industry. They currently have 98 members within the association. The National Cannabis Industry Association is its national group, with 852 members across the country.

4. ESTIMATE THE PERCENTAGE OF PRACTITIONERS WHO SUPPORT THIS REQUEST FOR REGULATION. DOCUMENT THE SOURCE OF THIS ESTIMATE.

   No survey has been performed by any group to estimate the percentage of practitioners who support this request for regulation. However, California's Field Poll in February 2013 gave 72% support for California's medical marijuana law. And the federal government has indicated in the Cole memo that the state and local governments (that allow medical marijuana should) implement strong and effective regulatory and enforcement systems that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests.

5. NAME THE APPLICANT GROUP REPRESENTING THE PRACTITIOENRS IN THIS EFFORT TO SEEK REGULATION. HOW WAS THIS GROUP SELECTED TO REPRESENT PRACTITIONERS?

   The following groups were self-selected to represent practitioners seeking a regulatory framework for medicinal cannabis:

   - California Cannabis Industry Association (described in question 3)
   - California Medical Association (represents health care providers who provide recommendations to patients for medical cannabis)

6. ARE ALL PRACTITIONER GROUPS LISTED IN RESPONSE TO QUESTION 2 REPRESENTED IN THE ORGANIZATION SEEKING REGULATION? IF NOT, WHY NOT?

   Again, there is no sponsor to the legislation, however the practitioners described in question 2 are represented by the California Cannabis Industry Association.

Section B: Consumer Group Identification

This section of the questionnaire is designed to identify consumers who typically seek practitioner services and to identify non-applicant groups with an interest in the proposed regulation.

7. DO PRACTITIONERS TYPICALLY DEAL WITH A SPECIFIC CONSUMER POPULATION? ARE CLIENTS GENERALLY INDIVIDUALS OR ORGANIZATIONS?

   Yes, practitioners deal with patients who are recommended medical cannabis for purposes of treating diseases. Clients are currently both individuals and collectives. While there is significant individual cultivation, or cultivation by a registered caregiver for their patients, many patients rely on medical marijuana collectives or dispensaries, which either cultivate in house or purchase from outside cultivators. Under Proposition 215, both individuals and collectives are allowed to grow, distribute, process, transport medical cannabis products. According to a 2013 survey conducted by the California Behavioral Risk Factor Surveillance System, a representative health survey of 7,525 California adults produced by the Public Health Institute in partnership with the CDC, 92 percent said that medical marijuana alleviated symptoms of their serious medical conditions, including chronic pain, arthritis, migraine, and cancer.

8. IDENTIFY ANY ADVOCACY GROUPS REPRESENTING CALIFORNIA CONSUMERS OF THIS SERVICE. LIST ALSO THE NAMES OF APPLICABLE NATIONAL ADVOCACY GROUPS.

   Americans for Safe Access– Don Duncan, don@safeaccessnow.org
   Coalition for Cannabis Policy Reform
   California NORML (NORML is national partner)
   Drug Policy Alliance (national)
   Marijuana Policy Project (national)

9. IDENTIFY ANY CONSUMER POPULATIONS NOT CURRENTLY USING PRACTITIONER SERVICES THAT ARE LIKELY TO DO SO IF REGULATION IS APPROVED.

   If regulations are approved, the medicine would be open to being applied to additional conditions, potentially expanding the consumer and patient populations. Furthermore, due to the lack of environmental, health, and safety standards governing the medical cannabis

industry, there are vulnerable populations—such as the immunosuppressed—who are naturally hesitant to try new medicine without proper consumer protections and controls. Finally, there is a significant and legitimate fear of the federal government, which is holding back potential patients from receiving the medicine they may in fact need, and the passage of this proposal will assuage that fear by complying with the federal Cole memo.

10. DOES THE APPLICANT GROUP INCLUDE CONSUMER ADVOCATE REPRESENTATION? IF NOT, WHY NOT?

    Again, there is no sponsor to the legislation. Our office is working with stakeholders throughout the industry, including consumer advocacy groups.

11. NAME ANY NON-APPLICANT GROUPS OPPOSED TO OR WITH AN INTEREST IN THE PROPOSED REGULATION. IF NONE, INDICATE EFFORTS MADE TO IDENTIFY THEM.

    Support: United Food and Commercial Workers (UFCW)
    Opposition: California Police Chiefs Association, League of California Cities, California Narcotics Officers Association, Los Angeles Deputy Sheriffs, Association of Deputy District Attorneys, the California Association of Code Enforcement Officers, California College and University Police Chiefs Association, the California Correctional Supervisors Organization, the Los Angeles Police Protective League, and the Riverside Sheriffs Association. Note: Other than the Police Chiefs and League of Cities, who are sponsoring their own bill, the remainder of the opposition is represented by two law enforcement lobbyists.
    No position at this time: CCIA, CMA, environmental groups, BOE, DCA

Section C: Sunrise Criteria

This part of the questionnaire is intended to provide a uniform method for obtaining information regarding the merits of a request for governmental regulation of an occupation. The information you provide will be used to rate arguments in favor of imposing new regulations (such as educational standards, experience requirements, or examinations) to assure occupational competence.

Part C1 – Sunrise Criteria and Questions

The following questions have been designed to allow presentation of data in support of application for regulation. Provide concise and accurate information in the form indicated in the *Instructions* portion of this questionnaire.

