DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

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

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 **Del.C.** Ch. 101 and authority as prescribed by 16 **Del.C.** Ch. 49A.

On April 1, 2012 (Volume 15, Issue 10), DHSS published in the Delaware *Register of Regulations* its notice of proposed regulations, pursuant to 29 **Del.C.** §10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by April 30, 2012, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

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

FINDINGS OF FACT

Based on public comments received, non-substantive changes were made to the proposed regulations. Additionally, some grammatical amendments 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.

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 (April 1, 2012 through April 30, 2012). Entities offering written comments included:

- Marijuana Policy Project
- Governor's Advisory Council for Exceptional Citizens (GACEC)
- State Council for Persons with Disabilities (SCPD)
- Dr. Richard Chong
- Stephen Haner
- Diane L. Jump
- Todd Kitchen
- Patricia Lake
- Elizabeth Wiberg
- John Wiberg

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

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 regulations developed by the Department of Health and Social Services relating to the Delaware Medical Marijuana Code entitled "Rules and Regulations Governing the Delaware Medical Use of Marijuana."

We are grateful to the Division of Public Health for its diligent work to craft medical marijuana rules. While we feel that most of the rules are reasonable, there are some provisions that we believe to be unnecessary, onerous, or contrary to the language of Delaware's medical marijuana law. In addition, we urge the division to add rules to regulate compassion centers, as is being done in other states, including neighboring New Jersey and the District of Columbia.

When appropriate, the department's proposed regulations are initially quoted exactly as they appear in the April 1, 2012 edition of the Delaware Register of Regulations. MPP's suggestions are found in the comment box with underscored and struck-through language being additions or redactions to the language found in the proposed regulations.

Thank you very much for your consideration and attention to the changes MPP deems necessary to these regulations.

Your thorough examination of this matter is greatly appreciated.

4.0 Designated Caregiver Registry Identification Card Application Requirements

4.1.3: Section 4.1 of the proposed regulations, among other requirements, mandates certain information and documentation be given to the medical marijuana program in order for an individual to obtain a caregiver registry identification card. Regulation 4.1.3 requires a potential caregiver to submit "written approval by the qualified patient(s) and the qualified patient(s)' Physician(s) authorizing responsibility for managing the wellbeing of a qualified patient(s) with respect to the use of marijuana."

MPP comment: § 4908A of Title 16 of the Delaware Code contains no requirement that potential caregivers seek and show evidence of approval from their patient(s)' physician(s) in order to obtain an identification card as a registered caregiver. In fact, an application to obtain a caregiver ID card may only be denied if certain conditions are met; none of these requirements is physician approval of the caregiver. Del. Code Title 16 §4910A(b).

Besides being contrary to the letter of the law, MPP believes that requiring physicians to approve of all caregivers is bad policy. This requirement moves dangerously close to involving the physician in the medical marijuana supply chain that could lead to adverse actions against them by the federal government. The Ninth Circuit Court of Appeals has held that physicians have a First Amendment right to discuss the use of medical marijuana with their patients. Conant v. Walters 309 F.3d 629 (2003), cert denied. However, physicians cannot do so with the specific intent that the patient use the recommendation to obtain medical marijuana. If the physician were required to designate a person to obtain marijuana for the patient, it is possible that intent could be implied.

Finally, this regulation will make it much more difficult for patients to obtain their needed medicine. The severity of patients' medical conditions can change. A patient who is mobile at one point - and whose doctor may not think needs a caregiver at that time - may be hospitalized or bedridden at another time. A patient using prescription drugs can send their significant other or spouse to the pharmacy to pick up their medications without a doctor's approval. The requirement that a patient designate a single person to the department already is stricter than the standard for prescription medications.

We recommend amending 4.1.3 to read:

"written approval by the qualifying patient(s) and the qualified patient(s)' Physician(s) authorizing responsibility for managing the well-being of a the qualified patient(s) with respect to the use of marijuana."

Agency Response: The Agency appreciates this suggested revision to the proposed regulations. The requirement to have the physician provide written approval of the patient's caregiver was intended to allow for protection of at-risk population patients from abuse by someone who has more than a medicinal interest in marijuana. However, after further scrutiny of the Medical Marijuana Law, and additional discussion on ways to balance the needs of patients with the protection of the community, the Department has modified the regulations to remove the requirement of the physician's approval of a patient's care giver.

5.0 Registry Identification Cards

5.3.6: Section 5.3 of the proposed regulations lists several life events (including but not limited to a change of name, address, or status of a debilitating illness) that would require a registered identification cardholder to contact the department to notify them of the change. Section 5.3.6 gives teeth to the notification requirement stating that "A cardholder who fails to make a notification to the Department that is required by Section 3.5 is subject to a civil infraction, punishable by a penalty of no more than $150.00 shall result in the immediate revocation of the registry identification card and all lawful privileges provided under the act."

MPP comment: The immediate revocation of an identification card and privileges associated with being a cardholder is extreme and contrary to the intent and language of Delaware's medical marijuana law. § 4912A of Title 16 of the Delaware Code is the statutory companion to regulations section 3.5. § 4912A(d) states that a cardholder who fails to make a notification to the department required in § 4912A is subject to a civil violation of not more than $150. There is no statutory requirement that a failure to make a notification result in a revocation of the card and its associated privileges.

If the Delaware Legislature intended to penalize a patient or caregiver with revocation of an identification card and its privileges for failure to make a clerical notification, they would have enacted such a penalty in the law, like they did when enacting § 4919A(r) (a cardholder who sells marijuana to a non-cardholder shall have his or her card revoked). In fact, the medical marijuana law specifically states that revocation of a card will only be made for "multiple or serious" violations of the chapter. Del. Code Title 16 § 4919A(t). Immediate revocation for a first time failure to notify the department of a life change does not fit this description. For example, a patient's condition could worsen and force a move into an assisted living facility. At a time of great emotional and physical distress, denying a person the right to use his or her medicine for a single oversight would be unwarranted and cruel. If the department feels that repeated failures to adhere to the notification requirement should result in a revocation, it could do so under the letter of the law, but we urge it to do so based on the totality of the circumstances and after the cardholder has an opportunity to be heard.

We recommend amending 5.3.3 to read:

"A cardholder who fails to make a notification to the Department that is required by Section 3.5 is subject to a civil infraction, punishable by a penalty of no more than $150.00 shall result in the immediate revocation of the registry identification card and all lawful privileges provided under the act."

Agency Response: The Agency respectfully disagrees. One of the tasks of the Medical Marijuana Program is to provide balance between patient protection and that of the community. This regulation gives authority to allow maximum punitive action if required; however, it does not provide for absolute action by the Department. In fact, section 5.3.1 allows for extension of the required time for notification with the showing of good cause. This regulation is not intended to punish patients, but instead to protect them. If a card is lost, for example, the need to have the ID number removed from the registry would be an important timely action. For clarification, we will modify the text in Section 5.3.6 to read as follows. "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, and is also subject to the immediate revocation of the registry identification card and all lawful privileges provided under the act."

6.0 Registration and Operation of Compassion Centers

The department has reserved sections for future rules and regulations governing the compassion center program. Presumably, this decision was made after Gov. Markell stated that he would not allow the compassion centers to open to avoid adverse actions taken toward the centers by the federal government.

MPP comment: We feel it is unnecessary to wait to make rules for compassion centers and urge the department to move forward with the rule-making process. Patients need a safe source of medical marijuana.

State regulated and registered medical marijuana providers are openly and actively serving patients in New Mexico, Colorado, and Maine. Additionally, the Rhode Island General Assembly has been working with Gov. Lincoln Chafee on legislation that will result in the opening of three compassion centers across their state. Arizona, Vermont, New Jersey, and Washington, D.C. are all moving forward with regulations to implement dispensary programs as well. No state worker has ever been prosecuted for implementing a dispensary program, and no court has ever found that registering and regulating compassion centers would be a federal crime. We maintain that it is not a crime, and we believe it is inconceivable that the federal government would prosecute a state employee for implementing a regulatory program, particularly without a prior explicit warning or civil action.

While MPP appreciates that the sections were reserved for compassion center rules, we respectfully request that the department move forward with compassion center regulations. The department would be best served by reviewing regulations passed by the New Mexico Department of Health, the Rhode Island Department of Health, the Maine Department of Health and Human Services, and the Colorado Department of Public Health and Environment.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking public comments regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

7.0 Registration and Operation of Testing Facility Centers

The department has reserved sections for future rules and regulations governing the medical marijuana safety compliance facilities. Presumably, this decision was made after Gov. Markell stated that he would not allow the compassion centers to open to avoid adverse actions taken toward the centers by the federal government.

