

# DEPARTMENT OF HEALTH AND SOCIAL SERVICES

## DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Chapter 49A (16 **Del.C.**, Ch. 49A)  
16 **DE Admin. Code** 4470

### FINAL

### ORDER

#### 4470 State of Delaware Medical Marijuana Code

#### NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("DHSS") initiated proceedings to adopt the State of Delaware Medical Marijuana Code. The DHSS proceedings to adopt the regulations were initiated pursuant to 29 **Delaware Code** Chapter 101 and authority as prescribed by 16 **Delaware Code**, Chapter 49A.

On October 1, 2013 (Volume 17, Issue 4), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 **Delaware Code** Section 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by October 31, 2013, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying "Summary of Evidence."

#### SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) regulations governing the State of Delaware Medical Marijuana Act were published in the *Delaware State News*, the *News Journal* and the *Delaware Register of Regulations*. Written comments were received on the proposed regulations during the public comment period (October 1, 2013 through October 31, 2013). Entities offering written comments included:

- "Marijuana Policy Project
- "David Turner
- "Todd Kitchen
- "Jim Phillips
- "Governor's Advisory Council for Exceptional Citizens
- "State Council for Persons with Disabilities
- "Paul Baumbach, State Representative, 23rd RD
- "Arlene Gordon
- "Cindy Hall
- "Nicole Harris
- "Janet Schwartz
- "Joseph H. Carsello
- "Theresa Jelenek
- "Joseph Lynch
- "M.S. Lally & Associates on behalf of DE Compassion Care, Inc.
- "Christopher & Elizabeth Cusack
- "Thomas P. McGonigle, Drinker Biddle & Reath LLP
- "Americans for Safe Access

Public comments and the DHSS (Agency) responses are as follows:

#### **Marijuana Policy Project:**

From: Robert J. Capecchi, Deputy Director of State Policies, Marijuana Policy Project

The Marijuana Policy Project (MPP), which has been working in partnership with patients and patient advocates in Delaware for several years, submits the following comments on the proposed medical marijuana compassion center regulations developed by the Department of Health and Social Services. We are grateful to the Division of Public Health for its diligent work crafting the rules. While most of the rules are fair and reasonable, there are some provisions that we are concerned are unnecessary or contrary to the language of Delaware's medical marijuana law.

We are particularly concerned that a few of the proposed rules would result in a problem we have seen in New Jersey and in the first years of New Mexico's program - an inadequate supply of medical marijuana. Failing to allow for an

adequate supply will cause qualifying patients to continue either have to frequent the criminal market or suffer without a medicine that can improve their quality of life. It would also seriously compromise the financial sustainability of successful compassion center applicants.

When appropriate, the department's proposed regulations are initially quoted exactly as they appear in the October 1, 2013 edition of the Delaware *Register of Regulations*. MPP's suggestions are found in the comment boxes with underscored and struck-through language being additions to or redactions from the language found in the proposed regulations.

Thank you very much for your consideration and attention to the changes MPP believes are vital to ensuring a workable program for patients who are facing debilitating medical conditions in Delaware.

## 2.0 Definitions

**Post-Traumatic Stress Disorder:** In the proposed regulations, the department adds a definition for Post-Traumatic Stress Disorder, providing that the patient must meet "the diagnostic criteria for Post-Traumatic Stress Disorder (PTSD), per DSM-5 or subsequent current edition, including symptoms of intense physical reactions, such as tachycardia, shortness of breath, rapid breathing, muscle-tension, and sweating."

**MPP comment:** The Delaware medical marijuana law (16 Del.C. §4902A) does not define Post-Traumatic Stress Disorder (PTSD). MPP feels it is unnecessary for the department to define PTSD as it already has a clinical definition. However, if it were defined, the definition should be limited to when "a patient meets the diagnostic criteria for Post-Traumatic Stress Disorder (PTSD), per DSM-5 or subsequent current edition." MPP is very concerned that the proposed rules' definition of PTSD goes beyond the requirement that the "patient meets the diagnostic criteria for [PTSD] ... per DSM-5 or subsequent edition" by adding "including symptoms of intense physical reactions, such as tachycardia, shortness of breath, rapid breathing, muscle-tension, and sweating."

The DSM-5 requires any one of five enumerated intrusion symptoms for a PTSD diagnosis. One of those five possible intrusion symptoms is "marked physiologic reactivity after exposure to trauma-related stimuli." The other four intrusion symptoms are not physical reactions. Defining PTSD in this way in the regulations would result in situations where a patient has been accurately diagnosed with PTSD by a licensed psychiatrist, but cannot use medical marijuana because the symptoms he or she presents do not include the criteria listed in the regulations (such as tachycardia). There is no medical reason to restrict medical marijuana to patients with physical intrusion symptoms when that restriction is not necessary to make the diagnosis.

**We recommend deleting the proposed definition of Post-Traumatic Stress Disorder found in 2.0. In the alternative, we recommend amending the definition to read:**

"Post-Traumatic Stress Disorder means that a patient meets the diagnostic criteria for Post-Traumatic Stress Disorder (PTSD), per DSM-5 or subsequent current edition.,~~including symptoms of intense physical reactions, such as tachycardia, shortness of breath, rapid breathing, muscle-tension, and sweating.~~"

**Agency Response:** The Agency appreciates and acknowledges these comments. The definition of PTSD was amplified in the regulations to indicate what symptoms are considered debilitating.

### 7.1.1.4 to 7.1.1.4.2.4 and 7.8.10. Prohibition on using pesticides

The proposed rules provide: "Use of pesticides is prohibited." The rules also provide that no pesticides are authorized for use on marijuana and that a compassion center may not apply pesticides in marijuana cultivation, including organochlorines, organophosphates, carymatates, and insecticidal, fungicidal, or growth regulatory compounds.

**MPP comment:** MPP strongly supports ensuring that marijuana is safe from dangerous pesticides. However, a complete ban on any pesticides is unnecessarily broad and may result in infestations that would prevent compassion centers from being viable, while driving patients to the criminal market. Maine initially had a complete ban on pesticides, but recognized earlier this year that pesticides that are so safe they are exempt from federal registration are safe for use on marijuana, with some limitations. Meanwhile, Washington state created a list of pesticides allowed on marijuana, and Colorado approved a list of pesticides that are not allowed on marijuana. We recommend that Delaware adopt essentially the same standard as was adopted in either Maine, Colorado, or Washington state. (22MRSA 2428, sub- 9, G)

**We recommend revising the prohibition on pesticides. A revision based on Maine's law would read:**

"7.1.1.4 A compassion center may not use a pesticide on marijuana unless all of the following apply:

7.1.1.4.1 The pesticide is exempt from the federal registration requirements pursuant to 7 United States Code, Section 136w(b);

7.1.1.4.2 The pesticide is registered with the Department of Agriculture pursuant to 3-601 Del. Admin. Code;

7.1.1.4.3. All compassion center agents handling pesticides are certified with the department of agriculture pursuant to 3-601 Del. Admin. Code, § 4.2;

7.1.1.4.4. All compassion center agents handling pesticides have received the training required by 3-601 Del. Admin. Code, § 4.2; and

7.1.1.4.5 All compassion center employees who have direct contact with treated plants have completed safety training pursuant to 40 Code of Federal Regulations, Part 170.130."

**We also recommend revising 7.8.10 to read:**

"the applicant's ability to grow marijuana without use of **prohibited** pesticides."

**Agency Response:** The Agency appreciates and acknowledges these comments, currently, the use of any pesticide

on medical marijuana is prohibited. The issue of pesticide use on medical marijuana is under further study and has been referred to the Delaware Governor's Panel on Pesticide Use. When the Panel issues a recommendation, further clarification will be issued.

#### 7.2.6 Maximum amount of compassion center inventory

The proposed regulations restrict medical marijuana compassion centers in Delaware to possessing no more than "150 marijuana plants irrespective of the stages of growth" and "no more than 1,500 ounces of usable marijuana regardless of formulation."

**MPP comment:** MPP feels it is unnecessary and contrary to the purposes of the Delaware Medical Marijuana Act to limit the amount of marijuana plants and usable marijuana compassion centers may possess at any given time. These caps will greatly restrict the amount of medicine available to the patient population in Delaware, resulting in a situation where patients are forced to continue to purchase unregulated medicine from the criminal market or to suffer without a medicine that can help them and that the legislature authorized.

To address a shifting and unclear federal position on medical marijuana - which at the time included some signs that the federal government was particularly concerned with large-scale medical marijuana cultivation - Gov. Markell announced on August 15, 2013 that he was asking the DHSS to propose rules that would limit Delaware's compassion center to cultivating no more than 150 plants and having an on-site inventory of no more than 1,500 ounces of medical marijuana. However, since Gov. Markell's announcement, the federal government has finally clarified its enforcement policies. The most recent U.S. Department of Justice memo, authored by Deputy Attorney General James Cole, along with the department's practices, make it clear that it is not necessary to limit the number of plants or usable marijuana.

The August 29, 2013 "Cole memo" states that:

The previous guidance [from DOJ] drew a distinction between the seriously ill and their caregivers, on the one hand, and large-scale, for profit commercial enterprises, on the other, and advised that the latter continued to be appropriate targets for federal enforcement and prosecution.

As explained above, however, both the existence of a strong and effective state regulatory system, and an operation's compliance with such a system, may allay the threat that an operation's size poses to federal enforcement interests. Accordingly, in exercising prosecutorial discretion, **prosecutors should not consider the size or commercial nature of a marijuana operation alone** as a proxy for assessing whether marijuana trafficking implicates [DOJ's] enforcement priorities. (emphasis added)

Instead of focusing on the size of the operation, the DOJ will focus its enforcement efforts on individuals and entities that are threatening or violating stated "priorities that are particularly important to the federal government." The memo cites eight specific areas of concern, such as restricting access to minors, which are addressed by Delaware's medical marijuana act and other regulations.

Not only is the 150-plant and 1,500-ounce cap unnecessary, it is also virtually guaranteed to result in shortages, driving patients to the illicit market. Only two other states - New Mexico and Rhode Island - have capped the number of plants a dispensary may cultivate at a finite number. An important distinction is that both of those states also allow patients to grow their own medicine, which is not allowed in Delaware.

Even with the option of home cultivation, there have been major problems with shortages in New Mexico. There have been multiple instances in which New Mexico's dispensaries ("licensed producers") did not produce an adequate supply to serve all of the registered patients of the state.<sup>1</sup> New Mexico's dispensaries were unable to meet patients' needs even when there were 17 licensed producers cultivating 95 plants. That's a total of 1,615 plants in a state that only has a little more than two times the population of Delaware.

In Rhode Island, the only reason there have not been shortages is that compassion centers do not depend on the 150 plants they may grow. Instead, they purchase most of their supply from patients and caregivers. Each of Rhode Island's more than 4,000 patients may grow 12 plants. In addition, each patient may have up to two caregivers, each of whom may also grow up to 12 plants. All of these individuals are allowed to sell their excess medicine to compassion centers. Home cultivation is prohibited in Delaware, so there is every reason to believe compassion centers would be unable to supply all of the state's patients with the limitation of 150 plants.

In New Jersey, there is no finite limit on plants, but nonetheless, the single dispensary ("alternative treatment center") that is operational has been unable to meet demand. Since late March, Greenleaf Compassion Center in Montclair has limited itself to north Jersey residents. This has left the remainder of the state's patients with no legal supply at all. Matters got even worse in late June when the dispensary closed because it did not have quality cannabis to sell, leaving all of the state's patients once again without access until it finally re-opened in mid-August.<sup>2</sup>

<sup>1</sup> Tim Korte, "New Mexico OKs fees for medical marijuana program," *Bloomberg*, Dec. 17, 2010. (Noting that the state was licensing eight more growers, bringing the total number to 25 and increasing mature plant limits from 95 to 150. The article noted, "Since the program started in 2007, the state has faced problems ensuring a steady supply.")

<sup>2</sup> "Medical Marijuana Update," *Drug War Chronicle*, Issue #797, August 22, 2013; "New hope for sick kids: Christie eases stance on medical marijuana," *The Record*, August 16, 2013. (The law allows for six dispensaries, but only one has opened, and the demand has been so high that it had to close for several weeks to cultivate more marijuana. New Jersey

law does not allow patients to have their own plants, and dispensaries must cultivate their own supply.)

While New Mexico and New Jersey's programs have resulted in shortages, that has generally not been a problem in states without fixed caps on how much marijuana can be cultivated and where there are a larger number of dispensaries. Nor have federal law enforcement targeted large-scale producers in any of the states where there are clear state regulations that are being complied with. There is no need to impose a restriction on the number of plants or ounces allowed in Delaware. A cap would be detrimental to the well-being of patients who have already waited more than two years to have safe access to medical marijuana, pursuant to the medical marijuana act they worked so hard to pass.

**We strongly recommend removing the possession limitation placed on compassion centers for marijuana plants and usable marijuana.**

**Agency Response:** The Agency appreciates and acknowledges these comments, however, to address Federal Justice Department concerns, the center will be limited to cultivate up to 150 marijuana plants irrespective of stages of growth, and maintain an inventory of no more than 1,500 ounces of useable marijuana.

#### 7.2.8.1.2 Written instructions to patients

This section provides that "Patients and designated caregivers should receive written instruction that the marijuana shall remain in this container when it is not being prepared for ingestion or being ingested."

**MPP comment:** This warning should be revised to only require marijuana to be stored in the container when it is outside the person's residence and when it is not being ingested or prepared for ingestion, pursuant to § 4919(x). The instructions the patient is given should track the language of the law to avoid misinforming patients. For a variety of reasons, it may make more sense for a patient to store marijuana in different containers than the ones they obtained from the compassion center while they are at home. Elderly patients and patients with arthritis or other problems using their hands may have problems opening and closing the containers, depending on their design. Also, they may need to separate out each dosage, just as prescriptions are often separated by each day of the week. Finally, they may cook marijuana into food, such as small cookies, that they eat over a period of time. Of course, the food would be too large to store in the original container.

**We recommend amending 7.2.8.1.2 to read:**

"Patients and designated caregivers should receive written instruction that the marijuana shall remain in this container when it is outside the patient's residence, unless it is being prepared for ingestion or being ingested."

**Agency Response:** The Agency appreciates and acknowledges these comments, however in an effort to prevent diversion and patient protection, through proper identification of the product, Medical Marijuana should be stored in the container it was purchased, when not being prepared for ingestion or being ingested.

#### 7.5.2 Registry identification cards and background checks for principal officers, board members, agents, volunteers, or employees of a compassion center

This section requires the department to "issue a registry photo identification card to each principal officer, board member, agent, volunteer or employee of a compassion center who is associated with a compassion center and meets the requirements under these regulations."

**MPP comment:** We agree with the idea of compassion center personnel receiving identification cards, but believe it would be more efficient and desirable to require the compassion centers themselves to conduct background checks and issue identification cards to all principal officers, board members, agents, volunteers, and employees. This is also what the law itself envisions. § 4918A requires the compassion center - not the state - to perform background checks on employees. In addition, the law defines "cardholder" as "a qualifying patient or a designated caregiver who has been issued and possesses a valid registry identification card" and registry identification card as "a document issued by the Department that identifies a person as a registered qualifying patient or registered designated caregiver."

Requiring the department to issue employees identification cards would impose an additional burden on the state. It is not clear if the staffer can begin work before they have the ID card, which the regulations propose giving the state 30 days to issue. If they are not allowed to begin work before then, it could make it difficult for the compassion centers to be fully staffed. Employers frequently have turnover, and they need to be able to swiftly replace staff to ensure they are fully staffed to meet patients' needs.

Instead of taking responsibility for performing background checks and issuing identification cards to compassion center staffers, the department could and should leave that to compassion centers. The department could then audit the centers' employee records, verify that employees are issued identification cards by the compassion centers, and perhaps perform a few random background checks on employees.

We recommend deleting 7.5.2.1.1 to 7.5.3 and amending 7.5.2.1 to read:

"In response to the requirements of this rule, and upon the approval of the submitted application, ~~the Department~~ compassion center shall issue a registry photo identification card to each principal officer, board member, agent, volunteer or employee of a compassion center who is associated with a compassion center and meets the requirements under these regulations."

**Agency Response:** The Agency appreciates and acknowledges these comments however, to address Federal Justice Department concerns, the Delaware Medical Marijuana Office will require multi-jurisdiction background check be conducted and Medical Marijuana program office issued identification card for all individuals with access to the restricted

areas of a compassion center.

#### 8.0 Registration and operation of testing facilities center

The draft regulations do not include regulations for testing facilities. Instead, the department continues to reserve the rulemaking for regulations governing the medical marijuana safety compliance facilities.

