



Advancing Legal Medical Marijuana Therapeutics and Research

TO: Massachusetts Department of Public Health

FROM: Americans for Safe Access

DATE: April 22, 2013

RE: Comments on the proposed regulations for 105 CMR 725.000  
"IMPLEMENTATION OF AN ACT FOR THE HUMANITARIAN  
MEDICAL USE OF MARIJUANA"

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## **Summary**

Americans for Safe Access (ASA) would like to thank the Massachusetts Department of Public Health (DPH) for the opportunity to comment on the proposed regulations for 105 MCR 725.000, IMPLEMENTATION OF AN ACT FOR THE HUMANITARIAN MEDICAL USE OF MARIJUANA. It is clear that DPH has been thoughtful in drafting the proposed regulations, although in their present form the regulations are adversely restrictive in ways that needlessly burden both patients and physicians. However, ASA is confident that if certain changes are made, the revised regulations can serve as the basis for a program that should adequately and sufficiently serve the needs of patients in Massachusetts. The following are the provisions that are in need of revision, prefaced with a brief note on particular aspects of the draft regulations that are particularly commendable from ASA's patient-focused perspective.

## **Notable Pro-Patient Provisions in the Current Draft**

### **1. Qualifying Conditions Language Allows Physicians to Best Serve Their Patients**

The defining of qualifying conditions commendably provides guidance to physicians, while permitting them to recommend medical marijuana therapy to their patients in a manner guided by science rather bureaucracy.

### **2. Respecting Financially Vulnerable Patients**

By permitting patients with verifiable financial hardship the ability to cultivate their own medicine, waiving certain fees, and requiring Medical Marijuana Treatment Centers (MMTCs) to provide free or reduced cost medicine to such patients, DPH has taken steps to help make sure medical marijuana therapy is not denied to those with the greatest need for financial assistance.

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### 3. Requiring MMTCs to Provide Educational Materials

This provision will help make certain that patients will be well-informed about the medicine they are using, including how to administer medical marijuana through means other than smoking, such as vaporization or the consumption of marijuana infused products (MIPs).

### 4. Possession Amount Should Ensure that All Patients are Protected

Although the presumptive possession limit amount falls somewhat short of the amount of medicine provided by the federal government to patients enrolled in the Compassionate Investigational New Drug program (16-18 ounces every two months), many patients will adequately covered by the presumptive limit.<sup>1</sup> Additionally, the language is sensible because it permits physicians to recommend legally recommend amounts above the presumptive limit, and for patients be able to legally possess such amounts when recommended by their physician.

## Regulations that Should be Improved to Best Serve Patients

### 1. Unnecessary Burdens to Physicians Recommending Medical Marijuana to their Patients

#### 725.005: Registration of Certifying Physicians

*(B) To register as a certifying physician, a physician shall submit, in a form and manner determined by the Department, the physician's:*

- (1) Full name and business address;*
- (2) License number issued by the Massachusetts Board of Registration in Medicine;*
- (3) Massachusetts Controlled Substances Registration number; and*
- (4) Any other information required by the Department.*

*(C) Once registered, a certifying physician will retain indefinitely a registration to certify a debilitating medical condition for a qualifying patient unless:*

- (1) The physician's license to practice medicine in Massachusetts is suspended, revoked, or restricted with regard to prescribing, or the physician has voluntarily agreed not to practice medicine in Massachusetts;*
- (2) The physician's Massachusetts Controlled Substances Registration is suspended or revoked;*

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“Who are the patients receiving medical marijuana through the federal government's Compassionate IND program?,” <http://medicalmarijuana.procon.org/view.answers.php?questionID=000257> (Last accessed April 19, 2013).

