ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

"SUNRISE" REGULATORY REQUEST QUESTIONNAIRE

Instructions for completing this questionnaire

- Responses to this questionnaire should be typed and dated. Each question should be answered within a single main document, which is limited to 50 pages. Supporting evidence for your responses may be included as an appendix, but all essential information should be included within the main document.

- Each question from the questionnaire should be stated in upper case (capital) letters. The response should follow in lower case letters.

- Each part of every question must be addressed. If there is no information available to answer the question, state this as your response and describe what you did to attempt to find information that would answer the question. If you think the question is not applicable, state this and explain your response.

- When supporting documentation is appropriate, include it as an appendix. Appendices would be labeled as follows: Each document appended should be lettered in alphabetical order. Pages within each appendix should be numbered sequentially. For example, the third page of the first appendix will be labeled A3, and the fifth page of the second appendix will be labeled B5. References within the main document to information contained in appendices should use these page labels.

- Please read the entire questionnaire before answering any questions so that you will understand what information is being requested and how questions relate to each other.

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 are multiple occupational groups interested in state regulation, representing a growing marijuana industry: cultivators, manufacturers, distributors, researchers, dispensary operators, testing laboratories, producers of marijuana edibles, and those involved in transport of the product, from large shipments to discrete deliveries to individual patients. As this industry is

virtually unregulated today, and to a large degree operates in the shadows for fear of local, state, and federal enforcement action, there may be other occupational groups with a stake in the proposed regulation of which sponsors are currently unaware.

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.

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.

   Due to many contributing factors, no formal association capable of claiming representation of even a majority of California practitioners has yet formed. Among these factors are the fact that marijuana remains federally prohibited, being classified as a Schedule I drug by the U.S. Food and Drug Administration, the U.S. Department of Justice, and the U.S. Drug Enforcement Administration, and having no recognized medicinal value whatsoever; Practitioners in this industry are denied banking services in FDIC-insured institutions due to the federal ban, and must execute all transactions in cash; U.S. Attorneys with jurisdiction over California and neighboring states remain capable of launching enforcement actions at any time. In addition, many California jurisdictions, roughly estimated by the League of California Cities at 50 percent pending completion of a statewide survey, ban the cultivation and sale of medical marijuana altogether. It is not yet fully legal for recreational use in California. The regulatory, legal, financial and enforcement arms of the federal government – aided in many instances by state and local government, who rely on the Fed for guidance -- contribute significantly to a climate in which it is not yet possible for practitioners to operate with sufficient openness to form an association of the type this question inquires about.

   The one association sponsors know about, which plays a significant and expanding role but cannot yet claim outright leadership of the bulk of this industry, or the ability to speak as the lone, authoritative industry voice, is the California Cannabis Industry Association, who were instrumental in helping complete this questionnaire (the associated national group is the National Cannabis Industry Association (NCIA)).

4. Estimate the percentage of practitioners who support this request for regulation. Document the source of this estimate.

   The nature of this industry makes an accurate estimate extremely difficult. A great many practitioners operate in the shadows, in part due to legitimate fears about federal, if not state enforcement action, being taken against them. A key reason there has been no successful effort at state regulation in this area since the passage of Proposition 215 – aside from the admittedly traditional opposition of law enforcement and cities -- is the very vocal opposition of many marijuana advocates, some of whom favor outright legalization without significant state regulation, and some of whom prefer the largely unregulated status quo in which there

are for example, no state taxes, no labor standards, no health and safety standards, no mandated security requirements, and no employee protections. Our estimate is based solely on anecdotal evidence of practitioners we have worked with in various jurisdictions including the cities of Berkeley, Oakland, Los Angeles, San Francisco, Sacramento, Sebastopol, Santa Rosa, and the counties of Mendocino, Humboldt, Fresno, Contra Costa, Orange, Nevada, Sonoma, Lake, Trinity, Siskiyou, and Yuba. Based on these interactions, we estimate that 55% of industry practitioners support state regulation of medical marijuana.

5. Name the applicant group representing the practitioners in this effort to seek regulation. How was this group selected to represent practitioners?

   Two groups that are confirmed as supportive of the effort to seek regulation are the California Cannabis Industry Association (CCIA), and Americans for Safe Access, a nationwide patient advocates entity. These groups were self-selected.

6. Are all practitioner groups listed in response to question 2 represented in the organization seeking regulation? If not, why not?

   No. The California Cannabis Industry Association represents primarily cultivators and dispensaries. Also there is a lack of consensus among *all practitioners* as to: a) the need for regulation; and b) the specific form that state regulation should take. This dynamic also applies to the crafting of a ballot measure to legalize marijuana. A key reason for this is that the marijuana industry to a large degree represents an all-cash, underground economy that is virtually unregulated, and for the most part untaxed, and many practitioners currently have strong economic incentive to keep it that way.

