

7/17/14

Chairman James Roger Madalena  
Interim Legislative Health and Human Services Committee Members

Chairman Madelena and committee members,

Thank you for the opportunity to present a response to the NM Dept. of Health's proposed changes to the rules and regulations governing the medical cannabis program.

In addition to the handout provided by Emily Kaltenbach, Drug Policy Alliance, please find in your packets:

1. Response to NM DOH frequently asked question regarding the rules
2. Legal memo from Drug Policy Alliance
3. American Herbal Products Association guidelines
  - a. Cannabis Laboratory Operations
  - b. Cannabis Cultivation and Processing
  - c. Cannabis Dispensing Operations

Jessica Gelay  
Policy Coordinator, Drug Policy Alliance



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July 1, 2014

Prepared by Drug Policy Alliance staff for Interim Legislative Health and Human Services committee members in response to the FAQ sheet posted on the NM Dept. of Health, Medical Cannabis Program webpage.

## 1. Are the proposed rule changes meant to lead to a reduction in product?

DOH Answer: No. The Department of Health is proposing changes to the regulations that are intended to increase the availability of medical cannabis for qualified patients in the Program. Licensed non-profit producers would be permitted under the proposed regulations to triple the number of plants that they grow and the Department also plans to license additional non-profit producers throughout the State of New Mexico after the rule change process is complete.

The question should not be whether the proposed changes are *meant* to lead to a reduction in product, but whether proposed changes *could* lead to a reduction. Furthermore, the following rules will absolutely lead to a reduction in medical cannabis:

**7.34.4.8 A. (1) Which reduces the amount of plants patients with personal product licenses can grow. Currently patients can grow up to four (4) mature plants and have up to twelve (12) seedlings; proposed rule would slash the plants patients are allowed to grow to two (2) mature plants and six (6) seedlings.**

This amount leaves no room for error, this is unacceptable for a live plant, which could easily have its yield demolished by an agricultural pest or other environmental contaminant.

**7.34.4.7. FF Which redefines “Personal Production License” to eliminate a patient’s primary caregiver’s ability to grow medicine.**

There is a child with severe epilepsy in Las Cruces whose family cannot afford to pay for the medicine their child needs. Under the current rules the parents would be allowed to grow the medicine; the change in this definition would make eliminate the possibility that they could grow this medicine for their sick child.

**734.4.8 N. Which limits the concentration of THC in cannabis derived products that state licensed producers can sell, unless patient can present a specific medical exemption.**

If the majority of patients aren’t allowed to purchase medication in concentrations of more than 60% it is unlikely that producers will produce it at all. Cannabis, unlike opioids and other narcotic medicines, has never caused an overdose death. Limiting concentration will require cannabis concentrates to be adulterated for dilution. Again, this would harm New Mexico’s sickest patients forcing them to buy more, less effective, medicine to get the relief they need.

## **2. Will fees for all non-profit producers increase under the proposed rules?**

DOH Answer: **No.** Non-profit producers who choose to remain at the current plant count would pay essentially the same fee that they pay right now. Non-profit producers would only have to pay the increased fee if they choose to increase their plant count.

This is not true. Under the proposed changes a producer would have to pay \$10,000 for 100 vegetative plants and \$20,000.00 for 50 flowering plants, equals \$30,000. However, most producers that are growing 150 plant are flowering between 80-120 at any one time so you would be paying between \$50,000.00 to \$70,000.00 to produce the same amount as is produced currently: \$10,000.00 for the 100 vegetative plants plus \$40,000.00 (100 plants) to \$60,000.00 (150 plants) for the flowering plants.

Furthermore, it is likely that many producers will not have the necessary funding to both increase their operation size to grow more plants and to pay the increase in licensing fees. Therefore it is likely that many producers will choose to stay at their current rate of production.

Although the Department has announced plans to license more producers, they have not released information on application requirements or procedures. The initial application fee would increase ten times the current amount, from \$1,000 to \$10,000, with another \$90,000 due before the producer is allowed to open their doors. \$100,000 is an exorbitant cost simply for licensing of a non-profit and will prohibit most interested parties from even considering becoming licensed medical cannabis producers.

## **3. Is it true that the Department of Health developed these regulations without any input from producers and other stakeholders?**

DOH Answer: **No.** The Department used information from many sources, including patients in a 2013 survey it commissioned about the Medical Cannabis Program. We have taken written input and met with the Licensed Producers and informed them the Department would be working on new regulations and sought their suggestions on potential issues they would like to see addressed in the regulations. Information was also obtained from the Medical Cannabis Advisory Board, professional organizations, advocacy groups, other medical cannabis states and daily communication with various stakeholders and interested parties. The Department is currently accepting written comments from the public, and will accept oral comment at the public hearing on June 16<sup>th</sup> at the Harold Runnels Auditorium, 1190 S. St Francis Drive, in Santa Fe. The proposed rules are not yet final, and the rules may be amended by the Department in response to public comments received. The Department encourages producers, stakeholders and the public to provide feedback on the proposed rule changes. The perspectives and insights of stakeholders is an integral part of the rule making process.

No prominent medical cannabis advocacy groups in New Mexico were consulted. The following groups communicate regularly with the Department on behalf of medical cannabis patients and

none were asked for input: Drug Policy Alliance, New Mexico Medical Cannabis Patients Alliance, South East New Mexico Cannabis Patients Alliance, nor the NM Producers' Guild. In regards to the patient survey done in 2013, this does not constitute responsible and meaningful consultation with patients in the program.

Furthermore, the Medical Advisory Board, consisting of eight physicians, tasked with recommending what amount of medical cannabis constitutes an "adequate supply" of medicine and with making other recommendations about the regulation of the program was not consulted in a formal manner. Written communication dated May 27<sup>th</sup>, 2014 confirms this fact:

**From:** "Cannabis, Medical, DOH" <[Medical.Cannabis@state.nm.us](mailto:Medical.Cannabis@state.nm.us)>

**Date:** May 27, 2014 at 10:34:58 AM MDT

The Medical Advisory Board was not consulted regarding the regulation changes. The Medical Advisory Board was informed at the April 2014 meeting that the rule changes were being composed.

Any communications with Chris Woodward would be considered attorney/client communications and not subject to disclosure.

Thank you,

Medical Cannabis Program

1190 St. Francis Dr Suite S-3400

505-827-2321

Santa Fe, NM 87505

<http://www.nmhealth.org/mcp/>

#### **4. Why is the department proposing to increase fees?**

DOH Answer: The Department is proposing (1) to institute a \$50 patient registry fee, (2) implement a fee for providing replacement cards, and (3) implement a staggered fee structure for non-profit producers that would impose maximum possible fees on non-profit producers of three-times the current fees, while simultaneously permitting non-profit producers to triple their production (and thus triple their revenue) if they choose.

Under the proposal, qualified patients currently enrolled in Medicaid are eligible for both a waiver of all of the personal production fee and part of the patient registry fee.

While we recognize that increased fees can be a burden for some, the Department of Health has to balance its duty to effectively and responsibly carry out its statutory duties of oversight and implementation of the program and the needs of patients along with the concerns of the producers and other interested parties.

The Medical Cannabis Program relies entirely on fees, and does not receive legislative appropriation for its administration. The Program is unable at this time to continue to meet increased administrative burdens without additional funding. The proposed fees would be used to hire staff to support the administrative and oversight responsibilities of the program, ensure that patients have access to safe product and improve the outreach and education components of the program.

Instituting annual patient registry fees punishes the most vulnerable patients in the program, and will likely lead to a significant decrease in the number of program applicants. Proposed rules already include substantial increases in fees for producers, which should be plenty to effectively run the program. In fact, in 2013 the MCP *returned* excess revenue to the New Mexico General Fund. In written communication dated June 13, 2013 the Department confirms that the medical cannabis program gave \$162,992 in unused funds collected from producers back to the New Mexico General Fund.

If in fact the Department is in need of additional funds, on top of the producers fees, in order to run the program, it should not be on the backs of patients. Pursuing a legislative appropriation is a much more appropriate avenue. Balancing administrative duty on the backs of sick people is egregious and points to the fact that these changes are meant to be punitive. A patient registry fee would unfairly restrict access to the program.

Furthermore, the department should produce a detailed budget that explains *exactly* what additional funds would be used for.

## **5. Is it true that the State is increasing the price of medical cannabis?**

DOH Answer: **No.** The Department of Health does not set prices for medical cannabis.

No, the department does not set the price of medical cannabis. However, producers facing increases in annual fees and administrative costs could easily lead to patients seeing higher prices for medicine.

## **6. Is it true that the program is ending and that patients are leaving?**

DOH Answer: **No.** Since the program's inception there have always been a percentage of patients who do not renew for various reasons. The number of overall patients has increased

since the inception of the program and the number of qualifying conditions has also been increased by the Department during the last two years.

The New Mexico Medical Cannabis Program is thriving, and the proposed rules are intended to meet the needs of the program as it has evolved. In May 2013 there were 9,210 active patients and as of May 30, 2014 there are 11,237 active patients in the program.

Although the number of patients is growing, the program is not without its problems. Many patients report extreme difficulty accessing certifying providers, stricter interpretations and application requirements, poor customer service by the department and lack of access to medicine in areas beyond the Albuquerque metro area and Santa Fe. These problems have lead many who enroll in the program to let their active status lapse, even though they still need medical cannabis.

## **7. Why is the Department proposing to decrease the plant count for personal production licenses?**

DOH Answer: Personal production licenses (PPL) are the one area where the Department most often encounters law enforcement concerns regarding diversion of cannabis. To address this issue, and to also ensure that patients do not exceed the adequate supply of 170 units/six ounces over three months, the Department has proposed a decrease in the number of plants that a qualified patient may possess under a PPL. This plant count proposed is consistent with the number of plants allowed in medical cannabis programs in other states.

The Department also anticipates that the proposed increases in plant totals for non-profit producers will enable non-profit producers to grow and sell significantly more seedlings, and that this will enable qualified patients who hold personal production licenses to grow healthier, more robust plants.

First, the department has not shown any evidence that patients with PPLS are diverting medicine. Second, decreasing the plant count for personal production is not likely to have the desired effect of decreasing diversion, if in fact this practice exists. If people are breaking the rules and diverting medicine, changing the rules is not likely to change that behavior.

To ensure that patients do not exceed the adequate supply limit, regulatory changes should address the known problem facing patients who grow one outdoor crop per year. A provision should exist that allows patients some method to store medicine in excess of the three month adequate supply. The existing requirement to turn excess medicine over to law enforcement for destruction is nonsensical.

Cutting the number of plants allowed in a personal garden in half because “increases in plant totals...will enable non-profit producers to grow and sell significantly more seedlings” ignores the fact that many patients grow one outdoor crop. The fact that seedlings may be more readily available from LNPs is neither here nor there when you have a single growing season.

The number of plants currently allowed is already low and does not take into account the high potential for crop failure due to pests or other contaminants. In fact the proposed plant count is NOT consistent with other states that allow personal cultivation. The most common number of plants allowed is six (6) (AK, CA, CO, ME). Michigan, similar to New Mexico in having a single growing season allows 12 plants. Rhode Island also allows up to 12 plants (or a caregiver can cultivate collectively for patients up to 24 plants for two or more patients). Of the 15 states that allow home cultivation, the only state to limit patients to 2 plants, as DOH proposes is Vermont.

Furthermore, there is more information becoming known about the beneficial effects of juicing leaves. The NM Medical Cannabis Patients' Association believes that patients should be allowed thirty plants to enable patients to juice a plant a day. Juicing plants is gaining in popularity because it is a way to derive benefits of cannabis without smoking it and without a psychoactive high. Patients who make oils and edible products also need greater amounts of plant material to make effective products.