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*(3) The physician has fraudulently issued a written certification of a debilitating medical condition; or  
(4) The physician has certified a qualifying patient for a debilitating medical condition on or after January 1, 2014, without appropriate completion of continuing professional development credits pursuant to 105 CMR 725.010(A).*

*(D) After registering, a certifying physician is responsible for notifying the Department, in a form and manner determined by the Department, within five business days after any changes to the physician's information.*

**Problem:** This provision will harm patients by preventing physicians from being able to recommend medical marijuana as they would any other legal medication. Physicians must already be licensed with the state in order to practice, and only licensed physicians may legally recommend medical marijuana under the law. There is no need to require physicians to go through an additional burden of registering with the state, a burden that will no doubt have a chilling effect on the number of physicians available to recommend medical marijuana to qualified patients in Massachusetts. More over, this additional layer of bureaucracy will likely add needless financial expense to the state in administering the program

**Solution:** Delete subsections (B) and (D), strike “Once registered” from (C).

*725.010: Certifying Physician's Written Certification of a Debilitating Medical Condition for a Qualifying Patient*

*(A) A certifying physician issuing a written certification for a qualifying patient, on or after January 1, 2014, must have completed a minimum of 2.0 Category I continuing professional development credits as defined in 243 CMR 2.06(6)(a)1 (AMA PRA Category 1 Credit, AAFP Prescribed credit, or AOA Category I-A) from an organization accredited by the Accreditation Council for Continuing Medical Education (ACME), American Osteopathic Association, American Academy of Family Physicians, or a state medical society recognized by the ACCME. Such program must explain the proper use of marijuana, including contraindications, side effects, and dosage, and shall also include information on substance abuse recognition, diagnosis, and treatment related to marijuana.*

**Problem:** While the desire to have physicians be as educated as possible prior to recommending medical marijuana to their patients is a laudable intent, in reality this is an extra burden on physicians for a substance that is far more benign than many prescription drug treatments that a physician can write a prescription for without any special training. Like the registration requirement, this will have a chilling effect on the number of

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physicians available to recommend medical marijuana to patients. This, in turn, will drive patients to finding the few available physicians who have the certification, which could lead to unintended outcomes.

**Solution:** Physician education on medical marijuana is something that can benefit patients and should be a part of the comprehensive training that physicians receive in the ordinary course of the work. Making medical marijuana education a component of CME course available is preferable to requiring its fulfillment in advance of recommending medical marijuana.

## 2. Limiting Patient Choice by Locking them into a Single will Hamper Treatment

### 725.015: Registration of Qualifying Patients

*(A) To obtain a registration card, a qualifying patient shall submit, in a form and manner determined by the Department, the following:*

*(5) The name and address of the designated MMTC from which the qualifying patient or his or her personal caregiver will purchase marijuana, unless the qualifying patient will be applying for a hardship cultivation registration;*

*(7) A registration fee. If the fee poses a verified financial hardship, the qualifying patient may request a waiver of the fee in a form and manner determined by the Department;*

*(E) A registered qualifying patient may change his or her designated MMTC once in a 120-day period. A registered qualifying patient must notify the Department of his or her change of designated MMTC in a manner and form determined by the Department. The Department's interoperable on-line database shall notify each MMTC of a registered qualifying patient who designates or ceases to designate the MMTC.*

**Problem:** By requiring patients to register with a single MMTC from which they can purchase medicine, patients will be placed at risk of hardships or barriers to treatment. Medically, patients may not be able to find the particular strain that works best for them at their MMTC on a regular basis. Moreover, some MMTCs are likely to have better selections of MIPS than others, but patients will have little ability to know what their other options are if they stuck with a single MMTC where they can shop. Financially, patients will be at risk of high prices due to the lack of market competition.

**Solution:** Strike all provisions pertaining to requiring patients to register with a single dispensary.

Additionally, patients should not be charged registration fees.

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### **3. Provision to Help Financially Vulnerable Patients Should be more Inclusive**

*Verified financial hardship means that an individual is a recipient of MassHealth, or Supplemental Security Income, or the individual's income does not exceed 133% of the federal poverty level, adjusted for family size.*

**Problem:** This provision is good, but it could be better, as 133% of the poverty level is still really only the poorest of the poor. Although many financially disadvantaged patients will qualify for financial hardship via participation through in MassHealth or SSI, this provision could be more inclusive to help additional vulnerable populations.

