

HEALTH AND SENIOR SERVICES

PUBLIC HEALTH SERVICES BRANCH

ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICES DIVISION

MEDICINAL MARIJUANA PROGRAM

Medicinal Marijuana Program Rules

Adopted New Rules: N.J.A.C. 8:64

Proposed: February 22, 2011 at 43 N.J.R. 340(a).

Adopted: November 23, 2011 by Mary E. O’Dowd, MPH, Commissioner, Department of Health and Senior Services.

Filed: November 23, 2011 as R.2011 d.314, **without change**.

Authority: N.J.S.A. 24:6I-1 et seq., particularly 24:6I-7 and 16.

Effective Date: December 19, 2011.

Expiration Date: December 19, 2018.

Summary of Hearing Officer’s Recommendations and Agency’s Response:

Samuel T. Stewart, Regulatory Officer in the Department’s Office of Legal and Regulatory Compliance, served as the hearing officer at the March 7, 2011 public hearing held at the War Memorial Building, 1 Memorial Drive, Trenton, New Jersey. Terry Clancy, Ph.D., Executive Assistant in the Department’s Public Health Services Branch, served as a panelist with the hearing officer. The comment period for the notice of proposal closed on April 23, 2011. Thirty-one commenters presented comments at the public hearing. The hearing officer took no position on the rulemaking except to recommend that the agency review and respond to the comments in the context of reviewing and responding to the written comments submitted on the original notice of proposal dated November 15, 2010 at 42 N.J.R. 2668(a) and the notice of reproposal dated February 22, 2011 at 43 N.J.R. 340(a). The Department has accepted the hearing officer’s recommendation. A record of the public hearing is available for inspection in accordance with applicable law by contacting:

Department of Health and Senior Services

Office of Legal and Regulatory Compliance

John Fitch Plaza

P.O. Box 360

Trenton, New Jersey 08625-0360

Summary of Public Comments and Agency Responses:

The Department received public comments on the original notice of proposal dated November 15, 2010, the notice of reproposal dated February 22, 2011, and at the public hearing on March 7, 2011. Accordingly, the comments and responses have been arranged in two sections. The first part provides a summary of the public comments and agency responses bearing on the notice of proposal dated November 15, 2010. The second part provides a summary of the public comments and agency responses bearing on the notice of reproposal dated February 22, 2011. Persons commenting at the public hearing testified exclusively with regard to the notice of reproposal dated February 22, 2011. Therefore, the Department identifies those commenters and responds to their comments in the second part of the summary of public comments and agency responses. The Department identifies twice those persons commenting on matters relevant to both parts.

Part One

1. Irvina Booker, Englewood, NJ
2. Association of Safe Access Providers (ASAP), Montclair, NJ by Marianne Bays, Ph.d
3. Marjaree Mayne, Pittstown, NJ
4. Coalition for Medical Marijuana - New Jersey, Inc., Trenton, NJ by Ken Wolski, RN MPA, Executive Director
5. New Jersey State Nurses Association, Trenton, NJ by Carolyn Torre, RN, MA, APN, Director, Regulatory Affairs
6. Charles Kwiatkowski (address not listed)
7. Bonnie L. Johnson, Absecon, NJ
8. Trish Buker, Riverside, NJ
9. New Jersey Hospice and Palliative Care Organization, Scotch Plains, NJ by Nora Giurici, BSN, CHPCA, Board of Trustees
10. Robert J. Schenk Jr., RPh, CCP, Colts Neck, NJ
11. Elaine Terranova, Little Egg Harbor, NJ
12. Elise Karen Segal, Winonah, NJ

13. Jim Mazzeo, Nutley, NJ
14. Barbara Rakoczy, Swedesboro, NJ
15. Robert James Kane, Bound Brook, NJ
16. American Civil liberties Union of New Jersey, Newark, NJ by Ed Barocas, Legal Director
17. National Organization for the Reform of Marijuana Laws – New Jersey, Brick, NJ by Anne M. Davis, Esq, Executive Director
18. Global Advisors Smokefree Policy, Summit, NJ by Karen Blumenfeld, Esq., Executive Director
19. Roger Tower, Lawrenceville, NJ
20. Edward Grimes, East Hanover, NJ
21. Edward R. Hannaman, Esq, Ewing, NJ
22. Drug Policy Alliance, Trenton, NJ by Roseanne Scotti
23. TA Davis, (address not listed)
24. Dennis J. Petro MD, Catasauqua, PA
25. Don & Gerry McGrath, Robbinsville, NJ
26. Anthony Kimmick, Toms River, NJ
27. Samuel A. Tait, Jr., Audubon, NJ
28. Marta Portuguese, Roselle Park, NJ
29. Medical Society of New Jersey, Lawrenceville, NJ by Lawrence Downs, Esq, General Counsel
30. New Jersey League for Nursing, Garwood, NJ by Eileen P. Williamson, RN, MSN, President
31. Louis Santiago, Freehold, NJ
32. New Jersey Hospice and Palliative Care Organization, Scotch Plains, NJ by Donald Pendley, M.A., CAE, APR, President
33. Justin Escher Alpert, Esq., Livingston, NJ

34. National Organization for the Reform of Marijuana Laws – Washington, DC by Paul Armentano, Deputy Director

35. Diane Riportella, Egg Harbor, NJ

36. Jeffrey S. Pollack, M.D., Mays Landing, NJ

37. Christiane Oliveri, Clifton, NJ

38. Michael Oliveri, Clifton, NJ

39. Lisa (Oliveri) Serafino, Clifton, NJ

The numbers in parenthesis after each comment below identify the respective commenters listed above.

General Comments

1. COMMENT: A number of commenters state that N.J.A.C. 8:64-10.6(c)5 and 10.7(c), which limit the percentage of delta-9-tetrahydrocannabinol (THC) in medicinal marijuana to no more than 10 percent, are inappropriate and overly restrictive rules. The commenters generally point out that other states do not limit THC content in their medicinal marijuana and that such provides patients with greater medicinal options for relief from pain and suffering. The commenters generally state that medicinal marijuana with a maximum of 10 percent THC will be less effective than marijuana with a higher THC content and that this will require higher dosages to achieve a palliative effect and may discourage some patients from participating in the Medicinal Marijuana Program (MMP) because they can obtain higher potency marijuana on the black market. (1, 2, 5, 6, 7, 9, 12, 16, 17, 21, 22, 24, 25, 28, 30, 32, 33, 35, 36, 37, and 38)

RESPONSE: By limiting medicinal marijuana to a maximum of 10 percent THC and mandating the sale of three strains of medicinal marijuana in a low, medium, and high potency, the Department is able to ensure that doctors and their patients have a reliable and standardized choice of potency options from which to choose. Relevant United States research studies, such as the study concluded in 2010 by the Medicinal Cannabis Research Center at the University of California San Diego, used medicinal marijuana that was no more than 10 percent THC, which was grown by the University of Mississippi. The Medicinal Cannabis Research Center study, conducted over a period of 10 years, demonstrated that medicinal marijuana from the University of Mississippi had a significant clinical effect. In October 2011, the Dutch Government announced that it would outlaw the sale of cannabis in coffee shops with a THC content greater than 15 percent, citing that marijuana with a greater THC concentration should be categorized with hard drugs such as cocaine and heroin. The 10 percent limit on THC content at the inception of the MMP will provide patients with effective medicine to start and allow the Department to collect data from patients and to evaluate whether the 10 percent limit on THC content should be revisited in future rulemaking.

2. COMMENT: A number of commenters state that N.J.A.C. 8:64-10.7(a), which limits the number of strains of medicinal marijuana that an Alternative Treatment Center (ATC) may cultivate to three, is an unreasonable limitation on each patient's choice of medicine. The commenters generally state that patients should be free to try many strains of medicinal marijuana as certain strains relieve conditions such as nausea, while other strains relieve conditions such as spasticity, and still other strains relieve pain. (1, 5, 6, 7, 9, 12, 16, 17, 21, 22, 24, 25, 28, 30, 32, 33, 34, 36, 37, and 38)

RESPONSE: By mandating the sale of three strains of medicinal marijuana of a low, medium, and high dose, the Department is able to ensure patients have a reliable and standardized choice of potency options to choose from. Generally, marijuana is classified as a Schedule I drug under the Federal Controlled Dangerous Substances Act of 1970 and has not gone through a Food and Drug Administration testing process for safety or efficacy. The three strain mandate is a reasonable balancing of State action in developing the MMP to limit distribution to only registered qualifying patients, which is authorized under State law but still considered illegal under Federal law. In addition, the three-strain mandate will assist law enforcement authorities in identifying medicinal marijuana that originated from a permitted ATC, which will help prevent possible diversion and establish public trust in the program, a process that has proven challenging in other states. Inasmuch as this is a new program, data collected by the Department will help guide ATCs in choosing the best medicinal strains and help the Department determine through future rulemaking whether different or additional strains would prove beneficial to patients.

3. COMMENT: A number of commenters state that N.J.A.C. 8:64-5.1(a), which provides that the Commissioner shall not take action to approve additional debilitating medical conditions until the Department makes at least two annual reports to the Governor and the State Legislature concerning the MMP, is inappropriate and overly restrictive. The commenters generally point out that other states allow medicinal marijuana use for a wider array of debilitating medical conditions and that it is in the best interests of patient care to consider expanding the list of debilitating medical conditions without delay. (1, 3, 5, 6, 15, 16, 17, 21, 22, 30, 33, 35, 36, 37, and 38)

RESPONSE: The New Jersey Legislature held hearings prior to passage of the Act and made a determination as to the inclusion of specific debilitating medical conditions and, while considering the qualifying medical conditions under the medicinal marijuana laws in other states, defined its list of debilitating medical conditions as provided by N.J.S.A. 24:6I-3 to start the MMP. N.J.A.C. 8:64-4.3 requires ATCs to report patient survey information to the Department. Consistent with this approach, the Department disagrees that new qualifying conditions should be added before two years' time. The Department will approve new qualifying conditions only after sufficient data is collected and analyzed to support any such addition. Two years' time will provide the Department with the ability to collect the requisite data necessary to determine what new conditions, if any, should be added to the list of qualifying conditions. In addition, two years' time will provide petitioners seeking to establish additional debilitating medical conditions under N.J.A.C. 8:64-5 with additional data to support a bona fide petition for the same.

4. COMMENT: A number of commenters state that two medicinal marijuana growers and four dispensers will not be sufficient to meet patient demand or to provide convenient access to patients and primary caregivers. These comments generally state that six ATCs will not be sufficient to meet patient demand or to provide convenient access to patients and primary caregivers. These commenters generally point out that traveling long distances to the closest ATC will be a hardship for those patients who are very ill and/or do not have a primary caregiver. (4, 5, 17, 19, 21, 34, 35, and 37)

RESPONSE: The Department agrees that two cultivators and four dispensers may not be sufficient to meet patient demand, accordingly, in the notice of reproposal dated February 22, 2011, the Department changed the definition of ATC at N.J.A.C. 8:64-1.2 to allow ATCs to both cultivate and dispense medicinal marijuana. As required by N.J.S.A. 24:6I-7a, which requires at least two ATCs in the northern, central, and southern regions of the State, the Department will follow the development of the MMP and seek to ensure the availability of a sufficient number of ATCs. Inasmuch as the MMP is a new program, the Department is without sufficient data upon which to formulate an opinion as to whether additional ATCs will be necessary at this time.

5. COMMENT: Three commenters state that two ounces per month is an insufficient amount of medicinal marijuana because it will only permit a patient to use marijuana once or twice per day. The commenters state that since the medicinal marijuana available under the proposed rules will be limited to 10 percent THC content, patients will be forced to consume higher dosages and will, therefore, run out of medicinal marijuana quickly if limited to no more than two ounces per month. (5, 36, and 37)

RESPONSE: The two ounces per month limitation is set by statute at N.J.S.A. 24:6I-10a, which provides that a physician may only authorize, and an ATC may only dispense, a maximum of two ounces of medicinal marijuana to a patient in a 30-day time period. Accordingly, the Department is required to comply with the statute and does not have the authority to exceed the two ounces per 30-day time period limit. The Department does not have sufficient data upon which to base a determination concerning the dosages and frequencies of dosages of medicinal marijuana for various debilitating medical conditions that physicians will determine, in consultation with their patients, to be effective.

6. COMMENT: A number of commenters stated that the requirement at N.J.A.C. 8:64-2.5(a)9i, which would require physicians to certify that a patient has not responded to conventional medical treatment prior to the physician's recommendation that the patient may benefit from the medicinal use of marijuana, is inappropriate and inconsistent with the definition of "debilitating medical condition" in the enabling statute at N.J.S.A. 24:6I-3. (4, 5, 6, 9, 15, 22, 36, and 37)

RESPONSE: The Department agrees with the comments. N.J.S.A. 24:6I-3 of the enabling statute provides that only seizure disorders, including epilepsy, intractable skeletal muscular spasticity, and glaucoma must be resistant to conventional medical therapy before qualifying as debilitating medical conditions. In recognition of this, the Department removed this requirement from N.J.A.C. 8:64-2.5(a)9i, except for the conditions named in N.J.S.A. 24:6I-3, in the notice of reproposal dated February 22.