I. UNREGULATED PRACTICE OF THIS OCCUPATION WILL HARM OR ENDANGER THE PUBLIC HEALTH SAFETY AND WELFARE

12. IS THERE OR HAS THERE BEEN SIGNIFICANT PUBLIC DEMAND FOR A REGULATORY STANDARD? IF SO, PROVIDE DOCUMENTATION. IF NOT, WHAT IS THE BASIS FOR THIS APPLICATION?

As mentioned previously, over 70% of California voters supported medical cannabis (http://www.field.com/fieldpollonline/subscribers/Rls2442.pdf). With that number so high, and the clear issues with the regulatory scheme that has been outlined in the proposal and over the course of the past decade (since the passage of SB 420) and almost two decades since the passage of Prop 215, it is clear that California remains very much in the Wild West of medical marijuana, despite the fact that the industry is generations old in rural Humboldt county and other areas of the Emerald Triangle. Additionally, 55% of voters now support legalization, a step even further than is proposed in this legislation (http://www.field.com/fieldpollonline/subscribers/Rls2455.pdf).

Beyond these other harms, there is also the harm and the threat of federal action looming over California patients until the state has enacted the comprehensive and robust regulatory system as demanded in the Cole memo. The Cole memo specifically outlined the following areas that a regulatory system must address:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;

- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and,
- Preventing marijuana possession or use on federal property.

Additionally, the issues with an unregulated medical cannabis industry have been well documented in the news, with the unlicensed and haphazard attempts at refining cannabis into hash oil which has led to significant public safety risks. This proposal would license and regulate legitimate manufacturers, enabling funding to enforce the new laws and crack down on unlicensed bad actors.

Finally, medical cannabis cultivation has recently received significant attention within the media because of its utilization of scarce water supplies in the midst of a drought and associated environmental impacts from water diversion and pesticide use. The proposed regulatory structure would fund enforcement of existing standards while also requiring legitimate licensees to comply with state and local environmental regulations.

13. WHAT IS THE NATURE AND SEVERITY OF THE HARM? DOCUMENT THE PHYSICAL, SOCIAL, INTELLECTUAL, FINANCIAL, OR OTHER CONSEQUENCES TO THE CONSUMER RESULTING FROM INCOMPETENT PRACTICE.

The lack of regulation has resulted in crime in all aspects of the industry, from cultivation to manufacturing to retail.

The lack of regulation has encouraged operating at the edge of the law and in the grey area between state and federal rules. This has reduced consumer protections, worker protections, business operations, and even banking services, to name just a few areas which have been harmed by this regulatory uncertainty. Furthermore, the lack of statewide standards regarding suitability for receiving a license, when combined with a patchwork of local ordinances that have inconsistent basic standards for operation, have made it difficult for legitimate operators to engage in business above the board, and provided a competitive advantage to the black market operators—with potential ties to organized crime—that we are trying to reduce. Only by bringing medical marijuana above board and with comprehensive, rigorous regulations, can we tackle this harm to consumers and the industry as a whole.

Additionally, as has been mentioned previously, in 2014 Governor Brown appropriated $1.8 million to create a pilot program in Northern California called the "Watershed Enforcement Team" (WET). WET charged the State Water Board along with the North Coast Regional Water Board to create guidelines that address wastewater discharges from medical marijuana cultivation. The environmental harm caused by unregulated marijuana cultivation led to a significant local stream to run dry, and if it stays dry for three years, then the salmon population will be permanently devastated and will no longer return to spawn.

Furthermore, as mentioned previously, the unlicensed and hazardous production of hash oil has led to a rash of building explosions and endangering of lives, much like the methamphetamine labs before the increased regulation of Sudafed, except for a far less hazardous product when under property laboratory conditions and which has legitimate medicinal uses.

And, finally, there has been direct harm to people who have worked to patrol and shut down trespass grows, or illegal cultivations sites on public land. In a very high profile incident in the north coast, Fort Bragg city councilmember Jere Melo was killed in 2011 by an illegal trespasser while he was looking for a marijuana grow. He was not the first, and will not be the last, until we allow the good actors to come forward into the light and help fund the eradication of those who refuse to comply.

14. HOW LIKELY IS IT THAT HARM WILL OCCUR? CITE CASES OR INSTANCES OF CONSUMER INJURY. IF NONE, HOW IS HARM CURRENTLY AVOIDED?

There is substantive existing harm, particularly from the hash oil operations and in rural cultivation. Just a few days ago, five men in Redding were injured when their hash oil processing went awry, inflicting 3rd degree burns and blowing the roof off of the garage to 40 feet down the road. Last November in San Bernardino, one man was killed and two others injured when the house collapsed following an explosion attributed to hash oil. In a Walnut Creek explosion, three individuals were injured and 50 other evacuated after an explosion that broke windows 200 feet away. Over the past three years, there have been 68 children injured in hash oil explosions and treated at Shriners Hospital in Sacramento, with the average child having over 25% of their body burned.

With proper manufacturing standards and tracking of inventory, through robust regulation, it would be possible to avoid these significant and negative public safety impacts of hash oil production. For example, in industrial manufacturing, butane is not the only way to extract cannabinoids—water and steam processes, among many others, can create a purer and stronger product with less risk to the public.

Furthermore, this is before factoring in the fact that strong testing standards could prevent contaminated medicine from reaching immunosuppressed or otherwise compromised patients and causing direct harm.