MPP comment: We feel it is unnecessary to wait and urge the department to move forward with the rule-making process.

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 determine the percentage of various cannabinoids present so patients can more easily find a strain to address their particular debilitating disease or condition.

While we appreciate the department reserving the sections for future rules and regulations for the testing facilities, MPP respectfully requests that the department move forward with testing facility center regulations.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking public comments regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

8.0 Monitoring and Corrective Actions

8.1.1: Section 8.0 of the regulations lays out the duties and powers entrusted to the department to monitor for and subsequently correct violations of the medical marijuana law and regulations. Section 8.1.1 states, "The Department or its designee may perform on-site assessments of a qualified patient or primary caregiver to determine compliance with these rules. The Department may enter the premises of a qualified patient or primary caregiver during the business hours for the

purposes of monitoring and compliance. Twenty-four (24) hours notice will be provided to the qualified patient or primary caregiver prior to an on-site assessment except when the Department has a reasonable suspicion to believe that providing notice will result in the destruction of evidence or that providing such notice will impede the Department's ability to enforce these Regulations."

MPP comment: MPP believes that this provision is unlawful and should be removed in its entirety. Title 16, §4903A(m) of the Delaware code states that "mere possession of, or application for, a [medical marijuana] registry identification card or registration certificate shall not constitute probable cause or reasonable suspicion, nor shall it be used to support the search of the person, property, or home of the person possessing or applying for the registry identification card" (emphasis added). Allowing the department to conduct a search of a patient, caregiver, and/or their premises simply because they hold an identification card is in direct contrast to the above law.

We recommend amending 8.0 to remove "8.1 Monitoring" in its entirety. Delaware residents' homes are not invaded for searches to see that they are complying with the law for other medications they are prescribed. Patients and caregivers should not - and under Delaware law cannot - be treated like criminal suspects for being state-legal medical marijuana patients.

Agency Response: The Agency appreciates the comments and acknowledges the commenter's concern for Delaware's citizens. While the intent of this section was to allow for community protective action if and when the Department is made aware of an instance of abuse of these regulations, the Department has changed section 8.1 to refer instead to an interview process for a patient or caregiver who cannot leave their home. Please see the final posted regulations for the final text of this section.

8.0 Monitoring and Corrective Actions

8.3.1.3.6: Section 8.0 of the regulations lays out the duties and powers entrusted to the department to monitor for and subsequently correct violations of the medical marijuana law and regulations. 8.3.1.3.6 retains the right of the state to prosecute a medical marijuana patient or caregiver for possessing or transferring marijuana "outside Delaware or attempt[ing] to obtain or transport marijuana from outside Delaware."

MPP comment: This is an unnecessary regulation and will only result in harming patients. The law clearly protects patients and caregivers who possess up to a certain amount of marijuana. If they are over their possession limits, they may be subject to prosecution. In addition, Delaware patients could be traveling out of state to seek medical attention and would then be subject to prosecution for taking their physician-recommended medicine with them. Similarly, Delaware patients could be returning from a state where there is legal access to medical marijuana. Some states allow patients to give marijuana away to other patients. Patients should not have to destroy their marijuana when entering their home state, only to have to obtain more marijuana from the criminal market.

We recommend removing, in its entirety, 8.3.1.3.6.

Agency Response: The agency respectfully disagrees. It is the intent of the regulations to provide protection for the community against possible diversion of marijuana from a registered program patient or care giver to a non-registered person. The Division of Public Health is charged with administering Chapter 49A of Title 16 of the Delaware Code, The Delaware Medical Marijuana Act. The scope of the law does not allow for any program administration outside of the state of Delaware; therefore, we do not have the ability to relieve registered card holders from any punitive penalties with regard to marijuana-related activities outside of the state of Delaware. This section of the regulation simply emphasizes the limited scope of the regulations.

8.0 Monitoring and Corrective Actions

8.3.2: Section 8.0 of the regulations lays out the duties and powers entrusted to the department to monitor for and subsequently correct violations of the medical marijuana law and regulations. Section 8.3.2 states that a "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."

MPP comment: We oppose this rule for many of the same reasons we oppose

5.3.6 above. The medical marijuana law already contemplates when an
identification card can be revoked, and it is in the event of "multiple or serious"
violations of the chapter. Del. Code Title 16 § 4919A(t). Any regulation must take this language into account.

We recommend amending 8.0 to state: "Multiple or serious violations 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."

Agency Response: The Agency respectfully disagrees. One of the tasks of the Medical Marijuana Program is to

provide balance between patient protection and that of the community. This regulation gives authority to allow suspension or revocation of a registry card if required to protect the community; however, it does not provide for absolute action by the Department. It is not intended to punish patients, but instead to protect both them and the community from potential threats.

8.0 Monitoring and Corrective Actions

8.3.3: Section 8.0 of the regulations lays out the duties and powers entrusted to the department to monitor for and subsequently correct violations of the medical marijuana law and regulations. Section 8.3.3 states that a "A registry identification card may be revoked or suspended, and a renewal application may be denied for: 8.3.3.1 failure to comply with any provisions of these requirements; 8.3.3.2 failure to allow a monitoring visit by authorized representatives of the Department; 8.3.3.3 the discovery of repeated violations of these requirements during monitoring visits."

MPP comment: We oppose this rule for many of the same reasons we oppose 8.3.2 and 8.1.1 above. First and foremost, the medical marijuana law already contemplates when an identification card can be revoked, and it is in the event of "multiple or serious" violations of the chapter. Del. Code Title 16 § 4919A(t). Any regulation must take this language into account. Secondly, as discussed above, monitoring visits on the basis of being a cardholder are unlawful, so revocation based on said visits must be removed.

We recommend amending 8.3.3 to state: "A registry identification card may be revoked or suspended, and a renewal application may be denied for: 8.3.3.1 failure to comply with any provisions of these requirements; 8.3.3.2 failure to allow a monitoring visit by authorized representatives of the Department; 8.3.3.3 the discovery of repeated or serious violations of any provision of these requirements during monitoring visits."

Agency Response: The Agency respectfully disagrees. One of the tasks of the Medical Marijuana Program is to provide balance between patient protection and that of the community. This regulation gives authority to allow suspension or revocation of a registry card if required to protect the community; however, it does not provide for absolute action by the Department. It is not intended to punish patients, but instead to protect both them and the community from potential threats.

Governor's Advisory Council for Exceptional Citizens (GACEC):

The Governor's Advisory Council for Exceptional Citizens (GACEC) has reviewed the Division of Public Health proposal to adopt regulations implementing Delaware's law on medical use of marijuana enacted in May, 2011. The GACEC would like to share the following observations.

First, the regulations, including definitions, generally track the statute.

Second, §5.3.1 is somewhat vague and should be more clear in specifying the scope of information to be reported to the Division of Long Term Care.

Agency Response: The Agency appreciates this comment. There is no reporting to the Division of Long Term Care, but instead to the Division of Public Health. In order to provide clarity in the regulations, we will propose that section 5.3.1 be listed as individual situations that would require reporting to the Department, rather than a comma delimited list. So that the new section would read as follows. "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 up on 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 "physician" as defined in 2.0 of these regulations, 5.3.1.4 a change that renders the patient's caregiver no longer eligible as defined in these regulations.

Third, §5.3.6 authorizes a $150 civil penalty if a patient or caregiver cardholder fails to report a change in name, address, physician, disability condition, medical status, etc. This is consistent with Title 16 Del.C. §4912A. However, the regulation should include due process to contest the penalty. Compare §§8.2.5 (record review available to challenge suspension of registry identification card); and 8.4 (hearing available to challenge suspension or revocation of registry identification card).

Agency Response: The Agency respectfully disagrees. One of the tasks of the Medical Marijuana Program is to provide balance between patient protection and that of the community. This regulation gives authority to allow maximum punitive action if required; however, it does not provide for absolute action by the Department. In fact, section 5.3.1 allows for extension of the required time for notification with the showing of good cause. This regulation is not intended to punish patients, but instead to protect them. If a card is lost, for example, the need to have the ID number removed from the registry would be an important timely action. For clarification, we will modify the text in Section 5.3.6 to read as follows. "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, and is also subject to the immediate revocation of the registry identification card and all lawful privileges provided under the act."