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. Under the current cooperative and collective model, cultivators theoretically provide for a discrete and specific universe of qualified patients, caregivers, and/or dispensaries. Many dispensaries serve primarily local clientele, or patients. Clients are generally individuals.

8. Identify any advocacy groups representing California consumers of this service. List also the names of applicable national advocacy groups.

   Drug Policy Alliance
   Marijuana Policy Project

California Cannabis Industry Association
National Cannabis Industry Association
California NORML
NORML (the national organization)
California Cannabis Policy Reform
Americans for Safe Access (ASA)

9. Identify any consumer populations not currently using practitioner services that are likely to do so if regulation is approved.

   With proper regulation, which will entail health and safety standards, including testing standards which will usher in uniform quality assurance, there may be a significant increase in the number of qualified patients seeking medical marijuana suffering from ailments such as epilepsy, cancer, AIDS and other maladies requiring some form of pain management, arresting of seizures, or appetite stimulation, three therapies for which marijuana's medicinal properties have been recognized. These patients may wish to avoid pharmaceuticals as unnatural chemical substances they prefer not to introduce into their bodies, or they may have tried conventional pharmaceuticals and found them ineffective in addressing their specific ailment. Health and safety standards and uniform quality assurance will undoubtedly strengthen the public's confidence in the safety and legitimacy of medical marijuana.

   This projected increase in legitimate patient use becomes more likely in light of the fact that the federal ban on marijuana is relatively recent, coming into being only with the enactment of the Marijuana Tax Act of 1937, which criminalized possession or transfer of cannabis throughout the United States. Prior to that legislation, marijuana was commercially available in many pharmacies throughout the United States. According to a documentary first aired on the History Channel in 2010, "*Marijuana: A Chronic History",* many cultures going back to 3500 B.C. have recognized marijuana for its medicinal properties. That documentary is currently available on YouTube at https://www.youtube.com/watch?v=Dd6oJjx8ze0

10. Does the applicant group include consumer advocate representation? If not, why not?

    No. Many consumer advocates do not favor meaningful regulation of the medical-only framework created by Prop. 215, which is what this bill seeks to achieve. Rather, they almost uniformly prefer total legalization, and the likely vehicle for that is a ballot initiative. This despite the quasi-legal status marijuana has in California in the wake of SB 1449, Chapter 708, Statutes of 2010 by Senator Leno, which decriminalized possession of marijuana in amounts indicating personal use only.

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
    Opposition: California NORML, California Cannabis Policy Reform
    Position Pending: California Cannabis Industry Association, Americans for Safe Access

Tracking but no Position: Drug Policy Alliance, California Narcotics Officers Association, State Sheriffs Association

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?

    Yes. There is significant public demand for uniform standards in the field of health and safety, including maximum potency standards, product packaging and labeling standards, maximum tolerances for contaminants such as mold, fungus, pesticides, rodenticides, fecal matter, and other foreign substances. Among local government entities, many jurisdictions would like to see a uniform state regulatory structure, and have refused to allow cultivation or sale of marijuana within their boundaries in the absence of such a structure. There is also widespread public demand for marijuana cultivation standards that mirror established agricultural standards and that will alleviate environmental degradation.

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.

    No cultivation standards, and no health and safety standards of any kind exist for medial marijuana today. This is troubling given that it is both an agricultural product, and a psychotropic substance that is increasingly finding its way into edible products, often with harmful results. The harm suffered by consumers is that they are exposed to and in some cases ingesting unknown contaminants (mold, fungus, pesticides, rodenticides, fecal matter, and other foreign substances) for which no maximum tolerance has been established, and for which no formal, uniform testing procedures are currently in place. Edible marijuana products, particularly if they are laced with marijuana that is high in THC, a psychotropic

intoxicant, can be particularly dangerous because they generally contain marijuana in concentrated form. However, because they are consumed orally and are absorbed into the bloodstream via the digestive tract, they can take significantly longer than smoked marijuana cigarettes for the user to feel their effects. A single chocolate chip cookie infused with marijuana may contain the equivalent of six adult doses of high-THC marijuana, yet today there are no regulations requiring warning labels or setting potency standards. In some cases the results can be fatal.

In addition, there remains in many sectors of our society a social stigma associated with the use of marijuana, even for legitimate medicinal purposes. There has been a significant social impact on our society in terms of the resources expended on enforcement of marijuana laws, and the opportunity cost that those expenditures represent: funds allocated for enforcement and incarceration related to marijuana offenses alone could otherwise have been directed to streets and roads, mental health services, after school programs, improved police and fire services, transportation services, libraries, etc. The failure of the past two decades to enact a meaningful framework for the uniform regulation and distribution of marijuana has served to repeatedly postpone a range of shifts in policy and budgetary decisions that would benefit all Californians. This legislation will advance that effort by filling a regulatory void.