7. COMMENT: Three commenters object to the requirement at N.J.A.C. 8:64-2.5(a) that incorporates N.J.A.C. 13:35-7A by reference. Proposed N.J.A.C. 13:35-7A.5(c)3 would require physicians to “periodically make reasonable efforts, unless clinically contraindicated, to stop the medical use of marijuana, decrease the quantity authorized or try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.” The commenters generally state that medicinal marijuana patients are frequently terminally ill, and therefore, it makes no sense to attempt to wean these patients off of medicine that alleviates the patient’s suffering. (4, 15, and 24)

RESPONSE: The Department’s rule at N.J.A.C. 8:64-2.5(a) incorporates a Board of Medical Examiners (BME) rule at N.J.A.C. 13:35-7A by reference. The practice of medicine is regulated by the BME. The BME determined not to adopt the rule as proposed. Accordingly, the rule upon adoption will not require a physician to take steps periodically to stop or reduce the use of medicinal marijuana. The rule will provide, in relevant part at N.J.A.C. 13:35-7A.5(c), “[i]f the physician determines that the patient is achieving treatment objectives, and is not experiencing untoward side effects or physical or psychological problems associated with marijuana use, the physician may continue the patient’s treatment with medical marijuana without alteration.”

8. COMMENT: A number of commenters stated that proposed N.J.A.C. 8:64-12, Home delivery, is too restrictive. Generally, the comments stated that all patients should be eligible for home delivery automatically because most prospective qualifying patients are very ill and/or do not have a primary caregiver, making travel a hardship. (17, 19, 21, 22, 26, 32, 36, and 38) Two commenters stated that a one day wait for home delivery was cruel since it could cause a patient to suffer without his or her medicine. (21 and 32)

RESPONSE: A bi-partisan agreement between Governor Chris Christie and Assemblyman Reed Gusciora, one of the primary sponsors of the New Jersey Compassionate Use Medical Marijuana Act (the Act), that was announced on December 3, 2010, eliminated home delivery as part of an effort to reach a compromise to implement the MMP. In addition, the Department's concern for the security of patients, ATC employees, the potential for diversion, and the need to ensure the safety of the public weighed against home delivery in this rulemaking. Experience with the program will determine whether home delivery is needed in the future. The rules ensure that registered primary caregivers may purchase medicinal marijuana from ATCs for those patients who have difficulty traveling. Accordingly, the Department removed the option of home delivery by ATCs from N.J.A.C. 8:64-12 in the notice of reproposal dated February 22, 2011.

9. COMMENT: Several commenters stated that additional continuing medical education for doctors in subject areas relevant to the treatment of patients with medicinal marijuana is not necessary because physicians who possess an active controlled dangerous substances registration issued by the Division of Consumer Affairs regularly prescribe deadly and addictive drugs and medicinal marijuana is not deadly in any known dose and possesses only a mild risk of addiction, similar to caffeine. (6, 12, 25, and 36)

RESPONSE: Specific proposals for continuing medical education for doctors in subject areas relevant to the treatment of patients with medicinal marijuana are under consideration by the BME but have not been formally proposed. The Department will consult with the BME and aid

in identifying specific subjects or particular courses as the BME continues to study this issue further.

10. COMMENT: A number of commenters stated that the fees to obtain registry identification cards for both qualifying patients and their primary caregivers are excessive. Generally, the commenters point out that the \$200.00 fee proposed by the Department at N.J.A.C. 8:64-2.1(c) is the highest in the nation and constitutes an undue burden on very sick patients who are unable to work and have high medical expenses. (1, 2, 4, 9, 12, 15, 21, 22, 25, 26, 32, and 38)

RESPONSE: The Department disagrees with the commenters. Arizona, for example, charges \$150.00 for a patient registry card that must be renewed annually. Colorado charges \$90.00 for a patient registry card that must be renewed each year. Michigan charges \$100.00 for a patient registry card that must be renewed each year. The Department charges \$200.00 for a patient registry card that is valid for a two-year period, making the annual cost \$100.00 per year. This is generally in accord with the fee schedule of the aforementioned states. In addition, N.J.S.A. 24:6I-11b provides that all fees collected shall be used to offset the cost of the MMP. In order to reduce the cost of registry identification cards for individuals with a limited income, the Department adopts N.J.A.C. 8:64-2.1(c)1, which provides that the fee for a registry identification card for an individual receiving Medicaid benefits, food stamp benefits (now known as the Supplemental Nutrition Assistance Program), New Jersey Temporary Disability Insurance benefits, Supplemental Security Income benefits, or Social Security Disability benefits will be \$20.00. Because all registry identification cards will be valid for a period of two years, re-registration is only necessary once every two years.

11. COMMENT: One commenter states that there are many serious medical conditions not on the qualifying conditions list and specifically wants Diabetic Neuropathy added to this list of qualifying conditions. The commenter has diabetic neuropathy for which she is prescribed fentanyl, oxycodone, ultram, and xanax, and does not understand how she can be advised to take these powerful drugs, yet is prohibited from the opportunity to use medicinal marijuana which is far safer. (3)

RESPONSE: The initial list of debilitating medical conditions that qualify for treatment with medicinal marijuana was set by statute at N.J.S.A. 24:6I-3. After the Department has filed two annual reports on the MMP with the Governor and the State Legislature, the Department will accept petitions to establish additional debilitating medical conditions under N.J.A.C. 8:64-5. The Department will approve new debilitating medical conditions only after sufficient data is collected and analyzed to support any such addition.

12. COMMENT: One commenter states that limiting the THC content of medicinal marijuana guarantees that patients will continue to access the illegal underground market for more potent medicine. The commenter states that the physician registry is an unnecessary bureaucratic addition that is not called for in the statute and will have a chilling effect on physician registration. The commenter states that the patient registration requirements create a bureaucratic "Catch-22" because the application must be complete or it will be rejected, yet it is impossible to complete the application because completion requires the patient to provide the physician's

certification and the address of the ATC the patient intends to use – neither of which is available yet. (4)

RESPONSE: Federally approved studies conducted in the United States use medicinal marijuana that is no more than 10 percent THC, which is grown by the University of Mississippi. The Department refers the commenter to the Response to Comment 1. Since medicinal marijuana with a THC content of no more than 10 percent has a significant clinical effect, patients will have access to effective medicine through the MMP. The physician registry will enable the Department to verify that each registered, qualifying patient has been diagnosed with a debilitating medical condition, that the physician is in good standing, and that the physician has certified that the patient may benefit from using medicinal marijuana. The Department will make every effort to provide an efficient patient and primary caregiver registration process. N.J.A.C. 8:64-2.2(b) requires the Department to notify an applicant in writing, by electronic mail, or by telephone that an application is incomplete and to explain what information will be necessary in order to complete the application. The applicant will have 30 days to complete the application. The Department will only reject those applications that remain incomplete after 30 days.

13. COMMENT: One commenter asks if medicinal marijuana that contains only 10 percent THC will be adequate to meet the needs of patients and states that a review of the literature suggests that, as with other drugs, the efficacy of medicinal marijuana for symptom relief is both dose and frequency related. Most patients are described as using between .5 and one gram in a smoked form at one time. Since the New Jersey statute limits the quantity of marijuana to two ounces per month (about 57 grams), patients will already be restricted to using their supply no more than twice per day; if the strength of the THC is limited as well, symptom relief may not be achieved. Canada provides medicinal marijuana containing 15 percent THC to patients who have registered with Health Canada. (5)

RESPONSE: The Department does not have sufficient data upon which to base a determination concerning the dosages and frequencies of dosages of medicinal marijuana for various debilitating medical conditions that physicians will determine, in consultation with their patients, to be effective. The two ounces per month limitation is set by N.J.S.A. 24:6I-10a, which provides that a physician may only authorize, and an ATC may only dispense, a maximum of two ounces of medicinal marijuana to a patient in a 30-day time period. The Department is not authorized to increase the two ounces per month limitation. Relevant United States research studies use medicinal marijuana that is no more than 10 percent THC, which is grown by the University of Mississippi. Studies have shown that medicinal marijuana from the University of Mississippi has a significant clinical effect. In addition, the Department refers the commenter to the responses to Comments 1 and 5 as they related to the issue of THC concentration.

14. COMMENT: One commenter states that she has fibromyalgia and chronic fatigue and comments that she dislikes the addictive and harmful pills she is prescribed including oxycodone and does not understand how a distinction can be drawn between legally prescribed marijuana and legal narcotics or alcohol. Gambling and alcohol caused increased crime rates, so why don't we make them both illegal if crime is such a big concern of these rules. (8)

RESPONSE: The Department is bound by State and Federal Law and will comply with both to minimize crime in all forms.

15. COMMENT: One commenter, a licensed pharmacist, comments that only licensed New Jersey pharmacists should be allowed to dispense medicinal marijuana. (10)

RESPONSE: Unlike New Jersey, and the other states that have legalized marijuana for medicinal use, the Federal government classifies marijuana as a Schedule I Controlled Dangerous Substance, which represents the Federal government's view that marijuana has no therapeutic value. As such, it is not approved by the U.S. Food and Drug Administration (FDA) and cannot be prescribed as medicine by doctors. Therefore, while the Department refers to the product as medicinal marijuana, technically, because of the supremacy of Federal law over State law in this regard, it is not an FDA-approved medicine and, therefore, cannot be dispensed as such by a pharmacist in New Jersey.

16. COMMENT: The commenter states that she suffers from fibromyalgia, chronic fatigue and Epstein-Barr syndrome and has been prescribed numerous drugs with no relief but has found marijuana has helped her. She feels the legal pills she is prescribed are harmful to her health and addictive, yet marijuana, which is not addictive and is safe is not available to her under the current rules. She doesn't want to be a criminal, but wants to use marijuana to help with her conditions and pain. (11)

RESPONSE: The Department will approve new qualifying conditions only after sufficient data is collected and analyzed to support any such addition. Two years' time provides the Department with the ability to collect the requisite data necessary to determine what new conditions, if any, should be added to the list of qualifying conditions. In addition, two years' time will provide petitioners seeking to establish additional debilitating medical conditions under N.J.A.C. 8:64-5 with additional data to support a bona fide petition for the same.

17. COMMENT: The commenter states that the proposed rules set up a monopoly and place ATCs at an unnecessary risk of Federal prosecution. (12)

RESPONSE: N.J.S.A. 24:6I-7 requires that the Department issue permits to at least six ATCs and provides that the Department "shall seek to ensure the availability of a sufficient number of alternative treatment centers throughout the State, pursuant to need..." The Department believes that the initial selection of six ATCs is a reasonable number of ATCs, inasmuch as the MMP is a new program, and the Department is without sufficient data upon which to formulate an opinion as to whether additional ATCs will be necessary at this time. The Department disagrees that the proposed rules place ATCs at an unnecessary risk of Federal prosecution because most marijuana prosecutions arise from arrests made under state law. N.J.S.A. 24:6I-2b states that according to the U.S. Sentencing Commission and the Federal Bureau of Investigation, 99 out of every 100 marijuana arrests in the United States are made under state law, rather than under Federal law. N.J.S.A. 24:6I-2e provides that the purpose of the Act is to protect from arrest, prosecution, property forfeiture, and criminal and other penalties, patients, physicians, primary caregivers, and those who are authorized to produce marijuana for medical purposes.

18. COMMENT: The commenter states that he is a Crohn's disease sufferer and credits marijuana for helping him cope with his disease for 40 years and strongly supports medicinal marijuana. (13)

RESPONSE: The Department thanks the commenter for his support of the program.

19. COMMENT: The commenter states that the Department has drafted appropriate rules to implement dispensing and advertising standards that will prevent the abuses seen in other states. The commenter supports standards that medicinal marijuana stores should not be able to advertise except in small dignified black and white advertising; that medicinal marijuana should not be visible to kids outside the store, that medicinal marijuana should not be sold in food form and should be dispensed in a plain container with a warning label that it is not approved by the FDA; that doctors who write orders for medicinal marijuana must perform a thorough and well-documented investigation of the patients medical condition; that organized crime should be prevented from running the medicinal marijuana stores; that medicinal marijuana stores should pay very high fees so taxpayers won't have to support the program; that there should be tough controls on medicinal marijuana stores and medicinal marijuana doctors; that there should be tough security and anti-loitering rules at the medicinal marijuana stores; that medicinal marijuana stores should not be near schools; and that doctors should warn patients that marijuana is not FDA approved. (14)

RESPONSE: The Department has included a number of safeguards in the rules in Subchapter 12 to restrict exterior signage of ATCs to black text on a white background and to prevent medicinal marijuana from being visible from outside of the building. N.J.A.C. 8:64-10.8(e) will limit the distribution of medicinal marijuana to three forms: dried, oral lozenges, and topical formulations. N.J.A.C. 8:64-2.5 will require physicians to have an ongoing bona-fide physician-patient relationship, which will help prevent abuse of the MMP. The Department will not approve of any ATC locations that are within 1,000 feet of a school. The Department wishes to assure the commenter that it will make every effort to thoroughly vet ATC applicants and to enforce security measures so that the public will have confidence in the program.