**Solution:** To improve this provision, the department should consider adding eligibility for Social Security Disability Insurance and increasing the percentage to 200% of the federal poverty level.

### **4. Language Restricting Access to Minor Patients Could be Too Little, Too Late**

*Life-Limiting Illness means a debilitating medical condition that does not respond to curative treatments, where reasonable estimates of prognosis suggest death may occur within six months.*

*Qualifying Patient means a Massachusetts resident 18 years of age or older who has been diagnosed by a Massachusetts licensed certifying physician as having a debilitating medical condition, or a Massachusetts resident under 18 years of age who has been diagnosed by two Massachusetts licensed certifying physicians, at least one of whom is a board-certified pediatrician, with a debilitating life-limiting illness.*

**Problem:** Combined, these two definitions mean that minors may only access medical marijuana as a medicine of last resort instead of allowing for it within a comprehensive therapy regimen in conjunction with other medical options. This is unfair to seriously ill young patients who could benefit from medical marijuana therapy prior to being on their death bed.

**Solution:** This provision can be easily remedied simply requiring the parent or legal guardian to grant informed consent and to require that adult to be the caregiver in charge of controlling and administering their young patient's medicine. The neighboring state of Rhode Island has good language on this issue (see below).

3.2 Registry Identification Cards for Minors. The Department shall not issue a registry identification card to a qualifying patient under the age of eighteen (18) unless:

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3.2.1 The qualifying patient's practitioner has explained the potential risks and benefits of the medical use of marijuana to the qualifying patient and to a parent, guardian or person having legal custody of the qualifying patient; and

3.2.2 A parent, guardian or person having legal custody consents in writing to:

(a) Allow the qualifying patient's medical use of marijuana;

(b) Serve as one of the qualifying patient's primary caregivers; and

(c) Control the acquisition of the marijuana, the dosage, and the frequency of the medical use of marijuana by the qualifying patient.<sup>2</sup>

## **5. Restrictions on Caregivers Create Needless Barriers to how they may Best Serve Patients**

### 725.020: Registration of Personal Caregivers

*(D) Except in the case of an employee of a hospice provider, nursing facility, medical facility providing care to a qualifying patient admitted to or residing at that facility, or a parent or guardian of more than one qualifying patient, an individual may not serve as a personal caregiver for more than one qualifying patient at one time.*

**Problem:** By limiting the number of patients a caregiver may serve to just a single patient, the regulations will prevent patients from benefiting from the experience of caregivers who serve multiple patients. Moreover, many of the burdens experienced by caregivers in the ordinary course of performing their caregiver duties would not have to be duplicated if caregivers could serve more than one patient. For example, a caregiver traveling to a MMTC to pick up medicine for one patient could just as easily do so for a small number of additional patients for whom they are registered to serve. Caregivers assisting patients with hardship cultivation could also better serve patients based upon similar economy of scale factors.

**Solution:** Caregivers should be serve a small, but reasonable of patients. This limit should be increased to at least five (5) patients per caregiver.

### 725.020: Registration of Personal Caregivers

*(E) A registered qualifying patient may designate up to two personal caregivers. However, only one caregiver may cultivate marijuana on behalf of the registered qualifying patient if the registered qualifying patient has been granted a hardship cultivation registration.*

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. Rules and Regulations of the Medical Marijuana Program, R21-28.6-MMP 3.2, (December 2012).

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**Problem:** Allowing patients to have two (2) designated caregivers makes good sense; however, limiting access to a cultivation site under a hardship license to just one of the caregivers is an impractical restriction. If the caregiver with cultivation access is unavailable due to work, travel, or health to fully and completely tend to the patient's garden, the patient may not be able to cultivate their medicine in an ideal manner.