**MPP comment:** We feel it is unnecessary to continue to delay the rulemaking for an independent testing facility, especially in light of the decision to promulgate regulations for a compassion center. State-regulated and registered medical marijuana testing facilities are openly and actively serving the medical marijuana program in Colorado. These facilities ensure that medical marijuana does not contain molds or contaminants and clearly states the percentage of various cannabinoids so patients can more easily find a strain to address their particular debilitating disease or condition.

In addition, the proposed compassion center rules include a provision allowing compassion centers to have their medical marijuana tested by a third party or the center itself. (See: 7.3.12.1). For the third party facilities to be exempt under state law for possessing marijuana, they should have the opportunity to be licensed as safety compliance facilities. While it is comforting that some testing can be done by the center, it is preferable to entrust that vital function to a third party to ensure an accredited and independent entity tests for things like mold, pesticides, and spider mites. It is possible that no entity will apply to operate a laboratory, but applications should be accepted in case there are willing applicants.

#### **MPP encourages the department to move forward with developing testing facility center regulations.**

**Agency Response:** The Agency appreciates and acknowledges these comments however, considering the narrow scope of the pilot compassion center concept, opening an independent testing center would not be a financially viable option at this point. The limited volume of testing would not be enough to sustain the lab and could jeopardize the program. The program will increase the physical inspection of the Compassion Center growing process and pest control.

#### Registration of one pilot program compassion center only

The department makes clear in the introduction of the proposed regulations that they are being established for the operation of "one compassion center" as opposed to the three (one in each county) mandated by law.

**MPP comment:** MPP feels it is unnecessary to limit the compassion center program to one pilot center. The governor and the department should move forward with implementing the letter of the law by registering one compassion center in each county, so long as qualified applicants exist.

Restricting the compassion center program to one pilot program will only serve to harm patients. Presumably, the department will register a pilot center that is located in a population center, meaning patients who live in the south of the state will be severely inconvenienced. Medical marijuana patients in Delaware are not allowed to grow their own medicine, so they must rely on the compassion centers for access.

We recognize that only a very modest number of patients have signed up for the medical marijuana program so far, but that is surely because they have no access to medical marijuana at this time, and thus have little incentive to sign up. Once compassion centers are available, however, the number of patients should rapidly increase. A single compassion center will not be able to meet demand. That has been the case in New Jersey, which has a more restrictive law. In New Jersey, the single operational compassion center was first initially unable to meet demand statewide and then completely shut down for over a month after its crop was inferior. Allowing only one compassion center would mean that any problems the center may experience - such as mites or blackouts that cause crop failures - could jeopardize the entire supply of medical marijuana in the state.

The likely result of allowing only one of the three compassion centers that the legislature required the department to approve would be leaving many patients with no choice but to continue either accessing their medicine through the criminal market or suffering without it.

#### **We recommend moving forward with issuing registrations to three compassion centers (one in each county) as mandated by Delaware's medical marijuana law.**

**Agency Response:** The Agency appreciates and acknowledges these comments however, to address Federal Justice Department concerns; the Delaware Medical Marijuana Office has limited the scope of the program to one (1) compassion center, operating as a pilot program to gauge demand.

#### **David Turner:**

After reading the recommendations of the MPP, I would like to confirm the suggestions made as very legitimate concerns and agree with the solutions offered by MPP.

**Agency Response:** The Agency appreciates and acknowledges these comments, after thorough review and consultation with various stakeholders; the program is unable to incorporate all the proposed solutions.

#### **Todd Kitchen:**

I agree with all MPP's recommended changes \*(as listed below)

\*Agency Note - see MPP comments referenced above

**Agency Response:** The Agency appreciates and acknowledges these comments, after thorough review and consultation with various stakeholders; the program is unable to incorporate all the proposed solutions.

#### **Jim Phillips on October 11 and October 29, 2013:**

**- October 11, 2013**

It's been brought to my attention that the State of Delaware's Division of Public Health is taking submissions concerning the DE Medical Marijuana regulations. I submit for your consideration the following testimony along with suggestions about what strains to grow and what m-edibles should be stocked.

My story...

I'm a husband and caregiver to my wife, Avanda. We've been married for over 25 years. Avanda had been a Nurse for most of her career but had to hang up the stethoscope a few years ago because of chronic pain in her neck and lower back region. She is 61 years old and now on permanent disability. For the last 7-10 years, she has had to live with the pain of degenerative disc disease in her neck and lower back. She had a disc infusion on her neck two years ago which provided some relief but the surgery failed and she has to have the plate and screws in her neck re-adjusted. She is in the process of scheduling a disc infusion in her lower back but a preexisting condition in the lower back needs surgery before the disc infusion surgery. She also suffers from osteoarthritis. The disfigurement and the pain of this disease is a daily constant reminder. Her cornucopia of pain medications, include Percocet, Morphine, Neurontin, Valium and Flexaril. Being a nurse, she understands the pitfalls (addiction) of these pain pills and tries everything in her power to limit her intake of these meds. However, some days, it's all she can do to get out of bed without the aid of a Percocet to help and knock down some of the pain. Her quality of life is almost nonexistent because of the daily battle with pain. We're not sure if she will ever be completely healed and since the efficacy of her pain meds seems to be waning, medical marijuana might be her only other option. I would like to bring to your attention, some of the therapeutic benefits that medical marijuana could provide for some of her maladies:

- Degenerative disc disease:

[TheSilverTour.org/thomas-orvald-md-discusses-medical-cannabis-degenerative-disc-disease](http://thesilvertour.org/thomas-orvald-md-discusses-medical-cannabis-degenerative-disc-disease)

<http://www.webmd.com/pain-management/news/20100830/marijuana-relieves-chronic-pain-research-show>

- Osteoarthritis

<http://www.ncbi.nlm.nih.gov/pubmed/18416822> Characterization of the cannabinoid receptor system in synovial tissue and fluid in patients with osteoarthritis and rheumatoid arthritis

My research of medical marijuana has led me to believe that a high CBD and low THC ratio (or 1:1) could provide some type of relief for her. With that being said, I think the following medical marijuana strains should be considered as part of the Delaware grow operation:

Breeder/(Strain)

CBD Crew/(Nordle)

CBD Crew/(Skunk Haze)

CBD Crew/(Shark)

Reggae Seeds/(Juanita Lagromosa)

Humboldt Seed Company/(Sour Tsunami)

In addition, m-edibles and tinctures should also be stocked at the dispensary. The m-edibles should list both the THC and CBD contents in milligrams as well as the strain and the same goes for the tinctures. Since my wife also has COPD, m-edibles and tinctures may be the only delivery systems that she could tolerate. Thank you for your time.

**Agency Response:** The Agency appreciates and acknowledges these comments, however which strains, delivery methods and products the compassion center decides to produce and sell is a business decision that rests with the compassion center. The compassion center's selection and variety of products will be considered during the RFP process as one of many factors in selecting the winning bid.

**- October 29, 2013:**

I submit the following comments on the proposed medical marijuana compassion center regulations developed by the Department of Health and Social Services. The hard work the Division of Public Health has put forth on this project is very much appreciated. There are a couple of provisions that I am concerned with and would like to elaborate upon. I'm going to reference part of the code and comment as such.

-Registration of one pilot program compassion center only:

AND

-7.2.6 Maximum amount of compassion center inventory. A registered compassion center:

7.2.6.1 shall possess no more than 150 marijuana plants irrespective of the stages of growth.

7.2.6.2 shall possess no more than 1,500 ounces of usable marijuana regardless of formulation.

I feel the spirit of the law was to provide the maximum number of centers (3) allowable by law. Gov. Markell recently announced a change in course and indicated one compassion center would be rolled out instead of three. That is arbitrary and capricious. Not only will one compassion center create a hardship for the patients who have to travel to the center but the potential inventory for three centers has now been cut by two thirds. This scenario is destined to fail as it recently happened with New Jersey's sole compassion center. Running out of inventory and closing shop temporarily is not a way to run a business, especially when patients are relying on this medicine to treat their illnesses. If any problems occur with the one compassion center e.g. bug infestations or power outages, this could ruin the entire inventory of crops and jeopardize the supply for the entire state. If Gov. Markell wants to continue down the path of one compassion center, than he needs to lift the moratorium on the 150 plants/1500 ounces provision.

I have heard that not many patients have signed up for the program yet. I can only surmise that this is because there is no product in the ground. What is the incentive to sign-up, spend \$\$ for a MMJ card, have it expire and then renew it again, even before a product has been harvested? Timing is everything and I think you will see an influx of applications, the closer a harvest date has been set.

**Agency Response:** The Agency appreciates and acknowledges these comments. To address Federal Justice Department concerns, the Delaware Medical Marijuana Office has limited the scope of the program to one (1) compassion center, operating as a pilot program to gauge demand. The State of Delaware is issuing a Request For Proposal (RFP) for the operation of the Compassion Center. The location of the Compassion Center is one of many factors evaluated in the RFP process. The exact location of the Compassion Center will not be known until the completion of the RFP process. In addressing the Federal Justice Department concerns, the center will be limited to cultivate up to 150 marijuana plants irrespective of stages of growth, and maintain an inventory of no more than 1,500 ounces of useable marijuana.

**The State Council for Persons with Disabilities; and, The Governor's Advisory Council for Exceptional Citizens submitted the following comments:**

The State Council for Persons with Disabilities (SCPD), The Governor's Advisory Council for Exceptional Citizens (GACEC) has reviewed the Department of Health and Social Services/Division of Public Health's (DPH's) proposal to adopt a regulation governing the State of Delaware Medical Marijuana Act. The proposed regulation was published as 17 DE Reg. 405 in the October 1, 2013 issue of the *Register of Regulations*.

As background, legislation (S.B. 17) was enacted in 2011 to authorize the establishment of a medical marijuana program in Delaware. SCPD, the GACEC commented on an initial set of implementing regulations in April 2012 which covered eligibility, registration cards, etc. Although final regulations were adopted in June 2012, the State placed the actual growing and distribution of marijuana "on hold" when the federal Justice Department warned that State employees involved in the processing and distribution of marijuana could be prosecuted under federal drug laws. There are now at least nineteen (19) states with medical marijuana laws enacted and the Governor issued a letter to legislators in September, 2013 indicating that the administration has reassessed the legal landscape and plans to move forward to have the Delaware program operational in 2014.

DPH has now formally issued a proposed regulation to address the operation of "compassion centers" which would actually grow and distribute marijuana. There are many safeguards, including constant video surveillance, alarms, random inspections, personnel background checks, and audits. A facility could only cultivate a maximum of 150 plants and maintain a stockpile of less than 1,500 ounces. A compassion center must operate on a "not-for-profit" basis. See §7.0. The State plans to only initially authorize the establishment of a single compassion center which the DHSS website characterizes as a "pilot". Another curtailment in the program is elimination of an authorization for a "visiting qualifying patient" with an out-of-state medical marijuana identification card obtaining marijuana in Delaware. See §2.0, definition of "visiting qualifying patient". An RFP will be issued and the successful applicant will be authorized to begin growing medical marijuana on July 1, 2014.

SCPD, the GACEC endorses the proposed regulation subject to the Division's consideration of the following technical observations.

First, in §5.3.7, there is a plural pronoun ("their") with a singular antecedent ("patient"). SCPD, the GACEC recommends substitution of "the patient's" for "their".

**Agency Response:** The Agency appreciates and acknowledges these comments, and that recommended change will be made in the finalized regulations.

Second, the compassion center and each growing site are required to comply with local zoning standards. See §§7.6.3.1.1, 7.8.2, and 7.93.11. This could prove somewhat problematic since local zoning codes may not address an entity such as a compassion center. The Division may wish to reconsider this aspect of the standards.

**Agency Response:** The Agency appreciates and acknowledges these comments, zoning ordinance decisions are made at the local municipality level. The program will respect the enforcement of local zoning decisions notwithstanding section §4917A of the Act.

Third, §7.10.3 recites as follows:

7.10.3. Suspension: The Department will suspend a registration certificate authorizing the operation of a compassion center, with or without notice, for any violation of an applicable law or regulation.

Literally, this is a rather "brittle" standard. If there is a single, minor violation of a regulation, the Department would have no choice but to "suspend" the registration. There may be instances in which the Department would prefer to simply accept a remedial plan or prompt correction of non-compliance. SCPD recommends substituting "may" for "shall" so the Department has some flexibility in its response to identification of a violation of a law or regulation.

**Agency Response:** The Agency appreciates and acknowledges these comments, in accordance with the state's administrative procedures act, the program will use unambiguous language to eliminate confusion or set unacceptable standard.

**Paul Baumbach, State Representative, 23rd RD:**

I have reviewed the proposed regulations, and I have some comments for your consideration:

In the section of definitions, Department refers to DPHH. Why is this DPHH and not DPH.

**Agency Response:** The Agency appreciates and acknowledges these comments, the program will comb through the draft again to try to locate the DPHH inconsistency.

In section 7.2.1.2 that addresses the lighting of the premises. Is it intended that the lighting be high 24 hours a day, or only during working or operating hours? It could be advisable to be clear about this.

**Agency Response:** The Agency appreciates and acknowledges these comments, however the lighting is to prevent shadows and dark spots that would reduce the effectiveness of the security cameras. (7.2.1.2 The outside perimeter of the premises shall be well lighted to enhance the operation of the security cameras.)

7.2.2.2. Is the alarm check every 30 days warranted? I would think that every 90 days would be sufficient. Is a 30 day alarm check used in similar establishments, such as pharmacies and doctors offices that inventory pain prescriptions.

**Agency Response:** The Agency appreciates and acknowledges these comments, the 30 days standard was inspired by the security requirements in Rhode Island Medical Marijuana regulations. The Program adopted several best practices from contemporary programs.

7.2.2.3.2. Would you like to require that inventory is removed from premises which have a malfunctioning alarm systems?

**Agency Response:** The Agency appreciates and acknowledges these comments, the facility could enact other compensatory security measures such as 24-hour on-site security guard, which would need to be approved by the program. The program did not want to limit the ability to resolve the issue and maintain routine operations.

7.2.4.1.1. Aren't the caregivers ID numbers also recorded?

**Agency Response:** The Agency appreciates and acknowledges these comments, and yes, caregiver purchases will be documented. However, the tracking of purchases will be based off the patient's card number to ensure the patient does not receive over the authorized allotment in any given period. A caregiver could be purchasing product for several different patients, and in so exceed the threshold of 3 ounces in a 14-day period.

7.2.5.6. Should it more more common for multiple individuals to be conducting the audit? If so, should this be recommended or required? If so, shouldn't the word "individuals" be used instead of "individual"?

**Agency Response:** The Agency appreciates and acknowledges these comments, an excellent point which also pointed out another minor administrative error. 7.2.5.6 should be 7.2.5.3 Yes, it would be reasonable to expect more than one individual to conduct the inventory; we will change it to "individual(s)". The Compassion Center is responsible for writing the audit procedures they will follow in the Operations Manual, which will be evaluated in the RFP scoring process. If the procedures are inadequate, the program will direct the Compassion Center to enhance them.

7.2.6.3 how does a compassion center first start up? Cynically speaking, should the first DE compassion center create it's starting inventory by immaculate inception? Is a DE compassion center permitted to purchase inventory from another state's compassion center.

**Agency Response:** The Agency appreciates and acknowledges these comments, the expectation is seeds will be acquired outside the state and brought into the state for propagation. All plants will start from seeds in the state after the permit is issued on 1 July 2014.

7.2.7.1 aren't caregivers information be included in these inspections?

**Agency Response:** The Agency appreciates and acknowledges these comments; however, the tracking of purchases will be based off the patient's card number to ensure the patient does not receive over the authorized allotment in any given period. A caregiver could be purchasing product for several different patients, and in so exceed the threshold of 3 ounces in a 14-day period.

7.2.8.1.2. Is medical marijuana only ingested? Is there any topical administration of medical marijuana? The definitions reference a tincture, and a topical treatment. This is not covered by the wording of this section 7.2.8.3.1.3. Under what circumstances would a compassion center dispense a marijuana plant?

**Agency Response:** The Agency appreciates and acknowledges these comments; there is no foreseeable scenario where a patient would receive a plant. The words (or marijuana plants) will be deleted. Tincture and topical creams will be sold by the weight values of the cannabinoid content.

7.3.3 is there better wording for "do not suggest re-distribution"?

**Agency Response:** The Agency appreciates and acknowledges these comments. The context of this element is to address the Deputy Attorney General James M. Cole's Memorandum subject Guidance Regarding Marijuana Enforcement. One of the key enforcement priorities is "Preventing the diversion of marijuana from states where it is legal under state law in some form to other states." Additionally, this language is consistent with New Jersey and Rhode Island regulations.

7.5.2.1. Is the medical marijuana program defined somewhere? Later e MMP is referred to, at other places the Department, and at others DPH.