For legitimate, qualified patients who have a heightened need for a safe product that they take in lieu of conventional pharmaceuticals, the lack of established testing protocols as well as health and safety standards places them particularly at risk. An epileptic patient who needs marijuana that is high in CBD content to alleviate and even reduce her seizures, will be especially sensitive to high THC marijuana, for not only will it fail to alleviate her condition, it could be dangerous for her to the point of potentially inducing and intensifying her seizures – a life-threatening outcome. A cancer patient undergoing chemotherapy, with its appetite-withering side effects, must have high THC marijuana to stimulate his desire for food, if he is to remain strong enough to combat the disease. Administering high CBD marijuana to him would have no more effect than a sugar pill, and do nothing to reverse or even halt his physical decline. For these patients, there is a critical need for meaningful regulatory standards addressing testing, purity, potency, labelling, the identification and elimination of contaminants, and secure protocols for processing and transport of the product. Today, there are none.

In addition, there is a need to enact uniform standards addressing the knowledge of dispensary employees about the product being sold to patients. AB 266 addresses this via the required establishment of an apprenticeship program.

14. How likely is it that harm will occur? Cite cases or instances of consumer injury. If none, how is harm currently avoided?

    Harm to consumers is very likely given that no health and safety standards exist for marijuana, so there are none to be enforced. The same is true in regard to requirements pertaining to packaging, labelling, and seed-to-sale tracking. Patients can only avoid harm by doing their own private research to identify the strain or strains of marijuana that will best

address their condition, identifying reputable testing labs to check the product they propose to ingest, and paying for testing at their own expense. Under the status quo, testing, dosing, and background research are all left to the consumer in most instances. The potential for harm is significant given the unregulated use of pesticides and illegal rodenticides in marijuana cultivation and the absence of any standards regarding the removal of such residue from the plant product.

This hazard to the public is magnified in the case of edibles, due to the concentrated nature of the marijuana they contain, and depending on the strain, its attendant psychotropic and hallucinogenic properties, combined with the current total absence of regulatory standards. Additionally, edibles are not currently labeled to disclose any potential allergens.

15. What provisions of the proposed regulation would preclude consumer injury?

Provisions requiring the establishment of uniform health and safety standards, and requiring mandatory, random sample product testing, both of which are referenced with greater specificity below. In addition, multiple additional provisions of the proposed regulation will preclude consumer injury, as follows:

Section 18101: Establishing a licensing requirement for all operators in the stream of commerce associated with medical marijuana. This dovetails with a provision elsewhere in the bill eliminating cooperatives and collectives (with a limited exemption for primary caregivers), which would be extremely difficult to regulate appropriately, given that they require no licensure or registration whatsoever.

Section 18101(d): Requiring the establishment of cultivation standards.

Section 18101(h): Establishing both the Medical Marijuana Regulation Fund, and the Special Account for Environmental Enforcement, addressing both the funding needs triggered by this entire regulatory structure, as well as the requirement for the enforcement of environmental laws and related clean-up at licensing cultivation sites, which will have a direct impact on consumer safety.

Section 18101(j): Requiring certification of laboratories to perform testing of medical marijuana, for the purpose of identifying various contaminants in the marijuana and determining their concentration.

Section 18104(a)(6)(A) and (B): Requiring the establishment of standards for the certification of laboratories.
(**Please note:** The Committee's notification of the fact that certification of laboratories is currently performed by the Department of Public Health (DPH) has not been disregarded; it is under strong consideration as an amendment, and conversations with DPH are pending).

Section 18104(a)(7)(A): Requiring the establishment of sanitation standards in connection with edible marijuana products.

Section 18104(a)(7)(B) and (C): Additional regulations pertaining to edible marijuana products.

Section 18104(a)(7)(E): Establishing standards for pesticides and rodenticides to be used in cultivation of medical marijuana.

Section 18104(b): Establishing standards for statewide health and safety regulations, and quality assurance (testing) regulations related to cultivation, storage, transport, manufacture, and sale of all medical marijuana produced in California.

Section 18109: Requiring all activities associated with dispensing, cultivation, manufacture, transport, furnishing and testing of medical marijuana be appropriately licensed. The objective of this provision is to effectively replace the current cooperative/collective model with licensed operators throughout the stream of product cultivation, testing, distribution, and sale.

Section 18117(b): Establishing a revenue stream for enforcement activities by the relevant state agencies pertaining to environmental clean-up and enforcement of existing law at all licensed cultivation sites.

II. EXISTING PROTECTIONS AVAILABLE TO THE CONSUMER ARE INSUFFICIENT

16. To what extent do consumers currently control their exposure to risk? How do clients locate and select practitioners?

