



Marijuana Policy Project  
236 Massachusetts Ave. NE, Suite 400  
Washington, DC 20002  
p: (202) 462-5747 • f: (202) 232-0442  
info@mpp.org • www.mpp.org

*"We change laws."*

April 12, 2013

William Rubenstein  
Commissioner  
Department of Consumer Protection  
State Office Building  
Room 133  
165 Capitol Avenue  
Hartford, CT 06106

**RECEIVED**

**APR 18 2013**

DEPT OF CONSUMER PROTECTION  
OFFICE OF THE COMMISSIONER

Re: Notice of Intent to Adopt Regulations Concerning the Palliative Use of Marijuana

Dear Commissioner:

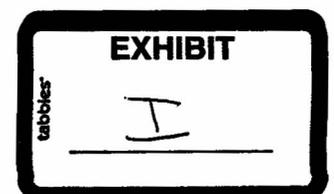
Enclosed, please find written arguments with respect to the proposed regulations published on March 19, 2013 concerning the Act Concerning the Palliative Use of Marijuana. Included with this mailing are an original and ten (10) copies.

We appreciate the opportunity to comment on these proposed rules.

Sincerely,

Chris Lindsey  
Legislative Analyst  
Marijuana Policy Project  
202-462-5747, ext. 2036 (phone), 202-232-0442 (fax)  
clindsey@mpp.org, <http://www.mpp.org>

Encl: Original  
Copies (10)





Marijuana Policy Project  
236 Massachusetts Ave. NE, Suite 400  
Washington, DC 20002  
p: (202) 462-5747 • f: (202) 232-0442  
info@mpp.org • www.mpp.org

*“We change laws.”*

## **Interested Party Statement On Proposed Regulations Concerning Palliative Use of Marijuana**

Submitted by:  
Marijuana Policy Project  
236 Massachusetts Ave. NE, Suite 400  
Washington, D.C. 20002

The Marijuana Policy Project (“MPP”) appreciates the sincere and robust set of regulations proposed by the Department of Consumer Protection to create a pharmaceutical grade standard for marijuana, a well-regulated medical marijuana industry, and to control diversion. Upon review of the proposed regulations, we submit the following recommendations:

### **1. Ensuring Producers Meet Minimum Financial Requirements**

Among other things, the Act Concerning the Palliative Use of Marijuana (herein referred to as the “Act”) empowers the Commissioner of Consumer Protection to:

Establish financial requirements for producers, under which (i) each applicant demonstrates the financial capacity to build and operate a marijuana production facility, and (ii) each licensed producer may be required to maintain an escrow account in a financial institution in this state in an amount of two million dollars.  
CT ST § 21a-408i(G)

In this section, the Act allows the Commissioner of Consumer Protection discretion over whether or not producers are required to maintain an escrow account of up to 2 million dollars. The law neither requires that the amount in escrow be 2 million dollars, nor does it require that an escrow account exist at all. These are both discretionary under the Act.

The clear purpose of the Act is to insure that an “applicant demonstrates the financial capacity to build and operate a production facility.” As it states on its face, the purpose of the escrow account is to prove a producer has financial resources to open and continue operations in order to meet the needs of patients in the state.

Under the proposed rules appearing at 21a-408-52(e), however, the escrow account is used simply as a penalty against the producer. Rather than operate as a resource for the operator to ensure it has the financial wherewithal to sustain unforeseen challenges, the rules require that the funds are instead made payable directly to the state should the producer fail to perform as required. This clearly turns the purpose of this statutory provision on its head. The escrow account, if deemed necessary by the Commissioner, should be available to ensure that financial resources are there for the producer. The money in escrow should not be held hostage by the state to be used as a penalty if a producer fails as a business.

In addition, there is no rational basis for the state to receive the funds at all, apart from serving as a punishment for a producer who fails to satisfactorily run a business. Producers are already

required to pay the most expensive licensing fees in the U.S., which includes a \$25,000 non-refundable application fee plus an additional \$75,000 licensing fee, not including any of the other fees prescribed by the proposed rules. Indeed, these fees likely exceed the financial burden of the state as they are, let alone an additional 2 million dollars above and beyond the cost of sustaining the regulatory system.