**Agency Response:** The Agency appreciates and acknowledges these comments. In the course of these regulations, there are various levels of responsibility, from the program level or Office of Medical Marijuana Program (OMMP), the Director of Public Health (DPH or Division) and the authority of the Cabinet Secretary (DHSS or Department). The regulations attempt to acknowledge the appropriate level of authority for the action or task described.

7.5.2.1.7. Here we go with MMP. (See 7.6.1) 7.5.3. How are the ID cards for board members etc renewed? ID renewal for patients and caregivers is detailed, but not for board members.

**Agency Response:** The Agency appreciates and acknowledges these comments. Employees and Compassion Center board members will submit program application with the same documentation as required for a Caregiver.

7.6.1. Please ensure that the payable party identification is consistent with the rest of these regulations.

**Agency Response:** The Agency appreciates and acknowledges these comments. There should be only one (1) payable party, the program "Division of Public Health, Medical Marijuana Program" who would receive the payment for the issue of ID Cards for Patients, Caregivers and Compassion Center Agents. The regulations will be updated to change the payee to "Division of Public Health, Medical Marijuana Program" throughout the regulation.

7.6.11. In the second line, "is in" should replace "in in"

**Agency Response:** The Agency appreciates and acknowledges these comments. Thank you, that change will be made.

7.8.2 shouldn't proximity to caregivers also be considered?

**Agency Response:** The Agency appreciates and acknowledges these comments; however, as a Caregiver is a supportive position by nature and may assist up to five (5) patients, the program will continue to focus on the qualifying patients over caregivers.

7.8.7 on the first line, "an" should replace "a an"

**Agency Response:** The Agency appreciates and acknowledges these comments. Thank you, that change will be made.

7.9.1. Please ensure that the payee is consistent with the rest of these regulations

**Agency Response:** The Agency appreciates and acknowledges these comments. There should be only one (1) payable party, the program "Division of Public Health, Medical Marijuana Program" who would receive the payment for the issue of ID Cards for Patients, Caregivers and Compassion Center Agents. The regulations will be update to change the payee to "Division of Public Health, Medical Marijuana Program" throughout the regulation.

9.3 is there any plan to direct employers from discriminating against employees who fail a drug test during periods when they are legally receiving epically marijuana?

**Agency Response:** The Agency appreciates and acknowledges these comments. No, not in these regulations, but the issue is covered in 16 Del. C. § 4905 A.

9.10 And 9.12 I believe that each instance of Division should be replaced by Department

**Agency Response:** The Agency appreciates and acknowledges these comments. This particular issue deals with hearings and the various levels of responsibilities in that process. Some of the tasks are at the Office of the DHSS Secretary (Department) and some of the tasks are handled by the Division of Public Health Director, (Division).

9.13.2 the 30 days after the hearing is inconsistent... see 7.10.4.1

**Agency Response:** The Agency appreciates and acknowledges these comments. The Hearing Officer will prepare the written decision including recommended action and send it to the Cabinet Secretary (Department) within 30 days of the completion of the hearing. That change will be made to Chapter 7.10.4.1

#### **Arlene Gordon:**

I support implementation of the State of Delaware Medical Marijuana Code and the pilot program compassion center. As a person living with Multiple Sclerosis, I am personally aware of many people who will benefit from access to this medication. As a resident of Sussex County, I am asking that this pilot compassion center be placed in a centrally accessible location such as Dover. It is my belief that if the center is located in New Castle County, access will be difficult and therefore limited for residents of Sussex County.

Thank you for your time and consideration.

**Agency Response:** The Agency appreciates and acknowledges these comments. The State of Delaware is issuing a Request For Proposal (RFP) for the operation of the Compassion Center. The location of the Compassion Center is one of many factors evaluated in the RFP process. The exact location of the Compassion Center will not be known until the completion of the RFP process.

#### **Cindy Hall:**

I support implementation of the State of Delaware Medical Marijuana Code and the pilot program compassion center. As a person living with Multiple Sclerosis, I am personally aware of many people who will benefit from access to this medication. As a resident of Sussex County, I am asking that this pilot compassion center be placed in a centrally accessible location such as Dover. It is my belief that if the center is located in New Castle County, access will be difficult and therefore limited for residents of Sussex County.

Thank you for your time and consideration.

**Agency Response:** The Agency appreciates and acknowledges these comments. The State of Delaware is issuing a Request For Proposal (RFP) for the operation of the Compassion Center. The location of the Compassion Center is one of many factors evaluated in the RFP process. The exact location of the Compassion Center will not be known until the completion of the RFP process.

#### **Nicole Harris:**

I support implementation of the State of Delaware Medical Marijuana Code and the pilot program compassion center. As a person living with Multiple Sclerosis, I am personally aware of many people who will benefit from access to this medication. As a resident of Sussex County, I am asking that this pilot compassion center be placed in a centrally accessible location such as Dover. It is my belief that if the center is located in New Castle County, access will be difficult and therefore limited for residents of Sussex County.

Thank you for your time and consideration.

**Agency Response:** The Agency appreciates and acknowledges these comments. The State of Delaware is issuing a Request For Proposal (RFP) for the operation of the Compassion Center. The location of the Compassion Center is one of many factors evaluated in the RFP process. The exact location of the Compassion Center will not be known until the completion of the RFP process.

**Janet Schwartz:**

My name is Janet Schwartz. I am a Senior in Newark, DE and have Multiple Sclerosis. I was at the signing of our Medical Marijuana Bill, had my picture taken, and remember thanking Governor Markell for the opportunity to try a different therapy for my MS other than my usual OxyContin, Vicodin, Soma and Dilaudid. I have my State of Delaware Medical Marijuana ID card in my wallet, but as of today, no prescription Marijuana. If California can have a "dispensary" on every street corner, why can't Delaware have just three "Care Centers" for our TINY state. I have NO family in Delaware and can't drive miles and miles to pick up a prescription. As far as a limit of 150 plants, I had a hippie friend in the 60's who had more than that in his back acre. I'm 66 years old and live in Newark Senior Housing. HOW MUCH LONGER DO I HAVE TO WAIT FOR THIS PRESCRIPTION THAT GOVERNOR MARKELL ALREADY SIGNED OFF ON. MS has me for the rest of my life, but I don't know how much longer that is. Please Governor, honor your promise to me.

**Agency Response:** The Agency appreciates and acknowledges these comments. To address Federal Justice Department concerns, the Delaware Medical Marijuana Office has limited the scope of the program to one (1) compassion center, operating as a pilot program to gauge demand. The State of Delaware is issuing a Request For Proposal (RFP) for the operation of the Compassion Center. The location of the Compassion Center is one of many factors evaluated in the RFP process. The exact location of the Compassion Center will not be known until the completion of the RFP process. In addressing Federal Justice Department concerns, the center will be limited to cultivate up to 150 marijuana plants irrespective of stages of growth, and maintain an inventory of no more than 1,500 ounces of useable marijuana.

**Joseph H. Carsello:**

I am formally submitting my comments concerning the proposed regulations to administer the Medical Marijuana Code in Delaware.

First, I have to say that limiting the implementation of the law to only one pilot compassion center is unrealistic. There should be at least three compassion centers in the state of Delaware. Having only one compassion center would make it very difficult for some patients to travel to only one center. There will probably be a number of patients who do not own cars or will have to find other means of transportation to travel only one center. In fact, I live in Sussex County (the city of Georgetown) and I am already considering it an inconvenience for me to travel to Dover just to pick up my state ID for the Medical Marijuana Program. That's an 80 mile round trip by car. Thus, I am recommending that the program have three compassion centers one in Dover; one in Wilmington, and one somewhere in Sussex or Kent County, all in compliance with the Medical Marijuana Code.

Secondly, limiting the number of plants to 150 which would yield approximately 1,500 ounces is also unrealistic. I know when Gov. Jack Markel signed the Delaware law there was some concern about limiting the number of plants. Since then the U.S. Department of Justice has stated that "the size or commercial nature of a marijuana operation alone" would not be grounds for federal prosecution of drug law violators.

I am counting on the government of Delaware to do the right thing in implementing this law that will enable every patient who is qualified to receive medical marijuana to treat their medical disorders and restore a better quality of life for them and me.

**Agency Response:** The Agency appreciates and acknowledges these comments. To address Federal Justice Department concerns, the Delaware Medical Marijuana Office has limited the scope of the program to one (1) compassion center, operating as a pilot program to gauge demand. The State of Delaware is issuing a Request For Proposal (RFP) for the operation of the Compassion Center. The location of the Compassion Center is one of many factors evaluated in the RFP process. The exact location of the Compassion Center will not be known until the completion of the RFP process. In addressing Federal Justice Department concerns, the center will be limited to cultivate up to 150 marijuana plants irrespective of stages of growth, and maintain an inventory of no more than 1,500 ounces of useable marijuana.

**Theresa Jelenek:**

Governor Markell,

My sister's daughter, Olivia, has intractable epilepsy as a result of a very rare brain malformation and has had multiple, daily seizures from the time she was 6 months old and ongoing (she is currently 20 years old). Olivia has been on every anti-convulsant medication available in the US, and she has also tried a few obtained from the UK and Canada. None of

these medications have reduced the number or intensity of her seizures, and her seizures continue to get worse. She has also tried the ketogenic diet and the vagus nerve stimulator to no avail. Surgery to split my niece's brain was the next recommendation by neurologists. However, this surgery would only reduce the intensity of her drop seizures, would not improve her other seizure types, and would possibly increase her already aggressive behaviors. Olivia has had to wear a helmet during her waking hours since her drop seizures increased to an average of five a day over the last four years. Her seizures cause her to fall straight backwards, usually with her head hitting the ground first, which resulted in many ER trips to have her head stitched/stapled. As you can imagine, my sister, her husband, and 2nd daughter (along with our large extended family) have been suffering along with Olivia as they have tried every version of medications to help relieve or minimize these heart-wrenching seizures.

Since reading the CNN article "Marijuana stops child's severe seizures" with Sanjay Gupta announcing his support on 8/7/13, my sister has researched the option of medical marijuana for my niece. My sister read the Delaware Online article "Gov. Markell's medical marijuana plan for Delaware criticized" on 10/22/13. I strongly agree with the concerns raised in this article by the Marijuana Policy Project. In particular, Delaware should move forward compassion center in each county - not one compassion center for the entire state. The true demand for medical marijuana will not be known until the compassion centers are available, and a single center will most likely not meet the demand. Additionally, what is the emergency preparedness plan if there is only one compassion center - in case of destruction from a hurricane or other storm - or plants being damaged or not growing as expected due to fungicide or bug infestation.

If medical marijuana reduces my niece's seizures to a point where she can reduce her pharmaceutical medications, she will be required to take the medical marijuana on a regular basis without any interruption. If there was a shortage of marijuana due to the proposed cap of 150 plants and other inventory restrictions, due to the increased demand, or due to a natural disaster, which resulted in Olivia not having her required medical marijuana - she could go into status epilepticus (a non-stop seizure requiring hospital treatment).

While Delaware is taking its time approving and planning the compassion center(s), Governor Markell, my sister and family are seriously investigating moving to another state with more progressive medical marijuana centers. My sister and her husband will follow the letter of the law to help their daughter find a new quality of life. This other state will allow my niece the medicine she needs, and who knows, it could be life changing for Olivia and her parents.

Please help my niece and the many others in Delaware that need to try medical marijuana by implementing the following recommendations:

- Open a compassion center in each county.
- Do not randomly restrict the number of plants grown at a compassion center. Remove the possession limitation placed on compassion centers for marijuana plants and usable marijuana.
- Move forward with developing testing facility center regulations.
- Ensure marijuana is safe. Marijuana should be grown without use of prohibited pesticides.
- Allow diversity of marijuana strain (my niece would require a high CBD plant, like Charlotte's Web available at Realm of Caring in Colorado).
- Allow diversity of method of administration (smoking, vaporizing, oil, capsule). My niece does not smoke and probably couldn't learn how to inhale. An oil or capsule format would be best for her.

Thank you for your kind attention. Please convene with others in the State to make Delaware a "First" in yet another of the many progressive activities.

**Agency Response:** The Agency appreciates and acknowledges these comments. To address Federal Justice Department concerns, the Delaware Medical Marijuana Office has limited the scope of the program to one (1) compassion center, operating as a pilot program to gauge demand. The State of Delaware is issuing a Request For Proposal (RFP) for the operation of the Compassion Center. The location of the Compassion Center is one of many factors evaluated in the RFP process. The exact location of the Compassion Center will not be known until the completion of the RFP process. In addressing Federal Justice Department concerns, the center will be limited to cultivate up to 150 marijuana plants irrespective of stages of growth, and maintain an inventory of no more than 1,500 ounces of useable marijuana. Considering the narrow scope of the pilot compassion center concept, opening an independent testing center would not be a financially viable option at this point. The limited volume of testing would not be enough to sustain the lab and could jeopardize the program. The program will increase the physical inspection of the Compassion Center growing process and pest control. Currently, the use of any pesticide on medical marijuana is prohibited. The issue of pesticide use on medical marijuana is under further study and has been referred to the Delaware Governor's Panel on Pesticide Use. When the Panel issues a recommendation, the regulations will reflect their opinion. Which strains, delivery methods and products the compassion center decides to produce is a business decision that rests with the compassion center. The compassion center's selection and variety of products will be considered during the RFP process as one of many factors in selecting the winning bid.

### **Christopher & Elizabeth Cusack:**

Our daughter, Olivia, was diagnosed with a very rare brain malformation when she was six months old at the time she developed infantile spasms. She is developmentally delayed (at a first grade level), has uncontrolled seizures (Leunox Gastaut Syndrome), and behavior issues. Over the last 19+ years, Olivia has tried just about every anti-epileptic

medication available in the US and a few obtained from the UK and Canada. She was on the Ketogenic Diet and had a Vagus Nerve Stimulator implanted in an attempt to control her seizures. To date none of the medications, diets, or medical procedures have reduced the number or severity of Olivia's seizures, and many of the medications had various negative side effects. Olivia wears a seizure helmet full-time (and has for the last three years) due to the number of her multiple, daily tonic-clonic seizures. The year prior to her wearing the helmet, she had numerous trips to the ER to have the back of her head stitched/stapled as a result of her seizures.

After we read the 8/7/13 CNN article "Marijuana stops child's severe seizures" with Dr. Sanjay Gupta announcing his support of medical marijuana and seeing the 8/11/13 CNN follow up "Weed" Documentary with Gupta, we decided to investigate what was available for Olivia in Delaware. Based on our research, we submitted our patient and caregiver applications in August to obtain our Delaware registry identification cards.

Since August we've researched the Realm of Caring in Colorado Springs and compassion centers in other approved states and found that the Realm of Caring is already established and much more progressive in their grow and test environments than what Delaware is currently proposing. We are looking at options to move to Colorado to have Olivia try the Realm of Caring's "Charlotte's Web" strain, since at best it looks like Delaware will not begin to grow the plants until next August.

Please consider our following comments and recommendations regarding the proposed medical marijuana compassion center regulations developed by the Department of Health and Social Services.

**1. Move forward with issuing registrations to three compassion centers (one in each county) as mandated by Delaware's medical marijuana law and as long as qualified applicants exist.**

Once compassion centers are available, the number of patients will rapidly increase and a single center will not meet the demand for the entire state. Obtaining the marijuana from a single compassion center once a patient is approved could prove to be onerous based on the location of the center, the person's home location, and the potential number of multiple trips to the physical location each month required to obtain the marijuana. Why should ease of access to medicine important to our loved one be determined by address?

Additionally, one facility in the state does not take into account an emergency preparedness plan in the event something happens to the one facility. What is the back up plan if there is an inferior crop grown or some other crop failure - or a hurricane or tornado damages the one facility?

Most anti-epileptic medications are started at a very low level, then increased over several weeks to the maximum point of medication that can be given based on the person's size and weight. If at that time the medication is not reducing the number or severity of seizures, the person is weaned off the medicine as slowly as it was given. If a person is taking marijuana and has successful seizure reduction, then bluntly ceasing to take the marijuana due to crop failure or facility damage could cause a person with seizures to have a medical emergency called status epilepticus - prolonged, non-stop seizures requiring emergency hospital treatment.

**Agency Response:** The Agency appreciates and acknowledges these comments. To address Federal Justice Department concerns, the Delaware Medical Marijuana Office has limited the scope of the program to one (1) compassion center, operating as a pilot program to gauge demand.

**2. Remove the possession limitation placed on compassion centers for the number of marijuana plants (no more than 150 plants) and usable marijuana (no more than 1,500 ounces).**

It is unnecessary and contrary to the purposes of the Delaware Medical Marijuana Act to limit the amount of marijuana plants and usable marijuana that compassion centers may possess at any given time. These caps will greatly restrict the amount of medicine available to the patient population in Delaware, which could result in detrimental consequences if the medicine given to a patient is abruptly stopped.