Fourth, §8.5.3 recites that "(a)ll hearings held pursuant to this section shall be open to the public." Such hearings would typically involve confidential medical records and otherwise sensitive evidence. The statute explicitly contemplates that such information is confidential and protected, not "open to the public". See Title 16 Del.C. §4920A. For similar reasons, §8.14.4 is problematic since it makes a final hearing decision "public information" without redaction. . Cf.16 DE Admin Code 5000, §5502 [DHSS hearing decisions can be published but in redacted form].

Agency Response: The Agency acknowledges this comment and appreciates the concern for the protection of confidential medical records and the individuals to whom they pertain. While the meeting may be public, the Board can go into "executive session," which is off the record and in private, if one of the nine conditions is met under the FOIA statute - Title 29, section 1004(b). In addition, anything confidential under HIPPA says protected health information is confidential from disclosure to the public without consent. The hearing officer will guide this process, requesting people not to disclose information as part of the public hearing, and also reviewing information before it is made public.

Fifth, in §8.8, substitute "bear" for "endure".

Agency Response: The Agency appreciates this suggestion and will adopt the suggested substitution.

Sixth, §8.11 imposes the burden of proof on the patient or caregiver in all hearings. The traditional approach in administrative hearings is to impose the burden of proof on the "consumer" for denials of initial applications while imposing the burden of proof on the agency for terminations. The rationale is that there must be some change in circumstances to justify a termination. The agency should have the burden of showing the change in circumstances.

Agency Response: The Agency appreciates the comments regarding the burden of proof. We have removed sub section 8.11 entirely and will refer to the Administrative Procedures Act if and when questions arise regarding this issue.

Seventh, the word "Secretary" should be capitalized in §§8.14.1, 8.14.2, and 8.14.3.

Agency Response: The Agency appreciates this suggestion and will adopt the suggested capitalization.

Eighth, §8.14.3 contemplates the hearing officer's issuance of a "recommended decision" which is subject to the Secretary's revision. Since the Secretary was not involved in the hearing, it is unclear as to why this approach is being taken. The general DHSS approach is to authorize its hearing officers to issue a final decision. Compare 16 DE Admin Code 5000, §5304.5.

Agency Response: The Agency appreciates but respectfully disagrees with this comment. It is, in fact, the Secretary who releases/approves the final order. The hearing officer can only make a recommendation to the Secretary based on the hearing proceedings.

State Council for Persons with Disabilities (SCPD):

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services/ Division of Public Health's proposal to adopt regulations governing the State of Delaware Medical Marijuana Act. SCPD has the following observations.

First, the regulations, including definitions, generally track the statute.

Second, §5.3.6 authorizes a $150 civil penalty if a patient or caregiver cardholder fails to report a change in address, physician, medical status, etc. This is consistent with Title 16 Del.C. §4912A. However, the regulation should include due process to contest the penalty. Compare §§8.2.5 (record review available to challenge suspension of registry identification card); and 8.4 (hearing available to challenge suspension or revocation of registry identification card).

Agency Response: The Agency respectfully disagrees. One of the tasks of the Medical Marijuana Program is to provide balance between patient protection and that of the community. This regulation gives authority to allow maximum punitive action if required; however, it does not provide for absolute action by the Department. In fact, section 5.3.1 allows for extension of the required time for notification with the showing of good cause. This regulation is not intended to punish patients, but instead to protect them. If a card is lost, for example, the need to have the ID number removed from the registry would be an important timely action. For clarification, we will modify the text in Section 5.3.6 to read as follows. "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, and is also subject to the immediate revocation of the registry identification

card and all lawful privileges provided under the act."

Also, SCPD recommends clarifying the term "qualified patient's Physician status" in Section 5.3.1. While the regulation may contain be a definition for "Physician", the meaning of "qualified patient's Physician status" could be misconstrued in the reporting context. In addition, the requirement to report a "change in the status of the qualified patient's debilitating medical condition" is overburdening on the patient. For example, a person's medical condition may change from day to day. Fining someone $150 (Section 5.3.6) for not accurately reporting all changes in their medical condition is not fair. The Division may wish to limit such reporting to a change in condition which disqualifies them from the medical marijuana program.

Agency Response: The Agency appreciates this comment. In order to provide clarity in the regulations, we will propose that section 5.3.1 be listed as individual situations that would require reporting to the Department, rather than a comma delimited list. So that the new section would read as follows. "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 up on 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 "physician" as defined in 2.0 of these regulations, 5.3.1.4 a change that renders the patient's caregiver no longer eligible as defined in these regulations.

Third, §8.5.3 recites that "(a)ll hearings held pursuant to this section shall be open to the public." Such hearings would typically involve confidential medical records and otherwise sensitive evidence. The statute explicitly contemplates that such information is confidential and protected, not "open to the public". See Title 16 Del.C. §4920A. For similar reasons, §8.14.4 is problematic since it makes a final hearing decision "public information" without redaction. . Cf.16 DE Admin Code 5000, §5502 [DHSS hearing decisions can be published but in redacted form].

Agency Response: The Agency acknowledges this comment and appreciates the concern for the protection of confidential medical records and the individuals to whom they pertain. While the meeting may be public, the Board can go into "executive session," which is off the record and in private, if one of the nine conditions is met under the FOIA statute - Title 29, section 1004(b). In addition, anything confidential under HIPPA says protected health information is confidential from disclosure to the public without consent. The hearing officer will guide this process, requesting people not to disclose information as part of the public hearing, and also reviewing information before it is made public.

Fourth, in §8.8, substitute "bear" for "endure".

Agency Response: The Agency appreciates this suggestion and will adopt the suggested substitution.

Fifth, §8.11 imposes the burden of proof on the patient or caregiver in all hearings. The traditional approach in administrative hearings is to impose the burden of proof on the "consumer" for denials of initial applications while imposing the burden of proof on the agency for terminations. The rationale is that there must be some change in circumstances to justify a termination. The agency should have the burden of showing the change in circumstances.

Agency Response: The Agency appreciates the comments regarding the burden of proof. We have removed regulation 8.11 entirely and will refer to the Administrative Procedures Act if and when questions arise regarding this issue.

Sixth, the word "Secretary" should be capitalized in §§8.14.1, 8.14.2, and 8.14.3.

Agency Response: The Agency appreciates this suggestion and will adopt the suggested capitalization.

Seventh, §8.14.3 contemplates the hearing officer's issuance of a "recommended decision" which is subject to the Secretary's revision. Since the Secretary was not involved in the hearing, this approach makes little sense. The general DHSS approach is to authorize its hearing officers to issue a final decision. Compare 16 DE Admin Code 5000, §5304.5.

Agency Response: The Agency appreciates but respectfully disagrees with this comment. It is, in fact, the Secretary who releases/approves the final order. The hearing officer can only make a recommendation to the Secretary based on the hearing proceedings.

Dr. Richard Chong:

The publicized driver for suspending SB 17 appears to be primarily based on the potential legal liability of state

employees from federal prosecution and the state's large distribution model. The federal government has red flagged the "large centralized distribution model". While Delaware's bill does not actively suggest a large central distribution model, it does not eliminate it from consideration either. A use of the federal mandatory minimum sentence guideline for marijuana possession of plants should be considered. New Mexico and the District of Columbia limit cultivation of 95 plants per center (over a 100 plants is a mandatory minimum federal jail sentence). New Mexico recently increased the number of plants per center. New Mexico has released data about their medical cannabis program that suggest this limited plant model can support up to 800 patients with restrictions on the amount of cannabis a patient can receive at a time. New Mexico and Maine have medical cannabis programs that has not cause any federal intervention.

A resource the state of Delaware may want to collaborate with is Eric E. Sterling, Esquire, the president of the Criminal Justice Policy Foundation. He authored an article about Delaware's medical marijuana program and legal analysis of Charles Oberly's letter to the governor in the Baltimore Sun. Eric lectures to bar associations about medical marijuana and was counsel to the US House Judiciary committee from 1979-1989, where he worked on medical marijuana legislation.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking public comments regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

Stephen Haner:

I attended the hearings in Dover to help get SB 17 passed. I suffer from Multiple Sclerosis and have found that smoking 2-3 tokes of marijuana immediately lessens my pain level and completely subsides my fatigue level. I continue to purchase marijuana illegally and am at risk of arrest and jail. By making it legal to either grow it myself or purchase it in a compassion center avoids the risk of unhealthy additives that may be included in the marijuana I buy. Delaware should continue the passage of SB17. In this day and age, I should be purchasing from a compassion center with tax dollars going to the State of Delaware, not into the hands of the Drug Cartels, which is where the money trail ends. If Delaware is afraid of State employees being involved in any way in the sale of Med. Mar., they should allow those patients who suffer from a qualifying disease, to grow a small number of plants themselves.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking public comments regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

Diane L. Jump:

My name is Diane Jump, and I am so excited by the potential progress that Delaware is making for Medical Marijuana Patients to have peace of mind. I am fighting for the day that we have Safe Access. I understand that medical cards are going to be distributed with a qualifying letter from the patients Primary Care Physician. Do you have a sample letter for our PCP to use as a template? (My PCP and my Oncologist are both willing to write the letter, they would just like to see a sample of what you are looking for.)