7.34.4.17 Which proposes limits a personal productions to just one location *either indoors or outdoors* prevents patients from being able to have a crop outdoors in the summertime and one indoors in the winter time. Current rules specify "one location," which is understood to mean the garden is at one residence, and allows the flexibility within that location for the cultivator to move the garden as required by weather.

## **8. Why is the Department proposing to require criminal history screening for persons who apply for personal production licensure?**

DOH Answer: This change is being proposed to ensure that medical cannabis is used only by qualified patients for their personal use. The Department is proposing to require criminal history screening for qualified patients who wish to grow cannabis using a personal production license. Persons who have been convicted of violating the controlled substances act may be prohibited from holding personal production licensure.

7.34.4.8 H Which would require patients to pay for nationwide and statewide criminal background checks. A person's history has nothing to do with medical need and background checks should not be forced upon patients seeking to grow their own medicine. This is one of the most offensive proposed changes, especially for veterans, many of whom have held military security clearances.

Additionally, patients have legal protection under LECUA and should not be entered into any federally run system for any type of check in order to participate in the State's medical cannabis program. This proposed change is insulting to all patients and has no merit.

## 9. Does the Department intend to require criminal history screening of all applicants for enrollment?

DOH Answer: **No.** The Department is not proposing to require criminal history screening in order for a person to enroll as a patient in the Medical Cannabis Program.

7.34.3.10 The department may not *require* criminal history screening for all patients, but it reserves the right to ask for “bio-metric” information from any applicant it chooses. Again, like the proposed criminal background check requirement for obtaining a PPL, this proposed provision seeks to demonstrate criminality, which has NOTHING to do with whether a person has a medical condition that qualifies them to participate in the medical cannabis program.

## 10. The Department is proposing to change the measurement of “adequate supply” limits for the possession of cannabis from ounces to units. How does this work and why the change?

DOH Answer: With respect to dried cannabis leaves & flowers, the 6-ounce limit for a 3 month period has not changed.

However, the Department is proposing to change the measurement description from ounces to “units”. The change to a “unit”-based system is proposed to address new methods of manufacturing and ingestion of cannabis-derived products (CDPs) that were not widely known when the current Rules were initially created. These include such products as concentrated CDPs.

A “unit” is identified in the rule as one gram of dried cannabis, or 0.2 grams of THC in cannabis-derived products. Thus, for cannabis-derived products, the amount of THC, the primary psychoactive ingredient, is used to determine the unit equivalent.

The proposed limits would look like this:

- Dried leaves & flowers = 170 units = 6 ounces = 170 grams (unchanged from existing rule)
- Cannabis-derived products/chocolate bar = 170 units = .2 grams/200 milligrams X 170 = 34 grams of THC
- Concentrate/wax = 170 units = .2 grams/200 milligrams X 170 = 34 grams of THC at no more than 60% by weight

First and foremost, any change to the language regarding adequate supply must be done in consultation with the Medical Advisory Board, which is tasked with making recommendations to the Department regarding this matter. Current regulations do not specifically require particular concentrations, therefore newly defined “unit” measurements for cannabis derived products cannot be made consistently. DOH should not be attempting to police patients who, for reasons of income or residential location may find it necessary to purchase medicine in bulk.

## **11. Why is the Department proposing to limit the amount of THC in high THC products?**

DOH Answer: The Department is concerned that the documented risks of high THC products outweigh the benefits at this time for the general population of patients in the Program. The proposed 60% cap on THC levels in cannabis derived products is also generally consistent with the maximum quantity of THC that is contained in most cannabis-derived products, and the Department anticipates that the proposed 60% cap would not impact the availability of cannabis-derived products for qualified patients.

It's also important to note that if a qualified patient needs a higher concentration of THC due to their medical condition, the patient can request an exception to the rule by submitting a statement from a certifying practitioner verifying that this is medically needed.

According to cannabis extract manufacturing experts, the typical quantity of THC in an extracted concentrate can easily be 80%. Setting a limit of 60% THC by volume is not rational and is cause for concern. Additionally, although an exemption is allowed so that patients who need a stronger medicine is included, it is unlikely that any producer will stock such a product if the general program participant cannot purchase it. Finally, many patients won't know that they need to ask their medical provider for an exemption and thus may be unable to access the appropriate medicine. This creates more work for everyone involved and there is no medical reason for such a limit as medical cannabis will not cause cardiac arrest or otherwise cause death.

For additional information please contact Jessica Gelay at 505-983-3277 or [jgelay@drugpolicy.org](mailto:jgelay@drugpolicy.org)

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June 12, 2014

Ms. Retta Ward, Cabinet Secretary  
New Mexico Department of Health  
Harold Runnels Building  
1190 St. Francis Drive  
Santa Fe, New Mexico

RE: Proposed Rule Changes to 7.34.2, 7.34.3 and 7.34.4 NMAC

Dear Secretary Ward:

The Drug Policy Alliance (DPA) is the nation's leading organization working to promote alternatives to punitive drug laws. We advocate for new drug policies that are grounded in science, compassion, health and human rights. DPA has assisted in the drafting, passage, and implementation of medical marijuana legislation in a number of jurisdictions nationwide. DPA's New Mexico office was deeply involved in the drafting, passage, and implementation of the Lynn and Erin Compassionate Use Act (LECUA) enacted by the New Mexico legislature in 2007 establishing the New Mexico Medical Cannabis Program (NMMCP).

DPA's Office of Legal Affairs has litigated numerous issues in state and federal courts to ensure that state medical marijuana laws are implemented properly and that medical marijuana patients and recommending physicians and practitioners are properly protected.

DPA is committed to the continuing efficacy of the LECUA consistent with the original intents and purposes of that law. It is against this backdrop that DPA offers the comments below on the NMMB's proposed rules.

**I. The Proposed Regulations Will Deprive Many Parents of the Ability to Provide Medicine to their Seriously Ill Children.**

New Mexico's medical marijuana program was established so that patients, including minors, could obtain critically needed medicine. Current regulations allow any qualified patients to obtain a personal production license, or to have that license issued to their primary caregiver. (7.34.3.7.AA NMAC) For patients who are children, this means that parents can grow their child's medical cannabis at home.

The Martinez Administration's proposed regulations, however, restrict the issuance of personal production licenses only to qualified patients preventing caregivers from growing medicine on behalf of patients, prohibiting many parents from providing medicine for their children. (7.34.3.7.FF) As a result of these restrictions, New Mexican families with a sick or dying child who cannot afford to purchase medical cannabis from a licensed producer, who do not have adequate or consistent access to a licensed producer because of where they live, or who rely on a particular strain of medical cannabis not offered by a nearby producer, would be legally prevented from cultivating cannabis for their child.

Furthermore, this proposed change, if enacted, would violate the purpose and intent of New Mexico's Lynn and Erin Compassionate Use Act. As importantly, it would undermine the health and well-being of low-income and rural families across the state.

## **II. The Proposed Regulations Unfairly and Illegally Place New and Crushing Burdens on Poor Families.**

New Mexico's Lynn and Erin Compassionate Use Act is intended to ensure that New Mexicans can have adequate access to critically important medicine. (N.M.S.A. 1978, § 26-2B-2)

The Martinez Administration's proposed regulations seek to impose new, unprecedented and potentially crippling financial burdens on low-income families, one or more of whose members is a qualified patient in need of medical cannabis. The proposed regulations, if enacted, would impose substantial fees for applying for state-issued registry identification cards (\$50 or \$25 dollars if patient is on Medicaid) and additional fees for replacing lost or stolen cards (\$50). (7.34.3.10, 7.34.3.11) Low-income families in New Mexico already struggle with crushing medical costs. Even though the state agency already plans to increase its revenue by millions of dollars through levying higher fees on prospective and current licensed medical cannabis producers, it nevertheless would saddle poor patients and their families with an even higher financial burden.

When the proposed price increase for patient registration cards is combined with the proposed restrictions on cannabis cultivation, the Martinez Administration's proposed changes create an extreme hardship for low-income New Mexicans. By effectively obstructing low-income families from accessing critically important medicine, they are deeply at odds with the intent of underlying law and fly in the face of New Mexican values.

### **III. The Proposed Regulations Give a Lone, Non-Certifying Practitioner Power to Veto a Patient's Legal Access to Medical Cannabis Even Though the Patient's Other Treating Physicians Consider Medical Cannabis Appropriate.**

New Mexico's Lynn and Erin Compassionate Use Act intends that a patient who suffers from one or more qualifying conditions and who is receiving medical care from a New Mexico medical practitioner may qualify under the state's medical cannabis if that practitioner, pursuant to their professional judgment, believes that medical cannabis is an appropriate treatment for the patient's condition. (N.M.S.A. 1978, § 26-2B-3)

It is also a fact of life that New Mexicans who suffer from one or more qualifying conditions often receive medical care from more than one provider because of the serious and complex nature of their illness. The Martinez Administration's proposed regulations, if enacted, would allow a single medical provider to override the considered judgments of each and every other medical provider of a patient regarding medical cannabis. (7.34.3.11.D) This means that if one or more treating physicians of a seriously ill patient believe that medical cannabis could alleviate the patient's suffering, but one of the patient's medical practitioners is unalterably opposed to medical cannabis – for example, because they lack medical knowledge about cannabis, lack knowledge about the full extent of the patient's medical problems, or for political, religious or some other reason – the patient would be rendered ineligible to obtain the protections and benefits offered by New Mexico's medical cannabis law.

Under current regulations, a patient's application for a registry card can be denied by the Department if the certifying doctor determines that medical cannabis use would be detrimental to the patient's health. (7.34.3.10.D NMAC) The Department's newly proposed regulations allow *any* medical provider, not just a patient's certifying practitioner, who is identified in the patient's application or supporting documents to make this determination (7.34.3.11.D), thwarting the patient's application by opposing it. The proposed regulations also empower the Department to contact any and all medical providers identified in the patient's medical paperwork and solicit objections to medical cannabis from those practitioners, without the knowledge of the patient. This creates a system in which one medical provider could have absolute veto power over the professional opinions of medical practitioners who support medical cannabis as a treatment for approved debilitating medical conditions. This system is in direct opposition to a fundamental concept in medical ethics: respect for patient autonomy. Patients have the right to make decisions about their medical care, and health care providers cannot make these decisions for their patient. Permitting a single medical provider to deny a patient a treatment that has been approved by another medical provider is an affront to the patient's right to use their best judgment when given a range of treatment options.

This proposed change to the determination of patient-eligibility for New Mexico's cannabis program not only flouts fundamental principles of patient autonomy, it is inconsistent

with the intent of the Lynn and Erin Compassionate Use Act by vesting undue, unwarranted and largely unchecked discretion in the hands of the Department of Health to override the considered medical judgments of patients' health practitioners.

#### **IV. The Proposed Regulations Establish New and Serious Disciplinary Actions that Rest on Vague and Ill-Defined Violations.**

The Department's proposed changes to disciplinary actions raise a host of procedural problems and threaten to expose patients and their caregivers to overly harsh and unjust punishment, all without adequate legal notice. The proposed new grounds that authorize the agency to take disciplinary action against patients and caregivers are worded vaguely and broadly, opening the door for abuse of administrative power and the imposition of harsh punishment, including, but not limited to, the arbitrary revocation of rights established under the Lynn and Erin Compassionate Use Act. (7.34.3.16.B) The proposed regulations, if enacted, would thus enable a Department hostile to the proper working or continued vitality of the Lynn and Erin Compassionate Use Act to work great mischief in the daily operation of the Act.