20. COMMENT: The commenter states that the rules should permit primary caregivers to assist more than one registered qualifying patient. In addition, the Department should estimate the number of doctors that will register under the MMP and estimate the number of jobs that will be created by the MMP. (15)

RESPONSE: The Department is constrained by N.J.S.A. 24:6I-3, which defines a primary caregiver as a person who is only serving one registered qualifying patient. As indicated in the original notice of proposal dated November 15, 2010, the Department is without data sufficient to support an accurate estimate of the number of doctors that will register under the MMP and to estimate the number of jobs that will be created by the MMP as this will depend on patient demand for medicinal marijuana.

21. COMMENT: Two commenters state that N.J.A.C. 8:64-13.1(d) (codified as N.J.A.C. 8:64-12.1(d) in the February 22, 2011 notice of reproposal), which will prohibit ATCs from advertising prices of medicinal marijuana except to registered qualifying patients and primary

caregivers inside the ATC itself, violates the First Amendment to the United States Constitution. The commenters state that the rule serves to deny legal consumers of products from being provided with truthful, non-misleading information about those products, which is necessary for them to make informed decisions about those products, and that the State has no justifiable interest, that can override the First Amendment, in precluding or severely limiting the dissemination of non-misleading pricing information to legal consumers. (16 and 33)

RESPONSE: The Department respectfully disagrees with the commenters. The provision in question is a reasonable restriction upon advertising by alternative treatment centers that is intended to ensure that only those who are legally entitled to use medicinal marijuana receive pricing information. The requirement is necessary to protect the State's substantial interest in ensuring that only those individuals who may legally purchase medicinal marijuana receive pricing information, thereby discouraging attempts by black market vendors to undercut lawful sales by alternative treatment centers. Unlike other forms of advertising, including advertising regarding alcohol and tobacco, it is significant that the use of marijuana remains illegal for most of the residents of the State. Since the use of marijuana is prohibited for most of the population, the need for its efficient allocation and distribution through commercial advertising is less compelling. Therefore, the advertising of medicinal marijuana must necessarily be limited and narrowly tailored to reach the small population of qualifying registered patients. Not only does the State have an interest in limiting advertising to legal users, the State has a substantial interest in discouraging commercial advertising of marijuana to the general public that would unavoidably encourage or trivialize the sale and use of an illegal drug. The rule directly advances the aforementioned substantial government interests and is not more extensive than necessary to serve those interests. The rule would not prevent alternative treatment centers from providing registered users with pricing information at the facility or when the qualifying registered patient otherwise contacts the facility, such as by phone. Although not defined in the proposed rules, the common meaning of the term, "advertise" is to make public announcement of, to make generally known or to call the attention of the public to a product or business. Therefore, the proposed rule is intended to prohibit ATCs from advertising prices to the public, but it is not intended to prohibit ATCs from providing pricing information to any qualifying registered patient or any registered primary caregiver. In addition, the advertising restriction is consistent with the Department's longstanding public health policies against tobacco use and the advertising and sale of tobacco products to minors. Therefore, the Department makes no change on adoption.

22. COMMENT: A few commenters state ingesting medicinal marijuana is much healthier for patients than smoking. The rules should permit ATCs to produce and sell additional forms of edible medicinal marijuana because the effect of edibles can be more beneficial for pain and last longer. The commenters generally state that the art of producing edibles includes such marketable items as blueberry biscotti, truffles, chocolates, salad dressings, oils, and cannabis butter that can be used to make a variety of products. (17, 19, 22, and 23)

RESPONSE: The Department agrees that ingesting medicinal marijuana is healthier for patients than smoking. For this reason, the rules at N.J.A.C. 8:64-10.8(e) allow for the dispensing of lozenges and a topical formulation for those that do not want to utilize the dried form for smoking purposes. The Department disagrees that ATCs should be permitted to manufacture all forms of edibles; however, because such manufacture will make it more difficult for ATCs and

registered qualifying patients to follow physician's dosage instructions and to comply with N.J.S.A. 24:6I-10a, which limits the amount of medicinal marijuana that an ATC can dispense to a patient to two ounces in a 30-day period. The rules do not prohibit a registered qualifying patient or a primary caregiver from manufacturing edibles at home.

23. COMMENT: The commenter is concerned that, in the confines of a multi-unit dwelling, the smoke or vapor from a registered qualifying patient's use of medicinal marijuana may escape into the atmosphere and be detected by others. The commenter requests that the Department adopt a rule that would operate to revoke the registration card of a patient in such circumstances. The commenter requests a rule that would require as a condition of registration that a patient be put on notice that their patient registration card would be revoked if the patient smoked anywhere in the presence of a minor, in the home during home healthcare visits, in the presence of anyone in the home who requires a smoke-free home environment, or outdoors within 25 feet of entrances/exits to public places. The commenter requests that the Department add a definition for the term, "smoking," that mirrors the definition for the same in the Smoke Free Air Act. The commenter requests that N.J.A.C. 8:64-2.5(a)8 and 9 be amended to specifically state that physicians may only authorize the use of non-smoked forms of medicinal marijuana. The commenter requests that N.J.A.C. 8:64-5.3 be amended to "address the concerns of smoking secondhand smoke exposure to any smoked product, as an additional debilitating medical condition." The commenter requests that N.J.A.C. 8:64-9.6(a) be amended to state, "[t]he ATC shall establish, implement and adhere to a written 100 percent alcohol, drug-free and tobacco (smoke)-free workplace policy." The commenter requests that N.J.A.C. 8:64-11.1(a)4 be amended to require physicians and ATCs to provide smoking cessation materials and resources to patients. The commenter requests that N.J.A.C. 8:64-13.1(a) (codified as N.J.A.C. 8:64-12.1(a) in the February 22, 2011 notice of reproposal) be amended to further restrict advertising by banning electronic communications; in addition, the rule should specify font size and type for signage. (18)

RESPONSE: N.J.S.A. 24:6I-8b contains a number of restrictions on smoking medicinal marijuana, including prohibitions against smoking the same in a school bus or other form of public transportation, in a private vehicle unless the vehicle is not in operation, on any school grounds, in any correctional facility, at any public park or beach, at any recreation center, or in any place where smoking is prohibited pursuant to N.J.S.A. 2C:33-13. The Department notes that smoking medicinal marijuana falls within the definition of "smoking" as set forth in the Smoke Free Air Act at N.J.S.A. 26:3D-57 and is, therefore, subject to the provisions of the Smoke Free Air Act. Since all of these prohibitions provide adequate protections for non-smokers, the Department declines to adopt the additional prohibitions suggested by the commenter. The Department declines to change N.J.A.C. 8:64-2.5(a)8 and 9 upon adoption as suggested by the commenter as such would be inconsistent with the definitions of "marijuana" and "usable marijuana" as set forth at N.J.S.A. 24:6I-3. The Department is not vested with the authority to add secondhand smoke exposure to the list of debilitating medical conditions and does not possess sufficient information upon which to conclude that secondhand smoke exposure is itself a diagnosis that may reasonably fall within the definition of debilitating medical condition as set forth in the Act. The commenter may file a petition to add secondhand smoke exposure as a debilitating medical condition under N.J.A.C. 8:64-5.3. The Department declines to change N.J.A.C. 8:64-9.6(a) upon adoption by adding the phrase "100 percent" because the language of

the rule, which requires an ATC to have an alcohol, drug-free, and smoke-free workplace policy, is sufficiently clear to render the phrase “100 percent” superfluous. The Department declines to change N.J.A.C. 8:64-11.1(a)4 upon adoption to require physicians and ATCs to provide smoking cessation materials and resources to patients because smoking is a recognized method of using medicinal marijuana and N.J.A.C. 8:64-11.1(a)5, which requires ATCs to provide information to patients concerning alternate methods and forms of consumption or inhalation by which one can use medicinal marijuana, addresses the concerns raised by the commenter. The Department declines to change N.J.A.C. 8:64-12.1(a) to further restrict advertising by banning electronic communications because additional restrictions beyond those already in the rule may be inconsistent with First Amendment guarantees of free speech under the United States Constitution. The Department refers the commenter to the responses to Comments 21 and 56. The Department declines to change N.J.A.C. 8:64-12.1(a) to specify font size and type upon adoption because such specifications are within the ambit of local zoning ordinances.

24. COMMENT: The commenter states that patients should be allowed to grow their own marijuana at home. The proposed rules do not keep marijuana off of our streets and out of our children’s hands. Since the Legislature passed the Act, marijuana cannot legally remain a Schedule I drug as this classification is unconstitutional. (19)

RESPONSE: N.J.S.A. 24:6I-1 et seq. does not authorize patients to engage in home cultivation. Accordingly, the Department is without authority to permit home cultivation. The rules at N.J.A.C. 8:64 pertain only to the legal cultivation and dispensing of marijuana for medicinal purposes. The rules are designed to establish a safe, clean Medicinal Marijuana Program that is an alternative to the black market for registered, qualifying patients. Marijuana is classified as a Schedule I drug by the Federal government. Changing this classification would require a change in existing Federal law. State laws, such as N.J.S.A. 24:6I-1, are subordinate to Federal laws under the Supremacy Clause of the United States Constitution.

25. COMMENT: The commenter states that his physician recommended that he use medicinal marijuana last year, but the physician does not want to be part of any State registry as he is already registered with the State and the Federal Drug Enforcement Agency. The commenter states that he has been driven to the black market for relief and asks what the point is in having a MMP if the government makes it too difficult for patients to have access to medicinal marijuana. (20)

RESPONSE: Consistent with the requirements of a medical model, N.J.A.C. 8:64-2.4 requires physicians to register with the MMP. As with the majority of professional decisions, a physician is free to choose whether to register with the MMP. To date, more than 100 physicians have chosen to register with the MMP, providing most registered qualifying patients a number of doctors with whom they may consult concerning medicinal marijuana and who may be recommended by a treating physician within the ambit of a bona fide physician-patient relationship as defined at N.J.A.C. 8:64-1.2.

26. COMMENT: The commenter makes a number of comments concerning the rule, generally stating that the rules are contrary to the legislative intent expressed in the Act from beginning to end. The bona fide doctor/patient relationship defined at N.J.A.C. 8:64-1.2 should not be defined

by treatment for a specific length of time, but rather on a reliance of the integrity of licensed physicians to determine whether they have a bona fide doctor/patient relationship. N.J.A.C. 8:64-2.2 mandates that for a patient to register, the treating physician must register and obtain a certification number, in violation of the definition of “qualified patient” in the Act. N.J.A.C. 8:64-2.5(a)6 requires the physician to disclose the patient’s diagnosis, which violates patient confidentiality, and is not called for in the Act. N.J.A.C. 8:64-2.5(a)9, which requires physicians to inform patients that there exists a lack of scientific consensus for the use of medicinal marijuana, is in direct conflict with the Act, which states that modern medical research has discovered beneficial uses for marijuana. The commenter states there has never been a single fatality from the use of marijuana and that it is impossible to overdose on it. The commenter states that N.J.A.C. 8:64-2.2(f)1, which states that the custodial parent of a registered qualifying patient who is a minor shall be issued a primary caregiver registration card by the Department for no additional fee, is inconsistent with N.J.A.C. 8:64-2.3, which would appear to require the custodial parent of a registered qualifying patient who is a minor to submit to a background check, pay for the same, and also to pay a \$200.00 fee for a registry identification card. The commenter states that N.J.A.C. 8:64-3.4(c), which requires registry cards to be surrendered to the Department when any information on the card changes or a new ATC is designated, will operate to deprive patients of medicinal marijuana between the time that the original registry certification card is surrendered and a new card is issued. N.J.A.C. 8:64-4.1(a) is inconsistent with the Act because the rule requires the qualifying patient, primary caregiver, parent, guardian, or other custodian of a qualifying patient who is a minor, to notify the Department of any change in the qualifying patient’s name, address, ATC, or physician within 10 days of the change, whereas the Act only places such notification requirements on qualifying patients. N.J.A.C. 8:64-4.3(a)2, which requires ATCs to report each patient’s diagnosis to the Department, encourages a violation of the Act, which provides that the patient’s application or receipt of a registry card does not constitute a waiver of the qualifying patient’s patient-physician privilege. The commenter states that N.J.A.C. 8:64-4.3(a)6 (codified as N.J.A.C. 8:64-4.3(a)5 in the February 22, 2011 notice of reproposal), which requires ATCs to provide a summary of patient surveys and evaluation of services to the Department, is an improper delegation to the ATCs of the Department’s responsibility to collect this information under the Act because the definition of ATC in the Act does not contain such obligations. N.J.A.C. 8:64-6.1(d), which states that the Department shall only accept and process ATC applications after making a formal request for applications (RFA), is in violation of the Act, which states that the Department “shall accept” ATC applications without such a constraint. N.J.A.C. 8:64-6.2 provides for a selection committee to review ATC applications, but the rule fails to include information as to the committee’s members or qualifications. N.J.A.C. 8:64-6.4 does not provide for a time frame within which the Department shall review and issue a decision on an ATC application. N.J.A.C. 8:64-7.1(b)2ii, which requires an ATC applicant to disclose the names, addresses, and other information concerning its employees, presumably before the ATC gets approval to operate, is not appropriate because it is inconsistent with how businesses operate. N.J.A.C. 8:64-9.3(a)9, which requires an ATC to disclose how it determines the prices it charges for medicinal marijuana, is of no legitimate concern to the Department. The requirements at N.J.A.C. 8:64-7.1(b) are unnecessary roadblocks to approval and are vague. N.J.A.C. 8:64-7.9(a)5 is not clear because it states an ATC-dispensary satellite location may not be within 1,000 feet of a school, yet the rules do not specify whether this restriction also applies to ATC-dispensaries themselves. The on-site prohibitions on food sales and consumption at N.J.A.C. 8:64-9.2, the on-site parking requirement at N.J.A.C. 8:64-