15. WHAT PROVISIONS OF THE PROPOSED REGULATION WOULD PRECLUDE CONSUMER INJURY?

- Health and safety code standards, such as for the facilities to ensure they abide by current law. Additionally, testing standards for the product, including Potency, Chemical residue, Microbiological contaminants, bacterial, pathogenic yeast, mold.
- Food safety requirements, such as sanitation, preparation, labeling, recall reporting, etc.
- Environmental regulations through the state water boards, food and ag, fish and wildlife, pesticides, and many more.
- Security standards for tracking to reduce diversion of product and track transactions between licensees.

II. EXISTING PROTECTIONS AVAILABLE TO THE CONSUMER ARE INSUFFICIENT

16. TO WHAT EXTENT TO CONSUMERS CURRENTLY CONTROL THEIR EXPOSURE TO RISK? HOW DO CLIENTS LOCATE AND SELECT PRACTITIONERS?

There are no resources available to properly educate consumers on the possible risks in the first place. Consumers must use unreliable or unverifiable sources such as the internet to evaluate different medicines and whether the medicine will be of good or risky quality.

Additionally, Consumers can currently choose to go to dispensaries that test their products for mold, pesticides, contaminants, etc. but there are no licensing or certification standards for those laboratories and testing the same product at two different locations can yield vastly different results. With regulation, the testing labs would be licensed and the product information far more standardized.

Once medical cannabis is recommended by a patient's physician, websites, one-site directory services and local newspapers are used to locate dispensaries and retailers who provide medical cannabis products.

17. ARE CLIENTS FREQUENTLY REFERRED TO PRACTITIONERS FOR SERVICES? GIVE EXAMPLES OF REFERRAL PATTERNS.

Existing law is silent on whether or not health care providers may direct patients to online resources. It's not uncommon for providers to recommend statewide and nationwide organizations that can provide resources to purchase medical cannabis products.

Legitimate issuers of recommendations for medical cannabis generally prefer a note from a primary care physician describing the conditions for which the patient believes medical cannabis will be of assistance.

18. ARE CLIENTS FREQUENTLY REFERRED ELSEWHERE BY PRACTITIONERS? GIVE EXAMPLES OF REFERRAL PATTERNS.

    Anecdotal evidence supports that if a dispensary or retailer does not have one product, they refer them to another dispensary or retailer which may supply the product needed by the patient.

19. WHAT SOURCES EXIST TO INFORM CONSUMERS OF THE RISK INHERENT IN INCOMPETENT PRACTICE AND OF WHAT PRACTITIONER BEHAVIORS CONSTITUTE COMPETENT PERFORMANCE?

    National advocacy groups provide outreach (Americans for Safe Access, Cal NORML, NORML, CCIA and NCIA) to educate consumers on current best practices within the field and attempt to self-report bad actors who are not complying with industry-set standards. Additionally, for-profit resources exist online which allow patients to rate providers of medicine and recommendations. However, these are not as comprehensive or robust as a comparable government system.

20. WHAT ADMINISTRATIVE OR LEGAL REMEDIES ARE CURRENTLY AVAILABLE TO REDRESS CONSUMER INJURY AND ABUSE IN THIS FIELD?

    To the best of our knowledge, if an individual is injured by a product or a recommender, there are no industry specific administrative or legal remedies or redress. This is a prime reason for the need for a strengthened regulatory structure.

21. ARE THE CURRENTLY AVAILABLE REMEDIES INSUFFICIENT OR INEFFECTIVE? IF SO, EXPLAIN WHY.

    Yes, because they're largely non-existent for consumers.

III. NO ALTERNATIVES TO REGULATION WILL ADEQUATELY PROTECT THE PUBLIC

22. EXPLAIN WHY MARKETPLACE FACTORS WILL NOT BE AS EFFECTIVE AS GOVERNMENTAL REGULATION IN ENSURING PUBLIC WELFARE. DOCUMENT SPECIFIC INSTANCES IN WHICH MARKET CONTROLS HAVE BROKEN DOWN OR PROVEN INEFFECTIVE IN ASSURING CONSUMER PROTECTION.

    There are no market controls—the market swings between being the freest and least regulated, and the hammer of the US federal government seizing property and shutting down licensed businesses, with practically nothing in between, and especially not for consumer protection. While there have been some moves towards self-regulation, such as the development of testing laboratories which work solely on medical cannabis, by and large the legal uncertainty has severely hindered protection of the public welfare in a manner

consistent with the exercise of the state's police powers, in conjunction with local government input. Until we fulfill the guidelines of the Cole memo, as outlined previously, the California medical marijuana industry will continue to swing between two unacceptable extremes.

23. ARE THERE OTHER STATES IN WHICH THIS OCCUPATION IS REGULATED? IF SO, IDENTIFY THE STATES AND INDICATE THE MANNER IN WHICH CONSUMER PROTECTION IS ENSURED IN THOSE STATES? PROVIDE, AS AN APPENDIX, COPIES OF THE REGULATORY PROVISIONS FROM THESE STATES.