Further, we are deeply concerned that banking institutions will refuse to establish such an escrow account on behalf of marijuana producers. Few, if any, banks in the U.S. currently accept funds from marijuana producers. To require such an account at a bank as a condition precedent for a license for *any* amount of money, much less an amount running into millions of dollars, is to run the significant risk that no producer will qualify under the Department's proposed rules. As a result, this requirement would inadvertently go against the will of the legislature in having established such a program, harm patients who would otherwise benefit from a well-regulated system, and deny the state any revenue whatsoever from such a program.

Similarly, a letter of credit would be just as unlikely from a bank for all the same reasons. In addition, it is likely that a new marijuana business would not have the assets or existing credit history necessary to qualify for such a line of credit.

Accordingly, we believe the Commissioner should focus on the purpose of this section – the producer/applicant must prove that he or she is financially stable enough to open in a timely manner and operate continuously – and the rules should reflect that concern. At a minimum, the Department should create a contingency plan in the event that no producer can meet this requirement. More appropriately, the Department should drop this requirement until there is evidence that it serves any purpose besides punitive. As written, the escrow requirement simply creates a punishment and an unrealistic and impractical standard that will serve to prevent even the most qualified of applicants from meeting the regulatory requirements.

## **2. Ensure The System Can Meet The Needs Of State Patients**

The Act establishes that the Commissioner shall determine the number of producers appropriate to meet the needs of qualifying patients in this state. CT ST § 21a-408i(b). It further states that the number of producer licenses issued should not exceed the number appropriate to meet the needs of qualifying patients in the state as determined by the Commissioner pursuant to Section 10. At a minimum, the regulations must “[i]ndicate the maximum number of producers that may be licensed in this state at any time, which number shall not be less than three nor more than ten producers...”<sup>1</sup> *Id* at (3). We recommend that the rules specify that the Department will license 10 producers if there are a sufficient number of qualified applicants.

It is worth highlighting established federal law enforcement policy issued by the U.S. Department of Justice, which cautions against the existence of large-scale marijuana growing operations with millions of dollars of revenue.<sup>1</sup> Producers who grow thousands of plants and potentially realize large amounts of revenue may become tempting targets for federal law enforcement officials. Further, a regulatory system that contains a very small number of producers would have very little redundancy to meet patient demand in the event one such operation ceases to operate.

---

<sup>1</sup> James M. Cole, Memorandum for United States Attorneys: Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use. United States Department of Justice, Office of the Deputy Attorney General. June 29, 2011.

In addition, as anyone who operates an agricultural enterprise can attest, crops can fail even under the best of circumstances for a wide range of reasons. Because agriculture is an unpredictable venture, there should be sufficient redundancy to enable supply to continue even where one particular producer is unable to meet the demands of its dispensary.

In marijuana agriculture, there is a 3 ½ to 4 month period from propagation to harvest. Currently, the amount of marijuana necessary for a “one month supply” is yet to be determined, and the total number of patients is unknown. Therefore, it may be difficult for one or a few marijuana producers to ramp up harvest quotas quickly enough to meet statewide demand. Further, it is likely that not every producer can start at the same time. Again, redundancy in the production capacity of the state will help alleviate the pressure on one or a handful of super-growers.

While it is statutorily required that the number of licensees “not exceed the number appropriate to meet the needs of qualifying patients” (CT ST § 21a-408i), the regulatory framework established by the Department is in fact self-moderating. Quite simply, the patients – not the state – will ultimately determine the volume of marijuana produced, which is to say that the volume of marijuana needed is determined by the needs of the dispensary, which is there to meet patient demand over the course of a month. CT ST § 21a-408l. Any amount of marijuana that exceeds the amount needed by dispensaries or their facility must be destroyed. Sec. 21a-408-64(a). Producers have a financial disincentive to over-produce because it is a waste of time, resources, and money.

In addition, marijuana is available in a wide range of varieties (often referred to as “strains”), which each have their own mix of active ingredients and medicinal qualities. This range of varieties will therefore be variously sought after by a wide range of patients with different qualifying conditions. Varieties often have their own specific requirements in terms of nutrients, supplements, and even life cycles. It is not unusual for specific growers to specialize in particular varieties. It is in the best interests of both dispensaries and their patients to have a choice of both varieties and producers who can meet that need, particularly as the market matures.