9.7(b), and the signage requirements at N.J.A.C. 8:64-13.1(c) (codified as N.J.A.C. 8:64-12.1(c) in the February 22, 2011 notice of reproposal) violate local land use laws, which are the province of local, not State, governments. The security requirements at N.J.A.C. 8:64-9.7(b) are overly burdensome and costly for the ATCs. N.J.A.C. 8:64-10.6(d)1 requires a statement on the medicinal marijuana package that states that the product is not intended to diagnose, treat, cure, or prevent any disease, which is inconsistent with the Act, which states that modern medical research has discovered beneficial uses for marijuana in treating or alleviating pain or other symptoms associated with certain debilitating medical conditions. N.J.A.C. 8:64-10.8(e) would allow oral lozenges to be dispensed by ATCs; however, oral lozenges are not used as a delivery method for medicinal marijuana according to most experienced people in the field. N.J.A.C. 8:64-10.11(e) provides that medicinal marijuana shall be transported in conformance with State and Federal laws, but since it is an illegal substance under Federal law, one is left to guess which Federal law applies. N.J.A.C. 8:64-11.1 requires the ATCs to provide educational materials to patients and primary caregivers, but this function should more properly be performed by the Department. N.J.A.C. 8:64-11.2(c), which requires ATCs to ask patients and primary caregivers for permission to contact them with information about peer review clinical studies concerning the use of medicinal marijuana, is a function that should be more properly performed by the Department. N.J.A.C. 8:64-11.3(b), which requires an ATC to maintain a copy of the registered qualifying patient's (and, if applicable, primary caregiver's) patient identification card and other form of government issued photo identification card, is violative of the Act, which only requires a patient to submit his or her patient identification card and physician's recommendation to the ATC in order to obtain medicinal marijuana. N.J.A.C. 8:64-11.4, which requires ATCs to document patient self-assessment of pain, is not the proper function of the ATC, but rather, the Department. N.J.A.C. 8:64-11.5(a), which requires an ATC to stop dispensing medicinal marijuana to an individual that the ATC believes is abusing the substance or redistributing it, treats marijuana as illegal and patients as criminals. N.J.A.C. 8:64-13.1(f) (codified as N.J.A.C. 8:64-12.1(f) in the February 22, 2011 notice of reproposal), which prohibits an ATC from selling t-shirts or other promotional items displaying a reference to marijuana, is unconstitutional because the sale of medicinal marijuana by an ATC is a legitimate business. N.J.A.C. 8:64-14.4(c) does not provide for testing of medicinal marijuana's THC content. The commenter points out that the rules contain two sections on enforcement and penalties (N.J.A.C. 8:64-14.6 and 14.7) (codified as N.J.A.C. 8:64-13.6 and 13.7, respectively, in the February 22, 2011 notice of reproposal) and only one section (N.J.A.C. 8:64-14.11) (codified as N.J.A.C. 8:64-13.11 in the February 22, 2011 notice of reproposal) referencing the protections from prosecution that patients are guaranteed under the Act, stating that generally, the rules are misguided. (21)

RESPONSE: The definition of "bona fide physician-patient relationship" relies on the integrity of licensed physicians in that it allows for such a relationship to exist when a physician assumes responsibility for the management and care of a patient's debilitating medical condition after conducting a comprehensive medical history and physical examination, including a personal review of the patient's medical history. The Department disagrees that the definition of "qualifying patient" in the Act precludes a physician registry. The Department is required to verify that a qualifying patient has a certification signed by a physician, which certification establishes that a patient has a debilitating medical condition under N.J.S.A. 24:6I-3. Accordingly, N.J.A.C. 8:64-2.5(a)6 requires a physician to provide the Department with the qualifying patient's diagnosis. The Department will not disclose patient identifiable health

information to third parties and will maintain this information in a confidential manner. The Department disagrees that N.J.A.C. 8:64-2.5(a)9, which requires physicians to inform patients that there exists a lack of scientific consensus for the use of medicinal marijuana, is inconsistent with the legislative findings and declarations stated at N.J.S.A. 24:6I-2a, that modern medical research has discovered a beneficial use for marijuana. Medicinal marijuana provides benefits in treating or alleviating pain or other symptoms associated with certain debilitating medical conditions; however, there exists a lack of scientific consensus concerning, but not limited to, the following areas: dosages, frequency of dosages, delivery routes and methods, the most suitable strains for the treatment of specific conditions, and which cannabinoid compounds affect which areas of the body. The Department is without sufficient information upon which to form an opinion concerning the commenter's statement that there has never been a single fatality from the use of marijuana and that it is impossible to overdose on it. The Department does not intend to require the parents of registered qualifying patients who are minors to submit to background checks or to pay a fee for a primary caregiver registration card as provided at N.J.A.C. 8:64-2.2(f)1. The Department does not intend to apply N.J.A.C. 8:64-3.4(c) in a manner that will cause a registered qualifying patient to be deprived of medicinal marijuana while the patient awaits the Department's issuance of a new registry identification card. N.J.A.C. 8:64-4.1(a) is consistent with the Act because the Act intends for the patient to notify the Department when certain material information changes and in some cases, where the patient is a minor or very ill, it is appropriate for the parent, guardian, or primary caregiver, who stands in the place of the patient, to provide such notification to the Department. The Department disagrees that N.J.A.C. 8:64-4.3(a)2 encourages a violation of patient confidentiality because the rule does not contain a requirement that the patient's identity be linked to a record of the patient's debilitating medical condition. The ATC reporting requirement at N.J.A.C. 8:64-4.3(a)6 is a means of collecting summaries of patient surveys by the Department, not a delegation of this responsibility to the ATCs. The Department disagrees that N.J.A.C. 8:64-6.1(d) is violative of the Act. The RFA process is a permitted exercise of the broad discretion granted to State agencies in determining how to fulfill their statutory obligations. The Department declines to specify selection committee members and qualifications at N.J.A.C. 8:64-6.2 upon adoption because this is not a requirement of the Act. In the event that the Department issues an RFA, the Commissioner will exercise discretion to appoint committee members who possess knowledge and expertise applicable to the committee's role in evaluating and scoring each application. The Department declines to adopt a time for reviewing ATC applications at N.J.A.C. 8:64-6.4 because the timeframe of 60 days is set by statute at N.J.S.A. 24:6I-7e. The Department disagrees with the statement that N.J.A.C. 8:64-7.1(b)2ii is not an appropriate rule because it is inconsistent with how businesses operate. Businesses in the health care field, such as air medical services, are generally required to provide the names, addresses, and professional training and qualifications of their employees on their applications for licensure. The Department will look at this issue as it gathers more data and experience in the MMP. The Department disagrees that N.J.A.C. 8:64-9.3(a)9, which requires an ATC to disclose how it determines the prices it charges for medicinal marijuana, is of no legitimate concern of the Department. N.J.S.A. 24:6I-12c requires the Department to report to the Governor and the Legislature whether any ATC has charged excessive prices for medicinal marijuana that the ATC has dispensed. The Department disagrees that N.J.A.C. 8:64-7.1(b), which requires an ATC applicant to disclose the legal name of the corporation, a copy of the corporate by-laws, the names and addresses of the ATC's owners, as well as other information, creates unnecessary and vague roadblocks to approval. The comment concerning N.J.A.C. 8:64-

7.9(a)5 is moot as the notice of reproposal dated February 22, 2011 does not provide for ATC satellite locations. The Department disagrees that the prohibitions on food sales and consumption at N.J.A.C. 8:64-9.2, the on-site parking requirement at N.J.A.C. 8:64-9.7(b), and the signage requirements at N.J.A.C. 8:64-13.1(c) (codified as N.J.A.C. 8:64-12.1(c) in the February 22, 2011 notice of reproposal) violate local land use laws, which are the sole province of local governments. It is well established that both the Department and local boards of health have joint authority to regulate in these areas for the benefit of public health and safety. The Department disagrees that the security requirements at N.J.A.C. 8:64-9.7(b) are overly burdensome to ATCs. The requirement that an ATC have a good alarm and security system is necessary to prevent diversion and cultivate public confidence in the MMP. The statement required by N.J.A.C. 8:64-10.6(d)1 is not inconsistent with the Act because the Act does not state that medicinal marijuana is intended to diagnose, treat, cure, or prevent specific diseases. The rule at N.J.A.C. 8:64-10.8(e) is intended by the Department to permit an ATC to offer an edible form of medicinal marijuana to registering qualifying patients. The rule at N.J.A.C. 8:64-10.11 is intended by the Department to ensure that medicinal marijuana is transported in compliance with all State and Federal laws, including motor vehicle laws. The specific requirement that an ATC – cultivation transport marijuana in conformance with State and Federal law contained in N.J.A.C. 8:64-10.11(e) of the November 15, 2010 original notice of proposal was not contained in the February 22, 2011 notice of reproposal; therefore, this specific issue is moot. The rules at N.J.A.C. 8:64-11.1 and 11.2(c) are intended by the Department to ensure that ATCs, which have more physical contact with patients than Department employees, disseminate educational materials and make an effort to share information about peer review clinical studies to registered qualifying patients. N.J.A.C. 8:64-11.3(b), which requires an ATC to keep a copy of a registered qualifying patient's photo identification card on file, is not violative of the Act. The rule is a valid exercise of the Department's rulemaking authority under N.J.S.A. 24:6I-16 and necessary to verify the identity of a registered qualifying patient and, if applicable, a primary caregiver upon their first visit to the ATC. The Department intends N.J.A.C. 8:64-11.4 to provide information to the Department for use in determining the effectiveness of the MMP. N.J.A.C. 8:64-11.5(a) is intended to confer authority upon the ATC to stop dispensing medicinal marijuana to an individual that the ATC believes is using the medicine for an illegal purpose, not to treat the medicinal use of marijuana as illegal or to characterize patients as criminals. N.J.A.C. 8:64-12.1(f) is a limited restriction on the use of symbols or references to marijuana on t-shirts or novelty or promotional items that is constitutionally permitted. It is not a complete ban on the sale of t-shirts or promotional items, and it does not by its terms apply to paraphernalia, such as a vaporizer, which may understandably contain symbols or references to marijuana in an instructive label or pamphlet. The Department acknowledges that N.J.A.C. 8:64-13.4(c) does not specifically provide for testing of THC content. The rule does, however, provide that testing may include other things in addition to the listed items such as mold, heavy metals, pesticides, etc. Accordingly, the Department reserves the right to test for THC content. The Department intends N.J.A.C. 8:64-13.6 and 13.7 to work together to provide a mechanism for the Department to enforce the provisions of the Act and the administrative rules. The Department intends N.J.A.C. 8:64-13.11 to reference the protections that patients are guaranteed under the Act and reserves the right to consider additional protections in future rulemaking.