For example, the Department's proposed regulations:

- Lack a well-defined administrative review process for patient and primary caregiver registry applications denied for failure to submit a completed application or failure to meet a submittal requirement (7.34.3.11.D);
- Subject patients and primary caregivers to new disciplinary actions by the Department, including summary revocations, which allow the Department to revoke a patient's or caregiver's rights under the Lynn and Erin Compassionate Use Act absent an investigation or hearing (7.34.3.15.A);
- Fail to provide guidance regarding what disciplinary actions apply to which types of violations (7.34.3.15);
- Employ overly vague language regarding violations, including the failure to adequately define the term "impeding" (in reference to a monitoring visit) (7.34.3.15.A(3)) and the phrase "failure to adhere to any acknowledgement, verification, or other representation made to the department" (in reference to any and all interactions with Department staff) (7.34.3.15.A(4)).

#### **V. The Proposed Regulations Remove Essential Departmental Oversight and Program Transparency.**

The Martinez Administration's proposed regulations seek to conceal the workings of the Medical Cannabis Program from patient and public scrutiny, while enriching program coffers by several million dollars. In so doing, the proposed regulations constitute bad government and will almost certainly result in mismanagement, misspending and unnecessary suffering.

The Department's proposed regulations eviscerate current Department oversight and transparency in the state's medical cannabis program (7.34.3.18 NMAC). By removing the requirement for regularly-issued assessment reports, the proposed regulations relieve the Department of its duty to properly and timely evaluate the medical cannabis program that it runs, and deprives taxpayers and the broader public the information necessary to determine whether this program operates consistently with the purposes of the Lynn and Erin Compassionate Use Act and the health and safety needs of New Mexicans.

#### **VI. The Department Failed to Consult with the Medical Advisory Board in Developing the Proposed Regulations.**

The Lynn and Erin Compassionate Use Act established the Medical Advisory Board partly for the purpose of providing the Department with valuable advice on promulgating rules regarding patient registry and determining an adequate supply of medicine for patients. However, as confirmed by both the Department and the Medical Advisory Board, the Department failed to consult with the Medical Advisory Board in developing the proposed regulations. The Department's failure to seek advice from this established board of medical experts is indicative of the Department's lack of meaningful deliberation over the proposed regulations' effects on New Mexico's medical cannabis patients.

New Mexico enacted the Lynn and Erin Compassionate Use Act for the purpose of allowing all qualified patients access to critically important medicine. The Martinez Administration's proposed medical cannabis regulations fail to live up to this intent and the purpose of the Lynn and Erin Compassionate Use Act. The proposed regulations threaten patient access to critical medicine and target vulnerable children and low-income families in particular. The Martinez Administration's proposed changes to current medical cannabis regulations further impose vaguely-worded and harsh disciplinary actions for equally vague violations. In addition, the proposed regulations strip the Department of oversight needed to ensure that the Department is in fact carrying out the purpose and intent of the Lynn and Erin Compassionate Use Act by safeguarding patient access to their medicine and proper, effective and efficient expenditure of taxpayer dollars towards promoting health and safety.

Should the New Mexico Department of Health move forward with the proposed

regulations as currently conceived, the Department will be in serious violation of the Lynn and Erin Compassionate Use Act and would open itself to a host of legal challenges by and on behalf of New Mexico patients, their caregivers and advocates.

Sincerely,

A handwritten signature in black ink, appearing to read 'Dan', with a long horizontal flourish extending to the right.

Daniel N. Abrahamson  
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Drug Policy Alliance  
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# Recommendations to Regulators: Cannabis Laboratory Operations

## July 2013

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The legal status of products derived from *Cannabis* spp. is in a transitional phase in many states in the United States. Where products that contain marijuana and its derivatives were formally illegal throughout the U.S., many state laws now allow adult use of these either for medical purposes only or for any social adult use.

The American Herbal Products Association (AHPA) chartered a Cannabis Committee in 2010 with an express purpose to address issues related to the safe use and responsible commerce of legally-marketed products derived from *Cannabis* species.

To meet its purpose the AHPA Cannabis Committee is in the process of developing recommendations to regulators for best practice rules to address four operational stages of *Cannabis* production and distribution: cultivation; manufacturing and related operations; laboratory practice; and dispensing.

The present document provides recommendations to regulators in the specific area of Cannabis Laboratory Operations, and is presented in the form of a draft regulation. These recommendations are intended to establish a basis for oversight of entities performing analysis of marijuana and hemp products. Developed as a complement to existing good laboratory practices, these recommendations focus on the personnel, security, sample handling and disposal, and data management and reporting activities that may be unique to laboratories analyzing cannabis samples.

The AHPA Cannabis Committee offers this document to states and local municipalities where use of marijuana is allowed under local law such that regulatory authorities can consider the adoption of these recommendations, in whole or in part, as the basis for development of jurisdiction-specific regulations.

Please contact AHPA for further information or to discuss this document further.

Point of contact: Michael McGuffin

P: 301-588-1171 x201 / E: [mmcguffin@ahpa.org](mailto:mmcguffin@ahpa.org)

**PART [X] – Cannabis laboratory operations**

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## SUBPART A – GENERAL PROVISIONS

### Section 1.1 Subject operations

- (a) Except as provided in paragraph (b) of this section, any person, group of persons, or business entity that conducts analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products in the jurisdiction in which this part applies<sup>1</sup> is a laboratory operation and is subject to this part.
- (b) A cannabis cultivation, manufacturing, or dispensing operation which performs analytical testing solely as a function of its internal operations is not subject to this part.

### Section 1.2 Other statutory provisions and regulations

In addition to this part, laboratory operations must comply with all other applicable statutory provisions and regulations related to cannabis laboratory operations in the jurisdiction in which this part applies, and related to all other business activities undertaken in conducting a laboratory operation.

### Section 1.3 Definitions

The following definitions apply to this part:

*Cannabis* means any of the aerial parts of a plant in the genus *Cannabis*, and does not mean hemp.

*Cannabis-derived product* means a product, other than cannabis itself, which contains or is derived from cannabis, and does not mean a product that contains or is derived from hemp.

*Cannabis waste* means cannabis or cannabis-derived product discarded by a laboratory operation.

*Compliant business* means a business that has met all legal requirements to obtain, possess, manufacture, distribute, or sell cannabis and cannabis-derived products in the jurisdiction where this part applies.

*Compliant individual* means a person who has met all legal requirements to obtain and use cannabis or cannabis-derived product in the jurisdiction where this part applies.

*Controlled access area* means an area in a laboratory facility designed to physically prevent entry by anyone except authorized personnel.

*Controlled substance* means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of 21 U.S.C. 802. It does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

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<sup>1</sup> This term “in the jurisdiction where this part applies” may be replaced throughout with the name of the specific jurisdiction.

*Hemp* means any part of a plant in the genus *Cannabis*, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 (three-tenths) percent on a dry weight basis.

*Hemp-derived product* means a product, other than hemp itself, which contains or is derived from hemp.

*Identity* means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of cannabis and hemp, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as other characteristics as applicable and as stated on the label or other labeling. In the case of cannabis-derived products or hemp-derived products, identity means the product name, strength, key features of its form or composition, grade, and other characteristics as applicable and as stated on the label or other labeling.

*Laboratory facility* means the physical location(s) of a laboratory operation.

*Laboratory operation* means a person, group of persons, or business entity that conducts analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products.

*Macroscopic examination* means using the naked eye or minor magnification (e.g., with a 10x magnifying glass) to observe and/or measure a sample or object.

*May* is used to indicate an action or activity that is permitted.

*Microscopic examination* means using a microscope to view samples and objects that cannot be seen with the unaided eye (objects that are not within the resolution range of the normal eye).

*Must* is used to state a requirement.

*Organoleptic examination* means testing by using sense organs to evaluate flavor, aroma, appearance, or texture.

*Primary reference standard* means a reference standard whose purity is determined with a high degree of confidence through comprehensive analysis using multiple test methods based on differing principles, such as HPLC or GC, MS, NMR, Karl-Fisher, etc.

*Purity* means the relative freedom from extraneous matter, contaminants, or impurities, whether or not harmful to the consumer or deleterious to the product.

*Secondary reference standard* means a reference standard whose purity is established by assaying it against a primary standard.

*Should* is used to state recommended or advisory procedures.

*Strength* means (a) for cannabis or hemp, the concentration or amount of specific chemical constituents or groups of chemical constituents; (b) for cannabis- or hemp-derived products, the concentration or amount of cannabis or hemp ingredient and, where applicable, of specific chemical constituents or groups of chemical constituents; or (c), for cannabis extracts, the ratio of the input quantity of crude cannabis, expressed on a dry weight basis, to the output quantity of final extract.

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*Test sample* means the specific portion of cannabis, cannabis-derived product, hemp, or hemp-derived product submitted for analysis.

*Volumetric solution* means a solution used for volumetric analysis, such as titration, wherein the content of analyte is determined by reacting the analyte with a known quantity of standardized reagent.

## **SUBPART B – LABORATORY FUNCTIONS**

### **Section 2 Scope of laboratory functions**

- (a) Laboratory operations may conduct any analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products.
- (b) Analytical testing of cannabis or hemp may include, among other things, analysis for:
  - (1) Identity;
  - (2) Purity, such as analysis of:
    - (i) Heavy metals;
    - (ii) Microbiological organisms (e.g., total plate count; pathogens; yeasts; molds; etc.) or microbial toxins;
    - (iii) Residues of pesticide or plant growth regulators;
    - (iv) Residual solvents;
    - (v) Foreign matter.
  - (3) Strength, such as analysis of:
    - (i) Cannabinoid content;
    - (ii) Terpenoid content.
  - (4) Other quality factors, such as weight loss on drying, oil content, ash, acid-insoluble ash, etc.
- (c) Analytical testing of cannabis-derived products may include, among other things:
  - (1) Any of the analyses identified in paragraph (b) of this section that are relevant to such product;
  - (2) Determination of any factor of a product's composition or nutritional content.
- (d) Laboratory operations may utilize any appropriate tests and examinations in its analyses, including:
  - (1) Gross organoleptic analysis;
  - (2) Macroscopic analysis;
  - (3) Microscopic analysis;

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- (4) Chemical analysis;
- (5) Genetic (DNA) analysis; or
- (6) Other scientifically valid methods.

## **SUBPART C – PERSONNEL**

### **Section 3 Personnel training**

- (a) Each person engaged in a laboratory operation must:
- (1) Have education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions.
  - (2) Have records of any training received for the performance of all assigned functions.
- (b) Laboratory operations should provide all employees with training that includes:
- (1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and
  - (2) Information on U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees.

## **SUBPART D – FACILITIES**

### **Section 4.1 Physical facilities**

- (a) Laboratory operations must:
- (1) Be operated in adherence with any regulation in the jurisdiction in which this part applies that is relevant to its specific operations, including:
    - (i) Locations and zoning;
    - (ii) Business hours;
    - (iii) Parking;
    - (iv) Drive-through services; and
    - (v) Signage.
  - (2) Be maintained in a clean and orderly condition;
  - (3) Be equipped with such utensils and equipment as are necessary to conduct all operations that occur at the laboratory facility; and
  - (4) Provide adequate space for laboratory operations, sample storage, and document storage.

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## **Section 4.2 Security**

- (a) Laboratory operations must establish and adhere to such security procedures as are provided by applicable regulation in the jurisdiction in which this part applies.
- (b) Laboratory operations should:
  - (1) Provide additional security as needed to protect the employees during working hours and in a manner appropriate for the community where it operates; and
  - (2) Provide training to make all employees aware of the operation's security procedures, and each individual employee's security roles and responsibilities.
- (c) Laboratory operations analyzing cannabis, cannabis-derived product, hemp, or hemp-derived product samples must be equipped with one or more controlled access areas for storage of the following:
  - (1) Cannabis and cannabis-derived test samples;
  - (2) Cannabis waste;
  - (3) Reference standards for analysis of cannabinoids; and
  - (4) Any other controlled substances.
- (d) Access to controlled access areas must be limited by locks, electronic badge readers, biometric identifiers, or other means.
- (e) Appropriate steps must be taken to ensure access privileges to the laboratory facility and to controlled access areas, as applicable, are revoked for personnel who are no longer employed by the operation.
- (f) There must be written procedures for security.