Given the policy limitations imposed by the U.S. Department of Justice, the uncertainties inherent in an agricultural enterprise, the factors such as patient demand, which are yet to be determined, and the broad range of varieties that will be in demand by patients, having a redundant system of a larger number of relatively smaller producers (in this case, 10) is a better solution than one or a few very large growers. Fee-generated revenues to the state will be higher, and most importantly, patients will have more reliable access to a broader range of marijuana varieties.

### **3. Producers Whose Licenses Have Been Revoked Should Be Able To Sell Quality Inventory To Other Producers**

Under the proposed regulations, producers whose licenses are revoked must destroy inventory regardless of its quality. 21a-408-64(a). In a well-regulated tracking system, there is no rational basis for such a rule. Pharmaceutical grade inventory is costly to produce for a wide variety of reasons and represents an important resource for patients, which is hard to replace. So long as there are tracking mechanisms and accountability in place, there is no public interest reason to simply require the inventories' destruction when ultimately it is there for the benefit of patients.

Where inventory passes the applicable tests, it should be available for transfer to other producers in situations in which dispensaries are unable to take additional inventory so it is available for patients.

#### **4. The Department Should Consider Contingencies If There Are No Certified Testing Labs**

The current proposed regulation requires that medical marijuana produced and sold in the state pass specific tests, which qualify it as “pharmaceutical grade.” These criteria include active ingredient analysis, a microbiological contaminants analysis, a mycotoxin analysis, a heavy metal analysis, and a pesticide chemical residue analysis that are to be completed on a batch basis by a laboratory and are uniform within 97% to 103% of labeled results. Sec. 21a-408-1(49)(B).

Currently, no testing labs in the state are equipped or have the staff necessary for the full range of tests required in these proposed rules. For that matter, MPP has been unable to identify any marijuana-testing lab anywhere in the U.S. that is able to test all these criteria. While we would hope a testing facility is or becomes available within the state of Connecticut with both the equipment and staff necessary to meet these standards, the Department should have a contingency plan in place if it is determined that available or interested labs are incapable of meeting this standard.

#### **5. Federal Law Enforcement Activity Should Not Affect State License Status**

The Act Concerning the Palliative Use of Marijuana is a state law enacted through the state legislature, and it regulates state activities. Yet, the proposed regulations allow the Commissioner to suspend or even revoke licenses of producers and dispensaries for violations of federal law. 21a-408-31B(2).

Under the Controlled Substances Act, it is illegal to possess, grow, or sell marijuana for any purpose, and therefore, every participant in the state system is by implication violating federal law. The state government should not so quickly dismiss those who participate in the program.

MPP suggests that the language here be limited as it is similarly limited in several parts of the proposed regulations to say that where there are violations of federal law that are not inconsistent with the purposes of the Act, the Department may suspend or revoke a licensee’s status. See e.g. Sec. 21a-408-14(c)(2)(D)(5).

#### **6. Producer Licenses Are Too Costly**

The current proposed fee scheme is by far the most expensive in the U.S. The proposed rules require a non-refundable application fee of \$25,000 and an additional licensing fee of \$75,000, regardless of the amount of marijuana produced or sold. 21a-408-28(12). A renewal license is an additional \$75,000 (*Id* at (13)) and due every year. 21a-408-24(a)(14)(b). Each additional facility location requires another \$100,000 (21a-408-28(14)), plus the associated renewal costs. The Department should significantly lower this fee scheme for licensing for at least two important reasons.

Initially, such a fee will have to be absorbed by the patients, who often have limited incomes. Medical marijuana is not recognized by medical insurance providers for purposes of coverage, and therefore patients are unable to recoup their own out-of-pocket expenses when they

purchase medical marijuana. This fee will create an additional burden on patients with debilitating medical conditions.

In addition, many highly qualified growers do not have the resources of large corporations. Where such a fee might be appropriate for national or international pharmaceutical companies, nearly all medical marijuana producers are small, often “mom and pop” businesses that should be nurtured and allowed to have a role in the Connecticut program, so long as they can meet the security, facility, and licensing requirements established under the proposed rules. Unusually large licensing fee schemes create a barrier for entry for these smaller businesses and foreclose the possibility their skills and resources will be available to patients.