This is partially addressed in the answer to Question 14. Today, consumers can only control their exposure to risk by educating themselves about the properties of various strains of marijuana, and their respective medical efficacy for specific maladies, and by identifying reputable testing laboratories and paying for private testing at their own expense, to: a) identify key components of marijuana and confirm their potency; and b) have any contaminants and their concentrations identified. However, this alone is not sufficient to ensure consumer safety, because no federal or state standards exist for maximum potency, or for maximum contaminant concentrations. Consumers must rely on the expertise of practitioners (primary dispensary employees and those in testing labs, if they incur the additional expense of testing) to alert them if medical marijuana they have purchased is unsafe. Expertise varies among these entities, as there is currently no defined industry standard, and in the case of dispensaries, any in-house expertise may be offset by the profit motive associated with retail sales. Furthermore, without legally accepted credentials or training, it is unknown as to if advice provided to patients is accurate or peer reviewed.

17. Are clients frequently referred to practitioners for services? Give examples of referral patterns.

    Yes. Today, most clients must rely on the knowledge of specific dispensary employees, whom they consult on their own initiative, or to whom they are referred. In addition, Proposition 215 provides that the initial pathway to obtaining medical marijuana is via the recommendation of a physician. Often private physicians fulfill this role, given that marijuana recommendations are not common within health maintenance organizations (HMO's) and some physicians are known to provide recommendations as a significant portion of their practice.

18. Are clients frequently referred elsewhere by practitioners? Give examples of referral patterns.

    As a rule, the entire industry is referral-driven. Absent the avenues of information referenced in the answer to Question 17, practitioners advise clients to perform their own research (consulting online and other resources), to experiment via trial-and-error, or to rely on the expertise of other patients transmitted by word-of-mouth.

19. What sources exist to inform consumers of the risk inherent in incompetent practice and of what practitioner behaviors constitute competent performance?

    News media accounts, marijuana blogs, speaking engagements, patient advocacy-sponsored printed material, independent research, and word-of-mouth. Currently no other mechanism exists in this industry to alert consumers of specific risks on a widespread basis.

20. What administrative or legal remedies are currently available to redress consumer injury and abuse in this field?

    Currently, none -- hence the need for the proposed regulation. Under federal law, marijuana remains a Schedule I drug that no legitimate pharmacy may dispense, and to which neither federal nor state food and drug laws apply. For this reason, a person (such as an epileptic patient) suffering ill effects from marijuana that is high in THC content, when she needed marijuana high in CBD content to alleviate her seizures, has no meaningful redress under California law today, because there are no health and safety standards, no potency standards, no labelling standards, and no testing standards to invoke in alleging any kind of violation. So long as there are no standards by which to gauge competent conduct by a practitioner in any of these areas, no consumer or potential plaintiff harmed by marijuana will have a basis on which to argue that a practitioner should be held accountable. The same is true of a cancer patient who ingests a THC-rich edible product to stimulate his appetite, where that product turns out to be far more potent than he imagined, inducing 12 hours of hallucinations during which he suffers severe physical injury; he too will have no legal redress.

21. Are the currently available remedies insufficient or ineffective? If so, explain why.

There are currently *no* available remedies, since the market for medical marijuana today is entirely unregulated and devoid of standards to protect consumer safety.

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.

    Marketplace factors have not addressed the need to establish uniform health and safety standards, in large part due to the state of federal law as it pertains to marijuana. Marijuana is both an agricultural product and a psychotropic substance, yet under current law it is subject to less regulation than ordinary lettuce because it is federally prohibited. The market also has not provided for uniform testing standards to identify and isolate contaminants that would endanger consumer safety. It must be acknowledged that this is a unique product in that it is in widespread use, but the federal ban has so far had a chilling effect on the establishment of a body of regulations that would ensure patient and consumer safety, so the normal market forces that would otherwise come into play have effectively been neutralized. Laissez faire economics have not been allowed to play their natural role. In addition, there is unfortunately a criminal element in the industry that if anything, represents a negative marketplace factor.

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.

    Colorado, Washington, Oregon. California is the only state that permits for medical marijuana in the absence of a robust state-wide regulator system. The following states have state-wide medical marijuana regulatory systems: Alaska; Arizona; Colorado; Washington DC; Delaware; Hawaii; Illinois; Maine; Maryland; Massachusetts; Michigan; Minnesota; Montana; Nevada; New Hampshire; New Jersey; New Mexico; New York; Oregon; Rhode Island; Vermont; Washington.