**Agency Response:** The Agency appreciates and acknowledges these comments. To address Federal Justice Department concerns, the center will be limited to cultivate up to 150 marijuana plants irrespective of stages of growth, and maintain an inventory of no more than 1,500 ounces of useable marijuana.

**3. Develop and implement regulations for independent test facility centers.**

State-regulated and registered medical marijuana testing facilities are openly and actively serving the medical marijuana program in Colorado. These facilities ensure that medical marijuana does not contain molds or contaminants and clearly states the percentage of various cannabinoids so patients can more easily find a strain to address their particular debilitating disease or condition.

In addition, the proposed compassion center rules include a provision allowing compassion centers to have their medical marijuana tested by a third party or the center itself. For the third party facilities to be exempt under state law for possessing marijuana, they should have the opportunity to be licensed as safety compliance facilities. While it is comforting that some testing can be done by the center, it is preferable to entrust that vital function to a third party to ensure an accredited and independent entity tests for things like mold, pesticides, and spider mites. It is possible that no entity will apply to operate a laboratory, but applications should be accepted in case there are willing applicants.

**Agency Response:** The Agency appreciates and acknowledges these comments. Considering the narrow scope of the pilot compassion center concept, opening an independent testing center would not be a financially viable option at this point. The limited volume of testing would not be enough to sustain the lab and could jeopardize the program. The program will increase the physical inspection of the Compassion Center growing process and pest control.

**4. Remove the prohibition of using pesticides within the compassion centers. Require centers to grow marijuana without the use of prohibited pesticides.**

A complete ban on any pesticides is unnecessarily broad and may result in infestations that would prevent compassion centers from being viable. Adopt the same standards that other states, such as Maine, Washington state, and Colorado, have implemented in regards to pesticide restrictions.

**Agency Response:** The Agency appreciates and acknowledges these comments. Currently, the use of any pesticide on medical marijuana is prohibited. The issue of pesticide use on medical marijuana is under further study and has been referred to the Delaware Governor's Panel on Pesticide Use. When the Panel issues a recommendation, the regulations will reflect their opinion.

**5. Ensure diversity of marijuana plant strain grown based on patient recommendation and demand.**

The Realm of Caring center in Colorado Springs grows and dispenses a concentrated Medicinal cannabis oil (Realm oil) high in CBD and low in THC (called Charlotte's Web), which they have found to help patients with intractable epilepsy significantly reduce and in some instances cease seizure activity. We are interested in trying this or a similar strain of marijuana for our daughter.

**Agency Response:** The Agency appreciates and acknowledges these comments. Which strains, delivery methods and products the compassion center decides to produce is a business decision that rests with the compassion center. The compassion center's selection and variety of products will be considered during the RFP process as one of many factors in selecting the winning bid.

**6. Ensure diversity of methods that the marijuana can be dispensed based on patient recommendation and demand.**

Marijuana should be dispensed in an oil format or a form for smoking or vaporizing depending on the patient need or demand. In the case of my daughter, she does not smoke and would most likely not be able to learn to smoke or vaporize the marijuana. Not to mention that this is not a skill we would want her to learn or that is necessarily healthy for her to learn. However, she would be able to successfully take the marijuana in an oil format.

**Agency Response:** The Agency appreciates and acknowledges these comments. The regulations allow the compassion center to create tincture, oils and creams for dispensing. The variety of products will be considered during the RFP process. The production and sale of these items are a business decision that will be made by the compassion centers.

**7. Monitor the pricing associated with being an approved "cardholder" and "designated caregiver" to ensure these costs do not cause an additional burden on the patient and/or family members who are already struggling with the "debilitating medical condition".**

Our costs associated with applying as a patient and caregiver are below. Keep in mind that the card is only valid for one year and that patients and caregivers must re-apply with the fees below, annually.

- Application fees for both patient and caregiver: \$250
- FBI background check \$62.50 + \$18.00
- Stamps to mail required documents
- Travel costs associated with obtaining background checks and medical documents

We have not heard how the pricing will be structured to actually purchase the marijuana from a compassion center. Will standard pricing be set? How and by whom? Will pricing be consistent if multiple compassion centers are established?

And depending on where the compassion center(s) are located with respect to our home, there are travel costs associated with being required to obtain the marijuana in person potentially more than once a month.

If the patient is disabled and currently receives DDS services, the application fee schedule and associated marijuana costs should depend on the patient's income, not total household income.

**Agency Response:** The Agency appreciates and acknowledges these comments. Pricing of products the compassion center decides to sell is a business decision that rests with the compassion center. The compassion center's ability to provide a variety of products at reasonable prices for Medicaid patients will be considered during the RFP process as one of many factors in selecting the winning bid.

**8. Remove the minimum age restriction (currently must be at least 18) to apply for medical marijuana in Delaware.**

Follow Colorado's progressive lead on allowing qualifying minors to apply for medical marijuana based on certain, active debilitating medical restrictions. Once a compassion center opens in Delaware, you can be certain that parents and caregivers of children under age 18 with debilitating medical conditions will challenge the current age restrictions - as was recently challenged and publicized in New Jersey.

**Agency Response:** The Agency appreciates and acknowledges these comments. To address Federal Justice Department concerns, specifically its top concern of preventing distribution of marijuana to minors, no one under the age of 18 is authorized to use or possess medical marijuana. The minimum age requirement (age 18) is found within the Act, Title 16 Chapter 49A Section 4909A Paragraph (b).

Thank you very much for your consideration and attention to our comments outlined above. We believe that addressing these issues are vital to ensuring a workable program for our daughter, other approved patients, and future applicants who face debilitating medical conditions in Delaware.

**Joseph Lynch:**

I urge you to ask the governor to reconsider making any changes regarding compassion center locations there should be one in each county as called for in the law that was passed!

This will create more hardship on patients who are dealing with too many hardships and challenges as it is!

If there is only one center and patients have to travel unnecessarily long distances it could increase any risks associated with traveling with medical cannabis in your vehicle!

I am against any changes to the original regulations

**Agency Response:** The Agency appreciates and acknowledges these comments. To address Federal Justice Department concerns, the Delaware Medical Marijuana Office has limited the scope of the program to one (1) compassion center, operating as a pilot program to gauge demand. The State of Delaware is issuing a Request For Proposal (RFP) for the operation of the Compassion Center. The location of the Compassion Center is one of many factors evaluated in the RFP process. The exact location of the Compassion Center will not be known until the completion of the RFP process.

**M.S. Lally & Associates on behalf of DE Compassion Care, Inc.:**

From: Delaware Compassion Care Inc.

On behalf of our Client, Delaware Compassion Care, Inc. (DCCI), whom is considering applying for a license to operate a Compassion Center in Delaware, here are their comments and/or questions below concerning the proposed medical marijuana compassion center regulations developed by the Department of Health and Social Services. While most of the rules seem reasonable, there are some provisions that cause them concern.

Delaware Compassion Care Inc., suggestions or questions are found in bold text and underneath excerpts of identified sections of the proposed regulations written in the October 1, 2013 publication of the Delaware *Register of Regulations*.

Thank you very much for your consideration and attention to our comments as we believe they are fundamental to ensure that a sensible program is developed for patients who are facing debilitating diseases and medical conditions in Delaware and for those held accountable to provide them those services.

7.1.4.1 Registered compassion centers shall keep detailed financial reports of proceeds and expenses.

7.1.4.2 Registered compassion centers shall maintain all inventory, sales and financial records in accordance with generally accepted accounting principles ("GAAP").

7.1.4.3 The Department or an audit firm contracted by the Department shall at all times have access to all books and records kept by any compassion center.

7.2 Security requirements: A compassion center shall implement appropriate security and safety measures to

**DCCI comment or question:** Can any of this information be obtained through FOIA through the state of Delaware or its Agency, if so we request that the language be changed to protect this information as some or all could be proprietary and compromising to the Compassion Center from competitors?

**Agency Response:** The Agency appreciates and acknowledges these comments. Pursuant to Title 16 Chapter, 49A Section 4920A information is not subject to FOIA.

7.2.6 Maximum amount of compassion center inventory. A registered compassion center:

7.2.6.1 shall possess no more than 150 marijuana plants irrespective of the stages of growth.

7.2.6.2 shall possess no more than 1,500 ounces of usable marijuana regardless of formulation.

**DCCI comment or question:** These caps will greatly restrict the ability to provide the medicine needed to the patient population resulting in patients being forced to seek their medicine from illegal sources which would be unregulated. Their other option would be to just have to suffer without it. These numbers seem to be arbitrary and selected to avoid any federal attention as opposed to a good estimate based on preliminary research of potential patient populations. A limit of inventory like this would put the compassion center in jeopardy of not being able to meet its operational needs to provide the needed medicine for the patients of Delaware. We would recommend an increase in these numbers or an allowance to operate based on demand and necessity.

**Agency Response:** The Agency appreciates and acknowledges these comments. To address Federal Justice Department concerns, the center will be limited to cultivate up to 150 marijuana plants irrespective of stages of growth, and maintain an inventory of no more than 1,500 ounces of useable marijuana.

7.2.6.3 may not purchase usable marijuana or mature marijuana plants from any person other than another registered compassion center.

**DCCI comment or question:** Since there isn't another registered compassion center in Delaware, can this be obtained from another registered compassion center out of state, such as New Jersey, if not, what compassion center are you referring to?

**Agency Response:** The Agency appreciates and acknowledges these comments.

A Compassion Center must grow product inventory in accordance with these regulations. The only exception to that premise is when more than one compassion center is operational in Delaware, a compassion center may purchase inventory from another compassion center within Delaware.

7.5.2.1 In response to the requirements of this rule, and upon the approval of the submitted application, the Department shall issue a registry photo identification card to each principal officer, board member, agent, volunteer or employee of a

compassion center who is associated with the compassion center and meets the requirements under these regulations. In order for a registry identification card to be obtained, the following items shall be submitted to the medical marijuana program.

7.5.2.1.1 birth certificate verifying that the applicant is at least 21 years of age;

7.5.2.1.2 a reasonable xerographic copy of the applicant's Delaware license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; identification card must be available for inspection/verification;

**DCCI comment or question:** since it states show their Delaware drivers license or other identification verifying Delaware residence, are you restricting the compassion centers to only allow them to hire Delaware residents?

**Agency Response:** The Agency appreciates and acknowledges these comments. Compassion Center agents and employees or other individuals requiring access to restricted areas of a compassion center must be in possession of valid Medical Marijuana program office issued employee card. Requirements to receive an employee card include a valid State of Delaware issued identification and Delaware residence.

### **Americans for Safe Access:**

RE: Comments on the proposed regulations for the Delaware Medical Marijuana Act

#### **Summary**

Americans for Safe Access (ASA) would like to thank the Delaware Department of Health and Human Services (DHHS) for the opportunity to comment on the proposed regulations for the Delaware Medical Marijuana Act (Act). Generally speaking, many of the proposed regulations are will provide for a solid basis upon which DHHS can establish a workable medical marijuana distribution system. However, there are several areas throughout the proposed regulations that may have the unintended consequence of inhibiting Delaware patients from being able to receive the desired benefit of their physician-recommended medical marijuana therapy. The following comments and recommendations are offered to help DHHS issue final regulations that will best serve the needs of Delaware patients.

#### **Comments**

##### **2.0 Definitions**

"Compassion center agent" and "Excluded felony offense"

**Problem:** The definition for "compassion center agent" states that a person may not become a compassion center agent if they have been "convicted of an excluded felony offense," or 'convicted of a drug misdemeanor within five years." Later, subpart (b)(2) of the definition for "excluded felony offense" allows for an exception if:

"an offense that consisted of conduct for which 16 Del.C. Ch. 49A would likely have prevented a conviction, but the conduct either occurred prior to July 1, 2011, or was prosecuted by an authority other than the State of Delaware."

**Solution:** Delete the misdemeanor conviction disqualification. It seems impractical to exclude individuals with misdemeanor drug offenses whose conduct would not likely have resulted in a conviction under the Act. However, if such a requirement is deemed necessary, misdemeanor conduct should qualify for the same exemption as found in subpart (b)(2) of the definition for "excluded felony offense."

**Agency Response:** The Agency appreciates and acknowledges these comments. The definition of an excluded offense or misdemeanor is not under review as it pertains to these regulations. The definition of an "excluded felony offense" is found within the Act, Title 16 Chapter 49A Section 4902A Paragraph (7).

"Post-Traumatic Stress Disorder"

**Problem:** By defining Post-Traumatic Stress Disorder (PTSD), it has become significantly more restrictive than any of the other debilitating medical conditions permitted by the Act. The basis for this additional level of scrutiny seems to be needlessly burdensome for both patients and physicians, as no other condition faces this definition. In fact, based upon the construction of the proposed language, a patient must suffer from all of the included symptoms in order to have a legally sufficient PTSD diagnosis ("including symptoms of intense physical reactions such as tachycardia, shortness of breath, rapid breathing, muscle-tension, **and** sweating," emphasis added). This seems like a particularly steep hurdle. In order for their be a clinical diagnosis of PTSD, a physician would be utilizing the DSM-5, which already contains criteria to be met with four symptom clusters and three additional criteria related duration of symptoms, functionality, and symptoms not being attributed to a substance or co-occurring medical condition.<sup>1</sup>

**Solution:** Delete the definition and do not included heightened requirements for a for PTSD as a qualifying condition. If DHHS finds it necessary to define the term, ASA suggests revising the definition to the following:

"Post-Traumatic Stress Disorder means that a patient meets the diagnostic criteria for Post-Traumatic Stress Disorder (PTSD), per DSM-5 or subsequent current edition.

<sup>1</sup>DSM-5 Criteria for PTSD, US Dept. of Veterans Affairs, available at [http://www.ptsd.va.gov/professional/pages/dsm5\\_criteria\\_ptsd.asp](http://www.ptsd.va.gov/professional/pages/dsm5_criteria_ptsd.asp), (last accessed October 30, 2013).

**Agency Response:** The Agency appreciates and acknowledges these comments. The definition of PTSD was amplified in the regulations to indicate what symptoms are considered debilitating.

#### 4.0 Designated Caregiver Registry Identification Card Application Requirements

Problem: There is currently explicit language informing parents and legal guardians of children younger than 18 years of age on how they may become the designated caregiver for a minor qualifying patient under their legal supervision. The statute forbids DHHS from issuing a registry identification card to a qualifying patient who is under the age of 18; however, there is no language that prevents a person who is younger than 18 years of age from becoming a qualifying patient. In fact, that provision that prohibits issuance of registry identification card to minors, 16 Del.C. § 4909A(b), specifically refers to "a qualifying patient who is younger than 18 years of age," (emphasis added). If the legislature intended for those younger than 18 years of age to be completely prohibited from becoming qualifying patients, the statute would expressly state that. Instead, the legislature recognized that minors can in fact be qualifying patients, but left it up to the regulatory stage to determine how this should take place. Parents and legal guardians should have clear guidance on how to become the designated caregiver for a minor patient under their supervision.

Solution: Insert language that expressly allows and provides guidance for parents and legal guardians to become the designated caregiver for their child if the child is younger than 18 years of age. Such a definition should include written consent from the parent or legal guardian, as well as a signed statement agreeing that they will be in charge of acquisition, possession, and dosage of the physician-recommended medicine. The District of Columbia provision on parental consent is similar to many other state approaches and is one that DHHS should consider adopting (see below).

"A qualifying patient who is a minor may possess and administer medical marijuana only if the parent or legal guardian of the minor has signed a written statement affirming that the parent or legal guardian:

"(1) Understands the qualifying medical condition or qualifying medical treatment of the minor;

"(2) Understands the potential benefits and potential adverse effects of the use of medical marijuana, generally, and, specifically, in the case of the minor;

"(3) Consents to the use of medical marijuana for the treatment of the minor's qualifying medical condition or treatment of the side effects of the minor's qualifying medical treatment; and

"(4) Consents to, or designates another adult to, serve as the caregiver for the qualifying patient and the caregiver controls the acquisition, possession, dosage, and frequency of use of medical marijuana by the qualifying patient."<sup>2</sup>

<sup>2</sup>D.C. Code § 7-1671.02(e).

**Agency Response:** The Agency appreciates and acknowledges these comments. To address Federal Justice Department concerns, the Delaware Medical Marijuana Office requires all participants are 18 years or older. Caregivers must be 21 years or older to be qualified.

#### 7.1.1.4 Use of pesticides is prohibited

Problem: Although there is clearly a laudable intent with respect to the safety of patients by including a prohibition on the use of pesticides during the cultivation of medical marijuana, a complete prohibition of pesticides is actually undesirable. A total prohibition upon pesticides would make the crops susceptible to infestation that could harm the cultivation of the medicine. Other states, such as Maine, Colorado, and Washington have adopted language that either specifies which specific pesticides are allowed or prohibited, rather than an outright ban.