Agency Response: The Agency appreciates your comments. Required documentation and how to access and submit that required documentation will be addressed through the development of Operating Procedures within the Division of Public Health and the Medical Marijuana Program. Those procedures are not part of the regulations and, as such, cannot be finalized until after the adoption of the Final Medical Marijuana Code. The Operating Procedures will include a fee assessment schedule, application instructions, and a timeline of operations. Those procedures will be communicated with the public after they are finalized.

Is there required DHSS documentation that the patient and caregivers will need to complete? Can that be done online / fax / mail if some patients cannot travel and the do not yet have a caregiver?

Agency Response: The Agency appreciates your questions regarding required documentation and how to access and submit that required documentation. Those questions will be addressed through the development of Operating Procedures within the Division of Public Health and the Medical Marijuana Program. Those procedures are not part of the regulations and, as such, cannot be finalized until after the adoption of the Final Medical Marijuana Code. The Operating Procedures will include a fee assessment schedule, application instructions, and a timeline of operations. Those procedures will be communicated with the public after they are finalized.

When and how do patients submit the required documentation,

Agency Response: The Agency appreciates your questions regarding required documentation and how to access and submit that required documentation. Those questions will be addressed through the development of Operating Procedures within the Division of Public Health and the Medical Marijuana Program. Those procedures are not part of the regulations and, as such, cannot be finalized until after the adoption of the Final Medical Marijuana Code. The Operating Procedures will include a fee assessment schedule, application instructions, and a timeline of operations. Those procedures will be communicated with the public after they are finalized.

Once all documentation has been submitted, how long will it take to be given the 10 digit number and receive a medical marijuana card.

Agency Response: The Agency appreciates your questions regarding required documentation and how to access and submit that required documentation. Those questions will be addressed through the development of Operating Procedures within the Division of Public Health and the Medical Marijuana Program. Those procedures are not part of the regulations and, as such, cannot be finalized until after the adoption of the Final Medical Marijuana Code. The Operating Procedures will include a fee assessment schedule, application instructions, and a timeline of operations. Those procedures will be communicated with the public after they are finalized.

I know that there is not much being said about the three compassion care centers. But Delaware needs to make this happen soon. Right now we are moving in the right direction, but even after we get a medical marijuana card, we are still criminals buying marijuana illegally off the street, and that is a serious problem.

I am a patient and I choose marijuana as my medication to relieve the most horrible symptoms of cancer and a chemotherapy regime that is difficult, painful, nauseating and has horrible side effects on my body.

I can absolutely say that by adding marijuana to my therapy along with, doctor prescribed medications, eating properly, exercise, my art, love and support from family and friends I have the chance to beat my cancer and become a survivor.

My CT scan readings are tomorrow with my doctor, we will decide if I continue on with this chemotherapy routine, or if we need to change medications. Friday, I will begin chemo again after a month break because my cell counts have been low.

There are so many patients just like myself, I am at Helen Graham on average three times a week, for test, bloodwork, Neulasta shots, port flushings, I talk to so many patients who are afraid of the legal implications of marijuana, So many people who want the relief that marijuana offers, but don't know how or where to buy it. People want to feel safe, and not worry that they are a criminal. I have showed and explained the affirmation defense to many, It doesn't really resonate with patients. No one wants to be hauled off to jail, fined and then try using that defense.

I am in school again beginning may, I will be finishing my degree after all these years in Paralegal Studies and will focus on Medical Marijuana law. I have completed all the book work and am earning certifications in cannabis education,

I appreciate everything Delaware is doing to move forward. and I want to be part of that movement.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act.

My caregiver is my longtime friend, He has been so since 2008. My doctor doesn't need to involve himself, when Huck picks up my medication from the pharmacy. So there is no need add unnecessary restrictions.

Patient Care Giver

As noted below, i recommend amending 4.1.3 to read:

written approval by the qualifying patient(s) and the qualified patient(s)' Physician(s) authorizing responsibility for managing the well-being of a the qualified patient(s) with respect to the use of marijuana."

Agency Response: The Agency appreciates this suggested revision to the proposed regulations. The requirement to have the physician provide written approval of the patient's caregiver was intended to allow for protection of at-risk population patients from abuse by someone who has more than a medicinal interest in marijuana. However, after further scrutiny of the Medical Marijuana Law, and additional discussion on ways to balance the needs of patients with the protection of the community, we have resigned to modify the regulations to remove the requirement of physician's approval of a patient's care giver.

We must move forward today: patients need safe access to medical marijuana NOW! You are forcing patients to buy

illegally and also subject themselves to risk as well as place themselves in harms way. Compassion care canters must be our focus point and need to be dressed immediately. It does no good to have a medical marijuana card in the street! My pot contact could care less if I have a card or not. The card only applies to the compassion care center.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. Those regulations do not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

The below section is ridiculous and against all we are trying to accomplish. Imagine obtaining quality medical marijuana from a different state that allows (I may have to go to New Jersey) outside patients to obtain medical marijuana, only to be a criminal again when I come back to my own state.

I am a grown law abiding citizen that doesn't need monitoring by some state appointed person who think they should have control over my medications.

8.0 Monitoring and Corrective Actions

8.3.1.3.6: Section 8.0 of the regulations lays out the duties and powers entrusted to the department to monitor for and subsequently correct violations of the medical marijuana law and regulations. 8.3.1.3.6 retains the right of the state to prosecute a medical marijuana patient or caregiver for possessing or transferring marijuana "outside Delaware or attempt[ing] to obtain or transport marijuana from outside Delaware

Agency Response: The agency respectfully disagrees. It is the intent of the regulations to provide protection for the community against possible diversion of marijuana from a registered program patient or care giver to a non-registered person. The Division of Public Health is charged with administering Chapter 49A of Title 16 of the Delaware Code, The Delaware Medical Marijuana Act. The scope of the law does not allow for any program administration outside of the state of Delaware; therefore, we do not have the ability to relieve registered card holders from any punitive penalties with regard to marijuana-related activities outside of the state of Delaware. This section of the regulation simply emphasizes the limited scope of the regulations.

Pre chemo yesterday. Doctor appointment today to discuss the CT scan I had on Monday, tomorrow I start chemo again, the days are running into each other and I am so sick as I try to manage my disease, my job, my life.

What helps me get through each day is marijuana. It takes the edge off.. It lessens the pain, eases the stress, it allows movement when everything else restricts me. When I smoke marijuana as part of my medication routine, it takes away the nausea... I smoke in the early morning, so i can take the pile of prescribed pills without throwing them up. I smoke and it allows me to eat a healthy breakfast, otherwise, I'm not hungry and I go without eating. Marijuana has so many therapeutic benefits, without the debilitating side effects of cancer, chemo and prescribed medications.

The prescribed medications help, and they hurt. their side effects (diarrhea, nausea, constipation, migraines and so many others) and the pain at times is unbearable. Then include the side effects of the chemotherapy and its just a another nightmare.

Marijuana is medication for so many of us and we know the therapeutic and healing value of it. We are asking for Safe Access to it. Many of us are at risk and are put in harms way when we purchase marijuana. And, we are never sure of the quality of our medication.

The only way to provide quality medical marijuana is through a compassion care center. Delaware has the ability to provide our sick who choose medical marijuana safe access to a quality product. We need to move forward with compassion care centers in each county.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act.

It's also reasonable for doctors to be concerned about whether they would be in compliance with Federal law, but like those States that worry about the absurd proposition that State employees might be prosecuted for the mundane day to day administration of medicinal cannabis patient protection laws this concern has been put to bed by the Federal Appellate Courts. This particular concern was put to rest in Conant v. Walters. (9th Cir 2002) 309 F.3d 629, (cert denied Oct. 14, 2003). Physicians have a First Amendment right to discuss medical marijuana with their patients, but not to help them obtain cannabis for medical use. http://www.chrisconrad.com/expert.witness/conant.htm

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act.