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: A specific code of ethics does not exist; ethical standards in this industry are anything but uniform, as this is an underground enterprise that largely operates in the shadows.
    b. Codes of practice enforced by professional associations: These too are non-existent; until very recently (2013) no professional associations existed, since the members who would comprise them were fearful of federal enforcement activity, a development which remains a possibility today, irrespective of which party heads the executive branch of the federal

government after the 2016 presidential election. For many of these practitioners, to operate openly is to place oneself and one's business enterprise in hazard.

c. Dispute-resolution mechanisms such as mediation or arbitration: Such mechanisms are usually only available for products and industries that can operate openly and entirely within the law. As of today, they do not exist for consumers of medical marijuana at all; for medical marijuana industry practitioners, such mechanisms exist only to the extent of the ability to file legal actions on relatively narrowly defined issues.
d. Recourse to current applicable law: Applicable federal law bans marijuana and does not recognize its medicinal value; notwithstanding Proposition 215, many local jurisdictions follow and enforce federal law. In such a climate, consumer patients have no body of law to call upon in trying to invoke legal redress for any harm suffered.
e. Regulation of those who employ or supervise practitioners: Systematic, statewide regulation in this area is non-existent for reasons previously stated; while there are non-uniform regulations that have evolved in a minority of local jurisdictions, there is no coherent regulatory policy that applies across all jurisdictions.
f. Other measures attempted: Previous attempts at statewide regulation have failed due to lack of consensus:

SB 1262 (Correa, 2014) Similar to AB 266, this bill sought to protect local control by making state licensing dependent on local approval. Included anti-diversion provisions and health and safety standards. Held in the Assembly Appropriations Committee August 2014.

AB 1894 (Ammiano, 2014) Similar to the current AB 26 (Jones-Sawyer), sought to set up a regulatory scheme of mandatory commercial registration for marijuana businesses that would have pre-empted local ordinances. Failed passage on the Assembly Floor 5/29/2013.

AB 473 (Ammiano, 2013) sought to establish a mandatory statewide commercial registration scheme for marijuana dispensaries. Failed passage on Assembly Floor 5/31/2013.

SB 439 (Steinberg, 2013) sought to exempt marijuana collectives and cooperatives from various forms of criminal prosecution under the California Health & Safety Code, as well as from local nuisance abatement actions under Health & Safety Code Section 11570. Hearing in Assembly Health Committee cancelled at request of author.

AB 604 (Ammiano, 2013) Similar to AB 1894. Sought to establish for-profit sales of marijuana by commercial operators, and significantly restrict municipal zoning powers and local law enforcement authority. Failed passage on Senate Floor 9/11/2013.

SB 420, Chapter 875, Statues of 2004. Established a voluntary program for the issuance of identification (ID) cards to qualified patients for the use of medical marijuana. Created a series of legal definitions, clarifications, and statutory

changes to implement a system providing medical marijuana to chronically ill patients, including the cooperatives and collectives through which many patients obtain marijuana.

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 that clause justified? What safeguards will be provided to consumers regarding this group?

    There is currently no grandfather clause in the proposed regulation. However, there may be one included in the stand-alone regulatory provisions contemplated for the City of Los Angeles, as part of the pending carve-out to preserve as much of their local Measure D regulatory structure as possible.

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?

    1) Health and safety standards will protect consumers by:
        a. Establishing cultivation standards to assist in product purity and reduce consumer exposure to excessive pesticide and rodenticide residue
        b. Establishing maximum potency standards: this will protect consumers by setting an upper limit on the concentration of the intoxicant THC that marijuana products may contain
        c. Establishing food safety standards for edibles
        d. Establishing maximum tolerances for known contaminants, including mold, fungus, pesticides, rodenticides and other foreign matter
    2) Quality assurance standards will protect patients by:
        a. Requiring uniform random sample product testing, to identify and eliminate contaminants
        b. Establishing labelling and packaging standards: this will identify for patients the ratio and concentration of specific, naturally occurring substances within marijuana (primarily THC and CBD) that will tell them how effective it will be in treating their condition, and conversely the degree of hazard it poses to them.
    3) Uniform security standards at dispensaries and in transport of the product will benefit the public by providing a deterrent to the portion of the industry representing a criminal element, and will provide greater safety for practitioners of what remains overwhelmingly an all-cash business.
    4) The above benefits seek to endure freedom from patients and industry professions.

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) Legitimate, qualified patients with bona fide medical conditions, some of whom may have a compromised immune system or unusual sensitivity to high-THC marijuana, are most in need of protection. This population has heightened health needs and will benefit most from regulation.
b) Patient consumers who use marijuana as an alternate form of a common pharmaceutical, either to relieve pain, ease muscular tension or as a sleep aid, are in need of less rigorous protection. They will benefit from regulation, but not to the same degree as those cited in 27.a).
c) Holders of medical marijuana cards who meet the legal definition of qualified patients, but who primarily use marijuana recreationally, are in need of the least protection. This group will benefit least from regulation.