Solution: Allow for certain pesticides and require labeling disclosure of pesticides used. ASA feels that Delaware could best balance the need for medicine free of harmful pesticides with allowing safe pesticides that enable reliable cultivation of medical marijuana free from infestation by adopting language based upon that found in the Maine regulations.<sup>3</sup> Along with the suggested language with Maine, ASA suggests adding labeling disclosure under 7.2.8.1 to provide patients with notice if pesticides have been used during the cultivation of the medicine.

7.1.1.4 A compassion center may not use a pesticide on marijuana unless all of the following apply:

7.1.1.4.1 The pesticide is exempt from the federal registration requirements pursuant to 7 United States Code, Section 136w(b);

7.1.1.4.2 The pesticide is registered with the Department of Agriculture pursuant to 3-601 Del. Admin. Code;

7.1.1.4.3. All compassion center agents handling pesticides are certified with the department of agriculture pursuant to 3-601 Del. Admin. Code, § 4.2;

7.1.1.4.4. All compassion center agents handling pesticides have received the training required by 3-601 Del. Admin. Code, § 4.2; and

7.1.1.4.5 All compassion center employees who have direct contact with treated plants have completed safety training pursuant to 40 Code of Federal Regulations, Part 170.130."

\*\*\*

7.2.8.1.3 If any pesticides were used during the cultivation of marijuana, the pesticides used shall be disclosed on a label affixed to the container that that marijuana is sold in. Compassion centers shall make available information about the potential risks and safety of any pesticides used in marijuana they make available for sale.

<sup>3</sup>22 MRSA 2428, sub- 9, G.

**Agency Response:** The Agency appreciates and acknowledges these comments. Currently, the use of any pesticide on medical marijuana is prohibited. The issue of pesticide use on medical marijuana is under further study and has been referred to the Delaware Governor's Panel on Pesticide Use. When the Panel issues a recommendation, the regulations will reflect their opinion.

#### 7.2.6 Maximum amount of compassion center inventory

**Problem:** By limiting compassion center inventory to a mere 150 plants and 1,500 ounces of usable medicine, DHHS is needlessly creating a situation in shortages of medicine are likely to be the ultimate outcome. According to the public notice accompanying the proposed regulations, Governor Markell has reduced "the number of compassion centers from three (one in each county) to one pilot program compassion center." This means that every patient in the state must be served by this extremely limited inventory. Because qualifying patients may receive up to three ounces of medicine in a 14-day period, the program would face medicine shortages if there are just 500 patients purchasing their full bi-weekly limit.

Worse still, this approach has been attempted by other states with less than desirable results. New Mexico sought to limit the number of plants that could be grown by cultivation facilities to 95 plants at the state's licensed cultivation facilities. The outcome was numerous shortages of medicine, which was harmful to wellness of New Mexico's patients.<sup>4</sup> While the District of Columbia has a similar provision, the only reason why there has not been a shortage of medicine in the District is due to the burdens the District Department of Health has imposed on physicians and patients in order to obtain a physician recommendation and registration identification card. As of October 21, 2013, there were only 59 patients registered in the District's program, meaning that fewer than 0.4% of the District's 15,000 HIV positive population are currently in the program. Therefore, DHHS should not look to the cultivation limits of the D.C. program as a basis for how to appropriately serve the needs of Delaware patients.

Moreover, the new U.S. Department of Justice memo on federal marijuana enforcement priorities states that the size of an operation is no longer the sole basis for triggering an investigation. Consequently, DHHS need not impose artificial caps on production and inventory based upon the fear of interference by federal agents.

**Solution:** Delete language imposing artificial caps on the number of plants and ounces of medicine that may be cultivated and possessed by a compassion center.

<sup>4</sup>New Mexico experiences pot shortage under tight medical marijuana rules, Associated Press, July 10, 2010, available at <http://www.foxnews.com/us/2010/07/16/new-mexico-experiences-potshortage-tight-medical-marijuana-rules/> (last accessed October 30, 2013).

**Agency Response:** The Agency appreciates and acknowledges these comments. To address Federal Justice Department concerns, the center will be limited to cultivate up to 150 marijuana plants irrespective of stages of growth, and maintain an inventory of no more than 1,500 ounces of useable marijuana.

#### 7.2.8.1 Design and security features of medical marijuana containers

**Problem:** The requirement in proposed rule 7.2.8.1.2 that all medicine must be stored inside the tamperproof container that medical marijuana is sold in may make sense upon first glance, but is ultimately a burden upon patients, particular those with debilitating pain. While such a limitation is reasonable when patients are transporting their medicine outside of their own personal residences, patients should have the ability to keep their medicine in containers that do exacerbate their condition so long as the medicine remains where the patient resides.

**Solution:** Insert language allowing reasonable store at home. ASA suggests the following language to replace the current language proposed in 7.2.8.1.2.

"Patients and designated caregivers should receive written instruction that The marijuana shall remain in this container when it is outside the patient's residence, unless it is being prepared for ingestion or being ingested."

**Agency Response:** The Agency appreciates and acknowledges these comments. In an effort to prevent diversion and patient protection, through proper identification of the product, Medical Marijuana should be stored in the container it was purchased, when not being prepared for ingestion or being ingested.

#### **Thomas P. McGonigle, Drinker Biddle & Reath LLP:**

Re: Proposed Regulations - The Delaware Medical Marijuana Act

This firm represents a potential applicant for the competitive bidding process to become certified to operate a Registered Compassion Center pursuant to Chapter 49A of Title 16 of the Delaware Code, the Delaware Medical Marijuana Act (the "Act"). In furtherance of implementing the Act, the Division of Public Health (the "Division") issued proposed regulations (the "Proposed Regulation") and sought suggestions and comments by October 31, 2013. To that end, this letter is to provide a few comments/suggestions on behalf of a potential applicant who has significance experience operating similar centers in other states.

First, both the Act and the Proposed Regulation contemplate that a Registered Compassion Center shall operate on a not-for-profit basis, but recognition as tax-exempt by the Internal Revenue Service is not required. While the Proposed Regulation provides that other written materials shall contain provisions evidencing the center's not-for-profit status, there is not much guidance on what those materials must provide. Since it can take some time to secure tax exempt status from

the IRS, this alternative avenue may be the more widely utilized mechanism to comply with these provisions and any specific guidelines in terms of what the Division will be looking for in this regard would be very helpful.

**Agency Response:** The Agency appreciates and acknowledges these comments.....

The requirement for a compassion center to be operated on a Not-for Profit status is found in the enabling legislation Title 16 Chapter 49A Section 4919A Paragraph (a).

Second, it is less than clear under the Proposed Regulation whether being certified as a Registered Compassion Center will also authorize that same entity to grow and cultivate the marijuana products on-site for eventual sale. Although the possibility of importing products for sale may be worth exploration, the unsettled federal legal ground around these issues makes that option challenging. In short, clarification that Registered Compassion Centers will be specifically authorized to grow and cultivate product on the premises would be helpful.

**Agency Response:** The Agency appreciates and acknowledges these comments. A Compassion Center must grow product inventory in accordance with these regulations. The only exception to that premise is when more than one compassion center is operational in Delaware, a compassion center may purchase inventory from another compassion center within Delaware.

Third, the Proposed Regulation provides for a Certification Fee of \$40,000 upon approval and re-certification every two years. While the fee itself (\$40,000 every two years) is not unreasonable, there are significant challenges presented by the two-year only certification process. It is likely that most applicants will need to secure land and make substantial capital investments to comply with the strenuous but important requirements of the Act, and the requirement to get re-certified every two years makes it difficult to finance those investments. By way of example, most commercial landlords seek a five year lease as a minimum, and lenders will want to be sure there is a viable business for some period of time, if they are going to provide financing.

We recognize the Act provides for renewals every two years, so there may be limitations on what can be done about this issue through the regulatory process. 16 Del. C. § 4916A. However, providing some additional structure around this process in the regulations would be helpful. For example, 16 Del. C. § 4916A(4) provides that applicants for re-certification must continue to comply with the criteria under §§ 4914A and 4915A. Such a requirement may make sense in the context of objective criteria such as ensuring that members of the Board have not been convicted of certain crimes or that the entity maintain its not-for-profit status. In contrast, issues like the "suitability of the proposed location" (16 Del. C. § 4915A(b)(2)), the sufficiency of the safety and security plans (16 Del. C. § 4914A(b)(6) and the "applicant's plan for making medical marijuana available on an affordable basis" for certain patients (16 Del. C. § 4914A(b)(7)), are very subjective. While certain subjective judgments may be necessary and appropriate with the initial certification, once an existing entity has been certified and invested significant resources into a business, such a process every two years presents real challenges in terms of the financing of these ventures.

To help provide some comfort with this process, in the absence of amending the Act, the Proposed Regulation should make it clear that once certified, issues like "suitability of the proposed location" cannot be re-opened in the re-certification process. In addition, with respect to other criteria and the re-certification process, we suggest a fairly rigorous hearing process with a requirement of an affirmative finding by a neutral arbitrator before a re-certification request is denied. For example, the Proposed Regulation contemplates a hearing process for revocations and suspensions, but does not appear to require such a process as part of a denial of re-certification. Such a process would at least provide comfort that such action would not be taken in the absence of an opportunity to be heard by a neutral decision maker and a finding by that decision maker that a substantial violation has occurred. Given the investment required to move forward with this venture, such a process is minimally required.

**Agency Response:** The Agency appreciates and acknowledges these comments. The State of Delaware is issuing a Request for Proposal (RFP) for the operation of the Compassion Center. After reviewing the wide variety of aspects covered under the RFP, one bidder will be selected and permitted to open the compassion center. The permit to operate will expire in 24 months; the compassion center operator will receive non-competitive subsequent operating permits after demonstrating consistent compliance with 16 DE Admin. Code 4470 regulations and receipt of the required application including permit fee by the Medical Marijuana Office

In closing, our client views the Proposed Regulation as a positive step forward and submits these suggestions as a way to improve upon this framework. Thank you for your consideration of these suggestions.

The public comment period was open from October 1, 2013 through October 31, 2013.

Based on comments received during the public comment period only non-substantive changes have been made to the proposed regulation. The regulation has been approved by the Cabinet Secretary of DHSS.

#### **FINDINGS OF FACT:**

Based on public comments received, non-substantive changes were made to the proposed regulations. The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

**THEREFORE, IT IS ORDERED**, that the proposed State of Delaware Medical Marijuana Code regulations are adopted and shall become effective January 11, 2014, after publication of the final regulation in the *Delaware Register of Regulations*.

## 4470 State of Delaware Medical Marijuana Code

### Preamble

The Secretary of Delaware Health and Social Services adopts these Regulations in response to the authority vested in the Secretary by 16 ~~Delaware Code~~ Del.C. Chapter Ch. 49A, The Delaware ~~Health and Social Services~~ Medical Marijuana Act. These Regulations establish the standards for the procedures for issuing a certificate of registration to qualified patients and primary caregivers. These Regulations provide a system of permitting and inspection, as well as governing confidentiality, payments of fees, and enforcement of these rules.

### Purpose

These Regulations shall be liberally construed and applied to promote their underlying purpose of protecting the public's health.

### 1.0 State of Delaware Medical Marijuana Code

These Regulations shall hereby be known as the "State of Delaware Medical Marijuana Code."

### 2.0 Definitions

The following words and terms, when used in these Regulations, should have the following meaning, unless the context clearly indicates otherwise:

**"Act"** means the Delaware Marijuana Act, 16 **Del.C.** §§4901A *et seq.*

**"Adulterated"** means made impure or inferior by adding extraneous ingredients. Goods that are prepared in food establishments that are licensed facilities in response to 16 **Del.C.** §122(3)(u) and 16 **Del.C.** §134, and that contain marijuana for medical use by a registered patient, are not considered to be adulterated.

**"Advisory board"** means a nine member committee established, chaired, and appointed by the General Assembly of Delaware to evaluate and make recommendations to the state legislature and the Department.

**"Applicant"** means any person applying to participate in the Delaware Office of Medical Marijuana Program, hereinafter OMMP.

**"Cardholder"** means a registered patient or a registered designated caregiver who has been issued and possesses a valid registry identification card.

**"Compassion center agent"** means a principal officer, board member, employee, or agent of a registered compassion center who is 21 years of age or older and has not been convicted of an excluded felony offense, and has not been convicted of a drug misdemeanor within five years.

**"Debilitating medical condition"** means one or more of the following:

(a) cancer, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), decompensated cirrhosis (hepatitis C), amyotrophic lateral sclerosis (ALS or Lou Gehrig's Disease), post-traumatic stress disorder (PTSD), and agitation of Alzheimer's disease or the treatment of these conditions;

(b) a chronic or debilitating disease, medical condition or symptom listed in these rules and as defined in 16 **Del.C.** §4902A(3) that qualifies for the medical use of marijuana by a registered patient its treatment that produces one or more of the following: cachexia or wasting syndrome; severe, debilitating pain that has not responded to previously prescribed medication or surgical measures for more than three months or for which other treatment options produced serious side effects; intractable nausea; seizures; or severe and persistent muscle spasms, including but not limited to those characteristic of multiple sclerosis;

(c) any other medical condition or its treatment added by the Department, as provided for in 16 **Del.C.** §4906A and Section 6.0 of this code..

**"Department"** means the Delaware Department of Health and Social Services.

**"Designated caregiver"** means a person who:

- (a) is at least 21 years of age
- (b) has agreed to assist with a patient's medical use of marijuana
- (c) has not been convicted of an excluded felony offense; and
- (d) assists no more than five qualifying patients with their medical use of marijuana

**"Excluded felony offense"** means:

- (a) a violent crime defined in 11 **Del.C.** §4201(c), that was classified as a felony in the jurisdiction where the person was convicted; or
- (b) a violation of a state or federal controlled substance law that was classified as a felony in the jurisdiction where the person was convicted, not including:
  - (1) an offense for which the sentence, including any term of probation, incarceration, or supervised release, was completed 10 or more years earlier; or
  - (2) an offense that consisted of conduct for which ~~this chapter~~ 16 Del.C. Ch. 49A would likely have prevented a conviction, but the conduct either occurred prior to ~~the enactment of this chapter~~ July 1, 2011, or was prosecuted by an authority other than the ~~s~~State of Delaware.

**"Incidental amount of marijuana"** means marijuana seeds, stalks and roots of the plant that are not included when calculating the allowable amounts of marijuana specified in these rules. This includes the weight of any non-marijuana ingredients combined with marijuana, such as ingredients added to prepare a topical ointment, food or drink.

**"Marijuana"** means the same as defined in 16 **Del.C.** §4701 (23).

**"Marijuana paraphernalia"** is limited to equipment, products and materials that are ordinarily used in planting, propagating, cultivating, growing, harvesting, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, ingesting, inhaling or otherwise introducing marijuana into the human body. It includes:

- (a) Scales and balances used or intended for use in weighing or measuring marijuana;
- (b) Separation gins and sifters, used or intended for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana;
- (c) Envelopes and other containers used or intended for use in packaging small quantities of marijuana for medical use;
- (d) Containers and other objects used or intended for use in storing medical marijuana; and
- (e) Objects used or intended for use in ingesting, inhaling or otherwise introducing marijuana into the human body, including but not limited to:
  - (1) Metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with or without screens, permanent screens, hashish heads or punctured metal bowls;
  - (2) Water pipes;
  - (3) Carburetion tubes and devices;
  - (4) Smoking and carburetion masks;
  - (5) Roach clips, meaning objects used to hold burning marijuana cigarettes that have become too small or too short to be held in the hand;
  - (6) Chamber pipes;
  - (7) Carburetor pipes;
  - (8) Electric pipes;
  - (9) Air-driven pipes;
  - (10) Chillums;
  - (11) Bongs designed for marijuana and not for cocaine; or
  - (12) Ice pipes or chillers.

**"Medical use"** means the acquisition, possession, use, delivery, transfer or transportation of marijuana or paraphernalia relating to the administration of marijuana to treat or alleviate a registered patient's debilitating medical condition or symptoms associated with the registered patient's debilitating medical condition.

**"Onsite assessment"** means a visit by an employee of the Department for the purpose of ensuring compliance with the requirements of these rules.

**"Physician"** means a properly licensed physician subject to 24 **Del.C.** Chs. 17 and 19, ~~except as otherwise provided in this subsection.~~ If the qualifying patient's debilitating medical condition is post-traumatic stress disorder, the physician must also be a licensed psychiatrist. ~~In relation to a visiting qualifying patient, "physician" means a person who is licensed with authority to prescribe drugs to humans and who may issue a written certification or its equivalent in the state of the patient's residence.~~

**"Post-Traumatic Stress Disorder"** means that a patient meets the diagnostic criteria for Post-Traumatic Stress Disorder (PTSD), per DSM-5 or subsequent current edition, including symptoms of intense physical reactions such as tachycardia, shortness of breath, rapid breathing, muscle-tension, and sweating.