## **SUBPART E – SAMPLE RECEIPT, HANDLING, AND DISPOSITION**

### **Section 5.1 Sample receipt**

- (a) Laboratory operations may receive test samples from any compliant business or compliant individual, or may be contracted to collect test samples on behalf of those entities.
- (b) Laboratory operations should establish and implement policies for:
  - (1) Collecting test samples in a manner that ensures that the test sample accurately represents the material being sampled; and
  - (2) Other parameters affecting sample preparation, documentation, and transport, including, if applicable:
    - (i) Accepted test sample types;

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- (ii) Minimum test sample size;
- (iii) Recommended test sample container;
- (iv) Test sample labeling;
- (v) Transport and storage conditions, such as refrigeration if required;
- (vi) Other requirements, such as use of preservatives, inert gas, or other measures designed to protect sample integrity; and
- (vii) Use of sample chain of custody forms.

(c) Laboratory operations must:

- (1) Record each receipt of a test sample. This record must include:
  - (i) The name and contact information of any compliant business or compliant individual that was the source of the sample;
  - (ii) An appropriately complete and specific description of the sample;
  - (iii) The date of receipt of the sample;
  - (iv) A statement of the quantity (weight, volume, number, or other amount) of the sample; and
  - (v) A unique sample identifier for the sample.
- (2) Inform each compliant business and compliant individual that submits test samples of the policies established in paragraph (b) of this section.

### **Section 5.2 Sample handling and disposal**

- (a) Laboratory operations must establish sample handling procedures for the tracking of test samples through the analytical process (by weight, volume, number, or other appropriate measure) to prevent any diversion.
- (b) Laboratory operations must store each test sample under the appropriate conditions to protect the physical and chemical integrity of the sample.
- (c) Analyzed test samples consisting of cannabis or cannabis-derived product must be appropriately segregated, controlled, and held in a controlled access area pending destruction or other disposal.
- (d) Any portion of a cannabis or cannabis-derived test sample that is not destroyed during analysis must be:
  - (1) Returned to the same compliant individual or compliant business that provided the sample;
  - (2) Stored and retained in conformity with a laboratory operation's sample retention policy, if any; or
  - (3) Destroyed in a manner which prevents unauthorized use. Such destruction must be documented and witnessed by at least two employees, one of whom

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must be supervisory, managerial, or quality control personnel; except that if video surveillance is used, only one employee is required.

- (e) Any portion of a hemp or hemp-derived product test sample that is not destroyed during analysis may be:
- (1) Returned to the same compliant individual or compliant business that provided the sample;
  - (2) Stored and retained in conformity with a laboratory operation's sample retention policy, if any; or
  - (3) Disposed of in any appropriate manner.

## **SUBPART F – EQUIPMENT AND REAGENTS**

### **Section 6.1 Equipment**

- (a) Equipment used for the analysis of test samples must be adequately inspected, cleaned, and maintained. Equipment used for the generation or measurement of data must be adequately tested and calibrated on an appropriate schedule, as applicable.
- (b) Laboratory operations must document procedures setting forth in sufficient detail the methods and schedules to be used in the routine inspection, cleaning, maintenance, testing, and calibration of equipment, and must specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The procedures must designate the personnel responsible for the performance of each operation.
- (c) Records must be maintained of all inspection, maintenance, testing, and calibrating operations. These records must include the date of the operation, the person who performed it, the written procedure used, and any deviations from the written procedure. Records must be kept of non-routine repairs performed on equipment as a result of failure and malfunction. Such records must document the nature of the repair, how and when the need for the repair was discovered, and any remedial action taken in response to the repair.
- (d) Computer systems used for the analysis of samples, retention of data, sample tracking, calibration scheduling, management of reference standards, or other critical laboratory management functions should ensure that electronic records, electronic signatures, and handwritten signatures executed to electronic records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

### **Section 6.2 Reagents, solutions, and reference standards**

- (a) Analytical reagents, solutions, and reference standards must be:

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- (1) Labeled to indicate identity, date received or prepared, and expiration or requalification date, and, where applicable, concentration or purity, storage requirements, and date opened.
  - (2) Stored under appropriate conditions to minimize degradation or deterioration of the material.
  - (3) Be within their expiration or requalification dates at the time of use.
- (b) Deteriorated or outdated reagents and solutions must be properly discarded.
- (c) Laboratory operations may acquire commercial reference standards for cannabinoids including, but not limited to:
- (1) Tetrahydrocannabinolic acid (THC-acid);
  - (2) Delta-9 tetrahydrocannabinol ( $\Delta^9$  THC);
  - (3) Cannabidiolic acid (CBD-acid);
  - (4) Cannabidiol (CBD);
  - (5) Cannabichromene (CBC);
  - (6) Cannabigerol (CBG);
  - (7) Cannabinol (CBN); and
  - (8) Delta-8 tetrahydrocannabinol ( $\Delta^8$  THC).
- (d) Laboratory operations may elect to internally produce reference standards. When internally produced, laboratory operations should utilize standard analytical techniques to document the purity and concentration of the internally produced reference standards.
- (e) Laboratory operations must obtain or, for internally-produced standards, create a certificate of analysis (COA) for each lot of reference standard. Each COA must be kept on file and the lot number of the reference standard used should be recorded in the documentation for each analysis, where applicable.

## **SUBPART G – ANALYSIS OF SAMPLES**

### **Section 7.1 Analytical procedures**

- (a) Laboratory operations must:
- (1) Utilize analytical methods that are fit for purpose in their testing of cannabis, cannabis-derived products, hemp, and hemp-derived products.
  - (2) Require analysts to demonstrate proficiency in the performance of the analytical methods used.
  - (3) Have written procedures for the analytical method used for the analysis of each test sample, including for each of the following:
    - (i) Sample preparation;

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- (ii) Reagent, solution, and reference standard preparation;
  - (iii) Instrument setup, where applicable;
  - (iv) Standardization of volumetric reagent solutions, as applicable;
  - (v) Data acquisition; and
  - (vi) Calculation of results.
- (4) Specify, as applicable to each analytical method used, requirements for accuracy, precision, linearity, specificity, limit of detection, limit of quantitation, and other data quality parameters.
- (5) Ensure that no deviations from approved protocols or standard operating procedures are made during any analytical process without proper authorization and documentation.
- (b) Laboratory operations should use only primary standards or secondary standards for quantitative analyses.

### **Section 7.2 Recording of analytical data**

- (a) All data generated during the testing of a test sample, except those that are generated by automated data collection systems, must be recorded directly, promptly, and legibly in ink. All data must be annotated with the date of entry and signed or initialed by the person recording the data. Any change in entries must be made so as not to obscure the original entry, must indicate the reason for such change, and must be dated and signed or initialed at the time of the change.
- (b) In automated data collection systems, the individual responsible for direct data input must be identified at the time of data input. Any change in automated data entries must be made so as not to void or delete the original entry, must indicate the reason for change, must be dated, and the responsible individual must be identified.

### **Section 7.3 Data review**

For each final result reported, laboratory operations must verify that:

- (1) Any calculations or other data processing steps were performed correctly;
- (2) The data meet any data quality requirements such as for accuracy, precision, linearity, etc.;
- (3) Any reference standards used were of the appropriate purity and within their expiration or requalification dates;
- (4) Any volumetric solutions were properly standardized before use;
- (5) Any test or measuring equipment used has been properly tested, verified, and/or calibrated and is within its verification or calibration period.

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#### **Section 7.4 Data storage**

- (a) All raw data, documentation, protocols, and final reports associated with analysis of a test sample must be retained for two years from the date of the completion of analysis.
- (b) Laboratory operations must maintain the records identified in paragraph (a) of this section, either on the laboratory operation's premises or remotely. Such records must be maintained:
  - (1) In a manner that allows retrieval as needed;
  - (2) Under conditions of storage that minimize deterioration throughout the retention period; and
  - (3) In a manner that prevents unauthorized alteration.
- (c) Laboratory operation must designate an individual as responsible for records maintenance.
- (d) Only authorized personnel may enter or access the maintained records.

#### **Section 7.5 Data reporting**

- (a) All analytical results related to any test sample are the property of the compliant business or compliant individual which provided the sample, unless contracts or other written agreements specify otherwise.
- (b) A laboratory report given to a compliant business or compliant individual must contain the following information:
  - (1) Date of receipt of the test sample;
  - (2) Description of the type or form of the test sample (leaf, flower, powder, oil, specific edible product, etc.);
  - (3) The unique sample identifier as established in accordance with subparagraph 5.1 (b)(1)(v) of this part;
  - (4) Information on whether sampling was performed by the laboratory operation, by the compliant business or individual which submitted the test sample, or by a third-party;
  - (5) Date on which analysis occurred;
  - (6) The analytical method used, including at a minimum identification of the type of analytical equipment used (e.g., GC, HPLC, UV, etc.);
  - (7) The analytical results, including units of measure where applicable;
  - (8) The identity of the supervisory or management personnel who reviewed and verified the data and results and ensured that data quality, calibration, and other applicable requirements were met;
  - (9) The name, address, and contact information of the laboratory operation.

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- (c) If a laboratory operation reports cannabinoid values other than those directly measured in the test sample, the laboratory report must include the following:
  - (1) All calculations or conversion factors used to determine the reported non-measured results; and
  - (2) Written explanation of any assumptions, if any, associated with the reported non-measured results, such as the route of consumption of the product represented by the test sample.
- (d) The laboratory report must state that reported analytical results apply only to the test sample received.



# Recommendations to Regulators: Cannabis Cultivation and Processing Operations

November 2013

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The legal status of products derived from *Cannabis* spp. is in a transitional phase in many states in the United States. Where products that contain marijuana and its derivatives were formally illegal throughout the U.S., many state laws now allow adult use of these either for medical purposes only or for any social adult use.

The American Herbal Products Association (AHPA) chartered a Cannabis Committee in 2010 with an express purpose to address issues related to the safe use and responsible commerce of legally-marketed products derived from *Cannabis* species.

To meet its purpose, the AHPA Cannabis Committee is in the process of developing recommendations to regulators for best practice rules to address four operational stages of *Cannabis* production and distribution: cultivation and processing; manufacturing and related operations; laboratory practice; and dispensing.

The present document provides recommendations to regulators in the specific area of Cannabis Cultivation and Processing Operations, and is presented in the form of a draft regulation. These recommendations are intended to establish a basis for oversight of entities that cultivate cannabis in either outdoor or indoor facilities. The document address such topics as cultivation practices, facility requirements, management of water resources, recordkeeping and information disclosure. It also establishes best practices for operations that provide post-harvest processing of cannabis, for either distribution to dispensing operations, or to manufacturing operations for the production of cannabis-derived products.

The AHPA Cannabis Committee offers this document to states and local municipalities where use of marijuana is allowed under local law such that regulatory authorities can consider the adoption of these recommendations, in whole or in part, as the basis for development of jurisdiction-specific regulations.

Please contact AHPA for further information or to discuss this document further.