28. Provide evidence of "net" benefit when the following possible effects of regulation are considered:
    a. Restriction of opportunity to practice: Should regulation restrict opportunities to practice, it will benefit the public in the following ways:
        1) It will serve to reduce the administration and cost burdens associated with regulating the market;
        2) It will reduce opportunities for related criminal activity;
        3) It will increase practitioner accountability by reducing the likelihood of the continuation of questionable practices such as medical recommendations occurring at social events (concerts) or via Skype;
        4) Since marijuana is both a medicine and a recreational drug, it will help address concerns about over-concentration of retail outlets.
    b. Restricted supply of practitioners: Under this bill's regulatory protocol, all practitioners will have to be licensed by state and local government by a date certain. It this restricts the supply of practitioners, it will primarily be due to a certain element preferring to operate outside the law and attendant state and local regulation.
    c. Increased costs of service to consumer: There could be some increased costs to the consumer associated with the labor provisions in the bill, specifically the establishment of an apprenticeship program and the labor peace agreement which to a degree will facilitate unionization of practitioners' employees. But as this bill represents a medical-only regulatory framework, sponsors anticipate that increased costs to consumers will be controlled to a degree by existing prohibitions against taxing medicine.
    d. Increased governmental intervention in the marketplace: Since under today's status quo there is virtually no governmental intervention in this particular marketplace, aside from intermittent enforcement action, the more conventional forms of intervention in regard to enforcement of health and safety standards, for example, will be a welcome change. The ability to levy fees, if closely linked to the actual cost of regulatory activity, will address cost concerns about government intervention.

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?

    This varies depending on the specific activity engaged in by the practitioner. Practitioners (whether they are physicians, dispensary employees, or patients who are compelled by circumstance to develop their own knowledge) frequently make professional judgements of consequence in recommending or selecting particular strains of marijuana, deciding how much to ingest at one time, the form in which it is ingested, and the frequency.
    They must also decide whether to have the marijuana tested in advance of ingestion. These decisions may occur on a weekly, daily, or hourly basis, depending on the patient's need and condition. They can have serious consequences given that marijuana is a psychotropic substance which has not been the subject of comprehensive clinical trials due to the federal ban. Depending on its potency and the body chemistry of the individual patient, there can be unpredictable consequences, which is why so many patients must rely upon trial-and-error in trying out marijuana products, at least initially.

    Cultivators must decide upon indoor vs. outdoor cultivation, use and quantity of pesticides, rodenticides, fungicides, etc., and methods of subsequent cleaning upon harvest, all of which factor into potential hazards to consumers. Manufacturers must decide upon handling, packaging, sanitation and labelling policies. Dispensary operators make decisions about the standard of knowledge to which they will hold their employees, which affect the quality of referrals or recommendations about specific strains of cannabis, as well as handling and sanitation policies. Testing laboratories make decisions about testing methods, calibration to measure potency of the cannabis as well as the concentration of any contaminants, product formulation, and critical decisions about whether the product is in such poor condition that it can be classified as adulterated.

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 nature of this industry, which is not only unregulated but unstructured, practitioners operate independently as a matter of routine.

31. To what extent do decisions made by the practitioner require a high degree of skill or knowledge to avoid harm?

    Decisions about selecting a particular strain of marijuana for a patient based on its properties and their concentration, as well as decisions pertaining to testing, dispensing and advising patients, extraction to create concentrates, and the preparation of edibles, all require a high degree of skill.

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 designated job title or occupational description without a license?

The proposed regulatory scheme defines specific activities that will require licensure.

33. Describe the important functions, tasks and duties performed by practitioners. Identify the services and/or products provided.

    Cultivation, testing, packaging, transport, dispensing, and making recommendations to patients based on the patient's illness or condition, as well as knowledge of the psychotropic properties of marijuana and how it will likely interact with the patient, based on their medical condition.

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?

    No. That is why there is a need for the following, which will be ushered in by the proposed regulation: licensing requirements, the establishment of health and safety standards, including maximum tolerances, quality assurance or testing standards, and the establishment of an apprenticeship program. To a large degree, the pioneering efforts of Oaksterdam University, an internationally recognized Cannabis College in Oakland, can be relied upon as a template for possible future consensus on competent practice.

35. Are indicators of competent practice listed in response to question #34 measurable by objective standards such as peer review? Give examples.

    No.

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?

    a) Attempted extraction of oil from marijuana using butane that results in explosion, fire, or both. Butane is used for purposes ranging from cooking to cleaning. For example, it is used to extract caffeine, aloe vera, and vanilla and is considered a "food-safe solvent" by the Food and Drug Administration. Generally in the marijuana industry, butane is used to concentrate essential cannabinoids from the plant into a clean, effective medicine, which is sold as medical marijuana edibles, topicals, or vaporizers. The use of butane allows for maximum retention of medical benefits while leaving behind unwanted carbons found in the plant material. For instance, many people have allergies to the raw plant material, therefore capturing the active ingredients without the allergen provides greater options to medical patients. It is has also been determined that butane extraction allows the manufacturer to better extract targeted cannabinoids to address specific ailments.