**Solution:** Allowing both caregivers to have the ability to tend to a patient's cultivation location is a common sense revision to this otherwise welcomed provision.

725.025: Responsibilities of Personal Caregivers

- (B) A personal caregiver may not do the following:*
- (1) Consume, by any means, marijuana that has been dispensed to or cultivated on behalf of a registered qualifying patient;*
  - (2) Sell, provide, or otherwise divert marijuana that has been dispensed to or cultivated on behalf of a registered qualifying patient;*
  - (3) Cultivate marijuana for the personal caregiver's own use, unless the personal caregiver is also a registered qualifying patient who has obtained a hardship cultivation registration; or*
  - (4) Cultivate marijuana for purposes of selling or providing marijuana to anyone other than the registered qualifying patient.*

725.035: Hardship Cultivation Registration

*(E) Only one hardship cultivation registration may be issued for a given location, absent proof that more than one registered qualifying patient resides at the location.*

**Problem:** As written, as patient who is also a caregiver for someone who lives at another residence may not grow for both themselves and their qualifying patient at the residence of the caregiver who is also a patient. This bill would also prevent caregivers who share an address to not both be able to grow medicine for their respective patients in their shared dwelling

**Solution:** Strike 725.035(E).

**6. Prohibition on Samples may have the Consequence of Unintended Gift Exchanges of Medicine Amongst Qualifying Patients**

725.035: Hardship Cultivation Registration

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*(J) A registered qualifying patient is prohibited from selling, bartering, giving away or distributing in any manner marijuana, MIPs, or paraphernalia.*

725.105: Operational Requirements for Medical Marijuana Treatment Centers

*(N) Prohibitions*

*(5) A MMTC shall not give away or allow use of any samples of marijuana or MIPs.*

**Problem:** Medical marijuana is not an inexpensive treatment, and medical marijuana can come in several strains and delivery mechanisms, from smoked, to vaporized, to consumption through edible or other kinds of MIPs. Without the ability to access samples of medicine, patients will be placed in the unenviable position of either spending large sums of money on medicine that may not provide the relief they need, or risk illicitly allowing fellow patients to try out each other's various forms of medical marijuana.

Moreover, it seems peculiar that a sweeping prohibition on gift transfers of medicine between patients would be placed in the section of the regulations pertaining to hardship cultivation. A patient who does not possess a hardship cultivation license may read the regulations, skip the section pertaining hardship cultivation, and not realize that there is language in that section that affects them.

**Solution:** Ideally, both of these provisions would be removed; however, since the inclusion of 725.105(N)(5) encourages violations of 725.035(J), common sense should dictate that the prohibition on samples should be lifted to allow patients to see what medicine works before investing large sums of their limited financial resources.

Also, consider moving 725.035(J) to a section that more plainly appears to pertain to all patients.

## **7. Hardship Cultivation Application Process can Deny Due Process**

725.035: Hardship Cultivation Registration

*(A) A qualifying patient registered with the Department pursuant 105 CMR 725.015 may apply for a hardship cultivation registration if such patient can demonstrate that his or her access to a MMTC is limited by:*

- (1) Verified financial hardship,; or*
- (2) Physical incapacity to access reasonable transportation, as demonstrated by an inability to use public transportation or drive oneself, lack of a personal caregiver with a reliable source of transportation, and*

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*lack of a MMTC that will deliver marijuana to the patient's or personal caregiver's primary address; or*  
*(3) Lack of a MMTC within a reasonable distance of the patient's residence and lack of a MMTC that will deliver marijuana to the patient's or personal caregiver's primary address.*

*(B) To obtain a hardship cultivation registration, a registered qualifying patient shall, in a form and manner determined by the Department, submit the following:*