Delaware medical marijuana !

In 2009, 137 Delawareans died of drug overdoses, according to the Delaware Health Statistics Center -- 80 percent of them caused by prescription drugs.

Between 2009 and 2010, prescription narcotics and anti-anxiety medications killed significantly more Delawareans than traffic accidents, heroin, cocaine and alcohol combined.

The problem, some say, is that many people think because a doctor prescribed it, the drug must be safe.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act.

Check out this video on YouTube:

http://www.youtube.com/watch?v=59VNBnGo8B8&feature=youtube_gdata_player

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Bold and innovative. That's what Ethan Nadelmann, Executive Director of the Drug Policy Alliance, said he's looking for in proposed reform. The rest of drug policy shares this sentiment and has long been calling for something that could shape the future of reform. My friends, a group in Ohio is trying to do just that. The Ohio Medical Cannabis Amendment proposes a brand new model for medical marijuana that may very well be the game changer we've all been waiting for.

What does it do? First off, part of the OMCA's beauty is its simplicity. Go look and attempt to read other states' medical marijuana laws. Most are extremely long and riddled with specific regulation. In fact, if you're not bored to tears after the first page, you might notice that most of the laws look similar to each other. Not the OMCA. It's a 2 page amendment that very simply establishes rights for medical marijuana patients and delegates the rulemaking powers to a Commission of Cannabis Control.

Both of these functions are extremelyimportant-I'll explain why in turn.

The Rights. The OMCA states plainly and specifically that an eligible patient has the right to use, grow, and purchase medical marijuana to alleviate their suffering. No other medical marijuana law contains this language. Rather, other states with medical marijuana simply decriminalize the use and possession for patients, thus making it a privilege, not a right. This distinction has tremendous legal significance in the fight against the federal government because a privilege is prone to governmental interference without justification, whereas a right is subject to a higher level of scrutiny.

The OMCA also gives eligible patients the rights of confidentiality and privacy with respect to their medical marijuana use. These rights are not present in current medical marijuana laws. In fact, the opposite is true. Many states are free to hand over their patients' information to any federal agency that asks, while other states have 24 hour live-feed cameras to the police. None of these practices would exist in Ohio under the OMCA. "HIPAA applies to our patients for every other aspect of their medical care, so why shouldn't it apply to our patient's use of medical marijuana as well?" said Theresa Daniello, spokesperson for the OMCA. I agree.

Taking things one step further, the OMCA grants eligible patients the right to be free from state discrimination and interference with respect to their medical marijuana use. It also charges the State of Ohio with upholding and defending the rights listed in the OMCA. These two provisions combined are amazing for medical marijuana patients. What this essentially amounts to is a direct prohibition on any state employee of Ohio from discriminating or interfering with medical marijuana patients. Police would not be free to choose the federal law and join a DEA raid. Further, Ohio's Attorney General would not be able to just idly stand by while medical marijuana patients are raided either, he'd be charged with challenging federal intervention. Once more, medical marijuana laws elsewhere lack these provisions.

Last, but not least, the OMCA extends broad rights for the existence of a medical marijuana industry in Ohio. "We wanted to avoid problems present in states like Michigan, where there is some debate as to the legality of the sale of medical marijuana." said OMCA's general counsel Mark Ramach. "By providing for the rights of the industry to exist, our patients are protected in every facet of their medical marijuana use. Our goal in crafting the OMCA was to keep patients' rights first at all times. The rights granted are a result of that goal." The rights granted by the OMCA address most of the pitfalls in previous medical marijuana legislation. Any remaining issues are handled thanks to OMCA's commission.

The Commission. The OMCA seeks to avoid the headaches of other states by delegating rulemaking authority to a Commission of Cannabis Control. In doing so, the OMCA won't be victim to problems present in other medical marijuana

states that resulted from a lack of foresight in the law's implementation. Allow me to explain. In the past, medical marijuana laws have been written with regulation in the language. Such regulation has set possession limits, governed the purchase and sale, and delegated conflicting powers to both state and local governments. What those laws haven't come with, however, is an efficient and effective way to create or change regulation to address problems as they arise.

Enter the OMCA and its commission. This commission will be able to provide regulation for the medical marijuana industry in Ohio and will operate much like other regulatory bodies do in this country. Hearings will be public, and the people will have a say in proposed rules. The commission's ability to create and modify regulation is vital in medical marijuana policy. It'll provide an adaptable industry structure that can change over time in response to new scientific and medical studies. In short, Ohio won't be victim to unforeseen circumstances-were there ever to be a problem, the Commission could fix it.

To further ensure proper rulemaking, all members of the Commission are charged, via the OMCA's language, with creating regulation that upholds and defends the rights given by the amendment. This guarantees that patients' rights are always kept first and that regulation is made in a way that best protects the patients. The Commission will also be key in handling the federal government, were it to intervene. This brings me to my last point.

What about the Feds? The OMCA brings a new approach to the federal problem. In order to fully understand its significance, once must know how Gonzalez v. Raichchanged the game. Most by now know about Angel Raich and how the DEA raided her place and took her plants. Ms. Raich eventually challenged this action and found her way to the U.S. Supreme Court. Despite testimony from Angel Raich's doctor that Ms. Raich would die without use of her medical marijuana and regardless of the fact that Ms. Raich grew her own marijuana in her own house, never to sell to others or cross state lines, the Supreme Court held that Congress could use the Commerce Clause to regulate marijuana and thus the DEA raid was proper. Prior to Raich, the Court had not yet ruled on this question. This ruling opened the door for the continuous raids that we see to this day.

The logic behind the Court's reasoning is heavily debated and often difficult to explain, but it basically goes like this. So long as Congress is properly exercising an enumerated power, it can limit what states do. One of Congress's enumerated powers is the Commerce Clause. This clause gives Congress the power to regulate commerce among the States. Basically, anything that moves from state to state (or interstate), Congress can regulate. They can also regulate things like the roads, rivers, and airways. In 1942, the Supreme Court further interpreted the power to mean that Congress could regulate anything that, in the aggregate, has a substantial affect on interstate commerce.

Fast-forward to Raich. Raich did not purchase her marijuana outside of California. She was not going to sell it in or outside state lines. She grew it in California and was only going to use it personally. The Government argued that these actions, if everyone did it, would affect the black market on marijuana in the aggregate and therefore affect interstate commerce. There was no proof that Raich's actions actually had this effect, or that medical marijuana patient's in general growing their own would have that big of an impact on the black market, but the Court said it didn't matter. This decision basically closed the door on challenging the federal government on Commerce Clause principles.

What does all of this have to do with the OMCA? Well, the OMCA is a constitutional amendment that creates rights for medical marijuana patients in Ohio. Raich had to pursue her case using theories that came from California's law, which is a state statute that did not specifically address whether she in fact had a right to use marijuana. In short, California's language limited potential constitutional claims Raich could have brought. By specifically granting rights to its patients, the OMCA opens the door for new challenges against federal intervention.

Up until now, the federal government has hidden behind marijuana's federal status as a schedule 1 drug without having to justify its position against the overwhelming medical evidence to the contrary. Every court case related to medical marijuana has been decided on legal technicalities and not on the actual merits of whether marijuana in fact is medicine. The OMCA could force that discussion once and for all. Imagine the federal government having to justify its stance towards marijuana in light of Ohio's constitutional command that its sick citizens have the right to use, possess, and grow it. From what I've been told, this would bring up areas of constitutional law that have not seen a court room in some time.

Progress is slow, legal progress even slower. With that in mind however, simply having the ability to bring a new argument against the federal government puts our cause in a better position than ever before. The OMCA is the real deal. For more information on it and the group behind the language, check out www.omca2012.org If you're like me, and are already sold and want to do your part to help, please check out www.omca2012.org

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Glenn Greenwald writing in Salon.com:

The same person who directed the DOJ to shield torturers and illegal government eavesdroppers from criminal investigation, and who voted to retroactively immunize the nation's largest telecom giants when they got caught enabling criminal spying on Americans, and whose DOJ has failed to indict a single Wall Street executive in connection with the 2008 financial crisis or mortgage fraud scandal, suddenly discovers the imperatives of The Rule of Law when it comes to

those, in accordance with state law, providing medical marijuana to sick people with a prescription."

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act.

Does Delaware have a patient registry in place?

Agency Response: Thank you for your question regarding the Medical Marijuana Program. At this time, we are responding to the comments that were submitted in response to the proposed regulations. When the regulations are finalized, the agency will develop operating procedures for the program. Once they are finalized, the Medical Marijuana Program will begin to accept applications from the public for registry cards.