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# **PART [X] – Cannabis cultivation and processing operations**

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## **SUBPART A – GENERAL PROVISIONS**

### **Section 1.1 Subject operations**

- (a) Except as provided by paragraph (b) of this section, any person, group of persons, or business entity that cultivates cannabis for retail or wholesale transactions in the jurisdiction in which this part applies<sup>1</sup> is engaged in a cultivation operation, and is subject to this part.
- (b) A compliant individual who cultivates cannabis in accordance with local and state law for personal use is not subject to this part.
- (c) Except as provided by paragraph (d) of this section, any person, group of persons, or business entity that processes cannabis for retail or wholesale transactions in the jurisdiction in which this part applies<sup>1</sup> is engaged in a processing operation, and is subject to this part.
- (d) A compliant individual who processes cannabis in accordance with local and state law for personal use is not subject to this part.
- (e) Operations subject to this part are subject only to those sections of this part that directly apply to the operations conducted, such that:
  - (1) A cultivation operation is not subject to the processing sections of this part unless processing operations are also conducted by the cultivation operation; and
  - (2) A processing operation is not subject to the cultivation sections of this part unless cultivation operations are also conducted by the processing operation.

### **Section 1.2 Other statutory provisions and regulations**

In addition to this part, cultivation operations and processing operations must comply with all other applicable statutory provisions and regulations related to cannabis cultivation and processing in the jurisdiction in which this part applies, and related to all other business activities undertaken in conducting the cultivation operation or processing operation.

### **Section 1.3 Definitions**

The following definitions apply to this part:

*Batch* means a specific quantity of cannabis harvested during a specified time period from a specified cultivation area.

*Cannabis* means any of the aerial parts of a plant in the genus *Cannabis*, and does not mean hemp.

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<sup>1</sup> This term “in the jurisdiction where this part applies” may be replaced throughout with the name of the specific jurisdiction.

*Cannabis planting material* means cannabis seeds, seedlings, cuttings, clones, etc. used by a cultivation operation to grow cannabis.

*Cannabis waste* means cannabis discarded by the cultivation operation or processing operation.

*Compliant individual* means a person who has met all legal requirements to obtain and use cannabis or cannabis-derived products in the jurisdiction where this part applies.

*Cultivate* means to grow, harvest, dry, and cure cannabis. A person, group of persons, or business entity that cultivates is a *cultivator*, and a facility where cannabis plants are cultivated is a *cultivation operation*.

*Cultivation area* means the physical location of a structure or property at which cannabis is cultivated.

*Curing* means the process by which cannabis is prepared, preserved, or finished.

*Direct-from-garden* or *caregiver operation* means a dispensing operation whereby compliant individuals obtain cannabis or cannabis-derived product directly from a cannabis cultivator.

*Dispensing operation* means a person, group of persons, or business entity that provides cannabis or cannabis-derived product to compliant individuals and includes delivery services, direct-from-garden operations, growing co-ops, and storefront operations<sup>2</sup>.

*Drying* means the dehydration of harvested cannabis.

*Firewall assembly* means a fireproof barrier used to prevent the spread of fire between or through buildings or structures.

*Greenhouse* means a permanent structure located outdoors that is completely covered by a material that allows a controlled level of light transmission.

*Greenhouse cultivation* means the cultivation of cannabis inside of a greenhouse utilizing natural sun and possible supplemental artificial lighting.

*Harvest* means to gather cannabis plants from cultivation medium or to gather specific aerial parts of cannabis plants.

*Hemp* means any part of a plant in the genus *Cannabis*, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 (three-tenths) percent on a dry weight basis.

*High intensity discharge lamps* (HID lamps) means a type of electrical gas-discharge lamp which produces light by means of an electric arc between tungsten electrodes housed inside a translucent or transparent fused quartz or fused alumina arc tube.

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<sup>2</sup> Different jurisdictions may have other terminology for the type of operation that is defined as a dispensing operation in this document.

*Identity* means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of cannabis and other botanical ingredients, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as other characteristics as applicable.

*Indoor cultivation* means cultivation of cannabis grown in a fully enclosed location in which the only light source is artificial.

*Manufacture* means to make or otherwise produce cannabis-derived product. A person, group of persons, or business entity that manufactures is a *manufacturer*, and a facility where manufacture occurs is a *manufacturing operation*.

*May* is used to indicate an action or activity that is permitted.

*Medium* means the nutritive substrate that the cultivator is using to establish a root system.

*Must* is used to state a requirement.

*Nursery facility* means an indoor, greenhouse, or outdoor cultivation operation that produces cannabis plants for the purpose of providing planting material to other cultivation operations.

*Outdoor cultivation* means cultivation of cannabis out of doors utilizing natural sunlight and possibly supplemental artificial lighting.

*Personal use* means cannabis that is produced for a compliant individual's personal medical needs and is not sold or distributed in any manner.

*Planting* means to place cannabis seeds or young plants in soil or medium.

*Process* means to trim, inspect, or grade cannabis, or to place cannabis in bulk storage or retail containers. A person, group of persons, or business entity that processes cannabis is a *processor*, and a facility where cannabis is processed is a *processing operation*.

*Processing loss* means cannabis that, for any reason, during processing is deemed unfit for human consumption.

*Propagation materials* means all substances used in the cultivation of cannabis.

*Pruning* means cutting away dead or overgrown cannabis leaves, branches or stems.

*Should* is used to state recommended or advisory procedures.

*Supplemental lighting* means artificial lighting used to help or extend the vegetative life cycle of a cannabis plant.

*Trimming* means the removal of leaves and stems from harvested cannabis.

*Variety* means a specific stock, line, or breed of cannabis, also commonly referred to as strain.

*Vendor* means a person, group of persons, or business entity that supplies cannabis or cannabis-derived product to storefront or delivery service dispensing

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operations, and may be either the direct representative of a cultivation or manufacturing operation, or may function independently of such operations by purchasing cannabis or cannabis-derived product from such operations and reselling it to other operations.

## **SUBPART B – CULTIVATION AND PROCESSING OPERATIONS**

### **Section 2.1 Types of cultivation operations**

- (a) Cannabis may be cultivated by any of the following types of cultivation operations, as defined in section 1.3 in this part:
  - (1) Indoor cultivation operations;
  - (2) Greenhouse cultivation operations;
  - (3) Outdoor cultivation operations; and
  - (4) Nursery operations.
- (b) Cultivation operations may do the following, as allowed by applicable legislation and regulation:
  - (1) Produce their own cannabis planting material; and
  - (2) Obtain cannabis planting material from any of the following:
    - (i) Other cultivation operations;
    - (ii) Nursery operations; and
    - (iii) Compliant individuals.
- (c) Processing operations may obtain cannabis from any of the following, as allowed by applicable legislation and regulation:
  - (1) Cultivation operations;
  - (2) Compliant individuals, and
  - (3) Vendors.
- (d) Cultivation operations and processing operations may distribute cannabis to any of the following, as allowed by applicable legislation and regulation:
  - (1) Other cultivation operations;
  - (2) Other processing operations;
  - (3) Dispensing operations;
  - (4) Manufacturing operations;
  - (5) Vendors; and
  - (6) Compliant individuals.

### **Section 2.2 Ancillary operations**

- (a) Cultivation operations and processing operations may also engage in other operations, including:
  - (1) Manufacturing, packaging, labeling, and holding of cannabis-derived product;
  - (2) Laboratory operations;
  - (3) Dispensing of cannabis and cannabis-derived product; and
  - (4) Cultivation and marketing of products other than cannabis.
- (b) The ancillary operations identified in section 2.2(a) may be conducted:

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- (1) At the same location as cultivation or processing, so long as such operations are permitted at this location in the jurisdiction in which this part applies; or
  - (2) At another location at which such operations are permitted in the jurisdiction in which this part applies.
- (c) The ancillary operations identified in section 2.2(a) must be conducted in compliance with all regulations relevant to such operations in the jurisdiction in which this part applies.

### **Section 2.3 Cultivation practices**

#### **(a) Propagation materials**

- (1) Propagation materials used in cultivation operations must be appropriate for use in food production.
- (2) Cultivation operations must follow the manufacturer's usage, storage, and disposal recommendations for the propagation material.

#### **(b) Pesticides**

- (1) Pesticides used in cultivation operations must be one of the following:
  - (i) Subject to a tolerance established for application to cannabis by the US Environmental Protection Agency (EPA);
  - (ii) Identified by EPA regulation as exempted from tolerance;
  - (iii) Subject to a Section 18 emergency exemption under FIFRA<sup>3</sup>; or
  - (iv) Permitted for application to cannabis in other countries as long as the pesticide is also permitted for application to one or more food crops in the United States.
- (2) Cultivation operations must follow the manufacturer's application and storage recommendations, and disposal recommendations for the pesticide product.
- (3) Cultivation operations must follow the EPA Worker Protection Standard<sup>4</sup> when preparing and applying pesticides.
- (4) Indoor cultivation operations must comply with the pesticide manufacturer's published re-entry interval time periods when applying pesticides.

#### **(c) Nutrients**

- (1) Nutrients used in cultivation operations must be appropriate for use in food production.
- (2) Cultivation operations must follow the manufacturer's application, storage, and disposal recommendations for the nutrient product.
- (3) Cultivation operations must not return unused rooting hormone to the source container.
- (4) Nitrate-based and other oxidizing fertilizers must be stored away from solvents, fuels and pesticides.

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<sup>3</sup> Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to allow an unregistered use of a pesticide for a limited time if EPA determines that an emergency condition exists.

<sup>4</sup> The EPA Worker Protection Standard can be accessed at the following website - <http://www.epa.gov/agriculture/twor.html> (accessed September 9, 2013)

- (d) Carbon dioxide
  - (1) Indoor cultivation facilities utilizing carbon dioxide must maintain levels under 2000 ppm in cultivation areas when facility personnel may be present.
  - (2) Indoor cultivation facilities utilizing carbon dioxide at levels above 2000 ppm in a sealed room must prohibit personnel from entering the cultivation area unless personal protective equipment is provided.
  - (3) All regulators and environmental control systems that regulate carbon dioxide emissions must be maintained in good working order and be serviced in accordance with the manufacturer's recommendations.
- (e) Equipment and tools
  - (1) Equipment used for measuring, regulating, or recording temperatures, pH, humidity, or other conditions related to the cultivation and processing of cannabis must be accurate and adequately maintained.
  - (2) Cultivation and processing tools that come in direct contact with cannabis plants should be disinfected as needed to protect plant health.
  - (3) Scales used for the weighing of cannabis must be calibrated at regular intervals.

#### **Section 2.4 Processing practices**

- (a) Processing operations must be maintained in a clean and sanitary condition including all work surfaces and equipment.
- (b) Processing operations must implement protocols which prevent processing contamination and mold and mildew growth on cannabis.
- (c) Employees handling cannabis in processing operations must utilize facemasks and gloves in good operable condition as applicable to their job function.
- (d) Employees must wash hands sufficiently when handling cannabis or use gloves.

#### **Section 2.5 Distribution practices**

Cannabis distributed by cultivation operations and processing operations must be accompanied by the following information:

- (1) Cultivation or processing operation's name;
- (2) Identity of contents;
- (3) Net weight of contents; and
- (4) Sufficient information to trace the cannabis to its batch.

### **SUBPART C – PERSONNEL**

#### **Section 3.1 Personnel training**

- (a) Cultivation and processing operations must:

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- (1) Ensure that each person engaged in the operation has the education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions.
  - (2) Maintain records of any training provided to employees for the performance of all assigned functions.
- (b) Cultivation and processing operations should provide all employees with training that includes:
- (1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and
  - (2) Information on U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees.
- (c) Cultivation and processing operations must implement employee hygiene protocols and training, which at a minimum address:
- (1) Policies which prohibit employees who are showing signs of illness, open wounds, sores or skin infections from handling cannabis.
  - (2) Hygiene training for employees who handle cannabis with specific attention to preventing microbial contamination.
  - (3) Hand washing requirements including washing hands with soap and hot water before beginning work, after using the bathroom and after meal breaks.
  - (4) Instructive hand washing signage must be in appropriate areas such as bathrooms, kitchens, and lunch areas, and in multiple languages as needed.