27. COMMENT: The bona fide physician-patient relationship defined at N.J.A.C. 8:64-1.2 is inconsistent with the Act, which does not require that a physician treat a patient for a specific

period of time in order for the bona fide physician-patient relationship to be created. The commenter is concerned that this provision could result in an unnecessary delay for a patient to obtain a physician's certification to use medicinal marijuana. The word "certify" should be removed from the rules because Federal officials have the right to prosecute physicians for violations of Federal law, such as certifying or authorizing patients to use medicinal marijuana, and states should, therefore, avoid these words in order to protect physicians from Federal prosecution. N.J.A.C. 8:64-2.5(a)9, which requires physicians to inform patients that there exists a lack of scientific consensus for the use of medicinal marijuana, is more of a political statement than a medical statement and should be removed from the rules because it is an obtrusive interference with the physician-patient relationship. N.J.A.C. 8:64-3.4, which requires primary caregivers to execute a certification stating that they will comply with various conditions, including only purchasing medicinal marijuana from the designated ATC on his or her registry identification card, is not required by the Act and is unnecessarily and excessively intrusive. The requirement of approval of the local governing body where the ATC will be located is overly onerous and creates an unnecessary financial risk for ATCs. The restriction on consumption of food and beverages at ATCs is unique among medicinal marijuana states and is not justifiable. The complete ban on persons under the age of 18 in ATCs will present a hardship for patients and caregivers who need to pick up their medication but are unable to obtain child care. No such restriction applies to New Jersey pharmacies. The security requirements at N.J.A.C. 8:64-9, particularly the requirements to provide neighbors within 100 feet of the ATC with a phone number where they can reach an ATC employee after hours, the drug free school zone 1,000 foot location restriction, and the video monitoring requirements, are excessive. (22)

RESPONSE: N.J.S.A. 24:6I-3 defines "physician," in relevant part, as a person responsible for the ongoing treatment of a patient's debilitating medical condition, "provided, however, that such ongoing treatment shall not be limited to the provision of authorization for a patient to use medical marijuana or consultation solely for that purpose." The intent of the law is to prevent patients from simply consulting with a physician for the sole purpose of obtaining a patient registry identification card from the Department to use medicinal marijuana with no ongoing care or treatment from that physician. The definition of bona fide physician-patient relationship defined at N.J.A.C. 8:64-1.2 furthers the legislative intent through rulemaking, specifically by establishing what is meant by "ongoing" responsibility for the patient's care. The Department notes that the Board of Medical Examiners (BME), which is the agency responsible for regulating physicians, proposed similar language to define "ongoing responsibility" at N.J.A.C. 13:35-7A.2. Accordingly, in the notice of reproposal dated February 22, 2011, the Department incorporates the BME rule by reference. The word "certification" is a defined term at N.J.S.A. 24:6I-3. The Department is bound by the language in the statute, which requires physicians to "certify" that they have a bona fide physician-patient relationship with a qualifying patient and on which certification the physician authorizes the patient to apply for registration to the MMP. The Department disagrees that N.J.A.C. 8:64-2.5(a)9 is in conflict with the Act because a lack of scientific consensus exists concerning such matters as which strains, dosages, and frequencies of dosages are the most effective for treating certain debilitating medical conditions. The Department intends N.J.A.C. 8:64-3.4 to be a valid exercise of rulemaking authority under N.J.S.A. 24:6I-16 that is consistent with the Act and that explains to primary caregivers, through reading and agreeing to the certification, that they are responsible to only purchase medicinal marijuana from an ATC, that they may not grow marijuana for their patient, that they are

required to notify the Department if their patient wants to designate a new ATC, etc. The Department does not agree that requiring approval for the location of ATCs from local governments is overly restrictive. As a practical matter, ATCs and other businesses must generally locate in areas that local governments have zoned for their business activity. The restriction on the consumption of food and beverages at ATCs found at N.J.A.C. 8:64-9.2(b) is intended by the Department to foster a businesslike atmosphere at the ATC that is focused on providing the patient with medication. The general ban on persons under the age of 18 in ATCs at N.J.A.C. 8:64-9.2(d) does not apply to registered qualifying patients who are minors, as long as the minor is accompanied by his or her primary caregiver and is intended to limit the exposure of minors who are not registered qualifying patients to medicinal marijuana and paraphernalia. The Department believes that all of the security requirements are necessary in order to ensure a safe, adequate supply of medicinal marijuana to patients, to prevent diversion, and to instill public confidence in the integrity of the MMP.

28. COMMENT: The commenter states that he is a board-certified neurologist with over 25 years' experience in neurology and clinical pharmacology, has performed and published clinical research on THC, and is accepted as an expert on medical cannabis by courts in the USA, Canada, and the UK. There are serious problems with the regulations. In medical research, one uses proven clinical trial methodology and exposes the results to scientific review. The proposed regulations ignore the past 30 years of cannabis research and return New Jersey to the 1970s' model set by the Drug Enforcement Agency and the production of low quality marijuana at the University of Mississippi. Marijuana is recognized as safe and effective in patients who have not obtained symptom relief with conventional therapy in conditions such as neuropathic pain and spasticity. The regulations represent a missed opportunity for New Jersey to add to the medical development of cannabis. Additionally, seriously ill patients with cancer, MS, or ALS have very limited mobility. The logistics of access to medical marijuana as described in the regulations present an additional burden to caregivers. New Jersey has at least 1,800 pharmacies providing medication including Schedule II potent opiate drugs. The distribution of medicinal cannabis to seriously ill patients should minimize the bureaucratic excess demonstrated by the draft regulations. (24)

RESPONSE: The Department thanks the commenter for the comments concerning medical research. Although the Department relies upon the validity of the studies using marijuana grown by the University of Mississippi, the Department will collect data and continue its review of studies for use in future rulemaking. The rules ensure that registered primary caregivers may purchase medicinal marijuana from ATCs for those patients who have difficulty traveling.

29. COMMENT: The commenter states that he believes marijuana can be used as a treatment for some medical conditions. The commenter states that the rules should be focused and limited. The commenter does not think that anyone should be allowed to grow their own marijuana. The commenter does not want the general population to "go into a state of euphoria." Generally, the commenter does not want the MMP to be abused and turn into something destructive to society. (27)

RESPONSE: The Department thanks the commenter for his support of the Act and the rules.

30. COMMENT: The commenter states that she suffers from fibromyalgia and gastro paresis, among other medical conditions. The commenter states that medicinal marijuana works in conjunction with her other medications to stimulate her appetite, reduce her nausea, muscle spasms, and body pain and allows her to feel normal. The commenter states that medicinal marijuana allows her to spend more quality time with her family. (28)

RESPONSE: The Department thanks the commenter for her statement in support of medicinal marijuana.

31. COMMENT: The commenter supports the rules on the grounds that the MMP should be limited to patients with bona fide physician-patient relationships who have been certified by those physicians as having a debilitating medical condition enumerated in the Act. (29)

RESPONSE: The Department thanks the commenter for its support of the rules.

32. COMMENT: Two commenters state that implementation of the Act has taken too long and states that the Act should be implemented without further delay. (30, 37)

RESPONSE: The Department is working to implement the Act through rulemaking as soon as possible. In addition, the Department is working closely with the ATCs to ensure that medicinal marijuana is available to registered qualifying patients as soon as practicable.

33. COMMENT: The program is overly restrictive and should have third-party oversight in the form of laboratory quality control of cannabinoid content. (31)

RESPONSE: The Department's intent with regard to the rules is to ensure that the Act is implemented in a manner that provides access to medicinal marijuana by registered qualifying patients but also contains appropriate safeguards to prevent abuse and diversion, thus fostering public confidence in the integrity of the MMP. The Department's intent regarding N.J.A.C. 8:64-13.4(c) is to provide for testing of medicinal marijuana. The Department acknowledges that N.J.A.C. 8:64-13.4(c) does not specifically provide for testing of THC content. The rule does, however, provide that testing may include other things in addition to the listed items such as mold, heavy metals, pesticides, etc. Accordingly, the Department reserves the right to test for THC content.

34. COMMENT: The commenter states that N.J.A.C. 8:64-6.2(a), which requires documented involvement of an acute care hospital with an ATC, is unnecessary because medicinal marijuana is far more likely to be used in a home than in a hospital, and the administration of an ATC bears no relevance to that of a hospital. N.J.A.C. 8:64-11.4(b), which requires ATCs to assess a patient's pain, is not the business of a dispensary and should be left to medical professionals. (32)

RESPONSE: The Department's intent with regard to N.J.A.C. 8:64-6.2(a) is to accommodate a number of hospitals that have demonstrated a desire to share their expertise with ATCs in matters that are relevant to the functioning of ATCs. The Department does not intend N.J.A.C. 8:64-11.4(b) to direct the ATCs to assess the patient's pain, the rule is intended to require the

ATC to collect documentation of the patient's self-assessment of pain and to transmit that data to the Department for review and analysis.

35. COMMENT: The commenter states that the Department's rules are based on outright falsehoods and generally lack compassion; treat doctors, patients, and ATCs as criminals; and fail to carry out the spirit of the Act. The comment states that what is needed most is a change in attitude by the Department and the administration to recognize that we are not still fighting the abysmal war on drugs of the 1980s and to implement the Act in an honest and compassionate manner. (33)

RESPONSE: The Department intends the rules to strike a balance between the need to provide access to medicinal marijuana for registered qualifying patients and the need to establish adequate safeguards against abuse and diversion that will help foster public confidence in the integrity of the MMP.

36. COMMENT: The commenter states that he has been studying the medicinal use of marijuana since 1995 and has authored over 500 articles and white papers and a book on the subject. Chronic neuropathy should qualify as a debilitating medical condition under the rules. Neuropathic pain is treatable with medicinal marijuana and there is no legitimate reason to exclude this class of patients from relief under the MMP. (34)

RESPONSE: The Department is bound by the Act, which prescribes debilitating medical conditions at N.J.S.A. 24:6I-3. The law provides that the Commissioner may add additional debilitating medical conditions to the list. The Department has codified the process of accepting and processing petitions to add new debilitating medical conditions, which are found at N.J.A.C. 8:64-5.

37. COMMENT: The commenter is an internal medicine physician with an interest in the Act. The commenter states that there are a number of cannabinoids in addition to THC that the Department should consider in its regulatory decisions. One of these predominant cannabinoids is TetraHydroCannabiVarin (THCV), which is said to affect the pharmacokinetics of THC including time of onset and offset. If a strain has a high concentration of CBD and a low potency of THC, such as the strain types that the Department's rules will of necessity require ATCs to grow, that strain will produce in patients a strong, "dream-like head-stone." The point here is that if the State wants to legislate against patients "getting high," merely limiting the THC content will not suffice. The commenter does not favor such limits for medical reasons. Pharmacokinetics teaches us that Dose=Potency x Quantity. Limiting THC content will result in patients using more, not less, marijuana. Since the chemical brew of marijuana smoke contains plant sterols and terpenes, patients may suffer undetermined deleterious effects. The THC restriction, therefore, will expose the patient to a greater concentration of carcinogens, not less. The euphoric effect cannot be separated from the therapeutic effect. Using medical marijuana, even strictly as medicine, will cause the user to get high. To some patients, this is an unacceptable side effect. To others, this effect is euphoric and desirable. This limbic central nervous system effect may at times be desirable medically. The commenter believes that most legitimate medicinal marijuana patients would not use two ounces per month if the THC content was unrestricted. If, however, the THC content is artificially low, a greater proportion of patients will need the full two ounces

per month. Former Commissioner Alaiigh quoted a recent study from McGill University in Canada as influencing her 10 percent THC limit decision. In that study, cannabis of 2.5 percent THC did not work at all, was minimally effective at six percent THC, and clinically, but modestly, effective at 9.4 percent. There was no available strain to test the hypothesis that THC content stronger than 9.4 percent would work even better, but the content is at the very least intuitive. For all of these reasons, there should not be a limit on THC content or the number of strains that can be cultivated. Until the FDA understands the true risk/safety/benefit profile of marijuana and puts science and logic ahead of politics, marijuana will remain a Schedule I substance; therefore, it is appropriate for the Department to institute a physician registry. Instead of requiring that an ATC have an affiliation with a hospital, which may fear loss of Federal funding, it may be more appropriate to require that registered physicians be on staff at a New Jersey acute care hospital. There is no need to have physicians on the ATC advisory board as this will severely limit the functionality of the advisory boards due to the scarcity of physicians willing to serve in an uncompensated manner. (36)

RESPONSE: The Department thanks the commenter for the comments, refers the commenter to the Responses to Comments 1, 12, and 13 in regard to THC content and the Response to Comment 34 regarding the hospital affiliation requirement. The Department thanks the commenter for the comment in favor of a physician registry. The Department has a number of advisory boards upon which physicians serve without compensation, has not been advised by any prospective ATCs that physicians are unwilling to serve on their medical advisory boards, and believes that physicians will be available in sufficient numbers to serve on ATC medical advisory boards. Accordingly, the Department adopts the rule as proposed.

38. COMMENT: The commenter is a patient with muscular dystrophy who states that medicinal marijuana has enabled him to stop taking a variety of prescription medications because it alleviates his painful symptoms. The commenter states that in order to escape criminal prosecution, he moved to California, where he can now access medicinal marijuana without fear of prosecution. Unfortunately, this also places him 3,000 miles from his family. The commenter requests that the Department revise its regulations to more closely follow the Act. (38)

RESPONSE: The Department thanks the commenter for his testimonial supporting the effectiveness of medicinal marijuana. N.J.S.A. 24:6I-2e provides that the purpose of the Act is to protect from arrest, prosecution, property forfeiture, and criminal and other penalties, patients, physicians, primary caregivers, and those who are authorized to produce marijuana for medical purposes. The Department intends the rules for the MMP to implement the provisions of the Act in a responsible fashion.

39. COMMENT: The commenter is the sister of a patient with muscular dystrophy. She states that her brother became dull and lifeless on prescription medications such as opiates. When he started using medicinal marijuana, the results were instantaneous and positive, and he was able to quit all the pills he was taking. To avoid prosecution, he moved to California, but the commenter lives in New Jersey and is unable to help her brother with his activities of daily living. The commenter states that if you had a sick loved one, you would want him to have the highest quality medicine and the right strains for his condition. This is what all patients deserve. (39)

RESPONSE: The Department thanks the commenter for the comments in favor of medicinal marijuana.