Have Delaware physicians registered to participate in the program?

Agency Response: Thank you for your questions regarding the Medical Marijuana Program. The Delaware Medical Marijuana Code does not require physicians to register; however, they will have to complete an agency developed form for their patient to be submitted with the patient's application for the registry card.

Does the DHSS have a plan to address education of law INCLUDING enforcement officers?

Agency Response: The Agency appreciates your concern for the education of law enforcement officers with regard to the Medical Marijuana Program. The regulations allow for 24 hour access for law enforcement officers to be able to confirm a patient's or caregiver's participation in the Medical Marijuana Program.

Does Delaware have a Director for our Medical Marijuana Program?

Agency Response: Delaware does have a Program Director for the Medical Marijuana Program, as part of the Health Systems Protection Section of the Division of Public Health.

Will Delaware require a fee to register? For patients and caretaker?

Agency Response: At this time, we are responding to the comments that were submitted in response to the proposed regulations. When the regulations are finalized, the agency will develop operating procedures for the program. The fee schedule will be finalized in correlation with the operating procedures after the regulations are finalized.

Is there a list of participating physicians?

Agency Response: Thank you for your questions regarding the Medical Marijuana Program. The Delaware Medical Marijuana Code does not require physicians to register; however, they will have to complete an agency developed form for their patient, to be submitted with the patient's application for the registry card.

Does Delaware have a website so that physicians can submit their information?

Agency Response: Thank you for your questions regarding the Medical Marijuana Program. The Delaware Medical Marijuana Code does not require physicians to register; however, they will have to complete an agency developed form for their patient, to be submitted with the patient's application for the registry card.

Is there a secure website / patient registry, so patients can submit their medical illness, doctor letter?

Agency Response: Thank you for your questions regarding the Medical Marijuana Program. At this time, we are responding to the comments that were submitted in response to the proposed regulations. When the regulations are finalized, the agency will develop operating procedures for the program. Those operating procedures will include procedures for submitting application information to the program.

I've noticed there isn't a public meeting scheduled for Delaware medical marijuana in the next couple weeks. Will there be a public meeting? Will we discuss all comments and concerns submitted? Will we move forward?
I have submitted at least 20 emails and I get the same response each time.!

I know we are submitting our concerns through April 30th. But information about our path forward would be reassuring.

I still purchase my medical marijuana illegally, like so many others. I will continue to do so because I have no other options.

Agency Response: Thank you for your questions and comments. At this time, we are responding to the comments that were submitted in response to the proposed regulations. There is no public meeting scheduled for the Delaware Medical Marijuana Program. When the regulations are finalized, the agency will develop operating procedures for the program. Those operating procedures will include procedures for submitting application information to the program.

I'm always sorta shocked by the mentality of "The Powers That Be"

When I think Medical Marijuana, or I say Medical Marijuana, it's with such passion, conviction and belief that I will beat MY cancer because Marijuana part of therapy, therefore, part of the Cure.

My Doctor / Patient relationship believes in a balance of science and nature... I am in chemotherapy treatment w/ two drugs that have horrific disgusting side effects, and that requires MY recovery to be as important as MY treatment.

I know what MY body needs, I am a qualified expert at bringing MY mind and body back from the toxic hell where chemotherapy and prescribed narcotics dump me. I hydrate, medicate, rest and meditate.

For me to live through this disease, & treatment, I had to find my faith, change my life, find a team of Doctors who believes in me.

Just because the doctor prescribes a pill, doesn't mean it's going to cure the ill. It's checks and balance and I have to be a smart patient. I need to take care of my body and find medication that work for ME. I am in control of MY cancer.

I added Marijuana to my medication routine in 2009, almost one year after I was diagnosed. The same year I shared my personal story in Dover and became an advocate for Medical Marijuana.

When Gov. Markell halted progress in February after the Oberly Memo, I told my story to Chad Livengood. I was just consumed with fear of being a criminal, I was so sick from chemo and headline news.

Tomorrow is the deadline to submit our thoughts, testaments, concerns to DHSS. I've checked public meetings on the State website and I don't see any public meetings scheduled in the upcoming weeks. We are supposed to have registry and medical marijuana cards in 60 days.

Is there a secret panel of compassionate state government employees that are qualified to make decisions regarding my life? Because if so, I've written on 20 is so different occasions and have received the same generic response each time.

I am at my doctors office as I finish this letter, I just signed newly required documents (Nurse Sue said it is Delaware State Required) about the dangers of prescribed opiates. Imagine that, we are running years behind on an epidemic.

If the Delaware Powers That Be cannot get their heads around Medical Marijuana... Get out of office, you don't belong there. ..

NH Medical Marijuana resolve to putting state employees at risk is to do away with compassion care centers ..

Other provisions of the bill, which has been repeatedly revised, guard against the concerns raised by the law enforcement community, Forsythe said. The bill, which would allow patients diagnosed with a debilitating medical condition to cultivate up to six ounces of marijuana, no longer allows for distribution centers, a plan that officials said would place state employees in violation of federal law.

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Todd Kitchen:

My name is Todd and I was very involved with getting SB17 passed and attended the Bill signing ceremony with Gov. Markell. I still work closely with the people assigned to DE from MPP(Marijuana Policy Project) to get this bill in motion so that us patients relying on this bill can finally get the medicine we were promised and fought & worked so hard to finally get. My Doctor, who I have seen since I was a little kid has written out the paper work needed for me to get a card and be able to use medical marijuana. The statement certifies, under Del. Code Ann. tit. 16, 4913A, that my Doctors who I have established a bona fide physician-patient relationship under Del. Code Ann. tit. 16, 4913A. My Dr. has discussed the medical benefit & risks and in his professional opinion I would receive therapeutic or palliative benefits from medical marijuana. He will continually monitor my condition while I use the medical marijuana for my debilitating conditions. I am under my Doctors medical care/ and he treats me for my back diseases, stomach disease, wasting man syndrome, anxiety disorder, plus multiple other serious debilitating conditions. He stays in contact with all my other specialists also.

My Question is when can I get my ID card and what do I have to do or where do I have to go, and how much will it cost?

Agency Response: The Agency appreciates your questions regarding required processes in obtaining a Medical Marijuana registry card. Those questions will be addressed through the development of Operating Procedures within the

Division of Public Health and the Medical Marijuana Program. Those procedures are not part of the regulations and, as such, cannot be finalized until after the adoption of the Final Medical Marijuana Code. The Operating Procedures will include a fee assessment schedule, application instructions, and a timeline of operations. Those procedures will be communicated with the public after they are finalized.

I have a very serious issue that has just recently Passed and is being heavily discussed and its Delaware's Medical Marijuana Bill - SB17!! It's time to save lives and help people in massive pain who don't want opiates 24/7 for the rest of their life. There are so many harmful things that opiates do to your body that are horrible and Medical Marijuana use no bad side effects and it makes the quality of life way better and you don't have to take as many as your opiates and other harmful RX's. So please think about all the people who will have their lives improved and possibly SAVED and their Pain Levels significantly Decrease!!!

These are some emails I revived after i read something about the ID cards April 1, 2012. I have had my legal Doctor written note with important parts of the bill being cited and the amendments#s and everything required and needed by Senate Bill 17.

I told them everything, about me and my diseases and ailments and chronic pain and chronic problems. I also told them about the work I did and how i was invited to the Senate Bill17 signing ceremony and met with Gov. Markell. I also submitted some amendments & ideas to help save the bill and some people like my amendments and they say they were submitted to maby be used.

I've had the proper paperwork as soon as the bill was passed. And now I am trying to get my ID card and get the medical program back on track !! Back on track so that us patients that fought so hard, Fought so hard and won, and we ill and diseases and cancer having people were promised our medicine when this bill was passes, we want our medicine we were promised !!! Please let me know anything I can do to help Delaware's medical marijuana situation. It is going to save my life and many others and literally keeps me able to live a better quality of life with the medical use of marijuana.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act.

True medical users have NO Problem following the DE SB17 Medical Marijuana Laws. We just want our medicine we fought for, and won the right to have/use responsibly!

I am writing to ask you to rethink your decision to halt implementation of Delaware's medical marijuana program in light of the letter from U.S. Attorney Oberly, and instead stand up for our state and protect our seriously ill by moving forward. Our state lawmakers vigorously debated the topic and came to the same conclusion that you ultimately did when you signed the bill allowing medical marijuana is the compassionate thing to do.