       Due to the increasing demand of this form of medical marijuana (butane hash oil or butane honey oil), butane has found its way into the black market. Many manufacturers have been unsafely operating in private homes and commercial buildings without appropriate training or regulations in place. Other regulated states have recognized the

dangers associated with unregulated butane extraction operations and have begun to adopt regulations aimed at protecting the public and curtailing the spread of these unsafe and illicit black market operations.

b) Failure to inquire about a patient's specific condition before recommending marijuana, to determine whether high-THC or high-CBD marijuana will alleviate or worsen the patient's condition.

c) Failure to educate oneself about the effects of THC and CBD on the human body, the respective efficacy of the two substances, and the health complications that may arise for a patient if he is given the wrong substance, or marijuana with an improper ratio of the two substances, given that they often co-exist in varying ratios within a single marijuana plant, producing a variety of chemical reactions in the human body based on those ratios.

d) Disregard of the need for product testing. Regulations should be established to mandate systematic, random sample quality testing of medical marijuana. There are a growing number of dispensaries that are truly concerned about patient safety; however, the majority do not follow any quality control protocols to ensure patient safety. Appropriate protocols should include both microbiological and pesticide screening using methods widely accepted as relevant and accurate. Further, proper labeling for safety and accurate dosage, and tamper evident packaging of cannabis products should also be required.

e) Failure to adopt sanitary and safe handling procedures in preparation and transport of the product, to minimize exposure to many contaminants, the most common among them (per the testing labs) being e. coli bacteria.

f) Dishonesty is always a concern with any all-cash business, as the opportunities for fraud/embezzlement or outright theft are magnified. Any business can only withstand a certain amount of such activity, before beginning to pass the cost on to consumers.

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

37. What similar occupations have been regulated in California?

There may be no comparable occupation to the cultivation, distribution, and sale of medical marijuana, given the current total lack of regulation and the significantly different policies of the state and federal governments concerning this product.

However, given the medicinal nature of marijuana and the fact that recreational marijuana is still considered to be a controlled substance, a case can be made for a certification process that ensures dispensary workers' competency and qualification, at least insofar as might be necessary to protect the health and safety of consumers. To the extent that a medicinal marijuana dispensary is seen as an analogue to a pharmacy, a dispensary worker who handles

and sells medicinal marijuana and medical marijuana products, and who provides product information to consumers, is not unlike a pharmacy technician who, in California, must be licensed. In order to obtain the required California license, pharmacy technician applicants must undergo a criminal background check and show that they have obtained an appropriate amount of formal training or been certified by the Pharmacy Technician Certification Board or been trained as a pharmacy technician while serving in the armed services (See B&P Code Section 4202, referencing pharmacy technician licensing).

38. Describe functions performed by practitioners that differ from those performed by occupations listed in question #37.

    Similar consumer health and safety concerns and occupational parallels do not exist between agricultural employees, i.e. those who work in nurseries, and cannabis employees working at cultivation sites. Accordingly, the marijuana industry would argue that state-mandated competency/certification requirements as to those who work in cultivation sites are overly burdensome and unnecessary. However, sponsors maintain that at a minimum, comparable health and safety standards, as well as sanitation standards, should apply.

    Unlike pharmacy technicians, dispensary employees are handling a Schedule I narcotic that, under Federal law, does not have any accepted medical benefits. Consequently, dispensary employees are providing medical marijuana to patients with physician recommendations, not prescriptions.
    Furthermore, dispensary employees are not required to have any bona fide expertise, degree, of licensing. Employees are providing medicine that has no clinical standards or trial requirements.

39. Indicate the relationships among the groups listed in response to question #37 and practitioners. Can practitioners be considered a branch of currently regulated occupations?

    No, practitioners cannot be considered a branch of currently regulated occupations.

40. What impact will the requested regulation have upon the authority and scopes of practice of currently regulated groups?

    A threshold truth to highlight is the fact that there are no currently regulated groups in the marijuana industry. The requested regulation will have the following beneficial effects:
    - Establishing licensure requirements, increasing practitioner accountability
    - Establishing uniform health and safety standards, increasing patient safety
    - Establishing a benchmark for a degree of professional knowledge and training via an apprenticeship program, increasing practitioner accountability and patient safety
    - Enhancing public and employee safety with uniform security standards

41. Are there unregulated occupations performing services similar to those of the group to be regulated? If so, identify.

There is no comparable unregulated occupation. While there are unregulated criminal enterprises that also provide (by the federal definition) illicit drugs to the public, unlike marijuana, those drugs do not have any established medicinal value.

42. Describe the similarities and differences between practitioners and the groups identified in *Question 41*.

    Not applicable, for the reasons described in Question 41.

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.