    - 32 states and the District of Columbia have approved medical cannabis regulations to one degree or another. While California led the way in advancing medical cannabis with the Passage of Proposition 215 in 1996, since that time we have lagged far behind our peers. Even 2003's SB 420, the Medical Marijuana Program Act, while opening up access for business, was not nearly the comprehensive program that our state needed.
    - The National Council of State Legislatures provides the attached link, titled "STATE MEDICAL MARIJUANA LAWS" which details the breakdown of different jurisdictions. http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx

24. WHAT MEANS, OTHER THAN GOVERNMENTAL REGULATION, HAVE BEEN EMPLOYED IN CALIFORNIA TO ENSURE CONSUMER HEALTH AND SAFETY? INDICATE WHY THE FOLLOWING WOULD BE INADEQUATE: (A) CODE OF ETHICS; (B) CODES OF PRACTICE ENFORCED BY PROFESSIONAL ASSOCIATIONS; (C) DISPUTE-RESOLUTION MECHANISMS SUCH AS MEDIATION OR ARBITRATION; (D) RECOURSE TO CURRENT APPLICABLE LAW; REGULATION OF THOSE WHO EMPLOY OR SUPERVISE PRACTITIONERS; (F) OTHER MEASURES ATTEMPTED.

    The main government regulation which has been employed thus far is Proposition 215, establishing protections for patients but proving fairly legislatively inflexible. SB 420 has been interpreted in ways in line with and contrary to Proposition 215. Practically all aspects of the industry beyond the patients are operating in a grey area which desperately needs government regulation. Without state licensing, without professional standards, without base-level uniform regulations, without recognition under the current law, it is impossible to attain any of the above forms of redress.

25. IF A "GRANDFATHER" CLAUSE (IN WHICH CURRENT PRACTITIONERS ARE EXEMPTED FROM COMPLIANCE WITH PROPOSED ENTRY STANDARDS) HAS BEEN INCLUDED IN THE REGULATION PROPOSED BY THE APPLICANT GROUP, HOW IS THE CLAUSE JUSTIFIED? WHAT SAFEGUARDS WILL BE PROVIDED TO CONSUMERS REGARDING THIS GROUP?

    There are existing local ordinances which, if a locally licensed business was in compliance in prior to the enactment of this proposal, would set up the existing businesses to attain a

provisional license, as long as they also complied with the state standards. This legislation does not let the prior actors off the hook for non-compliance with existing local ordinances, or for not meeting the basic state standards, and as such consumer protections will be increased, and patients will not be denied access to medicine during the transition process.

IV. REGULATION WILL MITIGATE EXISTING PROBLEMS

26. WHAT SPECIFIC BENEFITS WILL THE PUBLIC REALIZE IF THIS OCCUPATION IS REGULATED? INDICATE HOW THE PROPOSED REGULATION WILL CORRECT OR PRECLUDE CONSUMER INJURY. DO THESE BENEFITS GO BEYOND FREEDOM FROM HARM? IF SO, IN WHAT WAY?

This legislation would establish and apply to the medical cannabis industry:

- HSC standards
- Environmental standards
- Quality assurance standards
- Uniform security standards
- Testing standards
- Workers' safety standards

While many of these standards are for the health and safety of the public, arguably if all were implemented it would go beyond freedom from harm and instead actively improve the lives of patients and the public. These proposals not only mitigate harm, but allow a vast and economically vibrant industry to thrive in a regulated fashion protected from the federal government. The economic benefits from this regulation—stimulating the local and state economy, providing significant tax revenues, and helping patients live more productive lives—are above and beyond the protections provided by these regulations.

27. WHICH CONSUMERS OF PRACTITIONER SERVICES ARE MOST IN NEED OF PROTECTION? WHICH REQUIRE THE LEAST PROTECTION? WHICH CONSUMERS WILL BENEFIT MOST AND LEAST FROM REGULATION?

a.) Most protection: The sole consumers of practitioner services—who are not practitioners themselves—will be medical cannabis patients, and they will clearly receive the most protection as well as have the greatest need for protection and transparency.

28. PROVIDE EVIDENCE OF "NET" BENFEFIT WHEN THE FOLLOWING POSSIBLE EFFECTS OF REGULATION ARE CONSIDERED: (A) RESTRICTION OF OPPORTUNITY TO PRACTICE; (B) RESTRICTED SUPPLY OF PRACTITIONERS; (C)

INCREASED COSTS OF SERVICE TO CONSUMER; (D) INCREASED GOVERNMENTAL INTERVENTION IN THE MARKETPLACE.

a. RESTRICTION OF OPPORTUNITY TO PRACTICE: By reducing the pool of eligible licensees, we can increase the quality of the applicant and ensure that patients remain protected from individuals with certain concerning backgrounds. Additionally, we are better able to control the quality of medicine with reasonable restrictions on access to participation.
b. RESTRICTED SUPPLY OF PRACTITIONERS: Once again, this raises the quality of the practitioner by filtering out, through our suitability language, applicants for whom it would not be appropriate to operate within the medical cannabis industry.
c. INCREASED COSTS OF SERVICE TO CONSUMER: The modest increases in costs will be more than offset by the peace of mind and protections brought by increased standards for health and safety, quality assurance, workers' rights, environmental protections, and safety of the public.
d. INCREASED GOVERNMENTAL INTERVENTION IN THE MARKETPLACE: This is an industry begging for constructive government intervention into the marketplace to provide a basic level of standards while also bringing medical cannabis in from the shadows. This reduces the potential liability from the federal Cole memo, as previously outlined, and also could open up access to FDIC-insured financial institutions, which would allow these lucrative businesses to move away from a cash-only basis and actually expand like the entrepreneurs they are.