- (1) A registration fee, unless waived pursuant to 105 CMR 725.015(A)(7);*
- (2) Information supporting a claim that access is limited due to one or more of the circumstances listed in 105 CMR 725.035 (A) (1)-(3)*
- (3) An explanation including lack of feasible alternatives to mitigate the limitation claimed under 105 CMR 725.035(A);*
- (4) A description and address of the single location that shall be used for the cultivation of marijuana;*
- (5) A written explanation of how the qualifying patient will cultivate marijuana in accordance with the requirements of 105 CMR 725.035;*
- (6) A description of the device or system that will be used to ensure security and prevent diversion of the marijuana plants being cultivated;*

*(C) The Department shall review and approve or deny an application for a hardship cultivation registration within 30 calendar days of receipt of a completed application.*

**Problem:** The process has a number of flaws that will lead to great frustration amongst patients. While it is wise to not rigidly define “reasonable distance”, and welcomed that the Department must approve or deny within a timely 30-day period, it is unfortunate that DPH will have the final say and leave patients without a clear path to appeal denials. This can lead to arbitrary decisions without basis in precedent.

Moreover, the requirement for patients to provide a lack of feasible alternatives in 725.035(B)(3) forces patients to build a case against themselves. Why must patients provide a list of alternatives, and how clever do patients have to be when coming up with “feasible alternatives”? If the Department decides after the fact that a patient who is granted a hardship license was not clever enough in their initial application, the patient would be considered in violation of the law.

**Solution:** A clear administrative appeals process should be included to ensure against arbitrary denials. Additionally, 725.035(B)(3) should be stricken.

## **8. Five-Year Validity of Cards may Confuse Patients**

### 725.015: Registration of Qualifying Patients

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*(B) A registration card will be valid for five years from the date of issue, and may be renewed, in a form and manner determined by the Department, by meeting the requirements in 105 CMR 725.015(A).*

725.010: Certifying Physician's Written Certification of a Debilitating Medical Condition for a Qualifying Patient

*(H) A certification must indicate the time period for which the certification is valid, and shall not be less than 15 calendar days nor longer than one year.*

**Problem:** These two provisions may create unintentional confusion amongst patients. If registration cards are valid for five years but certifications are only valid for a year, it is very possible that some patients may think they do not need to renew their certification each year.

**Solution:** A clear and bold print disclaimer should be required on the registration card which informs patients that they must renew their certification annually in order for their card to provide any legal protections.

**9. Requiring Patients and Caregivers to Provide Changes to Personal Information within 5 Days is Completely Impractical**

725.015: Registration of Qualifying Patients

*(D) After obtaining a registration card, a qualifying patient is responsible for notifying the Department, in a form and manner determined by the Department, within five business days after any change to his or her information or if the registration card has been lost or stolen.*

725.035: Hardship Cultivation Registration

*(M) After obtaining a hardship cultivation registration, a registered qualifying patient is responsible for notifying the Department, in a form and manner determined by the Department, within five business days after any change to his or her information or his or her personal caregiver's information. .*

**Problem:** Requiring patients and caregivers to provide any and all changes to their personal information within 5 business days is a remarkably burdensome imposition on ill patients and those who take care of them. Given the potential consequences of not fully adhering this notification provision, patients and caregivers would be placed in peril even if they make unsuccessful good faith effort to comply in the extremely short legal window to do so.

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Solution: The state grants itself 30 days to review patient applications. It seems fair and reasonable to give ill patients and their caregivers the same amount of time to provide updated information to the Department.

## 10. Banning Pesticides may Harm the Supply of Medicine

*725.105: Operational Requirements for Medical Marijuana Treatment Centers*

*(B) Cultivation Requirements*

*(4) Application of any pesticide in the cultivation of marijuana is prohibited. All cultivation must adhere to U.S. Department of Agriculture organic requirements at 7 CFR Part 205.*

**Problem:** While banning pesticides is clearly a move with best intentions towards patient well-being, a complete prohibition on pesticides may lead to medicine shortages. Given that the regulations will only permit a single cultivation location per MMTC, the MMTCs must be able to cultivate effectively in a limited space. If one area of the cultivation site becomes exposed to insects or mold, the entire facility may be at risk. Furthermore, not all pesticides are harmful to patients, for example, some inorganic pesticides may be applied to plant matter than will ultimately be consumed via smoking, while some organic pesticides may cause harm to those smoking plants that have been treated with them,

**Solution:** The ban on pesticides should be lifted and replaced with language calling for clear labeling of all medicine as to what, if any, kinds of pesticides were used to cultivate it.