### **Section 3.2 Employee safety**

- (a) Cultivation operations and processing operations must implement safety protocols and provide all employees with adequate safety training relevant to their specific job functions, which may include:
- (1) Emergency action response planning as necessary;
  - (2) Employee accident reporting and investigation policies;
  - (3) Fire prevention;
  - (4) Hazard communication policies, including maintenance of material safety data sheets (MSDS);
  - (5) Materials handling, spill, and disposal policies;
  - (6) Job hazard analyses; and
  - (7) Personal protective equipment policies, including respiratory protection.
- (b) Cultivation operations must provide and maintain at least one emergency eye flushing station readily accessible to all employees and access to adequate eye flushing water for each employee working in field operations.
- (c) Cultivation operations and processing operations must visibly post and maintain an emergency contact list which includes at a minimum:
- (1) Operation manager contacts;
  - (2) Emergency responder contacts;
  - (3) Poison control contacts;

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- (4) Fire department contacts; and
- (5) Spill response team contacts.

## **SUBPART D – FACILITIES**

### **Section 4.1 General compliance**

- (a) Cultivation operations must comply with all legal requirements pertaining to the following as applicable:
  - (1) Restrictions on the size of the cultivation area;
  - (2) Restrictions on the number of cannabis plants allowed or other quantitative limits; and
  - (3) Light pollution restrictions.
- (b) Location of cultivation operations:
  - (1) Indoor cultivation operations may be located on any property that is zoned for such use and must be located in a fully permitted, non-residential structure that:
    - (i) Was constructed in compliance with local building code;
    - (ii) Has a complete roof enclosure supported by connecting walls extending from the ground to the roof;
    - (iii) Is secure against unauthorized entry; and
    - (iv) Minimizes unnecessary visual, auditory or olfactory evidence of indoor cannabis cultivation.
  - (2) Outdoor cultivation operations and greenhouse cultivation operations may be located on any property that is zoned for such use.
  - (3) Outdoor cultivation operations and greenhouse operations must be located within any setbacks that pertain to the property where the cultivation is taking place.
  - (4) Greenhouse cultivation structures must be fully permitted and built to code at the time of construction.
- (c) Location of processing operations
  - (1) Processing operations may be located on any property that is zoned for such use.
  - (2) Processing operations must be located within any setbacks that pertain to the property where the processing is taking place.
  - (3) Processing operation structures must be fully permitted and constructed in compliance with local building code.
- (d) Outdoor cultivation or greenhouse cultivation operations must shield or downcast supplemental lighting.
- (e) Cultivation operations and processing operations that transport cannabis must do so in a secured enclosed container or secured trunk of the delivery vehicle.

## **Section 4.2 Fire prevention**

- (a) Any room in an indoor cultivation operation in which operational supplemental lighting, ballasts, or electrical control panels are located must be constructed with a minimum of a one-hour firewall assembly.
- (b) Indoor cultivation operations must:
  - (1) Provide at least one operating fire extinguisher, and
  - (2) Provide additional fire extinguishers in a number proportional to the watts of supplemental lighting used in the facility (one fire extinguisher per every 10,000 watts of lighting), or in accordance with local fire code.
- (c) Fire extinguishers must be:
  - (1) Easily accessible to employees from every room and in each hallway of the facility;
  - (2) Maintained annually or as otherwise specified by the manufacturer; and
  - (3) Of the appropriate class rating for the type of fire associated with the functions being performed in the facility (i.e., electrical, chemical).
- (d) Flammable products must be stored in a properly marked fire containment cabinet or area.
- (e) Signage that complies with National Fire Protection Association (NFPA) standard 704 must be placed at entrances to exposure areas.

## **Section 4.3 Sanitation practices**

- (a) Cultivation operations and processing operations must provide employees with adequate and readily-accessible toilet facilities.
  - (1) Toilet facilities must be maintained in a sanitary condition;
  - (2) Toilet facilities must be adequately stocked with toilet paper, soap, and single use paper towels or other drying devices; and
  - (3) Toilet facilities must be kept in good repair at all times.
- (b) Cultivation operations and processing operations must provide adequate and convenient hand-washing stations.
  - (1) Hand washing stations must be provided with running water of suitable temperature;
  - (2) Hand washing stations must be provided with effective hand cleaning or sanitizing preparations and single use paper towels or other drying devices;
  - (3) Hand washing stations must be located at points in the facility where good sanitary practices require employees to wash or sanitize their hands; and
  - (4) Outdoor and greenhouse cultivation operations must provide hand-washing stations at field locations as appropriate.
- (c) Cultivation operations and processing operations must implement sanitation practices, which at a minimum address:
  - (1) Removal of debris, and control of the growth of mold, mildew and algae in the cultivation area or processing area;
  - (2) Pest control practices, including maintenance and repair of caulk cracks and drain areas;

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- (3) Identification of hoses dedicated for use in cultivation; and
- (4) Maintenance and cleaning of irrigation systems.
- (d) Processing operations must protect cannabis from contact with birds, rodents, insects, and other animals and from exposure to the elements.

#### **Section 4.4 Electrical system**

- (a) The cultivation operation's electrical system must be of sufficient capacity to handle the actual electrical load and be installed in accordance with an approved electrical permit.
- (b) All electrical work and upgrades at cultivation operations must be performed with proper permitting.
- (c) All electrical equipment used by a cannabis cultivation operation should be connected to the electrical system in accordance with the equipment manufacturer's recommendations.

#### **Section 4.5 Ventilation system**

- (a) Enclosed cultivation operations and processing operations must be equipped with adequate ventilation to maintain proper humidity and temperature.
- (b) For indoor cultivation operations:
  - (1) If a mechanically propelled air intake system is used, a filter capable of removing 99.97% of particles with a diameter of 0.3 micrometers ( $\mu\text{m}$ ) must also be utilized, as necessary to control potential contamination with pathogenic organisms.
  - (2) If a non-mechanically propelled or passive intake system is being utilized, a grate and filter sufficient to reduce the intrusion of rodents and insects must be installed.

#### **Section 4.6 Disposal and waste practices**

- (a) Cannabis waste must be disposed of in a manner which prevents unauthorized use and such disposal must be documented.
- (b) Bulbs and ballasts utilized during the cultivation of cannabis must be disposed of in accordance with manufacturer's recommendations.

#### **Section 4.7 Security provisions**

- (a) Outdoor and greenhouse cultivation operations should be enclosed by a secure perimeter fence at least six (6) feet in height. The fence should include a lockable gate that is locked when a qualified employee is not in the immediate area. The fence must not violate any other ordinance, code section or provision of law regarding height and location restrictions.
- (b) Indoor cultivation facilities and processing facilities must have locking doors and windows which allow emergency ingress and egress in accordance with applicable regulations.
- (c) Cultivation operations and processing operations must implement and communicate security protocols to all personnel.
- (d) Visitors must be accompanied by an employee at all times.

## **SUBPART E – WATER RESOURCE MANAGEMENT**

### **Section 5.1 Cultivation water management**

- (a) In the absence of local or state water district regulations for cannabis production, cultivation operations must create and implement a cultivation water management plan to address the following:
  - (1) Erosion prevention; and
  - (2) Effluent and agricultural discharges.
- (b) Chemical solutions must be disposed of in accordance with applicable laws and regulations.
- (c) Application of nutrients or pesticides through an irrigation system (chemigation), must be performed in accordance with state or local agricultural regulations.

### **Section 5.2 Potable water for employee use**

- (a) Cultivation operations not utilizing a municipal source of potable water must test the potable water supply at least two times per year to ensure compliance with state primary drinking water standards.
- (b) Chemicals, fertilizers, pesticides, media and other products must be stored away from the potable water supply.

## **SUBPART F – RECORDKEEPING**

### **Section 6 Recordkeeping practices**

- (a) Cultivation operations must record the identity and source of all cannabis propagation material with sufficient specificity to ensure that the material can be traced to its source. Such records must be created whether the propagation material is obtained off-site or produced on-site.
- (b) For each batch of cannabis, cultivation operations must maintain cultivation records that include at a minimum:
  - (1) Planting records:
    - (i) Form of cannabis planted (e.g., seed, clone, seedlings, etc.);
    - (ii) Date(s) that planting took place;
    - (iii) Variety(ies) planted;
    - (iv) Size of the cultivation area; and
    - (v) Location of the cultivation area.
  - (2) Propagation records:
    - (i) Media used, and whether the media was reused or new product;
    - (ii) Description of all actions taken to prevent or treat the cannabis for disease or pest issues;
    - (iii) Soil amendments added, and strength of the application;
    - (iv) Nutrients added, and strength of the application;
    - (v) All substances applied to the plant(s) surface or used as a fumigant in the cultivation and/or nursery area, and
    - (vi) Pruning or other physical technique(s).

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- (3) Pesticide use records:
  - (i) Pesticide chemical name;
  - (ii) Brand name and manufacturer name;
  - (iii) Amount of pesticide applied;
  - (iv) Date pesticide applied;
  - (v) Identification or location of plants to which pesticide was applied; and
  - (vi) Name of applicator if required.
- (4) Harvest records:
  - (i) Identity of each variety harvested;
  - (ii) Date of harvest;
  - (iii) Gross weight of the cannabis harvested for processing (generally recorded after drying);
  - (iv) Total weight of cannabis waste resulting from the harvest, and
  - (v) Net weight of harvested cannabis (gross weight less waste).
- (c) Processing operations must maintain records for processed cannabis that include at a minimum:
  - (1) Identity of the variety processed;
  - (2) Sufficient information to trace the processed cannabis to its cultivation source;
  - (3) Date of processing;
  - (4) Initial weight; and
  - (5) Total weight of any processing loss (based on wet or dry weight).
- (d) Cultivation operations and processing operations must maintain records of the commercial sale of cannabis to other cultivation and processing operations, to manufacturing operations, and to dispensing operations that include at a minimum:
  - (1) Identity of the variety distributed;
  - (2) Total weight of each variety distributed;
  - (3) Date of distribution; and
  - (4) Identity of the receiving operation.
- (e) Cultivation operations and processing operations are not required to retain records of cannabis distributed for the following purposes:
  - (1) Samples provided for testing;
  - (2) Samples provided to other operations at no charge; and
  - (3) Samples provided to compliant individuals at no charge.

## **SUBPART G – INFORMATION DISCLOSURE**

### **Section 7 Information disclosure**

- (a) Cultivation operations must provide the following records to other cultivation operations, processing operations, manufacturing operations, and dispensing operations receiving cannabis from the cultivation operation, upon the receiving operation's request:
  - (1) Nutrients used during cultivation;

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- (2) All substances applied to the plant(s) surface or used as a fumigant in the cultivation area;
  - (3) Pesticides applied during cultivation; and
  - (4) Other substances used during cultivation that may result in a residue on cannabis.
- (b) Information provided by a cultivation operation, whether written or verbal, about the identity, quality, and cultivation conditions of cannabis it provides must be accurate.
- (c) Cultivation operations and processing operations must disclose the extent and type of testing and analysis conducted on the cannabis it provides, including:
- (1) The type of test, analysis or examination used, if any, to determine the particular strain or cultivar of each batch of cannabis provided;
  - (2) Any tests to determine the quantitative levels of contained constituents, and if so, the type of testing used;
  - (3) Any tests to determine the absence or presence of specific classes of potential contaminants, and if so, the type of testing used. The information required by this paragraph must be disclosed for each of the following:
    - (i) Pesticides;
    - (ii) Yeasts and molds; and
    - (iii) Other microbiological contaminants.
  - (4) Whether the testing was conducted by the cultivation or processing operation, or by an external laboratory.