V. PRACTITIONERS OPERATE INDEPENDENTLY, MAKING DECISIONS OF CONSEQUENCE

29. TO WHAT EXTENT DO INDIVIDUAL PRACTITIONERS MAKE PROFESSIONAL JUDGMENTS OF CONSEQUENCE? WHAT ARE THESE JUDGMENTS? HOW FREQUENTLY DO THEY OCCUR? WHAT ARE THE CONSEQUENCES?

Due to the lack of statewide regulations, practitioners within the medical cannabis industry create their own standards (e.g. labeling, potency, quality assurance, content, dosage etc.). While certain partners within the industry may collaborate with each other, there is no statewide or industry gold standard for practitioners to make professional judgments of consequence. The lack of regulations results in practitioners making these decisions on a daily basis during their business practices. The consequences can be that some products either do not meet or exceed current standards for other similar products within related industries. For example, some manufactured edible cannabis products that are being sold to patients may not have gone through the same stringent food retail and safety standards as other foods, or they could have gone through more.

30. TO WHAT EXTENT DO PRACTITIONERS WORK INDEPENDENTLY (AS OPPOSED TO WORKING UNDER THE AUSPICES OF AN ORGANIZATION, AN EMPLOYER, OR A SUPERVISOR)?

Due to the lack of any state licensing or recognition of the industry by the state, there is no hard data to determine whether or not practitioners are working independently. Most organizations within the industry are so loosely organized that it's unclear whether or not it's one person or a large group.

31. TO WHAT EXTENT DO DECISIONS MADE BY THE PRACTITIONER REQUIRE A HIGH DEGREE OF SKILL OR KNOWLEDGE TO AVOID HARM?

There are practices within the industry that require a high degree of skill. For example, manufacturers or processors who deal with extracting cannabinoid oils from the cannabis plant require a great deal of skill. The oil extraction process requires handling butane, a very volatile chemical which should be used in a controlled environment; when not handled properly it can result in explosions that can do damage to individuals, communities and the environment.

Other practices within the field are fairly standard as they relate to their part of the industry. For example, cultivating cannabis plants requires skills similar to those necessary for farming other agricultural products, and dispensing medical cannabis products requires similar skills to those required for other specialty medicinal products.

VI. FUNCTIONS AND TASKS OF THE OCCUPATION ARE CLEARLY DEFINED

32. DOES THE PROPOSED REGULATORY SCHEME DEFINE A SCOPE OF ACTIVITY WHICH REQUIRES LICENSURE, OR MERELY PREVENT THE USE OF A DESGINATED JOB TITEL OR OCCUPATIONAL DESCRIPTION WITHOUT A LICENSE?

The proposed regulatory structure defines the scope of activity which requires licensure.

33. DESCRIBE THE IMPORTANT FUNCTIONS, TASKS AND DUTIES PERFORMED BY PRACTITIONERS. IDENTIFY THE SERVICES AND/OR PRODUCTS PROVIDED.

The proposed language describes five types of licenses within the framework, with the ability of the regulating authorities to create other licenses at their discretion in order to better meet the need of businesses within the industry. These licenses are as follows:

1. Cultivation: growing and propagating cannabis plant, cannabis stock.
2. Manufacturing: preparation of edible, infused, topical, and extracted medical cannabis products.
3. Testing: safety and quality assurance testing of all medical cannabis prodcuts.
4. Dispensary/retail: provision/sale of medical cannabis products to consumers, i.e. persons who are recommended medical cannabis by their provider.
5. *Transportation: transport of medical cannabis products.

*Note that we are currently looking into dividing the licensing scheme among different departments, in which case we would no longer have a transportation license and would instead have a wholesale/distributing license, which would allow for the wholesale, storage and distribution of medical cannabis products to dispensaries.

34. IS THERE A CONSENSUS ON WHAT ACTIVITIES CONSTITUTE COMPETENT PRACTICE OF THE OCCUPATION? IF SO, PROVIDE DOCUMENTATION. IF NOT, WHAT IS THE BASIS FOR ASSESSING COMPETENCE?

    Not at this time, due to the lack of formal state recognition of the industry and regulations. As later discussed in question #46, there are schools that create their own rules and standards, however the schools themselves do not all abide by the same standards of competence. The regulatory structure of the bill bases standards for the cannabis industry off the existing regulations and standards of other similar industries.

35. ARE INDICATORS OF COMPETENT PRACTICE LISTED IN RESPONSE TO QUESTION #34 MEASURABLE BY OBJECTIVE STANDARDS SUCH AS PEER REVIEW? GIVE EXAMPLES.

    Yes, there are measurable objective standards. For example, the testing requirements in the proposed regulations must meet the current standards created by the International Organization for Standardization (ISO) for quality assurance testing. In addition, environmental damage is currently measured through various environmental standards as set forth by current law; the proposed regulations include the requirement to abide by all applicable existing environmental law.

36. SPECIFY ACTIVITIES OR PRACTICES THAT WOULD SUGGEST THAT A PRACTITIONER IS INCOMPETENT. TO WHAT EXTENT IS PUBLIC HARM CAUSED BY PERSONAL FACTORS SUCH AS DISHONESTY?

    For physicians, public harm is clearly defined within amended sections 2220.05, 2242 and 2264 of the Business and Professions Code in the proposed language. For cultivators, not abiding by current environmental, agricultural and labor standards would constitute incompetence; dishonesty could lead to destruction of the environment, water diversion, product diversion, and poor treatment of workers. For manufacturers and testing facilities, not ensuring quality to the product and not abiding by health and safety standards would be considered incompetence; dishonesty could lead to low-quality product or consumers purchasing products that are inappropriate for their medical condition. For dispensaries, not following labor or consumer protection standards would be grounds for incompetence; dishonesty could lead to consumers purchasing the wrong product for their condition and poor working conditions for laborers.