**"Qualifying patient"** means a person who has been diagnosed by a physician as having a debilitating medical condition.

**“Registry identification card”** means a document issued by the Department that identifies a person as a registered patient or registered designated caregiver.

**“Tincture”** means a mixture created from a concentrated extract of marijuana.

**“Topical treatment”** means a mixture or extract of marijuana made into a balm, lotion, ointment or rubbing alcohol solution, that is applied transcutaneously.

**“Usable amount of medical marijuana for medical use”** means six ounces or less of usable marijuana as defined below.

**“Usable marijuana”** means the dried leaves and flowers of the marijuana plant, and any mixture or preparation of those dried leaves and flowers, including but not limited to tinctures, ointments, and other preparations. It does not include the weight of any non-marijuana ingredients combined with marijuana, such as ingredients added to prepare a topical administration, food, or drink.

**“Verification system”** means a phone or web-based system established and maintained by the Department that is available to law enforcement personnel and compassion center agents on a twenty-four-hour basis for verification of registry identification cards.

**“Visiting qualifying patient”** means a patient who:

- (a) ~~has been diagnosed with a debilitating medical condition;~~
- (b) ~~possesses a valid registry identification card, or its equivalent, that was issued pursuant to the laws of another state, district, territory, commonwealth, insular possession of the United States or country recognized by the United States that allows the person to use marijuana for medical purposes in the jurisdiction of issuance; and~~
- (c) ~~is not a resident of Delaware or who has been a resident of Delaware for less than 30 days.~~

**“Written certification”** means a document dated and signed by a physician, stating that in the physician’s opinion the patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient’s debilitating medical condition or symptoms associated with the debilitating medical condition. A written certification shall be made only in the course of a bona fide physician-patient relationship where the qualifying patient is under the physician’s care for ~~her or his~~ the qualifying patient’s primary care or for ~~her or his~~ the qualifying patient’s debilitating condition after the physician has completed an assessment of the qualifying patient’s medical history and current medical condition. The bona fide physician-patient relationship may not be limited to authorization for the patient to use medical marijuana or consultation for that purpose. The written certification shall specify the qualifying patient’s debilitating medical condition.

### 3.0 Qualifying Patient Identification Card Application Requirements

- 3.1 The Department shall issue a registry identification card to an applicant for the purpose of participating in the medical marijuana program upon the written certification of the applicant’s ~~P~~physician, supporting application documents and a non-refundable application fee with a personal check or a cashier’s check made out to **“[State of Delaware Division of Public Health], Medical Marijuana Program.”** The following information shall be provided in the participant enrollment form submitted to the Department in order for a registry identification card to be obtained and processed.
- 3.2 An attached original written certification for patient eligibility form shall contain:
  - 3.2.1 the name, address and telephone number of the applicant’s ~~P~~physician;
  - 3.2.2 the ~~P~~physician’s clinical licensure;
  - 3.2.3 the patient applicant’s name and date of birth;
  - 3.2.4 the medical justification for the ~~P~~physician’s certification of the patient’s debilitating medical condition;
  - 3.2.5 the ~~P~~physician’s signature and date;
  - 3.2.6 the name, address and date of birth of the applicant;
  - 3.2.7 the name, address and date of birth of the applicant’s primary caregiver(s), if any;
  - 3.2.8 a reasonable xerographic copy of the applicant’s Delaware driver’s license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; State of Delaware issued identification card must be available for inspection/verification;
  - 3.2.9 the length of time the applicant has been under the care of the ~~P~~physician providing the medical provider certification for patient eligibility;
  - 3.2.10 the applicant’s signature and date; and
  - 3.2.11 a signed consent for release of medical information related to the patient’s debilitating medical condition, on a form provided by the medical marijuana program.

#### 4.0 Designated Caregiver Registry Identification Card Application Requirements

- 4.1 The Department shall issue a registry identification card to a primary caregiver applicant for the purpose of managing the well-being of one to five qualified patients, including themselves if caregiver is a qualified patient, in response to the requirements of this rule upon the completion and approval of the primary caregiver application form, available from the medical marijuana program, and a non-refundable application fee, in the form of a personal check or a cashier's check made out to "~~State of Delaware~~ **Division of Public Health**, Medical Marijuana Program". In order for a registry identification card to be obtained and processed, the following information shall be submitted to the medical marijuana program:
- 4.1.1 birth certificate verifying that the applicant is at least (21) years of age;
  - 4.1.2 a reasonable xerographic copy of the applicant's Delaware license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; State of Delaware issued identification card must be available for inspection/verification.
  - 4.1.3 written approval by the qualified patient(s) authorizing responsibility for managing the well-being of a qualified patient(s) with respect to the use of marijuana;
  - 4.1.4 the name(s), address(es), telephone number(s) and date of birth of the qualified patient(s);
  - 4.1.5 the name, address and telephone number for each of the qualified patient's Pphysicians;
  - 4.1.6 the name, address, telephone number of the applicant; and
  - 4.1.7 the applicant's signature and date.
- 4.2 Designated caregiver application requirements:
- 4.2.1 Criminal history screening requirements:
    - 4.2.1.1 All designated caregiver applicants are required to consent to a nationwide and statewide criminal history screening background check. All applicable application fees associated with the nationwide and statewide criminal history screening background check shall be paid by the primary caregiver applicant.
    - 4.2.1.2 Individuals convicted of an excluded felony offense, as described in the definitions Section 2.0, and 16 **Del.C.** §4902A(7) are prohibited from serving as a designated caregiver. The applicant and qualified patient shall be notified by registered mail of his or her disqualification from being a designated caregiver.

#### 5.0 Registry Identification Cards

- 5.1 Department inquiry:
- 5.1.1 The Department may verify information on each application and accompanying documentation by the following methods:
    - 5.1.1.1 contacting each applicant by telephone, mail, or if proof of identity is uncertain, the Department shall require a face-to-face meeting and the production of additional identification materials
    - 5.1.1.2 contacting the Delaware Division of Professional Regulation to verify that the Pphysician is licensed to practice medicine in Delaware and is in good standing; and
    - 5.1.1.3 contacting the Pphysician to obtain further documentation that the applicant's medical diagnosis and medical condition qualify the applicant for enrollment in the medical use marijuana program.
  - 5.1.2 Upon verification of the information contained in an application submitted in response to this subsection, the Department shall approve or deny an application within 45 calendar days of receipt.
- 5.2 Department registry identification card: The Department shall issue a registry identification card within 30 calendar days of approving an application. A registry identification card shall contain a 10-digit alphanumeric identification, maintained by the Department, which identifies the qualified patient or primary caregiver. Unless renewed at an earlier date, suspended or revoked, or if the physician stated in the written certification that the qualifying patient would benefit from marijuana until a specified earlier date, a registry identification card shall be valid for a period of 4 one year from the date of issuance and shall expire at midnight on the day indicated on the registry identification card as the expiration date.
- 5.3 Supplemental requirement:
- 5.3.1 A registered qualifying patient or registered designated caregiver who possesses a registry identification card shall notify the Department of any of the following within 10 calendar days of the change. An extension shall be granted by the medical marijuana program upon the showing of good cause.
    - 5.3.1.1 a change in card holder's name or address,
    - 5.3.1.2 knowledge of a change that would render the patient no longer qualified to participate in the program, such as a cure of the debilitating condition causing the need for Medical Marijuana,

- 5.3.1.3 knowledge of a change that renders the patient's physician no longer a qualified "physician" as defined in 2.0 of these regulations,
- 5.3.1.4 knowledge of a change that renders the patient's caregiver no longer eligible as defined in these regulations.
- 5.3.2 Before a registered qualifying patient changes his or her designated caregiver, the qualifying patient must notify the Department in writing.
- 5.3.3 If a cardholder loses his or her registry identification card, he or she shall notify the Department in writing within 10 days of becoming aware the card has been lost. Upon notification, the Department shall issue a new registry identification card. Unless documentation in the initial application has changed, the qualified patient or designated caregiver shall not be required to submit a new application.
- 5.3.4 When a cardholder notifies the Department of items listed in Section 5.3 but remains eligible, the Department shall issue the cardholder a new registry identification card with a new random 10-digit alphanumeric identification number within 10 days of receiving the updated information and the cardholder shall pay a \$20 fee. If the person notifying the Department is a registered qualifying patient, the Department shall also issue his or her registered designated caregiver, if any, a new registry identification card within 10 days of receiving the updated information.
- 5.3.5 If a registered qualifying patient ceases to be a registered qualifying patient or changes his or her registered designated caregiver, the Department shall promptly notify the designated caregiver by legal process server. The registered designated caregiver's protections under this chapter as to that qualifying patient shall expire 15 days after notification by the Department.
- 5.3.6 A cardholder who fails to make a notification to the Department that is required by Section 5.3 is subject to a civil infraction, punishable by a penalty of no more than \$150.00 and is also subject to the immediate revocation of the registry identification card and all lawful privileges provided under the act.
- 5.3.7 If the registered qualifying patient's certifying physician notifies the Department in writing that either the registered qualifying patient has ceased to suffer from a debilitating medical condition or that the physician no longer believes the patient would receive therapeutic or palliative benefit from the medical use of marijuana, the card shall become null and void. However, the registered qualifying patient shall have 15 days to dispose of ~~his or her~~ **[their the patient's]** marijuana.
- 5.4 Registry identification card application denial: The DHSS Secretary or designee shall deny an application if the applicant fails to provide the information required, if the Department determines that the information provided is false, or if the patient does not have a debilitating medical condition eligible for enrollment in the program, as determined by the DHSS Secretary. A person whose application has been denied shall not reapply for ~~6~~ **six** months from the date of the denial, unless otherwise authorized by the Department, and is prohibited from all lawful privileges provided by this rule and act.
  - 5.4.1 The Department shall deny an application or renewal of a qualifying patient's registry identification card if the applicant:
    - 5.4.1.1 did not provide the required information and materials;
    - 5.4.1.2 previously had a registry identification card revoked; or
    - 5.4.1.3 provided false or falsified information.
  - 5.4.2 The Department shall deny an application or renewal for a designated caregiver chosen by a qualifying patient whose registry identification card was granted if:
    - 5.4.2.1 the designated caregiver does not meet the requirements of Section 4.2;
    - 5.4.2.2 the applicant did not provide the information required;
    - 5.4.2.3 the designated caregiver previously had a registry identification card revoked; or
    - 5.4.2.4 the applicant or the designated caregiver provides false or falsified information.
  - 5.4.3 The Department shall notify the qualifying patient who has designated someone to serve as his or her designated caregiver if a registry identification card will not be issued to the designated caregiver.
  - 5.4.4 Denial of an application or renewal is considered a final Department action, subject to judicial review. Jurisdiction and venue for judicial review are vested in the Superior Court.
- 5.5 Registry identification card renewal application: Each registry identification card issued by the Department is valid in accordance to Section 5.2. A qualified patient or primary caregiver shall apply for a registry identification card renewal no less than 45 calendar days prior to the expiration date of the existing registry identification card in order to prevent interruption of possession of a valid (unexpired) registry identification card.

- 5.6 Non-transferable registration of registry identification card: A registry identification card shall not be transferred, by assignment or otherwise, to other persons or locations. Any attempt shall result in the immediate revocation of the registry identification card and all lawful privileges provided by this rule and act.
- 5.7 Automatic expiration of registry identification card by administrative withdrawal: Upon request the qualified patient or designated caregiver shall discontinue the medical marijuana program by an administrative withdrawal. A qualified patient or designated caregiver that intends to seek an administrative withdrawal shall notify the licensing authority in writing no less than 30 calendar days prior to withdrawal.

## **6.0 Registration and Operation of Compassion Centers**

- ~~6.1 General Requirements for Operation of a Compassion Center. RESERVED~~
- ~~6.2 Security Requirements. RESERVED~~
- ~~6.3 Operations Manual. RESERVED~~
- ~~6.4 Required Training. RESERVED~~
- ~~6.5 Personnel Records. RESERVED~~
- ~~6.6 Application for Operation of Compassion Center. RESERVED~~
- ~~6.7 Complete Application Required. RESERVED~~
- ~~6.8 Compassion Center Application Review Criteria. RESERVED~~
- ~~6.9 Issuance of Registration Certificate Authorizing Operation of a Compassion Center. RESERVED~~
- ~~6.10 Registry Identification Cards for Principal Officers, Board Members, Agents, Volunteers or Employees of a Compassion Center. RESERVED~~
- ~~6.11 Expiration Date. RESERVED~~
- ~~6.12 Expiration, Termination or Renewal of a Registration Certificate Authorizing Operation of a Compassion Center. RESERVED~~
- ~~6.13 Non-transferable Registration Certificate Authorizing Operation of a Compassion Center. RESERVED~~
- ~~6.14 Maximum Amount of Usable Marijuana to be Dispensed. RESERVED~~
- ~~6.15 Inspection. RESERVED~~

## **6.0 Addition of Debilitating Medical Conditions**

- 6.1 Any citizen may petition the Department to add conditions or treatments to the list of debilitating medical conditions listed in 16 Del.C. §4902A(3).
- 6.2 The Department shall not add a condition or treatment to the list of debilitating medical conditions unless it finds that (1) the medical condition or treatment is debilitating and (2) marijuana is more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition or treatment.
- 6.3 Contents of the petition: In connection with any petition to add conditions or treatments to the list of debilitating medical conditions listed in 16 Del.C. §4902A(3), a petitioner shall provide the following information to the Department:
  - 6.3.1 The extent to which the condition is generally accepted by the medical community and other experts as a valid, existing debilitating medical condition;
  - 6.3.2 If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition;
  - 6.3.3 The extent to which the condition or treatments cause severe suffering, such as severe or chronic pain or severe nausea or vomiting, or otherwise severely impair the patient's ability to carry on activities of daily living;
  - 6.3.4 The ability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition or treatment;
  - 6.3.5 The extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition or treatment; and
  - 6.3.6 Letters of support from physicians or other licensed health care professionals knowledgeable about the condition or treatment.
- 6.4 Evaluation of a petition
  - 6.4.1 Upon review of materials submitted in response to Section 6.3 above, the Division of Public Health (DPH) shall make a determination as to whether the petition has merit.

- 6.4.2 A petition will be determined to have merit if it contains all of the material required in Section 6.3 above and the debilitating condition that is the subject of the petition has not been considered through this process in the prior two years, unless significant, generally accepted, scientific discoveries have been made that are substantially likely to reverse the prior decision.
- 6.4.3 A decision that a petition does not have merit will be made in writing, stating the reason(s) it has been determined not to have merit and that it is the final decision, subject to judicial review.
- 6.4.4 A final decision on a petition determined to have merit will be made within 180 days of receipt of the petition in response to the following process.
- 6.4.4.1 DPH will post the complete petition on the Department's website for a 60-day public comment period.
- 6.4.4.2 DPH will post notice of a public hearing no fewer than 10 days prior to the public hearing
- 6.4.4.3 DPH will hold a public hearing within the 60-day public comment period.
- 6.4.4.4 After the public hearing and closure of the 60-day public comment period, DPH will review the petition and comments. During this review, DPH may conduct additional research, including consultation with additional experts.
- 6.4.4.5 DPH will draft a written decision on whether to grant the petition and add the debilitating medical condition for review and ultimate decision by the Department Secretary. This written decision will be detailed enough to provide the specific grounds and references to support the decision. The Department Secretary will issue the final decision on the petition.
- 6.4.4.6 If the petition to add a debilitating medical condition is granted, draft regulations adding the condition to Section 2.0 will be drafted and published in response to the Administrative Procedures Act Process.
- 6.5 The approval or denial of any petition is a final decision of the Department subject to judicial review. Jurisdiction and venue are vested in the Superior Court.