Part Two

The Department received comments on the notice of reproposal dated February 22, 2011 via U.S. Mail and/or from the public hearing on March 7, 2011 from the following individuals:

1. New Jersey Prevention Network, Lakewood NJ by Diane Litterer, Executive Director
2. Steven Fenichel, M.D., Ocean City, NJ
3. Jeffrey S. Pollack, M.D., Mays Landing, NJ
4. New Jersey Hospice and Palliative Care Organization, Scotch Plains, NJ by Donald Pendley, M.A., CAE, APR, President
5. New Jersey Association of Mental Health and addiction agencies, Inc. (NJAMHAA) Mercerville, NJ by Debra L. Wentz, Ph.D., CEO
6. Russell W. Minor Sr., Barnegat, NJ
7. Charles Kwiatkowski (address not listed)
8. Lawrence M. Vargo, Jr., Trenton, NJ
9. Risa Sanders, Long Branch, NJ
10. Medical Marijuana Deliver Systems LLC, Seattle, WA by Jim Alekson, Managing Member
11. American Civil Liberties Union of New Jersey, Newark, NJ by Ed Barocas, Legal Director
12. New Jersey State Nurses Association, Trenton, NJ, by Carolyn Torre RN, MA, APN, Director, Regulatory Affairs
13. Drug Free Schools Coalition of New Jersey, Flemington, NJ by David G. Evans, Esq., Executive Director
14. Diane Riportella, Egg Harbor, NJ
15. Edward R. Hannaman, Esq, Ewing, NJ
16. Coalition for Medical Marijuana - New Jersey, Inc., Trenton, NJ by Ken Wolski, RN MPA, Executive Director
17. Justin Escher Alpert, Esq., Livingston, NJ

18. Nora Giuricci, Clark, NJ
19. Coalition for Medical Marijuana - New Jersey, Inc., Trenton, NJ by Ken Wolfenstein, RN
20. David Simms (address not listed)
21. A.J. Ballinger III (address not listed)
22. Don and Gerry McGrath, Robbinsville, NJ
23. Drug Policy Alliance, Trenton, NJ by Roseanne Scotti
24. Scott Hawkins, Kinnelon, NJ
25. Gold Leaf Organization, (address not listed) by Gregory Golden, Jr.
26. Jim Miller, Toms River, NJ
27. Association of Safe Access Providers (ASAP), Montclair, NJ by Marianne Bays, Ph.d
28. Coalition for Medical Marijuana - New Jersey, Inc., Trenton, NJ by Chris Goldstein
29. Jahan Marcu (address not listed)
30. Jack O'Brien, Laurel Lake, NJ
31. Jay Lassitier (address not listed)
32. NARC New Jersey, (address not listed) by Anne M. Davis, Esq.
33. Sandra Faiola (address not listed)
34. Jennifer Landi, Medford, NJ
35. Stephen Krisvillage (address not listed)
36. Flakewood Tucker, Marlton, NJ
37. Marta Portuguese (address not listed)
38. Rafael Portuguese (address not listed)
39. Luis Santiago, Freehold, NJ
40. David Barnes (address not listed)

41. North Jersey Professional Care (address not listed) and Veterans for Medical Cannabis Access (address not listed) by Darryl Milligan

42. Impact New Jersey (address not listed) and Compassionate Care Centers of America Foundation, Inc., (address not listed) by Raj Mukherji

43. Tom Ines (address not listed)

The numbers in parenthesis after each comment below identify the respective commenters listed above.

40. COMMENT: A number of commenters state that N.J.A.C. 8:64-10.6(c)5 and 10.7(c), which limit the percentage of THC in medicinal marijuana to no more than 10 percent, are inappropriate and overly restrictive rules. The commenters generally point out that other states do not limit THC content in their medicinal marijuana and that such provides patients with greater medicinal options for relief from pain and suffering. The commenters generally state that medicinal marijuana with a maximum of 10 percent THC will be less effective than marijuana with a higher THC content and that this will require higher dosages to achieve a palliative effect and may discourage some patients from participating in the Medicinal Marijuana Program because they can obtain higher potency marijuana on the black market. (2, 3, 4, 7, 9, 12, 14, 16, 18, 19, 23, 25, 27, 28, 29, 32, 34, 35, 36, and 37)

RESPONSE: By limiting medicinal marijuana to a maximum of 10 percent THC and mandating the sale of three strains of medicinal marijuana in a low, medium, and high potency, the Department is able to ensure that doctors and their patients have a reliable and standardized choice of potency options from which to choose. Relevant United States research studies, such as the study concluded in 2010 by the Medicinal Cannabis Research Center at the University of California San Diego, used medicinal marijuana that was no more than 10 percent THC, which was grown by the University of Mississippi. The Medicinal Cannabis Research Center study, conducted over a period of 10 years, demonstrated that medicinal marijuana from the University of Mississippi had a significant clinical effect. In October 2011, the Dutch Government announced that it would outlaw the sale of cannabis in coffee shops with a THC content greater than 15 percent, citing that marijuana with a greater THC concentration should be categorized with hard drugs, such as cocaine and heroin. The 10 percent limit on THC content at the inception of the MMP will provide patients with effective medicine to start and allow the Department to collect data from patients and to evaluate whether the 10 percent limit on THC content should be revisited in future rulemaking.

41. COMMENT: A number of commenters state that N.J.A.C. 8:64-10.7(a), which limits the number of strains of medicinal marijuana that an ATC may cultivate to three, is an unreasonable limitation on each patient's choice of medicine. The commenters generally state that patients should be free to try many strains of medicinal marijuana as certain strains relieve conditions such as nausea, other strains relieve conditions such as spasticity, and still other strains relieve pain. (2, 3, 4, 9, 12, 14, 16, 22, 23, 27, and 37)

RESPONSE: By mandating the sale of three strains of medicinal marijuana of a low, medium, and high dose, the Department is able to ensure patients have a reliable and standardized choice of potency options to choose from. Generally, marijuana is classified as a Schedule I drug under the Federal Controlled Dangerous Substances Act of 1970 and has not gone through a Food and Drug Administration testing process for safety or efficacy. The three strain mandate is a reasonable balancing of State action in developing the MMP to limit distribution to only registered qualifying patients, which is authorized under State law but still considered illegal under Federal law. In addition, the three strain mandate will assist law enforcement authorities in identifying medicinal marijuana that originated from a permitted ATC, which will help prevent possible diversion and establish public trust in the program, a process that has proven challenging in other states. Inasmuch as this is a new program, data collected by the Department will help guide ATCs in choosing the best medicinal strains and help the Department determine through future rulemaking whether different or additional strains would prove beneficial to patients.

42. COMMENT: A number of commenters state that N.J.A.C. 8:64-5.1(a), which provides that the Commissioner shall not take action to approve additional debilitating medical conditions until the Department makes at least two annual reports to the Governor and the State Legislature concerning the MMP, is inappropriate and overly restrictive. The commenters generally point out that other states allow medicinal marijuana use for a wider array of debilitating medical conditions and that it is in the best interests of patient care to consider expanding the list of debilitating medical conditions without delay. Some commenters ask that specific conditions, such as nausea or vomiting, be included. (2, 3, 14, 16, 19, 23, 27, 32, and 34)

RESPONSE: The New Jersey Legislature held hearings prior to passage of the Act and made a determination as to the inclusion of specific debilitating medical conditions and, while considering the qualifying medical conditions under the medicinal marijuana laws in other states, defined its list of debilitating medical conditions as provided by N.J.S.A. 24:6I-3 to start the MMP. N.J.A.C. 8:64-4.3 will require ATCs to report patient survey information to the Department. Consistent with this approach, the Department disagrees that new qualifying conditions should be added before two years' time. The Department will approve new qualifying conditions only after sufficient data is collected and analyzed to support any such addition. Two years' time will provide the Department with the ability to collect the requisite data necessary to determine what new conditions, if any, should be added to the list of qualifying conditions. In addition, two years' time will provide petitioners seeking to establish additional debilitating medical conditions under N.J.A.C. 8:64-5 with additional data to support a bona fide petition for the same.

43. COMMENT: A number of commenters state that six ATCs will not be sufficient to meet patient demand or to provide convenient access to patients and primary caregivers. These commenters generally point out that traveling long distances to the closest ATC will be a hardship for those patients who are very ill and/or do not have a primary caregiver. (3, 5, 14, and 16)

RESPONSE: N.J.S.A. 24:6I-7a requires at least two ATCs in the Northern, Central, and Southern regions of the State. The Department will follow the development of the Medicinal

Marijuana Program and seek to ensure the availability of a sufficient number of ATCs. Inasmuch as the MMP is a new program, the Department is without sufficient data upon which to formulate an opinion as to whether additional ATCs will be necessary at this time.

44. COMMENT: Three commenters state that two ounces per month is an insufficient amount of medicinal marijuana because it will only permit a patient to use marijuana once or twice per day. The comments state that since the medicinal marijuana available under the proposed rules will be limited to 10 percent THC content, patients will be forced to consume higher dosages and will, therefore, run out of medicinal marijuana quickly if limited to no more than two ounces per month. (3 and 12)

RESPONSE: The two ounces per month limitation is set by statute at N.J.S.A. 24:6I-10a, which provides that a physician may only authorize, and an ATC may only dispense, a maximum of two ounces of medicinal marijuana to a patient in a 30-day time period. Accordingly, the Department is required to comply with the statute and does not have the authority to exceed the two ounces per 30-day time period limit. The Department does not have sufficient data upon which to base a determination concerning the dosages and frequencies of dosages of medicinal marijuana for various debilitating medical conditions that physicians will determine, in consultation with their patients, to be effective.

45. COMMENT: The commenter testified that the ATC application process, with its RFA requirement and deadline to accept applications, was onerous and designed to discourage applications. (36)

RESPONSE: The Department created the application process in an effort to implement the Act. The RFA process was a valid exercise of administrative authority conferred upon the Department by N.J.S.A. 24:6I-16.

46. COMMENT: A number of commenters object to the requirement at N.J.A.C. 8:64-2.5(a), which incorporates N.J.A.C. 13:35-7A by reference. Proposed N.J.A.C. 13:35-7A.5(c)3 would require physicians to “periodically make reasonable efforts, unless clinically contraindicated, to stop the medical use of marijuana, decrease the quantity authorized or try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.” The commenters generally state that medicinal marijuana patients are frequently terminally ill, and therefore, it makes no sense to attempt to wean these patients off of medicine that alleviates the patient’s suffering. (3)

RESPONSE: The Department’s rule at N.J.A.C. 8:64-2.5(a) incorporates a Board of Medical Examiners rule at N.J.A.C. 13:35-7A by reference. The practice of medicine is regulated by the BME. The BME determined not to adopt the rule as proposed. Accordingly, the rule upon adoption will not require a physician to take steps periodically to stop or reduce the use of medicinal marijuana. The rule will provide, in relevant part at N.J.A.C. 13:35-7A.5(c), “[i]f the physician determines that the patient is achieving treatment objectives, and is not experiencing untoward side effects or physical or psychological problems associated with marijuana use, the physician may continue the patient’s treatment with medical marijuana without alteration.”

47. COMMENT: A number of commenters stated that proposed N.J.A.C. 8:64-12, Home delivery, is too restrictive. Generally, the commenters stated that all patients should be eligible for home delivery automatically because most prospective qualifying patients are very ill and/or do not have a primary caregiver, making travel a hardship. (4, 14, 16, 23, 27, 33, and 34) One commenter stated that a one day wait for home delivery was cruel since it could cause a patient to suffer without his or her medicine. (4)

RESPONSE: A bi-partisan agreement between Governor Chris Christie and Assemblyman Reed Gusciora, one of the primary sponsors of the Act, that was announced on December 3, 2010, eliminated home delivery as part of an effort to reach a compromise to implement the MMP. In addition, the Department's concern for the security of patients, ATC employees, the potential for diversion, and the need to ensure the safety of the public weighed against home delivery in this rulemaking. Experience with the program will determine whether home delivery is needed in the future. The rules ensure that registered primary caregivers may purchase medicinal marijuana from ATCs for those patients who have difficulty traveling, thereby allowing those patients who are unable to travel to an ATC to receive medicinal marijuana. Accordingly, the Department removed home delivery from N.J.A.C. 8:64-12 in the notice of reproposal dated February 22, 2011.

48. COMMENT: The commenter represents a network of substance abuse agencies providing services in New Jersey. The commenter opposed passage of the Act and is concerned that the rules will send a mixed message to our youth. Nevertheless, the commenter supports the rules because they are restrictive. (1)

RESPONSE: The Department thanks the commenter for its support of the rules.

49. COMMENT: A number of commenters stated that the fees to obtain registry identification cards for both qualifying patients and their primary caregivers are excessive. Generally, the commenters point out that the \$200.00 fee proposed by the Department at N.J.A.C. 8:64-2.1(c) is the highest in the nation and constitutes an undue burden on very sick patients that are unable to work and have high medical expenses. (2, 4, 14, 16, 18, 21, and 22)

RESPONSE: The Department disagrees with the comment. Arizona, for example, charges \$150.00 for a patient registry card that must be renewed annually. Colorado charges \$90.00 for a patient registry card that must be renewed each year. Michigan charges \$100.00 for a patient registry card that must be renewed each year. The Department charges \$200.00 for a patient registry card that is valid for a two-year period, making the annual cost \$100.00 per year. This is generally in accord with the fee schedule of the aforementioned states. In addition, N.J.S.A. 24:6I-11b provides that all fees collected shall be used to offset the cost of the MMP. In order to reduce the cost of registry identification cards for individuals with a limited income, the Department adopts N.J.A.C. 8:64-2.1(c)1, which provides that the fee for a registry identification card for an individual receiving Medicaid benefits, food stamp benefits (now known as the Supplemental Nutrition Assistance Program), New Jersey Temporary Disability Insurance benefits, Supplemental Security Income benefits, or Social Security Disability benefits will be \$20.00. Because all registry identification cards will be valid for a period of two years and re-registration is only necessary once every two years.