## **SUBPART H – RECALLS**

### **Section 8 Recall plan**

- (a) Each cultivation operation and processing operation must develop and implement a recall plan addressing at a minimum:
- (1) Factors which necessitate a recall procedure;
  - (2) Personnel responsible for a recall; and
  - (3) Notification protocols.
- (b) Each cultivation operation and processing operation must establish a policy for communicating a recall of cannabis that has been shown to present a reasonable or a remote probability that the use of or exposure to the product will cause serious adverse health consequences, or could cause temporary or medically reversible adverse health consequences. This policy should include:
- (1) A mechanism to contact all customers who have, or could have, obtained the cannabis from the cultivation operation or processing operation;
  - (2) Information on the return or destruction of any recalled product;
  - (3) A mechanism to contact the cultivation operation; and

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- (4) Communication and outreach via media, as necessary and appropriate.
- (c) Any recalled cannabis that is returned to a cultivation operation or processing operation must be disposed of in a manner that ensures that it cannot be salvaged and will not be used by a compliant individual or by any other person.

# Recommendations to Regulators: Cannabis Dispensing Operations

July 2013 (Rev. 2)

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The legal status of products derived from *Cannabis* spp. is in a transitional phase in many states in the United States. Where products that contain marijuana and its derivatives were formally illegal throughout the U.S., many state laws now allow adult use of these either for medical purposes only or for any social adult use.

The American Herbal Products Association (AHPA) chartered a Cannabis Committee in 2010 with an express purpose to address issues related to the safe use and responsible commerce of legally-marketed products derived from *Cannabis* species.

To meet its purpose the AHPA Cannabis Committee is in the process of developing recommendations to regulators for best practice rules to address four operational stages of *Cannabis* production and distribution: cultivation; manufacturing and related operations; laboratory practice; and dispensing.

The present document provides recommendations to regulators in the specific area of Cannabis Dispensing Operations, and is presented in the form of a draft regulation. These recommendations are intended to establish a basis for oversight of entities that provide marijuana products directly to compliant adult consumers. These recommendations focus on personnel, security, product acquisition, record keeping, customer policies, and other matters that can contribute to best practice in the dispensary setting.

The AHPA Cannabis Committee offers this document to states and local municipalities where use of marijuana is allowed under local law such that regulatory authorities can consider the adoption of these recommendations, in whole or in part, as the basis for development of jurisdiction-specific regulations.

Please contact AHPA for further information or to discuss this document further.

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## **PART [X] – Cannabis dispensing operations**

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## **SUBPART A – GENERAL PROVISIONS**

### **Section 1.1 Subject operations**

- (a) Except as provided by paragraph (b) of this section, any person, group of persons, or business entity that provides cannabis or cannabis-derived product to compliant individuals in the jurisdiction in which this part applies<sup>1</sup> is engaged in a cannabis dispensing operation<sup>2</sup>, and is subject to this part.
- (b) A compliant individual who transfers or gives cannabis or cannabis-derived product to another compliant individual at no charge is not a cannabis dispensing operation and is not subject to this part.

### **Section 1.2 Other statutory provisions and regulations**

In addition to this part, dispensing operations must comply with all other applicable statutory provisions and regulations related to providing cannabis or cannabis-derived product in the jurisdiction in which this part applies, and related to all other business activities undertaken in conducting the dispensing operation.

### **Section 1.3 Definitions**

The following definitions apply to this part:

*Cannabis* means any of the aerial parts of a plant in the genus *Cannabis*, and does not mean hemp.

*Cannabis-derived product* means a product, other than cannabis itself, which contains or is derived from cannabis, and does not mean a product that contains or is derived from hemp.

*Compliant individual* means a person who has met all legal requirements to obtain and use cannabis or cannabis-derived product in the jurisdiction where this part applies.

*Co-owned operation* means a cultivation or manufacturing operation that has the same ownership as a dispensing operation.

*Cultivate* means to grow plants in the genus *Cannabis*. A person, group of persons, or business entity that cultivates is a *cultivator*, and a facility where cannabis plants are cultivated is a *cultivation operation*.

*Delivery service* means a dispensing operation that delivers cannabis or cannabis-derived product to compliant individuals.

*Direct-from-garden or caregiver operation* means a dispensing operation whereby compliant individuals obtain cannabis or cannabis-derived product directly from a cannabis cultivator.

*Dispense* means to provide cannabis or cannabis-derived product to compliant individuals.

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<sup>1</sup> This term “in the jurisdiction where this part applies” may be replaced throughout with the name of the specific jurisdiction.

<sup>2</sup> It is noted that different jurisdictions may have other terminology for the type of operation that is defined as a dispensing operation in this document.

*Dispensing operation* means a person, group of persons, or business entity that provides cannabis or cannabis-derived product to compliant individuals and includes delivery services, direct-from-garden operations, growing co-ops, and storefront operations<sup>2</sup>.

*Growing co-op* means a dispensing operation that consists of a group of compliant individuals who grow cannabis collectively on property belonging to, leased or rented by, or otherwise authorized for use by the entire group, or by a member of the group, or who cooperatively produce cannabis-derived product for use by members of the group.

*Hemp* means any part of a plant in the genus *Cannabis*, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 (three-tenths) percent on a dry weight basis.

*Manufacture* means to make or otherwise produce cannabis-derived product. A person, group of persons, or business entity that manufactures is a *manufacturer*, and a facility where manufacture occurs is a *manufacturing operation*.

*May* is used to indicate an action or activity that is permitted; *may not* is used to indicate an action or activity that is not permitted.

*Must* is used to state a requirement.

*Oral cannabis* or *edible* means cannabis or cannabis-derived product that is ingested through the mouth and into the digestive system.

*Process* means to harvest, dry, cure, trim, inspect, and grade cannabis.

*Provide* means to offer for sale or to sell, including by barter, cannabis or cannabis-derived product to compliant individuals.

*Should* is used to state recommended or advisory procedures.

*Smoked cannabis* means cannabis or cannabis-derived product that is burned and inhaled into the lungs.

*Storefront operation* means a dispensing operation that provides cannabis or cannabis-derived product to compliant individuals at a physical location.

*Topical cannabis* or *topical* means a cannabis-derived product intended to be rubbed on the skin and not intended for oral consumption.

*Vaporized cannabis* means cannabis or a cannabis-derived product that is heated to a temperature at which the contained constituents are released into a vapor without combustion of the material.

*Vendor* means a person, group of persons, or business entity that supplies cannabis or cannabis-derived product to storefront or delivery service dispensing operations, and may be either the direct representative of a cultivation or manufacturing operation, or may function independently of such operations by purchasing cannabis or cannabis-derived product from such operations and reselling it to dispensing operations.

## **SUBPART B – DISPENSING OPERATIONS**

### **Section 2.1 Types of dispensing operations**

- (a) Except as provided by paragraph (c) of this section, cannabis or cannabis-derived product may be provided by any of the following types of dispensing operations, as defined in section 1.3, that are in compliance this part:
- (1) Storefront operations, which may also operate a delivery service operation from the same physical location;
  - (2) Delivery service operations, which may operate either with or without a storefront operation; and
  - (3) Direct-from-garden operations, which may:
    - (i) Operate either with or without a storefront operation; and
    - (ii) Be located either at the same location as cultivation occurs, or at another location.
  - (4) Growing co-op operations.
- (b) Dispensing operations may provide:
- (1) Cannabis that is cultivated by:
    - (i) The dispensing operation itself;
    - (ii) A co-owned cultivation operation; or
    - (iii) A cultivation operation that is not co-owned, which may be obtained by the dispensing operation either:
      - (A) Directly from the cultivation operation; or
      - (B) From a vendor of the cannabis;
  - (2) Cannabis-derived product that is manufactured by:
    - (i) The dispensing operation itself;
    - (ii) A co-owned manufacturing operation; or
    - (iii) A manufacturing operation that is not co-owned, which may be obtained by the dispensing operation either:
      - (A) Directly from the manufacturing operation; or
      - (B) From a vendor of the cannabis-derived product.
- (c) Notwithstanding paragraph (a) of this section, dispensing operations must be in compliance with all other legal requirements in the jurisdiction where this part applies.

### **Section 2.2 Ancillary operations**

- (a) In addition to providing cannabis or cannabis-derived product, a dispensing operation described in section 2.1 may also engage in other operations, including:
- (1) Cultivation of cannabis;
  - (2) Manufacturing, packaging, holding, and labeling of cannabis-derived product;
  - (3) Laboratory operations; and
  - (4) Sale and marketing of products other than cannabis or cannabis-derived product.
- (b) The ancillary operations identified in section 2.2(a) may be conducted:
- (1) At the same location as providing cannabis or cannabis-derived product, so long as such operations are permitted at this location in the jurisdiction in which this part applies; or

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- (2) At another location at which such operations are permitted in the jurisdiction in which this part applies.
- (c) The ancillary operations identified in section 2.2(a) must be conducted in compliance with all regulations relevant to such operations in the jurisdiction in which this part applies.

### **Section 2.3 Personnel**

- (a) All dispensing operation employees must have the education, training, or experience to perform all assigned functions.
- (b) Dispensing operations must:
  - (1) Provide employees who have any assigned functions that involve providing compliant individuals with cannabis or cannabis-derived product with training that includes:
    - (i) Specific uses of cannabis or a specific cannabis-derived product;
    - (ii) Clinical application of the specific constituents of cannabis;
    - (iii) The laws, regulations, and policies relevant to providing cannabis or cannabis-derived product to compliant individuals in the jurisdiction where this part applies.
- (c) Dispensing operations should provide all employees with training that includes:
  - (1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and
  - (2) The U.S. federal laws, regulations, and policies relating to individuals employed in dispensing operations, and the implications of these for employees and for compliant individuals.
- (d) Storefront operations should be prepared to administer cardiopulmonary resuscitation (CPR) at all times during which the operation is open for business. To do so, the operation should:
  - (1) Ensure that one or more employee has received adequate training to be capable of performing CPR;
  - (2) Schedule personnel to ensure that one such CPR-trained employee is on the premises at all times during which the operation is open for business.

### **Section 2.4 Physical facilities**

- (a) Physical facilities of dispensing operations must:
  - (1) Be operated in adherence with any regulation in the jurisdiction in which this part applies that is relevant to its specific operations, including:
    - (i) Locations and zoning, which can vary depending upon the specific operation or operations undertaken at each facility.
    - (ii) Business hours;
    - (iii) Parking;
    - (iv) Drive-through services; and
    - (v) Signage;
  - (2) Be maintained in a clean and orderly condition;
  - (3) Be equipped with such utensils and equipment as are necessary to conduct all operations, including ancillary operations as described in section 2.2 of this part, that occur at the facility;

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- (4) Implement policies that ensure the privacy of financial transactions; and
  - (5) Have information available to compliant individuals regarding local and federal laws on cannabis possession.
- (b) Physical facilities of dispensing operations should:
- (1) Provide and use appropriate storage conditions to protect the physical and chemical integrity of cannabis-derived product, as needed;
  - (2) Provide and use a secure area for storage of cannabis or cannabis-derived product in inventory; and
  - (3) Provide and use a secure area to manage financial transactions.
- (c) Storefront operations must:
- (1) Maintain Americans with Disabilities Act (ADA) compliance;
  - (2) Establish a policy regarding on-site consumption of cannabis or cannabis-derived product, except that, if a statutory or regulatory requirement exists in the location of the operation with regard to this practice, the operations must comply with such requirement. Any voluntary on-site consumption policy should address:
    - (i) The type or types of consumption allowed (e.g., eating; smoking; vaporizing; or topical application);
    - (ii) A limit on the amount of time that can be spent in on-site consumption if such a time limit is advisable;
    - (iii) A ventilation plan, if needed;
    - (iv) A protocol to prevent and to address a compliant individual who is or becomes over-medicated;
    - (v) Additional issues as needed.