## **7. Requirements For Pharmacist-Dispensaries Are Overly Burdensome**

A dispensary must be a pharmacist, in accordance with CT ST § 21a-408h(b)(2), and at least one dispensary must be designated the dispensary facility manager. 21a-408-13(c). There are significant requirements placed on the dispensary facility manager pursuant to 21a-408-41. These include, but are not limited to, each of the following:

- Registering and training technicians
- Recording retention
- Physical security of marijuana
- The presence of pharmaceutical reference materials
- Ensuring that appropriate signage is posted
- Ensuring that all required filings are filed or notifications posted on behalf of the facility
- Overseeing shipments from producers
- Quality assurance review and reporting
- Supervising technicians

In addition, the dispensary facility manager is required to be present at the facility no less than 35 hours each week. For the most part, the dispensary is responsible for dispensing marijuana to patients, which creates a tremendous amount of liability for an individual who typically works at a facility (a pharmacy) that must maintain a DEA registration.

The Act itself simply requires that dispensaries are also be designated as pharmacists and allows the Commissioner to establish health, safety, and security requirements for licensed dispensaries, which may include control against diversion, theft and loss, and the ability to maintain the knowledge, understanding, judgment, procedures, security controls, and ethics to ensure optimal safety and accuracy in the distributing, dispensing, and use of palliative marijuana. CT ST § 21a-408h(b)(G).

While the proposed regulations are aimed at achieving this statutory goal, they create an enormous burden on a person who must be licensed as a pharmacist. This is particularly true in light of the fact that the federal government classifies marijuana as a Schedule I drug, which is a drug that, according to the federal government, has a high potential for abuse, has no currently accepted medical use in treatment, and for which there is a lack of accepted safety for use of the drug. Pharmacists are not required to have a DEA registration, however, every pharmacy is required to have such a license, and this restriction places a pharmacist in a very difficult position with respect to his or her role as a pharmacist. Indeed, he or she is required by state law to distribute a drug the federal government treats as illegal.

It is reasonable for the state to establish standards for the health, safety, and security of licensed dispensary facilities, but those goals can be achieved without placing a pharmacist at risk of scrutiny by the DEA, nor any current or prospective employer-pharmacies at risk of losing their DEA licenses. We believe a pharmacist/dispensary can take a supervisory role over the activities and employees at the dispensary facility but not be required to physically work at the facility or be directly responsible for the distribution of a Schedule I drug. The Marijuana Policy Project believes that well-trained dispensary technicians, directly answerable to the dispensary, can take the burden off of a pharmacist and still achieve the goals established under the Act. In the event that no pharmacists are willing or qualified to take such a role, the Department should develop contingency plans that would enable the medical marijuana program to continue to operate.

#### **8. Ensure A Sufficient Number Of Dispensary Facilities Will Serve The Needs Of Patients**

The Act requires that the number of dispensary licenses issued should not exceed the number appropriate to meet the needs of qualifying patients in the state as determined by the commissioner. CT ST § 21a-408h(b)(3).

Sec. 21a-408-13(b) states that:

The commissioner shall commence the process set forth in section 21a-408-14 to issue at least one dispensary facility permit upon adoption of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies and may issue additional dispensary facility permits upon a determination that additional dispensary facilities are desirable to assure access to marijuana for qualifying patients, which determination shall be made based on the size and location of the dispensary facilities in operation, the number of qualifying patients registered with the department and the convenience and economic benefits to qualifying patients.

We recommend that the Commissioner initially allow twelve (12) dispensary facilities based on the following reasons.

Based on geography, Connecticut would have 12 dispensaries when compared with Rhode Island. Rhode Island has granted licenses to three dispensaries and has one dispensary for every 345 square miles. By comparison, with 12 dispensaries, Connecticut would have one for every 404 square miles. Further, Connecticut does not allow patients to grow their own marijuana as Rhode Island does, and so, the demand will be significantly greater at the dispensaries in Connecticut.

Looking to another medical marijuana state, Maine has eight dispensaries with a population of 1.3 million people. On a per capita basis, that would mean 21 or 22 dispensaries in Connecticut. As compared with Maine, an initial 12 dispensaries in Connecticut would be a fairly conservative start.

We have seen negative impacts on patients in states that started with too few dispensary locations who then tried to catch up with demand. New Jersey has had a poor roll out for their regulated system by allowing only one dispensary. Now, they are rushing to increase both the capacity of the system and locations in an effort to meet demand. MPP believes Connecticut can avoid making the same mistake by starting with a better estimate as compared with other New England states with similar programs.