VII. THE OCCUPATION IS CLEARLY DISTINGUISHABLE FROM OTHER OCCUPATIONS THAT ARE ALREADY REGULATED

37. WHAT SIMILAR OCCUPATIONS HAVE BEEN REGULATED IN CALIFORNIA?

Different parts of the cannabis industry are related to various occupations that are currently regulated: cultivators are similar to farmers; transporters are similar to any industry required to follow ISO standards and testing for quality assurance of a product; manufacturers are similar to food manufacturers or processors (more specifically, cannabinoid oil extractors are similar to extractors of vanilla bean and other common food extracts). Furthermore, the cannabis product must be tracked from "seed to sale," which is similar to regulations made on other medications, tobacco or alcohol, which require a type of batch or lot numbers, bar code, etc. in order to track the product.

38. DESCRIBE FUNCTIONS PERFORMED BY PRACTITIONERS THAT DIFFER FROM THOSE PERFORMED BY OCCUPATIONS LISTED IN QUESTION #37.

N/A: all parts of the cannabis industry are similar to other occupations that have been regulated in California.

39. INDICATE THE RELATIONSHIPS AMONG THE GROUPS LISTED IN RESPONSE TO QUESTION #37 AND PRACTITIONERS. CAN PRACTITIONRS BE CONSIDERED A BRANCH OF CURRENTLY REGULATED OCCUPATIONS?

Yes, practitioners can be considered a branch of currently regulated occupations, with the one caveat that they are working with a product that is listed as a Schedule 1 drug by federal law.

40. WHAT IMPACT WILL THE REQUESTED REGULATION HAVE UPON THE AUTHORITY AND SCOPES OF PRACTICE OF CURRENTLY REGULATED GROUPS?

To our knowledge, the requested regulation will have no impact on the authority or scopes of practice of currently regulated groups; that is not the intent of the proposed regulations.

41. ARE THERE UNREGULATED OCCUPATIONS PERFORMING SERVICES SIMILAR TO THSE OF THE GROUP TO BE REGULATED? IF SO, IDENTIFY.

With the exception of all individuals and groups providing cannabis for recreational use, to staff's knowledge there is no similar existing group to be regulated.

42. DESCRIBE THE SIMILARITIES AND DIFFERENCES BETWEEN PRACTITIONERS AND THE GROUPS IDENTIFIED IN QUESTION #41.

It is clear that the practitioners and groups identified in question #41 deal with the same product. The difference is within the state identification of legality of their practice. California has recognized the medicinal value of cannabis and therefore all industry practices related to providing medical cannabis for the treatment of medical conditions for qualified patients should be allowed by state law. All industry practices related to the recreational use of cannabis is currently illegal within the state of California.

VIII. THE OCCUPATION REQUIRES POSSESSION OF KNOWLEDGE, SKILLS AND ABILITIES THAT ARE BOTH TEACHABLE AND TESTABLE

43. IS THERE A GENERALLY ACCEPTED CORE SET OF KNOWLEDGE, SKILLS AND ABILITIES WITHOUT WHICH A PRACTITIONER MAY CAUSE PUBLIC HARM? PLEASE DESCRIBE AND PROVIDE DOCUMENTATION.

    Although there is no industry "gold standard" for the core set of knowledge and skills, it is generally accepted that manufacturers who extract cannabinoids using butane should have the skills, knowledge and abilities of those in other industries that work with chemicals necessary to perform extractions in a safe manner (e.g. the use of butane to extract chemicals from plants). Similarly, testing facilities often set their own standards for testing for quality assurance, such as those performed by the Sequoia Analytical Labs, include ISO-standardized quality assurance testing of potency, microbiological content, and pesticide content[1].

44. WHAT METHODS ARE CURRENTLY USED TO DEFINE THE REQUISITE KNOWLEDGE, SKILLS, AND ABILITIES? WHO IS RESPONSIBLE FOR DEFINING THESE KNOWLEDGE, SKILLS, AND ABILITIES?

    There are currently no standard methods used to define the requisite knowledge, skills, and abilities, they are simply defined individual group. Trade associations and consumer advocacy groups, such as the California Cannabis Industry Association and California NORML, respectively, provide suggestions to their membership and the industry as a whole, though practitioners are not required to follow those recommendations.

45. ARE THESE KNOWLEDGE, SKILLS AND ABILITIES TESTABLE? IS THE WORK OF THE GROUP SUFFICIENTLY DEFINED THAT COMPETENCE COULD BE EVALUATED BY SOME STANDARD (SUCH AS RATINGS OF EDUCATION, EXPERIENCE OR EXAM PERFORMANCE?

    Yes. Comparable industries use education, testing, certification and apprenticeship programs. For example, there are training programs and exams for agricultural workers, manufacturers, testers, etc. of food products.

46. LIST INSTITUTIONS AND PROGRAM TITLES OFFERING ACCREDITED AND NON-ACCREDITED PREPARATORY PROGRAMS IN CALIFORNIA. ESTIMATE THE ANNUAL NUMBER OF GRADUATES FROM EACH. IF NO SUCH PREPARATORY PROGRAMS EXIST WITHIN CALIFORNIA, LIST PROGRAMS FOUND ELSEWHERE.