## **Section 2.5 Security**

- (a) Dispensing operations must establish and adhere to such security procedures as are provided by applicable regulation in the jurisdiction in which this part applies.
- (b) Dispensing operations should:
- (1) Provide additional security as needed and in a manner appropriate for the community where it operates, and should include, as necessary:
    - (i) For storefront operations:
      - (A) In-store security personnel in sufficient number to ensure the safety of staff and served compliant individuals;
      - (B) In-store security cameras; and
      - (C) Monitoring of dedicated parking, if any, either with security personnel or with security cameras.
    - (ii) For delivery service operations:
      - (A) Security personnel at the facility where product is acquired, stored, or processed in sufficient number to ensure the safety of staff and security of all cannabis and cannabis-derived product on site.
      - (B) Training for delivery staff to ensure awareness of how to maintain personal and product safety and to provide contact information to police or other emergency personnel.

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- (C) Restriction of deliveries only to a private address and never to a public location.
- (D) Compliance with local regulations regarding delivery areas and hours of operation.
- (iii) For direct-from-garden and growing co-op operations:
  - (A) Security practices at the growing facility, and at associated locations where cannabis or cannabis-derived product or money are kept or from which money or cannabis or cannabis-derived product is transferred, sufficient to ensure the safety of staff and security of cannabis on site.
  - (2) Refrain from arming security personnel, except as allowed and in full compliance with all relevant legal requirements in the jurisdiction in which this part applies; and
  - (3) Provide training to make all staff aware of the operation's security procedures, and each individual employee's security roles and responsibilities.
- (c) Dispensing operations that are also engaged in cultivation or manufacturing operations must also comply with all security measures required for such operations, and should also establish and implement any relevant security measures recommended for such operations.

## **SUBPART C – CANNABIS PRODUCT**

### **Section 3.1 Subject cannabis products**

- (a) Dispensing operations that are subject to this part may provide cannabis and cannabis-derived product that meet any of the following definitions, as stated in section 1.3, and that are intended to be consumed consistent with these definitions:
  - (1) Smoked cannabis;
  - (2) Vaporized cannabis;
  - (3) Oral cannabis (edibles); and
  - (4) Topical cannabis (topicals).
- (b) Each dispensing operation must keep an up-to-date record of the cannabis and cannabis-derived product it provides, including:
  - (1) Identification of the cannabis and cannabis-derived product it provides, as described in section 3.1 (a)(1)-(a)(4);
  - (2) Information to indicate whether each cannabis or cannabis-derived product it offers to compliant individuals is provided or produced by a co-owned operation, or is from an operation that is not co-owned;
  - (3) For cannabis and cannabis-derived product obtained from an operation that is not co-owned:
    - (i) If obtained directly from a cultivation or manufacturing operation, the identity of the operation; or
    - (ii) If obtained from a vendor, the identity of the vendor;
  - (4) Restrictions, if any, on providing any specific cannabis or cannabis-derived product to compliant individuals, such as, for example:

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- (i) Limitations as to employees who may, or who may not, provide the specific cannabis or cannabis-derived product to compliant individuals;
- (ii) Limitations as to compliant individuals who may, or who may not, obtain the specific cannabis or cannabis-derived product.

### **Section 3.2 Cannabis product acquisition**

- (a) Dispensing operations that receive cannabis or cannabis-derived product from one or more cultivation or manufacturing operations, or from one or more vendors, should establish and implement policies for acquisition of such cannabis or cannabis-derived product, including policies on:
  - (1) Locations for receipt of cannabis or cannabis-derived product;
  - (2) Scheduling of deliveries, which may be made either:
    - (i) By scheduling appointments with specific vendors; or
    - (ii) By establishing open vending times, during which any vendor may make a delivery without a specific appointment.
  - (3) Any policies required of cultivation or manufacturing operations, or of vendors, if any, with regard to:
    - (i) Cultivation practices;
    - (ii) Manufacturing;
    - (iii) Packaging or labeling;
    - (iv) Chemical analysis; or
    - (v) Transport conditions, such as refrigeration.
- (b) Dispensing operations that receive cannabis or cannabis-derived product from one or more cultivation or manufacturing operations, or from one or more vendors must:
  - (1) Record each receipt of cannabis and cannabis-derived product, such record to include:
    - (i) The name of the cultivation or manufacturing operation, or of the vendor;
    - (ii) An appropriately complete and specific description of the cannabis or cannabis-derived product; and
    - (iii) A statement of the quantity of each cannabis or cannabis-derived product.
  - (2) If the operation is a storefront, minimize deliveries at times and in locations where compliant individuals are present, if space allows.
  - (3) Inform all cultivation and manufacturing operations and all vendors of the policies established in compliance with paragraph (a) of this section, and of the requirements set forth in paragraph (b) of this section.

### **Section 3.3 Cannabis product information**

- (a) Information provided by a dispensing operation, whether written or verbal, about the identity, quality, and cultivation conditions of cannabis it provides must be accurate.
- (b) A dispensing operation must disclose the extent and type of testing it conducts, or causes to have conducted, on the cannabis it provides, including:
  - (1) The type of test or examination used, if any, to determine the particular strain or cultivar of each lot of cannabis provided;
  - (2) Whether or not the cannabis provided is tested to determine the quantitative levels of contained constituents, and if so, the type of testing used;

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- (3) Whether or not the cannabis provided is tested to determine the absence or presence of specific classes of potential contaminants, and if so, the type of testing used. The information required by this paragraph must be disclosed for each of the following:
  - (i) Pesticides;
  - (ii) Yeasts and molds; and
  - (iii) Other microbiological contaminants.
- (4) The information required to be disclosed by this paragraph must be made available:
  - (i) At each physical facility maintained by a storefront dispensing operation, either:
    - (A) With posted and readily visible signage; or
    - (B) With printed handouts that are provided to each compliant individual prior to purchase of any cannabis.
  - (ii) On any website at which cannabis or cannabis-derived products are available for ordering by or sale to compliant individuals, by posting the information so that compliant individuals will see the information prior to ordering and purchasing.
- (c) Information provided by a dispensing operation about cannabis-derived product it provides must:
  - (1) Be provided in whatever manner is required in the jurisdiction in which this part applies, whether with labeling or with other markings, or with other written or verbal information;
  - (2) Be accurately conveyed:
    - (i) If manufactured by a co-owned operation, through labeling or other accurate markings or communications, in a manner that complies with all relevant requirements; or
    - (ii) If manufactured by another person or business entity, by providing the information as provided by each product's manufacturer, such that the dispensing operation may not modify the labeling or other information provided by such product's manufacturer.
  - (3) In the event that a dispensing operation has reason to believe that the information provided by the manufacturer of a cannabis-derived product is not accurate, the dispensing operation must seek clarification or correction of any such information.

### **Section 3.4 Cannabis product recalls**

- (a) Each dispensing operation must establish a policy for communicating a recall of a cannabis or cannabis-derived product that has been shown to present a reasonable or a remote probability that the use of or exposure to the product will cause serious adverse health consequences, or could cause temporary or medically reversible adverse health consequences. This policy should include:
  - (1) A mechanism to contact all customers who have, or could have, obtained the product from the dispensing operation, which communication must include information on the policy for return or destruction of the recalled product;

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- (2) A mechanism to contact the cultivation or manufacturing operation, or the vendor which supplied the product to the dispensing operation; and
  - (3) Communication and outreach via media, as necessary and appropriate.
- (b) Any recalled cannabis or cannabis-derived product that is returned to a dispensing operation must either:
- (1) Be disposed of by the dispensing operation in manner that ensures that it cannot be salvaged and will not be used by a compliant individual or by any other person; or
  - (2) Be returned to its cultivator or manufacturer for such disposal.

## **SUBPART D – COMPLIANT INDIVIDUALS**

### **Section 4.1 Requirements for purchase**

- (a) Dispensing operations may provide cannabis or cannabis-derived product only to compliant individuals and may not provide cannabis or cannabis-derived product to any other person.
- (b) If any restrictions exist by statute or regulation in the jurisdiction in which this part applies on the health or medical conditions for which cannabis or cannabis-derived product can be recommended, dispensing operations may not recommend use of any cannabis or cannabis-derived product for any other condition.
- (c) Dispensing operation employees who have any assigned functions that involve providing compliant individuals with cannabis or cannabis-derived product must be aware of the legal requirements for becoming a compliant individual.
- (d) Dispensing operations must make available information on the regulations that apply in the jurisdiction in which this part applies to obtaining and maintaining status as a compliant individual.

### **Section 4.2 Purchase limits**

- (a) Quantitative limitations on the amount of cannabis or cannabis-derived product obtained by a compliant individual in any given timeframe:
  - (1) Must be enforced by a dispensing operation in conformity with any statutory or regulatory restriction, if any exists in the jurisdiction in which this part applies;
  - (2) May be established by a dispensing operation in the absence of any statutory or regulatory limitation; and
  - (3) Should be clearly communicated to compliant individuals.

### **Section 4.3 Personal information**

- (a) Dispensing operations should obtain identifying information for each compliant individual to whom cannabis or cannabis-derived product is provided, including:
  - (1) The individual's name;
  - (2) Contact information of sufficient specificity to serve as a means of contact, such as a phone number, email address, or mailing address;
  - (3) A physician of record identified by the compliant individual; and

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- (4) Health or medical conditions for which cannabis or cannabis-derived product is used.
- (b) All identifying information obtained about any compliant individual must be obtained and stored in compliance the privacy and security rules of the Health Insurance Portability and Accountability Act (HIPAA).<sup>3</sup>

#### **Section 4.4 Adverse event records**

- (a) Dispensing operations should establish a policy for receiving and recording adverse event reports associated with use of the cannabis or cannabis-derived products it provides. Such policy should include:
  - (1) Identification of the minimum data elements to record for any adverse event report, which could include:
    - (i) An identifiable individual who is reported to have experienced the adverse event;
    - (ii) An initial reporter, who may be the same as the identifiable individual or another person;
    - (iii) The identity of the specific cannabis or cannabis-derived product used, if known; and
    - (iv) A description of the adverse event.
  - (2) A procedure for determining if an adverse event should:
    - (i) Be reported to any public health authority;
    - (ii) Be reported to the physician of record for the compliant individual reported to have experienced the adverse event, if known;
    - (iii) Require a product recall.
  - (3) Procedures for communicating the policy to:
    - (i) Employees of the dispensing operation with task assignments that require knowledge of the policy; and
    - (ii) Compliant individuals who are provided with cannabis or cannabis-derived products by the dispensing operation.
- (b) For purposes of this section, an adverse event is a health-related event associated with use of cannabis or a cannabis-derived product that is adverse, and that is unexpected or unusual.
- (c) For purposes of this section, an adverse event report recorded under a policy established by a dispensing operation may not be construed as an admission or as evidence that the cannabis or cannabis-derived product involved caused or contributed to the adverse event.

#### **Section 4.5 Rights and responsibilities of compliant individuals**

- (a) Each dispensing operation should establish a policy that describes the rights and responsibilities of compliant individuals who obtain cannabis or cannabis-derived products from the dispensing operation. Such policy should include:
  - (1) How compliant individuals can expect to be treated by employees of the dispensing operation;

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<sup>3</sup> These can be found at <http://www.hhs.gov/ocr/privacy>.

- (2) Information that each compliant individual will be required or requested to provide to the dispensing operation;
- (3) A procedure for providing feedback and suggestions, including procedures for communicating commendations and complaints;
- (4) Contact information for the dispensing operation, and for specific employees for a compliant individual to contact;
- (4) Hours of operation; and
- (5) The dispensing operation's policies related to:
  - (i) Payment for cannabis and cannabis-derived products;
  - (ii) Use of cannabis and cannabis-derived product on the premises;
  - (c) Any other applicable policies.