50. COMMENT: The commenter supports the positive innovation that the MMP should be limited to patients with bona fide physician-patient relationships as defined at N.J.A.C. 8:64-1.2. Marijuana is a Schedule I substance; therefore, it is appropriate for the Department to institute a physician registry, although the attestation is a major deterrent to physician participation because very few physicians have experience and training in pain management and addictive medicine. The Department does not yet understand that marijuana is not physically addictive. It is safe to immediately discontinue use, even in long-time users, and there are no physical withdrawal symptoms. The Department should remove the “experience and training in addictive medicine” attestation requirement. The physician certification statement at N.J.A.C. 8:64-2.5(a)9i should not have quotation marks, demonstrates the Department’s bias against medicinal marijuana, and is inappropriate because it must be stated exactly in all cases without regard for the individual circumstances of each patient. The list of qualifying debilitating medical conditions is a positive and clearly defines appropriate cannabis indications. (3)

RESPONSE: The Department thanks the commenter for the comments concerning the bona fide physician-patient relationship requirement, the physician registry, the safety of medicinal marijuana use, and the list of debilitating medical conditions. There is no requirement in the Department’s rules that a certifying physician must have or certify that he or she has “experience and training in addictive medicine.” The Department declines to remove the quotation marks from N.J.A.C. 8:64-2.5(a)9i because the Department intends this rule to memorialize that the certifying physician has explained the possible risks of medicinal marijuana use to the patient. The Department understands that marijuana may possess only mild physically addictive properties.

51. COMMENT: The commenter states that N.J.A.C. 8:64-6.2(a), which requires documented involvement of an acute care hospital with an ATC, is unnecessary because medicinal marijuana is far more likely to be used in a home than in a hospital and the administration of an ATC bears no relevance to that of a hospital. N.J.A.C. 8:64-11.4(b), which requires ATCs to assess patient’s pain, is not the business of a dispensary and should be left to medical professionals. (4)

RESPONSE: The Department’s intent with regard to N.J.A.C. 8:64-6.2(a) is to accommodate a number of hospitals that have demonstrated a desire to share their expertise with ATCs in matters that are relevant to the functioning of ATCs. The Department does not intend N.J.A.C. 8:64-11.4(b) to direct the ATCs to assess the patient’s pain, the rule is intended to require the ATC to collect documentation of the patient’s self-assessment of pain and to transmit that data to the Department for review and analysis.

52. COMMENT: The commenter supports the rules and would like to see the definition of “debilitating medical condition” at N.J.A.C. 8:64-1.2 modified to include a “time frame or a strong, general guideline provided for referring patients for marijuana therapy after resistance to conventional treatments becomes evident, in an effort to ease patients’ suffering.” (5)

RESPONSE: N.J.S.A. 24:6I-3 establishes the definition of the term, “debilitating medical condition.” The Department is bound by the definition in the statute.

53. COMMENT: A number of commenters state that marijuana helps relieve the pain that they have from a variety of ailments and injuries and that it helps them with nausea or stress. Some of these commenters testified that they have loved ones who benefit greatly from medicinal marijuana. Generally, these commenters state that they dislike being labeled as criminals because they have found that marijuana helps them to live more normal lives and they look forward to becoming registered qualifying patients. (6, 7, 20, 21, 26, 30, 31, 32, 33, 34, 35, 37, 38, 39, 40, and 41)

RESPONSE: The Department thanks the commenters for sharing their experiences in favor of medicinal marijuana.

54. COMMENT: The commenter states that the Department should include chronic pain and neuropathic pain as debilitating medical conditions. The commenter states that his physician estimates that he could reduce his dependency on serious pain medication, including daily regimens of morphine sulfate instant and extended relief and tramadol, by one half by using medicinal marijuana, but the commenter does not qualify under the current list of debilitating medical conditions. (8)

RESPONSE: The list of debilitating medical conditions is prescribed by statute at N.J.S.A. 24:6I-3. The Department has adopted a process whereby individuals can petition to add additional debilitating medical conditions to the list at N.J.A.C. 8:64-5.

55. COMMENT: The commenter states that he represents a business entity that has developed a patch for the transcutaneous delivery of medicinal marijuana to humans and animals. The commenter states that the patch is a superior medicinal marijuana delivery system when compared to smoking and consistently offers dependable dosages. The Department should consider taking “the lead in demonstrating to the rest of the United States that marijuana can be effectively controlled for medicinal purposes.” (10)

RESPONSE: The Department does not have sufficient information upon which to base an opinion concerning the comment. The product described by the commenter has not been approved for use by the Federal Food and Drug Administration and therefore cannot be approved for use by the Department. The Department will continue to review literature, government approved studies, and journal publications concerning the transcutaneous delivery of medicinal marijuana and may consider additional delivery methods in future rulemaking.

56. COMMENT: One commenter states that N.J.A.C. 8:64-13.1(d), which will prohibit ATCs from advertising prices of medicinal marijuana except to registered qualifying patients and primary caregivers inside the ATC itself, violates the First Amendment to the United States Constitution. The commenter states that the rule serves to deny legal consumers of products from being provided with truthful, non-misleading information about those products, which is necessary for them to make informed decisions about those products, and that the State has no justifiable interest, that can override the First Amendment, in precluding or severely limiting the dissemination of non-misleading pricing information to legal consumers. (11)

RESPONSE: The Department respectfully disagrees with the commenter. The provision in question is a reasonable restriction upon advertising by alternative treatment centers that is intended to ensure that only those who are legally entitled to use medicinal marijuana receive pricing information. The requirement is necessary to protect the State's substantial interest in ensuring that only those individuals who may legally purchase medicinal marijuana receive pricing information, thereby discouraging attempts by black market vendors to undercut lawful sales by alternative treatment centers. Unlike other forms of advertising, including advertising regarding alcohol and tobacco, it is significant that the use of marijuana remains illegal for most of the residents of the State. Since the use of marijuana is prohibited for most of the population, the need for its efficient allocation and distribution through commercial advertising is less compelling. Therefore, the advertising of medicinal marijuana must necessarily be limited and narrowly tailored to reach the small population of qualifying registered patients. Not only does the State have an interest in limiting advertising to legal users, the State has a substantial interest in discouraging commercial advertising of marijuana to the general public that would unavoidably encourage or trivialize the sale and use of an illegal drug. The rule directly advances the aforementioned substantial government interests and is not more extensive than necessary to serve those interests. The rule would not prevent alternative treatment centers from providing registered users with pricing information at the facility or when the qualifying registered patient otherwise contacts the facility, such as by phone. Although not defined in the proposed rules, the common meaning of the term, "advertise" is to make public announcement of, to make generally known or to call the attention of the public to a product or business. Therefore, the proposed rule is intended to prohibit ATCs from advertising prices to the public, but it is not intended to prohibit ATCs from providing pricing information to any qualifying registered patient or any registered primary caregiver. In addition, the advertising restriction is consistent with the Department's longstanding public health policies against tobacco use and the advertising and sale of tobacco products to minors. Therefore, the Department makes no change on adoption.

57. COMMENT: The commenter states that his organization opposed the Act. Marijuana has not been proven safe and effective. Marijuana is not medicine. The Act violates Federal law and is, therefore, illegal. The commenter is "not aware of any significant 'clinical' trials with smoked marijuana" and states that the 10 percent THC limit is too high. The commenter states that marijuana "is addictive at any level." (13)

RESPONSE: The New Jersey Legislature found that modern medical research has discovered a beneficial use for marijuana in treating or alleviating the pain or other symptoms associated with certain debilitating conditions as found by the National Academy of Science's Institute of Medicine in March 1999. This finding was declared at N.J.S.A. 24:6I-2.

58. COMMENT: The commenter makes a number of comments concerning the rule, generally stating that the rules are contrary to the legislative intent and effectively rewrite the Act from beginning to end. N.J.A.C. 8:64-2.2 mandates that for a patient to register, the treating physician must register and obtain a certification number, in violation of the definition of "qualified patient" in the Act. The commenter states that the Act purposely does not require a physician registry because marijuana is illegal under Federal law and it is unwise to create a registry of "marijuana doctors" who may then be in danger of Federal prosecution. N.J.A.C. 8:64-2.2 imposes conditions, such as requiring patients to provide a government photo identification card,

that will be difficult for many patients to meet. N.J.A.C. 8:64-2.5(a)6 requires the physician to disclose the patient's diagnosis, which violates patient confidentiality, and is not called for in the Act. N.J.A.C. 8:64-2.5(a)9, which requires physicians to inform patients that there exists a lack of scientific consensus for the use of medicinal marijuana, is in direct conflict with the Act, which states that modern medical research has discovered beneficial uses for marijuana. The commenter states there has never been a single fatality from the use of marijuana and that it is impossible to overdose on it. The commenter states that N.J.A.C. 8:64-2.2(f)1, which states that the custodial parent of a registered qualifying patient who is a minor shall be issued a primary caregiver registration card by the Department for no additional fee, is inconsistent with N.J.A.C. 8:64-2.3, which would appear to require the custodial parent of a registered qualifying patient who is a minor to submit to a background check, pay for the same, and also to pay a \$200.00 fee for a registry identification card. The commenter states that N.J.A.C. 8:64-3.4(c), which requires registry cards to be surrendered to the Department when any information on the card changes or an new ATC is designated, will operate to deprive patients of medicinal marijuana between the time that the original registry certification card is surrendered and a new card is issued. N.J.A.C. 8:64-4.1(a) is inconsistent with the Act because the rule requires the qualifying patient, primary caregiver, parent, guardian, or other custodian of a qualifying patient who is a minor, to notify the Department of any change in the qualifying patient's name, address, ATC, or physician within 10 days of the change, whereas the Act only places such notification requirements on qualifying patients. N.J.A.C. 8:64-4.3(a)2, which requires ATCs to report each patient's diagnosis to the Department, encourages a violation of the Act, which provides that the patient's application or receipt of a registry card does not constitute a waiver of the qualifying patient's patient-physician privilege. The commenter states that N.J.A.C. 8:64-4.3(a)6 (codified as N.J.A.C. 8:64-4.3(a)5 in the February 22, 2011 notice of reproposal), which requires ATCs to provide a summary of patient surveys and evaluation of services to the Department, is an improper delegation to the ATCs of the Department's responsibility to collect this information under the Act because the definition of ATC in the Act does not contain such obligations. N.J.A.C. 8:64-6.1(d), which states that the Department shall only accept and process ATC applications after making a formal request for applications (RFA), is in violation of the Act, which states that the Department "shall accept" ATC applications without such a constraint. N.J.A.C. 8:64-6.2 provides for a selection committee to review ATC applications, but the rule fails to include information as to the committee's members or qualifications. N.J.A.C. 8:64-6.4 does not provide for a time frame within which the Department shall review and issue a decision on an ATC application. N.J.A.C. 8:64-7.1(b)2ii, which requires an ATC applicant to disclose the names, addresses, and other information concerning its employees, presumably before the ATC gets approval to operate, is not appropriate because it is inconsistent with how businesses operate. N.J.A.C. 8:64-9.3(a)9, which requires an ATC to disclose how it determines the prices it charges for medicinal marijuana, is of no legitimate concern to the Department. The requirements at N.J.A.C. 8:64-7.1(b) are unnecessary roadblocks to approval and are vague. The on-site prohibitions on food sales and consumption at N.J.A.C. 8:64-9.2, the on-site parking requirement at N.J.A.C. 8:64-9.7(b) and the signage requirements at N.J.A.C. 8:64-13.1(c) (codified as N.J.A.C. 8:64-12.1(c) in the February 22, 2011 notice of reproposal) violate local land use laws which are the province of local, not State, governments. The security requirements at N.J.A.C. 8:64-9.7(b) are overly burdensome and costly for the ATCs. N.J.A.C. 8:64-10.6(d)1 requires a statement on the medicinal marijuana package that states that the product is not intended to diagnose, treat, cure, or prevent any disease, which is inconsistent with the Act,

which states that modern medical research has discovered beneficial uses for marijuana in treating or alleviating pain or other symptoms associated with certain debilitating medical conditions. N.J.A.C. 8:64-10.8(e) would allow oral lozenges to be dispensed by ATCs; however, oral lozenges are not used as a delivery method for medicinal marijuana according to most experienced people in the field. N.J.A.C. 8:64-10.11(e) (not codified in the February 22, 2011 notice of reproposal) provides that medicinal marijuana shall be transported in conformance with State and Federal laws, but since it is an illegal substance under Federal law, one is left to guess which Federal law applies. N.J.A.C. 8:64-11.1 requires the ATCs to provide educational materials to patients and primary caregivers, but this function should more properly be performed by the Department. N.J.A.C. 8:64-11.2(c), which requires ATCs to ask patients and primary caregivers for permission to contact them with information about peer review clinical studies concerning the use of medicinal marijuana, is a function that should be more properly performed by the Department. N.J.A.C. 8:64-11.3(b), which requires an ATC to maintain a copy of the registered qualifying patient's (and, if applicable, primary caregiver's) patient identification card and other form of government issued photo identification card, is violative of the Act, which only requires a patient to submit his or her patient identification card and physician's recommendation to the ATC in order to obtain medicinal marijuana. N.J.A.C. 8:64-11.4, which requires ATCs to document patient self-assessment of pain, is not the proper function of the ATC, but rather, the Department. N.J.A.C. 8:64-11.5(a), which requires an ATC to stop dispensing medicinal marijuana to an individual that the ATC believes is abusing the substance or redistributing it, treats marijuana as illegal and patients as criminals. N.J.A.C. 8:64-12.1(f), which prohibits an ATC from selling t-shirts or other promotional items displaying a reference to marijuana, is unconstitutional because the sale of medicinal marijuana by an ATC is a legitimate business. N.J.A.C. 8:64-13.4(c) does not provide for testing of medicinal marijuana's THC content. The commenter points out that N.J.A.C. 8:64-13.11, which references the protections from prosecution that patients are guaranteed under the Act, does not expand on the protections such as by providing that a patient shall not be fired from his job for using medicinal marijuana if there is no corresponding poor work performance. The commenter states that generally, the rules are not reasonable. (15)