## **7.0 Registration and operation of compassion centers**

- 7.1 Requirements for operation of a compassion center.
- 7.1.1 General requirements
- 7.1.1.1 No person shall operate a compassion center without a Department issued certificate of registration. The application and renewal requirements for a certificate of registration are in Sections 7.6 and 7.10 of these regulations.
- 7.1.1.2 A compassion center shall be operated on a not-for-profit basis. A compassion center need not be recognized as a tax-exempt organization by the Internal Revenue Service and is not required to incorporate in response to Title 8; however, a compassion center shall maintain appropriate documentation of its not-for-profit status, and such documentation shall be available for inspection in response to Section 7.2.7 of these Regulations.
- 7.1.1.3 A compassion center shall not acquire, possess, cultivate, manufacture, deliver, transfer, transport, supply or dispense marijuana for any purpose except to assist registered qualifying patients with the medical use of marijuana directly or through the qualifying patient's registered designated caregiver.
- 7.1.1.4 Use of pesticides is prohibited:
- 7.1.1.4.1 There are no pesticides authorized for use on marijuana; as such, a compassion center shall not apply pesticides in the cultivation of marijuana.
- 7.1.1.4.2 Prohibited pesticides include but are not limited to the following:
- 7.1.1.4.2.1 Organochlorines;
- 7.1.1.4.2.2 Organophosphates;
- 7.1.1.4.2.3 Carbamates; and
- 7.1.1.4.2.4 Insecticidal, fungicidal or growth regulatory compounds.
- 7.1.2 Location of a compassion center: A compassion center shall not be located within 1,000 feet of the property line of a preexisting public or private school.
- 7.1.3 Bylaws
- 7.1.3.1 A compassion center shall, as part of its initial application, provide to the Department a true, correct, and current copy of its bylaws, and shall maintain such bylaws in accordance with the Act and these regulations.
- 7.1.3.2 The bylaws of a compassion center shall include at a minimum:

- 7.1.3.2.1 the ownership structure of the compassion center;
- 7.1.3.2.2 the composition of the board of directors; and
- 7.1.3.2.3 such provisions relative to the disposition of revenues to establish and maintain the not-for-profit character of the compassion center.

7.1.4 Maintenance of accurate books and records

- 7.1.4.1 Registered compassion centers shall keep detailed financial reports of proceeds and expenses.
- 7.1.4.2 Registered compassion centers shall maintain all inventory, sales and financial records in accordance with generally accepted accounting principles ("GAAP").
- 7.1.4.3 The Department or an audit firm contracted by the Department shall at all times have access to all books and records kept by any compassion center.

7.2 Security requirements: A compassion center shall implement appropriate security and safety measures to deter and prevent the unauthorized entrance into areas containing marijuana and the theft of marijuana. Such measures shall include the following:

7.2.1 Exterior of premises: With respect to the exterior of a compassion center:

- 7.2.1.1 Access from outside the premises shall be kept to a minimum and be well controlled.
- 7.2.1.2 The outside perimeter of the premises shall be well lighted.
- 7.2.1.3 Entry into any area(s) where marijuana is held shall be limited to authorized personnel.

7.2.2 Alarm system:

7.2.2.1 A compassion center shall have a fully operational security alarm system at each authorized physical address that will provide suitable protection against theft and diversion. For the purpose of these regulations, a fully operational security alarm system shall include:

- 7.2.2.1.1 immediate automatic or electronic notification to alert local or municipal law enforcement agencies to an unauthorized breach of security at the compassion center or at any other authorized physical address;
- 7.2.2.1.2 immediate automatic or electronic notification to local or municipal public safety personnel of a loss of electrical support backup system; and
- 7.2.2.1.3 when appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

7.2.2.2 A compassion center shall conduct a maintenance inspection/test of the alarm system for each authorized location at intervals not to exceed 30 days from the previous inspection/test. A compassion center shall promptly make all necessary repairs to ensure the proper operation of the alarm system.

7.2.2.3 In the event of a failure of the security system, due to loss of electrical support or mechanical malfunction, that is expected to exceed an eight hour period, a compassion center shall:

- 7.2.2.3.1 within 24 hours of discovery of the event, notify the Department by telephone; and
- 7.2.2.3.2 provide alternative security measures approved by the Department or close the authorized physical address(es) impacted by the failure/malfunction until the security alarm system has been restored to full operation.

7.2.2.4 A compassion center shall maintain documentation in an auditable form for a period of at least 24 months after the event for:

- 7.2.2.4.1 all maintenance inspections/tests conducted in response to Section 7.2.2.2 of these regulations, and any servicing, modification or upgrade performed on the security alarm system. The record shall include, as a minimum, the date of the action, a summary of the action(s) performed and the name, signature and title of the individual who performed the action(s);
- 7.2.2.4.2 any alarm activation or other event which requires response by public safety personnel; and
- 7.2.2.4.3 any unauthorized breach(es) of security.

7.2.3 Video surveillance: A compassion center shall provide an appropriate video surveillance system that includes the following areas and access to recorded surveillance.

- 7.2.3.1 Video surveillance should record access areas, customer service areas, growing areas, and anywhere the marijuana is handled, to include processing and packaging areas.
- 7.2.3.2 Video footage will be digitally recorded and held for an appropriate time period consistent with the Division of Public Health's Records Retention Policy.
- 7.2.3.3 A compassion center shall provide the Department with access to the video 24-hours a day, seven days a week through a secure internet connection.

## 7.2.4 Inventory controls

### 7.2.4.1 Coding and computer interface: A compassion center shall:

7.2.4.1.1 employ a bar coding inventory control system to track batch, strain and amounts of marijuana in inventory and amounts sold, to include patients' card registration numbers.

7.2.4.1.2 be responsible for developing and hosting a secure computer interface to receive patient card user data from the Department.

### 7.2.4.2 Storage of marijuana: A compassion center shall ensure that usable marijuana is stored in a locked area with adequate security. For purpose of these regulations "adequate security," at a minimum, should be assessed, established and maintained based on:

7.2.4.2.1 the quantity of usable marijuana that will be kept on hand at each authorized location;

7.2.4.2.2 the compassion center's inventory system for tracking and dispensing usable marijuana;

7.2.4.2.3 the number of principal officers, board members, agents, volunteers or employees who have or could have access to the usable marijuana;

7.2.4.2.4 the geographic location of the compassion center (i.e.: high-crime or low-crime area);

7.2.4.2.5 the scope and sustainability of the alarm system; and

7.2.4.2.6 the root cause analysis of any breach of security and/or inventory discrepancy for usable marijuana at that location.

## 7.2.5 Comprehensive and monthly inventories

### 7.2.5.1 A compassion center shall:

7.2.5.1.1 notify the Department and local law enforcement within 24 hours any time there is a suspected loss of marijuana and shall cooperate fully with any investigation into the suspected loss.

7.2.5.1.2 conduct an initial comprehensive inventory of all medical marijuana, including usable marijuana available for dispensing, mature marijuana plants and unusable marijuana, at each authorized location on the date the compassion center first dispenses medical marijuana.

7.2.5.1.3 conduct the comprehensive inventory required by Section 7.2.5 of these regulations at intervals not to exceed 24 months from the date of the previous comprehensive inventory.

7.2.5.1.4 conduct a monthly inventory review of stored, usable marijuana.

7.2.5.2 If an inventory conducted in response to Section 7.2.5.1 of these regulations identifies a discrepancy, the Department and appropriate local law enforcement authorities will be notified of the discrepancy within 24 hours of discovery of the event.

7.2.5.[63] Documentation of all inventories conducted in response to Section 7.2.5.1 of these regulations shall include, as a minimum, the date of the inventory, a summary of the inventory findings and the name, signature and title of the [individual individual(s)] who conducted the inventory.

## 7.2.6 Maximum amount of compassion center inventory. A registered compassion center:

7.2.6.1 shall possess no more than 150 marijuana plants irrespective of the stages of growth.

7.2.6.2 shall possess no more than 1,500 ounces of usable marijuana regardless of formulation.

7.2.6.3 may not purchase usable marijuana or mature marijuana plants from any person other than another registered compassion center.

## 7.2.7 Inspection. Compassion centers are subject to random inspection by the Department's Office of Medical Marijuana.

7.2.7.1 During an inspection, the Department may review the compassion center's confidential records, including its financial and dispensing records, which may track transactions according to qualifying patients' registry identification numbers to protect their confidentiality and its security protocols.

7.2.7.2 The Department will review the facility to ensure compliance with Section 7.2 and Section 7.3 of these regulations.

7.2.7.3 The Department will inspect the facility for the presence of pesticides listed in Section 7.1.1.4, fungus and molds.

7.2.7.4 The Department may collect samples for random quality sampling by a laboratory selected by the Department.

7.2.7.4.1 Sample results will be compared to compassion center test results.

7.2.7.3.2 The compassion center will be invoiced for the cost of random sampling testing.

## 7.2.8 Dispensing marijuana.

7.2.8.1 Design and security features of medical marijuana containers

7.2.8.1.1 Marijuana shall be dispensed in sealed, tamperproof containers clearly identified as having been issued by the compassion center and that meet the requirements in Section 7.3.10 of these regulations.

7.2.8.1.2 Patients and designated caregivers should receive written instruction that the marijuana shall remain in this container when it is not being prepared for ingestion or being ingested.

7.2.8.2 No marijuana shall be dispensed unless or until the patient or caregiver identification card has been verified as valid in the computer system identified in Section 7.2.4.1.2 of these regulations.

7.2.8.3 Maximum amount of usable marijuana to be dispensed.

7.2.8.3.1 A compassion center or principal officer, board member, agent, volunteer or employee of a compassion center

7.2.8.3.1.1 shall not dispense, deliver or otherwise transfer marijuana to a person other than a qualifying patient who has designated the compassion center as a primary caregiver or to such patient's other primary caregiver.

7.2.8.3.1.2 shall not dispense more than three ounces of usable marijuana to a qualifying patient directly or through a qualifying patient's caregiver during a 14 day period.

7.2.8.3.1.3 shall not dispense an amount of usable marijuana [~~or marijuana plants~~] to a qualifying patient or a qualifying patient's caregiver that the compassion center principal officer, board member, agent, volunteer or employee knows would cause the recipient to possess more marijuana than is permitted under the Act or these regulations.

7.2.8.3.2 In addition to any other penalties that may be applicable under the Act or these regulations, any person found to have violated Section 7.2.8 of these regulations is not eligible to be an employee, agent, principal officer or board member of any compassion center and such person's registry identification card shall be immediately revoked.

7.3 Operations manual. A compassion center shall, as part of its initial application, provide to the Department a true, correct and current copy of its operating manual, and shall maintain such operating manual in accordance with the Act and these regulations. Such manual shall include, as a minimum, the following requirements:

7.3.1 procedures for the oversight of the compassion center including, but not limited to, documentation of the reporting and management structure of the compassion center;

7.3.2 procedures for safely dispensing medical marijuana to registered qualifying patients or their registered primary caregiver;

7.3.3 procedures to ensure accurate record keeping, including protocols to ensure that quantities purchased do not suggest re-distribution;

7.3.4 employee security policies;

7.3.5 safety and security procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;

7.3.6 personal safety and crime prevention techniques;

7.3.7 a job description or employment contract developed for all employees and a volunteer agreement for all volunteers which includes duties, responsibilities, authority, qualification and supervision;

7.3.8 the compassion center's alcohol and drug free work place policy;

7.3.9 a description of the compassion center's outreach activities to registered qualifying patients or their registered primary caregiver, which shall as a minimum include:

7.3.9.1 providing each new registered patient who visits the compassion center with frequently asked questions, designed by the Department, that explain the limitations on the right to use medical marijuana under state law;

7.3.9.2 ingestion options of usable marijuana provided by the compassion center;

7.3.9.3 safe smoking techniques that shall be provided to registered qualifying patients; and

7.3.9.4 potential side effects and how this information shall be communicated.

7.3.10 a description of the packaging of the useable marijuana that the compassion center shall be utilizing which shall, as a minimum, include:

7.3.10.1 the name of the strain, batch, and quantity;

7.3.10.2 the statement "this product is for medical use only, not for resale;" and

7.3.10.3 details indicating (1) the medical marijuana is free of contaminants and (2) the levels of active ingredients in the product.

7.3.11 a description of the documentation that will accompany a registered compassion center agent when transporting marijuana on behalf of the registered compassion center. In response to 16 Del.C. §4918A(b),

the documentation must specify, at least, the amount of marijuana being transported, the date the marijuana is being transported, the registry identification number of the registered compassion center, and a contact number to verify that the marijuana is being transported on behalf of the registered compassion center.

7.3.12 detailed procedures regarding the testing of medical marijuana. As part of its initial application, a compassion center shall provide to the Department detailed procedures regarding the testing of medical marijuana, and shall adhere to such procedures in connection with the operation of the compassion center. Such procedures shall include a description of how the marijuana will be tested, including:

7.3.12.1 whether the testing will be conducted in house or through a contracted facility;

7.3.12.2 how marijuana will be transported securely in connection with such testing;

7.3.12.3 what tests are conducted, including what testing procedures are used;

7.3.12.4 how results are tracked and how samples are disposed; and

7.3.12.5 the selection process and the number of samples tested.

7.4 Required training. Each compassion center shall develop, implement and maintain on the premises an on-site training curriculum, or enter into contractual relationships with outside resources capable of meeting employee, agent and volunteer training needs. Each employee, agent or volunteer, at the time of initial appointment, shall receive, as a minimum, training in the following:

7.4.1 professional conduct, ethics, and state and federal laws regarding patient confidentiality;

7.4.2 informational developments in the field of medical use of marijuana;

7.4.3 The proper use of security measures and controls that have been adopted; and

7.4.4 Specific procedural instructions for responding to an emergency, including robbery or violent accident.

7.5 Personnel

7.5.1 Records: Each compassion center shall maintain

7.5.1.1 a personnel record for each employee, agent or volunteer for a period of at least six months after termination of the individual's affiliation with the compassion center. The record shall include, as a minimum, the following:

7.5.1.1.1 an application for employment or to volunteer;

7.5.1.1.2 a record of any disciplinary action taken;

7.5.1.1.3 documentation of all required training. Documentation shall include a signed statement from the individual indicating the date, time and place of said training and topics discussed, including the name and title of presenters;

7.5.1.2 a record of the source of any funds that will be used to open or maintain the compassion center, including the name, address, and date of birth of any investor contributing more than \$5,000; and

7.5.1.3 a record of any instances in which a business or not-for-profit that any of the prospective board members managed or served on the board of was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding.

7.5.2 Registry identification cards and background checks for principal officers, board members, agents, volunteers or employees of a compassion center.

7.5.2.1 In response to the requirements of this rule, and upon the approval of the submitted application, the Department shall issue a registry photo identification card to each principal officer, board member, agent, volunteer or employee of a compassion center who is associated with the compassion center and meets the requirements under these regulations. In order for a registry identification card to be obtained, the following items shall be submitted to the medical marijuana program.

7.5.2.1.1 birth certificate verifying that the applicant is at least 21 years of age;

7.5.2.1.2 a reasonable xerographic copy of the applicant's Delaware license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; identification card must be available for inspection/verification;

7.5.2.1.3 a written and signed statement from an officer or executive staff member of the compassion center stating that the applicant is associated with the compassion center and in what capacity;

7.5.2.1.4 the name, address and telephone number of the applicant;

7.5.2.1.5 the name, address and telephone number of the compassion center with which the agent is associated;

7.5.2.1.6 the applicant's signature and date



- 7.6.7 a description of proposed security and safety measures which demonstrate compliance with Section 7.2 of these regulations;
- 7.6.8 a draft operations manual which demonstrates compliance with Section 7.3 of these regulations;
- 7.6.9 an example of the design and security features of medical marijuana containers which demonstrates compliance with Section 7.2.8 of these regulations;
- 7.6.10 a list of all persons or business entities having direct or indirect authority over the management or policies of the compassion center;
- 7.6.11 a list of all persons or business entities having 5.0% or more ownership in the compassion center, whether direct or indirect and whether the interest **[in is]** in profits, land or building, including owners of any business entity which owns all or part of the land or building, and;
- 7.6.12 the identities of all creditors holding a security interest in the premises, if any.
- 7.7 Complete application required. Only applications which the Department has determined to be complete (i.e. adequately addresses all requirements in these regulations and 16 **Del.C.** §§4914A and 4915A) shall be eligible for review in response to §7.8 of these regulations.
- 7.8 Compassion center application review criteria. The Department shall evaluate applications for a compassion center registration certificate using an impartial and numerically scored competitive bidding process developed by the Department in accordance with 16 **Del.C.** §4914A(b) and these regulations. The Department shall consider the following criteria:
  - 7.8.1 documentation of not-for-profit status, consistent with §7.6.5 of these regulations;
  - 7.8.2 the suitability of the proposed location or locations, including but not limited to compliance with any local zoning laws and the geographic convenience to patients from throughout the State of Delaware to compassion centers if the applicant were approved;
  - 7.8.3 the principal officer and board members' character and relevant experience, including any training or professional licensing related to medicine, pharmaceuticals, natural treatments, botany, or marijuana cultivation and preparation and their experience running business or not-for-profit entities;
  - 7.8.4 the proposed compassion center's plan for operations and services, including its staffing and training plans, whether it has sufficient capital to operate, and its ability to provide an adequate supply and variety of medical marijuana and medical marijuana based products to the registered patients in the State;
  - 7.8.5 the sufficiency of the applicant's plans for record keeping;
  - 7.8.6 the sufficiency of the applicant's plans for safety, security, and the prevention of diversion, including proposed locations and security devices employed;
  - 7.8.7 the applicant's plan for making medical marijuana available on **[a]** an affordable basis to registered qualifying patients enrolled in Medicaid or receiving Supplemental Security Income or Social Security Disability Insurance;
  - 7.8.8 the applicant's plan for safe and accurate packaging and labeling of medical marijuana, which shall include, without limitations, these minimum requirements for packaging and labeling:
    - 7.8.8.1 the name of the strain, batch, and quantity of the medical marijuana;
    - 7.8.8.2 a statement providing that "this product is for medical use only, not for resale";
    - 7.8.8.3 details indicating the medical marijuana is free of contaminants; and
    - 7.8.8.4 details indicating the levels of active ingredients in the product;
  - 7.8.9 the applicant's plan for testing medical marijuana for contaminants and potency of active ingredients; and
  - 7.8.10 the applicant's ability to grow marijuana without use of pesticides.
- 7.9 Issuance of a registration certificate authorizing operation of a compassion center. When an applicant to operate a compassion center is notified that the Department has approved its application, it shall submit the following additional items to the Department before the registration certificate authorizing operation of a compassion center will be issued.
  - 7.9.1 a certification fee, made payable to the Division of Public Health, **[State of Delaware Medical Marijuana Program]**, in the amount of \$40,000;
  - 7.9.2 the legal name, articles of incorporation, and bylaws of the compassion center;
  - 7.9.3 the physical address of the compassion center and any additional address(es) to be used for the secure cultivation of marijuana, including:
    - 7.9.3.1 evidence demonstrating the following:
      - 7.9.3.1.1 compliance with all local zoning laws for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana; and



transferred from the entity to whom the registration certificate authorizing operation of a compassion center was issued to a new manager, then a change of ownership has occurred.