The letter states that state employees will not be immune for any actions they take under state law that violate the CSA. To date, no state employee in any medical marijuana state has been targeted by the federal government. If this letter concerns you, you can ask U.S. Attorney Oberly what exactly he believes would violate the CSA. No court has held that simply registering dispensaries is a crime.

Patients in Delaware need safe, reliable, and (in many cases) immediate access to the medicine their physicians think best. Delaware law now recognizes the medical value of marijuana, so why would we want our sick and debilitated to have to frequent the dangerous criminal market to get their medicine?

Please take some time to think over this issue. I urge you to stay strong in this presence of vague threats from the U.S. attorney. Please follow state law and implement the medical marijuana program despite the saber rattling from our U.S. attorney.

1. Instead of "State employees" it could be people who have been screened and approved by the state so that way the people approved would be people the State would employ. This would be for anybody involved in the medical marijuana program. From growers, dispensary owners, dispensary employees, transportation, basically everything having to do with the whole process.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

2. Instead of 3 dispensaries (1 each county) maby 2-3 smaller ones in each county, not state owned or operates just Watched/Monitored by the State , again all approved and certified by the State. That way the state is not the "employer" but they still have control and can monitor it constantly.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

3. Have a camera system set up in every part of the medical Marijuana process. From the grows and drying/curing to dispensary sales. That way the state and the Law, revenue board, whoever can look at a screen and see what's going on at every part. (Something similar to what some are doing in Colorado, they have the cameras linked right to the police, so monitoring is not a problem)

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

4. Maby consider a Small home cultivation program, where again the state has to approve and randomly monitor it. - True Medical users will follow the law and wouldnt mind if a Sheriff had to inspect their grow every now ale then. Keep it SMALL. 6 flowering 6 vegetative maby 2-4 clones/seedlings to be able to start their medicine. True medical users who really need it will not mind to have to pay small registration fees and maby a visit every now and then to check and see if their home grow is up to code. We just want a less painful life and a better quality of life without all the Horrible side effects of all the opiates over all the years.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

5. If possible use Vacant State buildings for the grow rooms and dispensaries so that way the state could make Money off unused buildings just sitting there. Let the State certified citizens who want to open/run/grow and work at lease the buildings from the state. It will bring the state money to help fox many things. Colorado made over $8Million in 1Day off registration fees just to show you some numbers from around the country.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking comments from the public regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

Patricia Lake:

After witnessing and caring for several family members and friends who have suffered horribly from the effects of cancer and its accompanying treatments (chemotherapy and radiation), I would like to suggest that the Medical Marijuana Code be put into law.

While taking care of my mother in 1997 as she went through nauseating chemotherapy and lost weight dramatically, I tried to find marijuana to help relieve her nausea and increase her appetite; after asking around among my friends and colleagues I located a source. In fact, several were available to me. The problem with doing business with them was that they also dealt in the distribution of illegal and potentially fatal drugs such as heroin and cocaine, the use of which I will never support. I can't begin to express how difficult it was for me to allow my mother to continue with her suffering rather than to deal with potentially dangerous felons.

I completely support the code which would allow patients with debilitating and/or fatal diseases access to regulated marijuana.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking

public comments regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

Elizabeth Wiberg:

To all this should concern, It is apparent that the state of Delaware along with the other states in our union have lost all logic concerning right from wrong. Why is it right to give patients with chronic pain a pill that can KILL, yet a natural grown plant that the Lord has blessed us with that hurts nobody is wrong? Why are you afraid of the feds? D.C. is about to open the Walmart of Weed isn't that in the Feds back yard? Delaware doesn't want patients to grow there own, why? As a caregiver of a patient with Ehlers-Danlos Syndrom (a rare connective tissue disorter), you want to come into my home and see if I'm respectable enough to be a caregiver as well as if the person or persons I care for are worthy. Have we lost all common deceincy? Where is the humanity, the common sence. Please look into your own past, you're still here. I would be more than happy to speak with anyone who needs afformation about the benifits of Medical Marajuana.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking public comments regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

John Wiberg:

am an almost 80 year old retired clergyman .I am deeply concerned about the State of Delaware approach to medical marijuana. I spoke in Senate and House committees, in favor of legalization. Now I find total inertia. I do not understand why Delaware drags its feet while other states such as California, Colorado and others openly regulate the sale of marijuana. I now understand that in Washington DC they are about to, or have, openned a store know as "The Walmart" of marijuana. This in the seat of our Federal Goverment. Where are the law inforcers who are charged to close it down? It seems to me Delaware is afraid of a non- existent bogeyman. I am also concerned that Delaware is now moving to provide those who need medical marijuana with letters from doctors or ID cards so local and state law officers will not arrest people so approved for possession However they will be able to arrest them for buying marijuana from illegal vendors. Medical user are being forced to buy from illegal, unregulated street corner providers. What a mess! Delaware should bite the bullet and do it right! Since the State is worried about State employees being arrested by the Feds, I volunteer to be an inspector to assure regulated, quality products for approved users! I am sure there are people who would be willing to be approved growers! A better way would be to allow those who need it, to grow a certain amout, that would be sufficient for their need. Tell the Governor to be brave show some leadership. am tired of polititions standing in the way of progress. No one has ever died from an over dose of this producted. It could be simply reguated in terms of the number of plants and the amount in possession in public and treating it as alcohol in terms of driving regulations. This would leave it up to indviduals to deal with the Feds.

Agency Response: The Agency appreciates and acknowledges these comments. At this time, we are only taking public comments regarding the adoption of the Medical Marijuana Code as published in the April 1, 2012 edition of the Register of Regulations, Volume 15, Issue 10, the proposed Regulations Governing the State of Delaware Medical Marijuana Act. The scope of those regulations does not provide guidance on how a patient can obtain medical marijuana. Once the regulations are finalized, we will develop operating procedures to address the process of obtaining a registry card for both patients and caregivers, for which the regulations do provide guidance.

The public comment period was open from April 1- April 30, 2012.

Verifying documents are attached to the Hearing Officer's record. The regulation has been approved by the Delaware Attorney General's office and the Cabinet Secretary of DHSS.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Medical Marijuana Code is adopted and shall become effective June 11, 2012, after publication of the final regulation in the Delaware *Register of Regulations*.

Rita M. Landgraf, Secretary

Rules and Regulations Governing the Delaware Medical Use of Marijuana

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 Chapter 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:

"**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.

"**Debilitating medical condition"** means 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.

"**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 would likely have prevented a conviction, but the conduct either occurred prior to the enactment of this chapter or was prosecuted by an authority other than the 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.

"**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 primary care or for her or his 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 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, 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 Physician;

3.2.2 the Physician's clinical licensure;

3.2.3 the patient applicant's name and date of birth;

3.2.4 the medical justification for the Physician's certification of the patient's debilitating medical condition;

3.2.5 the 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 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, 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) **[~~and the qualified patient(s)' Physician(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 Physicians;

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 Physician is licensed to practice medicine in Delaware and is in good standing; and

5.1.1.3 contacting the Physician 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 1 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 **[~~change in the person's name, address, qualified patient's Physician status, qualified patient's designated caregiver status, or change in status of the qualified patient's debilitating medical condition~~ 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 **[~~shall result in~~, 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 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 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

7.0 Registration and Operation of Testing Facility Centers

7.1 General Requirements for Operation of a Testing Facility Center. RESERVED

7.2 Security Requirements: RESERVED

7.3 Operations Manual. RESERVED

7.4 Required Training. RESERVED

7.5 Personnel Records. RESERVED

7.6 Application for Operation of Testing Facility Center. RESERVED

7.7 Complete Application Required. RESERVED

7.8 Testing Facility Center Application Review Criteria. RESERVED

7.9 Issuance of Registration Certificate Authorizing Operation of a Testing Facility Center. RESERVED

7.10 Registry Identification Cards for Principal Officers, Board Members, Agents, Volunteers or Employees of a Testing Facility Center. RESERVED

7.11 Expiration Date. RESERVED

7.12 Expiration, Termination or Renewal of a Registration Certificate Authorizing Operation of a Testing Facility Center. RESERVED

7.13 Non-transferable Registration Certificate Authorizing Operation of a Testing Facility Center. RESERVED

7.14 Inspection. RESERVED

8.0 Monitoring and Corrective Actions

8.1 **[~~Monitoring:~~ On-site Visits/Interviews]**

8.1.1 The Department or its designee may perform on-site **[~~assessments~~ interviews]** of a qualified patient or primary caregiver to determine **[~~compliance with these rules~~ eligibility for the program]**. The Department may enter the premises of a qualified patient or primary caregiver during business hours for purposes of **[~~monitoring and compliance~~ interviewing a program applicant]**. Twenty-four (24) hours' notice will be provided to the qualified patient or primary caregiver prior to an on-site **[~~assessment except when the Department has a reasonable suspicion to believe that providing notice will result in the destruction of evidence or that providing such notice will impede the Department's ability to enforce these Regulations~~ interview]**.