    There are currently schools that are allowed, such as Oaksterdam University and others. There is no centralized location for a listing of all schools and institutions, however, so it is

[1] http://www.sequoia-labs.com/

difficult to list all programs within the state. Oaksterdam University states it has graduated thousands of students from its program since its opening in 2007[2].

47. APART FROM THE PROGRAMS LISTED IN QUESTION #46, INDICATE VARIOUS METHODS OF ACQUIRING REQUISITE KNOWLEDGE, SKILL AND ABILITY. EXAMPLES MAY INCLUDE APPRENTICESHIPS, INTERNSHIPS, ON-THE-JOB TRAINING, INDIVIDUAL STUDY, ETC.

    Currently a limited number of apprenticeships are occurring within the industry, however on-the-job training, internships are being done on an individual basis throughout the industry. The proposed regulations include an apprenticeship and certification programs for cultivators and dispensaries.

48. ESTIMATE THE PERCENTAGE OF CURRENT PRACTITIONERS TRAINED BY EACH OF THE METHODS DESCRIBED IN QUSETIONS 46 AND 47.

    There is currently no centralized registry on the numbers of current practitioners, thus there is no data available to share.

49. DOES ANY EXAMINATION OR OTHER MEASURE CURRENTLY EXIST TO TEST FOR FUNCTIONAL COMPETENCE? IF SO, INDICATE HOW AND BY WHOM EACH WAS CONSTRUCTED AND BY WHOM IT IS CURRENTLY ADMINSTERED. IF NOT, INDICATE SEARCH EFFORTS TO LOCATE SUCH MEASURES.

    Due to the lack of state licensing, there are no industry standards within the state. Practitioners are currently pushing for standards in a piecemeal, individual manner, such as those provided by Sequoia Analytical Labs, as aforementioned, for the testing of cannabis products. Schools such as Oaksterdam University currently teach a variety of safety standards and protocols they have developed (Appendix A1).

50. DESCRIBE THE FORMAT AND CONTENT OF EACH EXAMINATION LISTED IN QUESTION #49. WHAT COMPETENCIES ARE EACH DESIGNED TO MEASURE? HOW DO THESE RELATE TO THE KNOWLEDGE, SKILLS AND ABILITIES LISTED IN QUESTION #43?

    The specifics of the examinations are not known to staff, but our general research has shown that schools and testing facilities examine each applicant prior to allowing them to practice on his or her own.

51. IF MORE THAN ONE EXAMINATION IS LISTED ABOVE, WHICH STANDARD DO YOU INTEND TO SUPPORT? WHY? IF NONE OF THE ABOVE, WHY NOT, AND WHAT DO YOU PROPOSE AS AN ALTERNATIVE?

[2] http://oaksterdamuniversity.com/about/

The proposed regulations contain requirements for apprenticeship and certification programs for cultivators and dispensaries, which will be approved by the Department of Labor Enforcement and Standards. In the proposed amendments to the proposed regulations, the standards for examinations of other practitioners would be determined by the state authority responsible for creating the regulations or licensing in the relevant jurisdiction.

IX. ECONOMIC IMPACT OF REGULATION IS JUSTIFIED

52. HOW MANY PEOPLE ARE EXPOSED ANNUALLY TO THIS OCCUPATION? WILL REGULATION OF THE OCCUPATION AFFECT THIS FIGURE? IF SO, IN WHAT WAY?

According to California NORML there are 1.5 million qualified patients in California. There are an undetermined number of practitioners related to the industry. As regulations are promulgated and implemented, practitioners who were formerly working in the black market is expected to increase this number, based on anecdotal evidence within the industry of the desire of many practitioners to become licensed and right by the law.

53. WHAT IS THE CURRENT COST OF THE SERVICE PROVIDED? ESTIMATE THE AMOUNT OF MONEY SPENT ANNUALLY IN CALIFORNIA FOR THE SERVICES OF THIS GROUP. HOW WILL REGULATION AFFECT THESE COSTS? PROVIDE DOCUMENTATION FOR YOUR ANSWERS.

According to the California Cannabis Industry Association, patients pay a range of $300-500 per a month, depending on their medical need. Based on the patient number provided by California NORML, this is equal to approximately $750 million spent annually by patients for these services. The proposed regulations create a self-funded structure through licensing fees and penalties; thus it is expected that there will be a minimum impact to cost of service to patient consumers.

54. OUTLINE THE MAJOR GOVERNMENTAL ACTIVITIES YOU BELIEVE WILL BE NECESSARY TO APPROPRIATELY REGULATE PRACTITIONERS. EXAMPLES MAY INCLUDE SUCH PROGRAM ELEMENTS SUCH AS: QUALIFICATIONS EVALUATION, EXAMINATION DEVELOPMENT OR ADMINISTRATION, ENFORCEMENT, SCHOOL ACCREDITATION, ETC.

All of the examples above. In addition, staff believes it will be necessary for state authorities to promulgate environmental standards (related to diversion of the product) and labor standards for cultivators and dispensaries.

55. PROVIDE A COST ANALYSIS SUPPORTING REGULATORY SERVICES TO THIS OCCUPATION. INCLUDE COSTS TO PROVIDE ADEQUATE REGULATORY FUNCTIONS THROUGH THE FIRST THREE YEARS FOLLOWING IMPLEMNTATION OF THIS REGULATION. ASSURE THAT AT LEAST THE FOLLOWING HAVE BEEN INCLUDED: (A) COSTS OF PROGRAM ADMINISTRATION, INCLUDING STAFFING;

(B) COSTS OF DEVELOPING AND/OR ADMINISTERING EXAMINATIONS; (C) COSTS OF EFFECTIVE ENFORCEMENT PROGRAMS.