## **78.0 Registration and Operation of Testing Facility Centers**

- 78.1 General Requirements for Operation of a Testing Facility Center. RESERVED
- 78.2 Security Requirements: RESERVED
- 78.3 Operations Manual. RESERVED
- 78.4 Required Training. RESERVED
- 78.5 Personnel Records. RESERVED
- 78.6 Application for Operation of Testing Facility Center. RESERVED
- 78.7 Complete Application Required. RESERVED
- 78.8 Testing Facility Center Application Review Criteria. RESERVED
- 78.9 Issuance of Registration Certificate Authorizing Operation of a Testing Facility Center. RESERVED
- 78.10 Registry Identification Cards for Principal Officers, Board Members, Agents, Volunteers or Employees of a Testing Facility Center. RESERVED
- 78.11 Expiration Date. RESERVED
- 78.12 Expiration, Termination or Renewal of a Registration Certificate Authorizing Operation of a Testing Facility Center. RESERVED
- 78.13 Non-transferable Registration Certificate Authorizing Operation of a Testing Facility Center. RESERVED
- 78.14 Inspection. RESERVED

## **89.0 Monitoring and Corrective Actions**

### **89.1 On-site Visits/Interviews**

- 89.1.1 The Department or its designee may perform on-site interviews of a qualified patient or primary caregiver to determine eligibility for the program. The Department may enter the premises of a qualified patient or primary caregiver during business hours for purposes of interviewing a program applicant. Twenty-four (24) hours' notice will be provided to the qualified patient or primary caregiver prior to an on-site interview.
- 89.1.2 All qualified patients or primary caregivers shall provide the Department or the Department's designee immediate access to any material and information necessary for determining eligibility with these requirements.
- 89.1.3 Failure by the qualified patient or primary caregiver to provide the Department access to the premises or information may result in action up to and including the revocation of the qualified patient or primary caregiver registry identification card and referral to state law enforcement.
- 89.1.4 Any failure to adhere to these rules, documented by the Department during an interview, may result in sanction(s), including suspension, revocation, non-renewal or denial of licensure and referral to state or local law enforcement.
- 89.1.5 The Department shall refer credible criminal complaints against a qualified patient or primary caregiver to the appropriate Delaware state or appropriate local authorities.

### **89.2 Corrective action:**

- 89.2.1 If violations of these requirements are cited as a result of monitoring, the qualified patient or primary caregiver shall be provided with an official written report of the findings following the monitoring visit.
- 89.2.2 Unless otherwise specified by the Department, the qualified patient or primary caregiver shall correct the violation within 5 calendar days of receipt of the official written report citing the violation(s).
- 89.2.3 The violation shall not be deemed corrected until the Department verifies in writing after receiving notice of the corrective action that the corrective action is satisfactory.
- 89.2.4 If the violation has not been corrected, the Department may issue a notice of contemplated action to revoke the qualified patient's or designated caregiver's registry identification card.
- 89.2.5 Suspension of registry identification card without prior hearing: In accordance with the 16 ~~Delaware Code Chapter Del.C., Ch.~~ 49A, if immediate action is required to protect the health and safety of the general public, the Department may suspend the qualified patient or designated caregiver registry identification card without notice.
  - 89.2.5.1 A qualified patient or primary caregiver whose registry identification card has been summarily suspended is entitled to a record review not later than 30 calendar days after the registry identification card was summarily suspended.

- 89.2.5.2 The record review requested subsequent to a summary suspension shall be conducted by the Department.
- 89.2.5.3 The Department shall conduct the record review on the summary suspension by reviewing all documents submitted by both card holder and the Department.
- 89.2.5.4 The sole issue at a record review on a summary suspension is whether the card holder's registry identification card shall remain suspended pending a final adjudicatory hearing and ruling.
- 89.2.5.5 A card holder given notice of summary suspension by the division may submit a written request for a record review. To be effective, the written request shall:
  - 89.2.5.5.1 be made within 30 calendar days, as determined by the postmark, from the date of the notice issued by the Department;
  - 89.2.5.5.2 be properly addressed to the medical marijuana program;
  - 89.2.5.5.3 state the applicant's name, address, and telephone number(s);
  - 89.2.5.5.4 provide a brief narrative rebutting the circumstances of the suspension, and
  - 89.2.5.5.5 additional documentation must be included with the request for a record review.

89.3 Summary Suspension, Revocation and Appeal Process:

- 89.3.1 Participation in the medical marijuana program by a qualified patient or primary caregiver does not relieve the qualified patient or primary caregiver from:
  - 89.3.1.1 criminal prosecution or civil penalties for activities not authorized in this rule and act;
  - 89.3.1.2 liability for damages or criminal prosecution arising out of the operation of a vehicle while under the influence of marijuana; or
  - 89.3.1.3 criminal prosecution or civil penalty for possession, distribution or transfers of marijuana or use of marijuana:
    - 89.3.1.3.1 in a school bus or public vehicle;
    - 89.3.1.3.2 on school grounds or property;
    - 89.3.1.3.3 in the workplace of the qualified patient's or primary caregiver's employment;
    - 89.3.1.3.4 at a public park, recreation center, youth center or other public place;
    - 89.3.1.3.5 to a person not approved by the Department pursuant to this rule;
    - 89.3.1.3.6 outside Delaware or attempts to obtain or transport marijuana from outside Delaware; or
    - 89.3.1.3.7 that exceeds the allotted amount of usable medical use marijuana.
- 89.3.2 Revocation of registry identification card: Violation of any provision of this rule may result in either the summary suspension of the qualified patient's or primary caregiver's registry identification card, or a notice of contemplated action to suspend or revoke the qualified patient's or primary caregiver's registry identification card, and all lawful privileges under the act.
- 89.3.3 Grounds for revocation or suspension of registry identification card, denial of renewal application for registry identification card. A registry identification card may be revoked or suspended, and a renewal application may be denied for:
  - 89.3.3.1 failure to comply with any provisions of these requirements;
  - 89.3.3.2 failure to allow a monitoring visit by authorized representatives of the Department;
  - 89.3.3.3 the discovery of repeated violations of these requirements during monitoring visits.

89.4 Request for hearing: A qualified patient or primary caregiver whose registry identification card has been summarily suspended, or who has received a notice of contemplated action to suspend or revoke, may request a hearing, in addition to a request for a record review, for the purpose of review of such action. The request for hearing shall be filed within 30 calendar days of the date the action is taken or the notice of contemplated action is received. The request shall include the following:

- 89.4.1 a statement of the facts relevant to the review of the action;
- 89.4.2 a statement of the provision of the act and the rules promulgated under the act that are relevant to the review of the action;
- 89.4.3 a statement of the arguments that the qualified patient/primary caregiver considers relevant to the review of the action; and
- 89.4.4 any other evidence considered relevant.

89.5 Hearing process:

- 89.5.1 All formal adjudicatory hearings held in response to these Regulations shall be conducted by a hearing officer duly appointed by the DHSS Secretary.

- §9.5.2 Except for telephonic hearings, hearings shall be conducted in Dover or, upon written request by an aggrieved person, in the place or area affected.
- §9.5.3 All hearings held pursuant to this section shall be open to the public.
- §9.5.4 The hearing shall be recorded on audiotape or other means of sound reproduction, or by a certified court reporter. The decision as to the type of recording shall be at the discretion of the Department.
- §9.5.5 Any hearing provided for in this rule may be held telephonically, in the interest of a speedy resolution.
- §9.5.6 The Department shall schedule and hold the hearing as soon as practicable, however; in any event no later than 60 calendar days from the date the Department receives the request for hearing. The hearing officer shall extend the 60 day time period upon motion for good cause shown or the parties shall extend the 60 day time period by mutual agreement. The Department shall issue notice of hearing, not less than 20 days prior to the hearing, which shall include:
- §9.5.6.1 a statement of the time, place and nature of the hearing;
  - §9.5.6.2 a statement of the legal authority and jurisdiction under which the hearing is to be held;
  - §9.5.6.3 a short and plain statement of the matters of fact and law asserted;
  - §9.5.6.4 notice to any other parties to give prompt notice of issues controverted in fact or law; and
  - §9.5.6.5 all necessary telephone numbers if a telephonic hearing shall be conducted.
- §9.6 All parties shall be given the opportunity to respond and present evidence and argument on all relevant issues.
- §9.7 Record of proceeding: The record of the proceeding shall include the following:
- §9.7.1 all pleadings, motions and intermediate rulings;
  - §9.7.2 evidence received or considered;
  - §9.7.3 a statement of matters officially noticed;
  - §9.7.4 questions and offers of proof, objections and rulings thereon;
  - §9.7.5 proposed findings and conclusions; and
  - §9.7.6 any action recommended by the hearing officer.
- §9.8 A party may request a transcription of the proceedings. The party requesting the transcript shall bear the cost of transcription.
- §9.9 Procedures and evidence:
- §9.9.1 Any party shall be represented by a person licensed to practice law in Delaware or an individual may represent him or herself.
  - §9.9.2 The rules of evidence as applied in the courts do not apply in these proceedings. Any relevant evidence shall be admitted and such evidence shall be sufficient in itself to support a finding if the evidence is reliable, regardless of the existence of any statutory or common law rule that shall make admission of such evidence improper in a civil action. Irrelevant, immaterial or unduly repetitious evidence shall be excluded at a party's request or on the hearing officer's own initiative.
  - §9.9.3 Documentary evidence shall be received in evidence in the form of true copies of the original.
  - §9.9.4 Documentary and other physical evidence shall be authenticated or identified by any reasonable means that shows that the matter in question is what the proponent claims it to be.
  - §9.9.5 The experience, technical competence and specialized knowledge of the hearing officer, the Department or the Department's staff shall be used in the evaluation of evidence.
  - §9.9.6 Evidence on which the hearing officer shall base his or her decision is limited to the following:
    - §9.9.6.1 all evidence, including any records, investigation reports and documents in the Department's possession of which the Department desires to avail itself as evidence in making a decision that is offered and made a part of the record of the proceeding; and
    - §9.9.6.2 testimony and exhibits introduced by the parties.
  - §9.9.7 The record shall include all briefs, proposed findings and exceptions and shall show the ruling on each finding, exception or conclusion presented.
  - §9.9.8 A party to a hearing shall submit to the hearing officer, and to all other parties to the hearing, all documents to be introduced at the hearing no later than five business days from the scheduled hearing date to insure the hearing officer and other parties receive the documents prior to the hearing.
  - §9.9.9 The Department may choose to:
    - §9.9.9.1 issue subpoenas for witnesses and other sources of evidence, either on the agency's initiative or at the request of any party; and
    - §9.9.9.2 administer oaths to witnesses; limit unduly repetitive proof, rebuttal and cross-examination.

- 89.10 Conduct of proceeding: Unless the hearing officer reasonably determines a different procedure is appropriate, the hearing shall be conducted in accordance with the procedures set forth in this rule. The following procedures shall apply:
- 89.10.1 the Division shall present an opening statement on the merits and the Cardholder shall make a statement of the defense or reserve the statement until presentation of that party's case;
  - 89.10.2 after the opening statements, if made, the Division shall present its case in chief in support of the Division's petition;
  - 89.10.3 upon the conclusion of the Division's case, the Cardholder shall present its case in defense;
  - 89.10.4 upon conclusion of the Cardholder's case, the Division shall present rebuttal evidence;
  - 89.10.5 after presentation of the evidence by the parties, the Division shall present a closing argument; the Cardholder then shall present its closing argument and the Division shall present a rebuttal argument; and
  - 89.10.6 thereafter, the matter shall be submitted for recommendation by the hearing officer.
- 89.11 Continuances: The hearing officer shall not grant a continuance except for good cause shown. A motion to continue a hearing shall be made at least 10 calendar days before the hearing date.
- 89.12 Telephonic hearings:
- 89.12.1 Any party requesting a telephonic hearing shall do so within 10 business days of the date of the notice. Immediately after the parties agree to conduct the hearing by telephone, notice of the telephonic hearing shall be made to all parties and shall include all necessary telephone numbers.
  - 89.12.2 Any party that has agreed to a telephonic hearing, but subsequently requests an in-person hearing shall do so in writing to the hearing officer no later than 10 calendar days before the scheduled date of the hearing. The decision to grant or deny the request for an in-person hearing shall be at the discretion of the hearing officer for good cause shown. The hearing officer's decision to grant or deny the hearing shall be issued in writing and shall include the specific reasons for granting or denying the request. Should the hearing officer grant the request, the hearing shall be rescheduled to a time convenient for all parties. Should the hearing officer deny the request, the telephonic hearing shall proceed as scheduled.
  - 89.12.3 The location or locations of the parties during the hearing shall have a speaker telephone and facsimile machine available so that all shall hear the proceedings and documents shall be transmitted between witnesses and the hearing officer.
  - 89.12.4 The Cardholder shall initiate the telephone call. The Division is responsible for ensuring the telephone number to the Division's location for the telephonic hearing is accurate and the Division representative is available at said telephone number at the time the hearing is to commence. Failure to provide the correct telephone number or failure to be available at the commencement of the hearing shall be treated as a failure to appear and shall subject the petitioner to a default judgment.
  - 89.12.5 The in-person presence of some parties or witnesses at the hearing does not prevent the participation of other parties or witnesses by telephone with prior approval of the hearing officer.
- 89.13 Recommended action and final decision:
- 89.13.1 At the request of the hearing officer or upon motion by either party granted by the hearing officer, and before the hearing officer recommends action by the Secretary, the parties shall submit briefs including findings of fact and conclusions of law for consideration by the hearing officer. The hearing officer holds the discretion to request briefs or grant a motion to submit briefs on any point of law deemed appropriate by the hearing officer. Briefs submitted shall include supporting reasons for any findings or legal conclusions and citations to the record and to relevant law. Should the hearing officer request briefs or grant a party's motion to submit briefs, the hearing shall be continued until the hearing officer has given the briefs sufficient consideration and brings the hearing to a close. The hearing, however, shall be completed no later than 45 calendar days from the date of continuance.
  - 89.13.2 No more than 30 calendar days after completion of the hearing, the hearing officer shall prepare a written decision containing recommendation of action to be taken by the Secretary. The recommendation shall propose to sustain, modify or reverse the initial decision of the Department or the Department's agent.
  - 89.13.3 The Secretary shall accept, reject or modify the hearing officer's recommendation no later than 10 calendar days after receipt of the hearing officer's recommendation. The final decision or order shall be issued in writing and shall include:
    - 89.13.3.1 a brief summary of the evidence,
    - 89.13.3.2 a statement of findings of fact based upon the evidence,
    - 89.13.3.3 conclusions and the reasons thereof, on all material issues of fact, law or discretion involved,
    - 89.13.3.4 any other conclusions required by law of the Department, and

89.13.3.5 a concise statement of the Department's specific determination or action taken to sustain, modify or reverse the initial decision of the Department or the Department's agent.

89.13.3.6 Service shall be made by registered or certified mail.

89.13.4 The final decision or order shall be public information and shall become a part of the record.

**910.0 Severability**

In the event any particular clause or section of these Regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full effect.

**15 DE Reg. 1728 (06/01/12)**

**17 DE Reg. 738 (01/01/14)(Final)**