    Yes, particularly in the testing phase. The laboratory industry requires operators to meet specific standards that are overseen by the American Association of Cannabis Laboratories (ACCL). In addition, please see responses to Questions 29 and 36 c) and d).

    Other than testing, there has yet to be established a core set of standards regarding knowledge and skill sufficient to protect public safety – hence the need for this regulatory proposal. Americans for Safe Access operate a "Patient Focused Certification" (PFC) program. PFC is a third-party certification program for the medical cannabis industry based on the new quality standards for medical cannabis products and businesses issued by the American Herbal Products Association (AHPA) and the American Herbal Pharmacopeia (AHP) Cannabis monograph. Individual practitioners can elect to participate in this program. Hence the need for an apprenticeship program as contained in this regulatory proposal.

44. What methods are currently used to define the requisite knowledge, skills and abilities? Who is responsible for defining these knowledge, skills and abilities?

    A great deal of knowledge has been acquired by practitioners by their own trial-and-error, and that of the patients they are serving. Much of this knowledge is primarily transmitted by word of mouth.

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)?

    The knowledge, skills and abilities in the testing lab sector of the industry are verifiable based upon whether the owner/directors and employees of the laboratories have the requisite training consisting of undergraduate degrees in an appropriate field of science among the rank-and-file testing employees (chemistry, biology, or physics) and Masters or Ph.D. degrees among those who supervise them and/or head the entire laboratories.

Other than the testing lab sector, there are no uniform testing standards to determine an individual's level of knowledge among the other categories of practitioners.

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.

    - Oaksterdam University
    - Cannabis Career Institute
    - Americans for Safe Access PFC Program

    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. No other formal methods known at this time. Word-of-mouth, informal workshops and demonstrations, internet resources, literature.

48. Estimate the percentage of current practitioners trained by each of the methods described in questions 46 and 47.

    This is impossible to determine given the largely underground nature of this industry. Any estimate would be purely speculative.

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 administered. If not, indicate search efforts to locate such measures.

    No. That is why this regulatory proposal seeks to establish an apprenticeship program. Search efforts: Google, inquiries with practitioners including the California Cannabis Industry Association, Sequoia Testing Labs (Sacramento), and CW Analytical Labs (Oakland).

50. Describe the format and content of each examination listed in question 49. Describe the sections of each examination. What competencies are each designed to measure? How do these relate to the knowledge, skills and abilities listed in question 43?

    It is not yet possible to answer this question. See response to Question 49.

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?

    Not applicable.

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. Proper regulation will increase this number, as with the establishment of uniform health and safety and testing standards, the perception will likely disseminate though the public consciousness that marijuana is a safe and reputable medicinal product, moreso than under today's status quo.

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.

    We can only estimate – the cost of service provided is conservatively estimated to be in the low millions, generating amounts in the high hundreds of millions of dollars in untaxed sales statewide on an annual basis.

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.
    - State conditional licensing, requiring a criminal background check and vetting for state residency requirement, for:
        - Cultivation
        - Transport
        - Delivery services
        - Manufacture
        - Dispensing
    - Local licensing for all of the above activities, according to local ordinances (if cultivation and/or sale of medical marijuana are allowed in the jurisdiction)
    - Promulgation of uniform health and safety standards
    - Promulgation of uniform testing standards
    - Promulgation of uniform security standards
    - Certification of testing laboratories
    - Enforcement (primarily by local government agencies) of the various standards, including confirmation of systematic random sample product testing

55. Provide a cost analysis supporting regulatory services to this occupation. Include costs to provide adequate regulatory functions during the first three years following implementation 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

No accurate cost estimate is possible without consulting the staff of various agencies, primarily the Department of Consumer Affairs, but also the Department of Public Health and the various state agencies responsible for aspects of environmental enforcement at licensed cultivation sites. However, cost estimates generated by the Assembly Appropriations Committee for two recent bills proposing regulation of medical marijuana ranged from a low of $14 million for AB 1894 (Ammiano, 2014) to a high of $20 million for SB 1262 (Correa, 2014). Given that these two measures were similar in scope to AB 266, we believe the cost estimate for SB 1262 to have been somewhat inflated, and that for AB 1894 to have been unduly conservative. We believe a more realistic estimate lies in the middle range of $17-18 million.

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?

Our estimate after consulting the California Cannabis Industry Association is 3,000 to 5,000.

57. Does adoption of the requested regulation represent the most cost-effective form of regulation? Indicate alternatives considered and costs associated with each.

Yes. This proposal admittedly entails significant up-front state cost to develop regulations and standards, but those costs can be recovered via the state licensing fee. In the long run the primary cost driver will be enforcement. This regulatory proposal requires the bulk of enforcement to occur at the local level, consistent with the theme of local government having a critical role in the ongoing regulation of this industry under the dual licensing system.

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 5

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 5

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 5

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 3

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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