8.1.2 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 **[~~compliance~~ eligibility]** with these requirements.

8.1.3 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.

8.1.4 Any failure to adhere to these rules, documented by the Department during **[~~monitoring~~ an interview]**, may result in sanction(s), including suspension, revocation, non-renewal or denial of licensure and referral to state or local law enforcement.

8.1.5 The Department shall refer credible criminal complaints against a qualified patient or primary a caregiver to the appropriate Delaware state or appropriate local authorities.

8.2 Corrective action:

8.2.1 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.

8.2.2 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).

8.2.3 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.

8.2.4 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.

8.2.5 Suspension of registry identification card without prior hearing: In accordance with the 16 Delaware Code Chapter 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.

8.2.5.1 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.

8.2.5.2 The record review requested subsequent to a summary suspension shall be conducted by the Department.

8.2.5.3 The Department shall conduct the record review on the summary suspension by reviewing all documents submitted by both card holder and the Department.

8.2.5.4 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.

8.2.5.5 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:

8.2.5.5.1 be made within 30 calendar days, as determined by the postmark, from the date of the notice issued by the Department;

8.2.5.5.2 be properly addressed to the medical marijuana program;

8.2.5.5.3 state the applicant's name, address, and telephone number(s);

8.2.5.5.4 provide a brief narrative rebutting the circumstances of the suspension, and

8.2.5.5.5 additional documentation must be included with the request for a record review.

8.3 Summary Suspension, Revocation and Appeal Process:

8.3.1 Participation in the medical marijuana program by a qualified patient or primary caregiver does not relieve the qualified patient or primary caregiver from:

8.3.1.1 criminal prosecution or civil penalties for activities not authorized in this rule and act;

8.3.1.2 liability for damages or criminal prosecution arising out of the operation of a vehicle while under the influence of marijuana; or

8.3.1.3 criminal prosecution or civil penalty for possession, distribution or transfers of marijuana or use of marijuana:

8.3.1.3.1 in a school bus or public vehicle;

8.3.1.3.2 on school grounds or property;

8.3.1.3.3 in the workplace of the qualified patient's or primary caregiver's employment;

8.3.1.3.4 at a public park, recreation center, youth center or other public place;

8.3.1.3.5 to a person not approved by the Department pursuant to this rule;

8.3.1.3.6 outside Delaware or attempts to obtain or transport marijuana from outside Delaware; or

8.3.1.3.7 that exceeds the allotted amount of usable medical use marijuana.

8.3.2 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.

8.3.3 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:

8.3.3.1 failure to comply with any provisions of these requirements;

8.3.3.2 failure to allow a monitoring visit by authorized representatives of the Department;

8.3.3.3 the discovery of repeated violations of these requirements during monitoring visits.

8.4 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 **[~~appellant shall file 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:

8.4.1 a statement of the facts relevant to the review of the action;

8.4.2 a statement of the provision of the act and the rules promulgated under the act that are relevant to the review of the action;

8.4.3 a statement of the arguments that the **[~~appellant~~ qualified patient/primary caregiver]** considers relevant to the review of the action; and

8.4.4 any other evidence considered relevant.

8.5 Hearing process:

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

8.5.2 Except for telephonic hearings, hearings shall be conducted in Dover or, upon written request by an aggrieved person, in the place or area affected.

8.5.3 All hearings held pursuant to this section shall be open to the public.

8.5.4 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.

8.5.5 Any hearing provided for in this rule may be held telephonically, in the interest of a speedy resolution.

8.5.6 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 **[~~appellant's~~]** 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:

8.5.6.1 a statement of the time, place and nature of the hearing;

8.5.6.2 a statement of the legal authority and jurisdiction under which the hearing is to be held;

8.5.6.3 a short and plain statement of the matters of fact and law asserted;

8.5.6.4 notice to any other parties to give prompt notice of issues controverted in fact or law; and

8.5.6.5 all necessary telephone numbers if a telephonic hearing shall be conducted.

8.6 All parties shall be given the opportunity to respond and present evidence and argument on all relevant issues.

8.7 Record of proceeding: The record of the proceeding shall include the following:

8.7.1 all pleadings, motions and intermediate rulings;

8.7.2 evidence received or considered;

8.7.3 a statement of matters officially noticed;

8.7.4 questions and offers of proof, objections and rulings thereon;

8.7.5 proposed findings and conclusions; and

8.7.6 any action recommended by the hearing officer.

8.8 A party may request a transcription of the proceedings. The party requesting the transcript shall **[~~endure~~ bear]** the cost of transcription.

8.9 Procedures and evidence:

8.9.1 Any party shall be represented by a person licensed to practice law in Delaware or an individual **[~~appellant~~]** may represent him or herself.

8.9.2 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.

8.9.3 Documentary evidence shall be received in evidence in the form of true copies of the original.

8.9.4 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.

8.9.5 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.

8.9.6 Evidence on which the hearing officer shall base his or her decision is limited to the following:

8.9.6.1 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

8.9.6.2 testimony and exhibits introduced by the parties.

8.9.7 The record shall include all briefs, proposed findings and exceptions and shall show the ruling on each finding, exception or conclusion presented.

8.9.8 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.

8.9.9 The Department may choose to:

8.9.9.1 issue subpoenas for witnesses and other sources of evidence, either on the agency's initiative or at the request of any party; and

8.9.9.2 administer oaths to witnesses; limit unduly repetitive proof, rebuttal and cross-examination.

8.10 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:

8.10.1 the **[~~appellant~~ Division]** shall present an opening statement on the merits and the **[~~appellee~~ Cardholder]** shall make a statement of the defense or reserve the statement until presentation of that party's case;

8.10.2 after the opening statements, if made, the **[~~appellant~~ Division]** shall present its case in chief in support of the **[~~appellant's~~ Division's]** petition;

8.10.3 upon the conclusion of the **[~~appellee~~ Cardholder]** case, the **[~~appellee~~ Cardholder]** shall present its case in defense;

8.10.4 upon conclusion of the **[~~appellee's~~ Cardholder's]** case, the **[~~appellant~~ Division]** shall present rebuttal evidence;

8.10.5 after presentation of the evidence by the parties, the **[~~appellant~~ Division]** shall present a closing argument; the **[~~appellee~~ Cardholder]** then shall present its closing argument and the **[~~appellant~~ Division]** shall present a rebuttal argument; and

8.10.6 thereafter, the matter shall be submitted for recommendation by the hearing officer.

[**~~8.11 Burden of proof: The appellant bears the burden of showing by a preponderance of the evidence that the decision made by the Department or an agent of the Department shall be reversed or modified.~~**]

8.**[~~12~~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.

8.**[~~13~~12]**Telephonic hearings:

8.**[~~13~~12]**.1Any 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.

8.**[~~13~~12]**.2Any 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.

8.**[~~13~~12]**.3The 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.

8.**[~~13~~12]**.4The **[~~appellee~~ Cardholder]** shall initiate the telephone call. The **[~~appellant~~ Division]** is responsible for ensuring the telephone number to the **[~~appellant's~~ Division's]** location for the telephonic hearing is accurate and the **[~~appellant~~ 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.

8.**[~~13~~12]**.5The 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.

8.**[~~14~~13]**Recommended action and final decision:

8.**[~~14~~13]**.1At 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.

8.**[~~14~~13]**.2No 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.

8.**[~~14~~13]**.3The 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:

8.**[~~14~~13]**.3.1a brief summary of the evidence,

8.**[~~14~~13]**.3.2a statement of findings of fact based upon the evidence,

8.**[~~14~~13]**.3.3conclusions and the reasons thereof, on all material issues of fact, law or discretion involved,

8.**[~~14~~13]**.3.4any other conclusions required by law of the Department, and

8.**[~~14~~13]**.3.5a 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.

8.**[~~14~~13]**.3.6Service shall be made by registered or certified mail.

8.**[~~14~~13]**.4The final decision or order shall be public information and shall become a part of the record.

9.0 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) (Final)