## 11. Use-It or Lose-It Language May Result in Greater Delays to MMTCs Operating

*725.100: Registration of Medical Marijuana Treatment Centers*

*(B)(3) Phase 2 – Application: Within 30 days after receipt of an invitation to submit an application pursuant to 105 CMR 725.100(B)(2), each entity that proceeds to Phase 2 shall submit an application in a form and manner specified by the Department, which includes:*

*(g) Evidence that the MMTC will be ready to operate within 120 days of notification by the Department that the entity qualifies for registration;*

*(D) The MMTC must be operational within 120 days after registration by the Department.*

**Problem:** Not only will it be difficult for many qualified dispensary applicants to have their Phase 2 materials ready to submit within the 30-day window, the 120-day use-it or lose-it provision may result in delays in MMTCs coming into operation. If an approved applicant has been making good faith efforts to open on time, but needs a month or two

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longer, there is no mechanism to ensure that the good faith efforts will be not nullified by the strict timetable.

**Solution:** Extend the time offered to all approved applicants to from 120 to 180 days, and grant the Department authority to issue 180-day extensions to operators making good faith efforts to comply but need a little more time. Otherwise, applicants and the Department will have to start at square one, meaning delays in medicine to the patients that need it.

## 12. “Ceases to Operate” Lacks a Definition

### 725.100: Registration of Medical Marijuana Treatment Centers

*(C) MMTC Certificate of Registration*

*(4) A registration shall be immediately null and void if the MMTC ceases to operate, or if, without the permission of the Department, it relocates.*

**Problem:** Without defining “ceases to operate”, MMTC operators and the patients they serve will be at risk of having the MMTC's registration nullified for unclear reasons. There is no guarantee that a MMTC who has been given a work order under as a result from an inspection will be allowed to close their doors to adequately fix the problem without “ceasing to operate”.

**Solution:** This term needs a concrete definition that is not overly restrictive and at a minimum, must allow for necessary repairs and renovations to MMTC facilities, so that they may best serve their qualifying patients.

## 13. Unintended Outcomes Associated with Provision Aimed at Preventing Conflicts of Interest

### 725.010: Certifying Physician’s Written Certification of a Debilitating Medical Condition for a Qualifying Patient

*(J) A certifying physician, and such physician’s co-worker, employee, spouse, parent, or child, shall not:*

*(1) Have ever directly or indirectly accepted, solicited, or offered anything of value from or to a MMTC, a board member or executive of a MMTC, any personnel or any other person associated with a MMTC, or a personal caregiver;*

*(2) Offer a discount or any other thing of value to a qualifying patient based on the patient’s agreement or decision to use a particular personal caregiver or MMTC;*

*(3) Examine or counsel a patient at a MMTC;*

*(4) Have a direct or indirect financial interest in a MMTC; or*

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*(5) Directly or indirectly benefit from a patient obtaining a written certification, which shall not prohibit the physician from charging an appropriate fee for the clinical visit.*

**Problem:** By strictly prohibiting the people listed in (J) from offering anything of value to a MMTC, the provision would prevent physician's, their coworkers, employees, spouses, parents, and children from even purchasing medicine from a MMTC as legal qualifying patient, lest the physician in question lose their ability to recommend medical marijuana.

**Solution:** The provision should clearly state that (J)(1) does not apply to family and coworkers who are purchasing medicine as a qualifying patient or a designated caregiver.

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