Assembly Appropriations Committee analyses for similar proposed regulations estimated costs of $14 -20 million per year. Conservatively, this would equate to $60 million for the first three years of implementation. These costs are assumed to be absorbed by the industry through licensing fees and penalties.

56. HOW MANY PRACTITIONERS ARE LIKELY TO APPLY EACH YEAR FOR CERTIFICATION IF THIS REGULATION IS ADOPTED? IF SMALL NUMBERS WILL APPLY, HOW ARE COSTS JUSTIFIED?

    According to the California Cannabis Industry Association, a minimum range of 3,000-5,000 practitioners are expected apply each year for certification if this regulation is adopted.

57. DOES ADOPTION OF THE REQUESTED REGULATION REPRESENT THE MOST COST-EFFECTIVE OF REGULATION? INDICATE ALTERNATIVES CONSIDERED AND COSTS ASSOCIATED WITH EACH.

    As mentioned previously, the costs to the proposed regulations are expected to be absorbed by the industry through licensing fees and penalties. Alternative payments would be using taxpayer funds from the General Fund or requiring consumers to take on the cost; neither of these latter alternatives are preferable.

Part C2 – Rating on Sunrise Criteria

Assign each Criterion a numeric rating of 0–5 in the space provided. The rating should be supported by the answers provided to the questions in part C1. Scale descriptions are intended to give examples of characteristics indicative of ratings.

0_____1_____2_____3_____4_____5

(*Little Need for Regulation*) LOW HIGH (*Great Need for Regulation*)

I. UNREGULATED PRACTICE OF THIS OCCUPATION WILL HARM OR ENDANGER THE PUBLIC HEALTH SAFETY AND WELFARE ___5_

low: Regulation sought only by practitioners. Evidence of harm lacking or remote. Most effects secondary or tertiary. Little evidence that regulation would correct inequities.

high: Significant public demand. Patterns of repeated and severe harm, caused directly by incompetent practice. Suggested regulatory pattern deals effectively with inequity. Elements of protection from fraudulent activity and deceptive practice are included.

II. EXISTING PROTECTIONS AVAILABLE TO THE CONSUMER ARE INSUFFICIENT __5__

low: Other regulated groups control access to practitioners. Existing remedies are in place and effective. Clients are generally groups or organizations with adequate resources to seek protection.

high: Individual clients access practitioners directly. Current remedies are ineffective or nonexistent.

III. NO ALTERNATIVES TO REGULATION WILL ADEQUATELY PROTECT THE PUBLIC __4__

low: No alternatives considered. Practice unregulated in most other states. Current system for handling abuses adequate.

high: Exhaustive search of alternatives finds them lacking. Practice regulated elsewhere. Current system ineffective or nonexistent.

IV. REGULATION WILL MITIGATE EXISTING PROBLEMS __5__

low: Little or no evidence of public benefit from regulation. Case not demonstrated that regulation precludes harm. Net benefit does not indicate need for regulation.

high: Little or no doubt that regulation will ensure consumer protection. Greatest protection provided to those who are least able to protect themselves. Regulation likely to eliminate currently existing problems.

V. PRACTITIONERS OPERATE INDEPENDENTLY, MAKING DECISIONS OF CONSEQUENCE __5__

low: Practitioners operate under the supervision of another regulated profession or under the auspices of an organization which may be held responsible for services provided. Decisions made by practitioners are of little consequence.

high: Practitioners have little or no supervision. Decisions made by practitioners are of consequence, directly affecting important consumer concerns.

VI. FUNCTIONS AND TASKS OF THE OCCUPATION ARE CLEARLY DEFINED _3__

low: Definition of competent practice unclear or very subjective. Consensus does not exist regarding appropriate functions and measures of competence.

high: Important occupational functions are clearly defined, with quantifiable measures of successful practice. High degree of agreement regarding appropriate functions and measures of competence.

VII. THE OCCUPATION IS CLEARLY DISTINGUISHABLE FROM OTHER OCCUPATIONS THAT ARE ALREADY REGULATED __3__

low: High degree of overlap with currently regulated occupations. Little information given regarding the relationships among similar occupations.

high: Important occupational functions clearly different from those of currently regulated occupations. Similar non-regulated groups do not perform critical functions included in this occupation's practice.

VIII. THE OCCUPATION REQUIRES POSSESSION OF KNOWLEDGES, SKILLS AND ABILITIES THAT ARE BOTH TEACHABLE AND TESTABLE __5__

low: Required knowledge undefined. Preparatory programs limited in scope and availability. Low degree of required knowledge or training. Current standard sufficient to measure competence without regulation. Required skill subjectively determined; not teachable and/or not testable.

high: Required knowledges clearly defined. Measures of competence both objective and testable. Incompetent practice defined by lack of knowledge, skill or ability. No current standard effectively used to protect public interest.

IX. ECONOMIC IMPACT OF REGULATION IS JUSTIFIED __5__

low: Economic impact not fully considered. Dollar and staffing cost estimates inaccurate or poorly done.

high: Full analysis of all costs indicate net benefit of regulation is in the public interest.

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