RESPONSE: The Department disagrees that the definition of "qualifying patient" in the Act precludes a physician registry. The purpose of the physician registry is, consistent with a medical model of care, to place control for access to medicinal marijuana in the hands of qualified physicians. The requirement at N.J.A.C. 8:64-2.2 for a patient to provide a government photo identification card is intended to ensure proper patient identification. The Department is required to verify that a qualifying patient has a certification signed by a physician that establishes that a patient has a debilitating medical condition under N.J.S.A. 24:6I-3. Accordingly, N.J.A.C. 8:64-2.5(a)6 requires a physician to provide the Department with the qualifying patient's diagnosis. The Department will not disclose patient identifiable health information to third parties and will maintain this information in a confidential manner. The Department disagrees that N.J.A.C. 8:64-2.5(a)9, which requires physicians to inform patients that there exists a lack of scientific consensus for the use of medicinal marijuana, is inconsistent with the legislative findings and declarations stated at N.J.S.A. 24:6I-2a, that modern medical research has discovered a beneficial use for marijuana. Medicinal marijuana provides benefits in treating or alleviating pain or other symptoms associated with certain debilitating medical conditions; however, there exists a lack of scientific consensus concerning, but not limited to, the following areas: dosages,

frequency of dosages, delivery routes and methods, the most suitable strains for the treatment of specific conditions, and which cannabinoid compounds affect which areas of the body. The Department is without sufficient information upon which to form an opinion concerning the commenter's statement that there has never been a single fatality from the use of marijuana and that it is impossible to overdose on it. The Department does not intend to require the parents of registered qualifying patients who are minors to submit to background checks or to pay a fee for a primary caregiver registration card as provided at N.J.A.C. 8:64-2.2(f)1. The Department does not intend to apply N.J.A.C. 8:64-3.4(c) in a manner which will cause a registered qualifying patient to be deprived of medicinal marijuana while the patient awaits the Department issuance of a new registry identification card. N.J.A.C. 8:64-4.1(a) is consistent with the Act because the Act intends for the patient to notify the Department when certain material information changes and in some cases, where the patient is a minor or very ill, it is appropriate for the parent, guardian, or primary caregiver, who stands in the place of the patient, to provide such notification to the Department. The Department disagrees that N.J.A.C. 8:64-4.3(a)2 encourages a violation of patient confidentiality because the rule does not contain a requirement that the patient's identity be linked to a record of the patient's debilitating medical condition. The ATC reporting requirement at N.J.A.C. 8:64-4.3(a)6 is a means of collecting summaries of patient surveys by the Department, not a delegation of this responsibility to the ATCs. The Department disagrees that N.J.A.C. 8:64-6.1(d) is violative of the Act. The request for applications (RFA) process is a permitted exercise of the broad discretion granted to State agencies in determining how to fulfill their statutory obligations. In this case, N.J.A.C. 8:64-6.1(d) is reasonable and a permissible means of implementing the statutory requirements within the Department's discretion, as provided by the Act, to determine whether ATC applicants meet the standards set forth in the Act and the rules, and this rule is in keeping with the Department's discretion to issue additional permits "pursuant to need." The Department declines to specify selection committee members and qualifications at N.J.A.C. 8:64-6.2 upon adoption because this is not a requirement of the Act. In the event that the Department issues an RFA, the Commissioner will exercise discretion to appoint committee members who possess knowledge and expertise applicable to the committee's role in evaluating and scoring each application. The Department declines to adopt a time for reviewing ATC applications at N.J.A.C. 8:64-6.4 because the timeframe of 60 days is set by statute at N.J.S.A. 24:6I-7e. The Department disagrees with the statement that N.J.A.C. 8:64-7.1(b)2ii is not an appropriate rule because it is inconsistent with how businesses operate. Businesses in the health care field, such as air medical services, are generally required to provide the names, addresses, and professional training and qualifications of their employees on their applications for licensure. Accordingly, the rule is consistent with how businesses operate. The Department will look at this issue as it gathers more data and experience in the MMP. The Department disagrees that N.J.A.C. 8:64-9.3(a)9, which requires an ATC to disclose how it determines the prices it charges for medicinal marijuana, is of no legitimate concern of the Department. The rule at N.J.A.C. 8:64-10.8(e) is intended by the Department to permit an ATC to offer an edible form of medicinal marijuana to registering qualifying patients. Medicinal marijuana lozenges are available to patients in Colorado, Michigan, and other states that permit marijuana use for medicinal purposes.

N.J.S.A. 24:6I-12c requires the Department to report to the Governor and the Legislature whether any ATC has charged excessive prices for medicinal marijuana that the ATC has dispensed. The Department disagrees that N.J.A.C. 8:64-7.1(b), which requires an ATC applicant

to disclose the legal name of the corporation, a copy of the corporate by-laws, the names and addresses of the ATC's owners, as well as other information, creates unnecessary and vague roadblocks to approval. The Department disagrees that the prohibitions on food sales and consumption at N.J.A.C. 8:64-9.2, the on-site parking requirement at N.J.A.C. 8:64-9.7(b), and the signage requirements at N.J.A.C. 8:64-12.1(c) violate local land use laws, which are the sole province of local governments. It is well established that both the Department and local boards of health have joint authority to regulate in these areas for the benefit of public health and safety. The Department disagrees that the security requirements at N.J.A.C. 8:64-9.7(b) are overly burdensome to ATCs. The requirement that an ATC have a good alarm and security system is necessary to prevent diversion and cultivate public confidence in the MMP. The statement required by N.J.A.C. 8:64-10.6(d)1 is not inconsistent with the Act because the Act does not state that medicinal marijuana is intended to diagnose, treat, cure, or prevent specific diseases. The rule at N.J.A.C. 8:64-10.8(e) is intended by the Department to permit an ATC to offer an edible form of medicinal marijuana to registering qualifying patients. The rule at N.J.A.C. 8:64-10.11 is intended by the Department to ensure that medicinal marijuana is transported in compliance with all State and Federal laws, including motor vehicle laws. The specific requirement that an ATC – cultivation transport marijuana in conformance with State and Federal law contained in N.J.A.C. 8:64-10.11(e) of the November 15, 2010 original notice of proposal was not contained in the February 22, 2011 notice of reproposal; therefore, this specific issue is moot. The rules at N.J.A.C. 8:64-11.1 and 11.2(c) are intended by the Department to ensure that ATCs, who have more physical contact with patients than Department employees, disseminate educational materials, and make an effort to share information about peer review clinical studies to registered qualifying patients. N.J.A.C. 8:64-11.3(b), which requires an ATC to keep a copy of a registered qualifying patient's photo identification card on file, is not violative of the Act. The rule is a valid exercise of the Department's rulemaking authority under N.J.S.A. 24:6I-16 and necessary to verify the identity of a registered qualifying patient and, if applicable, a primary caregiver upon their first visit to the ATC. The Department intends N.J.A.C. 8:64-11.4 to provide information to the Department for use in determining the effectiveness of the MMP. N.J.A.C. 8:64-11.5(a) is intended to confer authority upon the ATC to stop dispensing medicinal marijuana to an individual that the ATC believes is using the medicine for an illegal purpose, not to treat the medicinal use of marijuana as illegal or to characterize patients as criminals. N.J.A.C. 8:64-12.1(f) is a limited restriction on the use of symbols or references to marijuana on t-shirts or novelty or promotional items that is constitutionally permitted. It is not a complete ban on the sale of t-shirts or promotional items and it does not by its terms apply to paraphernalia, such as a vaporizer, which may understandably contain symbols or references to marijuana in an instructive label or pamphlet. The Department acknowledges that N.J.A.C. 8:64-13.4(c) does not specifically provide for testing of THC content. The rule does, however, provide that testing may include other things in addition to the listed items such as mold, heavy metals, pesticides, etc. Accordingly, the Department reserves the right to test for THC content. The Department intends N.J.A.C. 8:64-13.6 and 13.7 to work together to provide a mechanism for the Department to enforce the provisions of the Act and the administrative rules. The Department intends N.J.A.C. 8:64-13.11 to reference the protections that patients are guaranteed under the Act and reserves the right to consider additional protections in future rulemaking.

59. COMMENT: The commenter states that the entire physician registry should be removed. The physician certification statement on the “lack of scientific consensus for the use of medicinal marijuana” should be removed. The requirement that a physician must also possess an active controlled dangerous substances registration should be removed. The requirement that a physician shall refer a minor to a pediatrician and a psychiatrist before recommending medicinal marijuana should be removed. The ATCs should be allowed to make up their own medical advisory boards, the ban on volume discounting should be removed, the ATCs should be allowed to carry an inventory equal to three month’s supply per patient, and home delivery should be permitted. The ATCs should not be permitted to collect patient identifiable health information or to survey patients. Patients should not be required to register with only one ATC at any given time and additional forms of proof of State residency should be permitted. The parent or guardian of a minor patient should not be required to qualify as a primary caregiver. (16)

RESPONSE: The Department disagrees that the physician registry should be removed. The purpose of the physician registry is, consistent with a medical model of care, to place control for access to medicinal marijuana in the hands of qualified physicians. The requirement at N.J.A.C. 8:64-2.2 for a patient to provide a government photo identification card is intended to ensure proper patient identification. The Department disagrees that N.J.A.C. 8:64-2.5(a)9, which requires physicians to inform patients that there exists a lack of scientific consensus for the use of medicinal marijuana, should be removed. Medicinal marijuana provides benefits in treating or alleviating pain or other symptoms associated with certain debilitating medical conditions; however, there exists a lack of scientific consensus concerning, but not limited to, the following areas: dosages, frequency of dosages, delivery routes and methods, the most suitable strains for the treatment of specific conditions, and which cannabinoid compounds affect which areas of the body. The requirement that a physician must possess an active controlled dangerous substances registration is appropriate and consistent with the current classification of marijuana as a Schedule I drug under Federal law. The requirements that a physician shall refer a minor to a pediatrician and a psychiatrist before recommending medicinal marijuana are intended by the Department to provide additional safeguards for the care of minors; therefore, the Department disagrees that they should be removed. N.J.A.C. 8:64-1.2 defines “medical advisory board” as a body that is appointed by the ATC. The Department’s intent with N.J.A.C. 8:64-10.1(a)2, which bans volume discounts on sales, is to discourage an ATC from becoming chiefly a cultivator that sells medicinal marijuana to other ATCs rather than a cultivator/dispenser that serves registered qualifying patients. The Department disagrees that three month’s supply per patient would be a reasonable inventory for an ATC to maintain. The Department intends N.J.A.C. 8:64-11.4, which requires an ATC to survey patients, to provide information to the Department for use in determining the effectiveness of the MMP. The Department intends N.J.A.C. 8:64-2.2(a)4i, which requires that a patient may register with only one ATC at any given time, to aid with control, monitoring, and inventory tracking at each ATC. The Department disagrees that additional forms of proof of State residency should be permitted because a driver’s license, government-issued identification card, or a utility bill is already acceptable as provided by N.J.A.C. 8:64-2.2(a)6. The Department disagrees that a parent or guardian of a minor registered qualifying patient should not be required to qualify as a primary caregiver. Accordingly, N.J.A.C. 8:64-2.2(f) requires such qualification; however, no application fee shall apply.

60. COMMENT: The commenter testified that the rules are arbitrary, capricious, and unconstitutional and that the Department needs to listen to patients and make significant changes. (17)

RESPONSE: The Department respectfully disagrees and considers the rules to be a valid exercise of the Department's rulemaking authority under N.J.S.A. 24:6I-16. The rules are rationally related to the State's objective of implementing a well-regulated medicinal marijuana program that will provide needed medicine to registered qualifying patients.

61. COMMENT: The bona fide physician-patient relationship defined at N.J.A.C. 8:64-1.2 is inconsistent with the Act, which does not require that a physician treat a patient for a specific period of time in order for the bona fide physician-patient relationship to be created. The commenter is concerned that this provision could result in an unnecessary delay for a patient to obtain a physician's certification to use medicinal marijuana. The word "certify" should be removed from the rules because Federal officials have the right to prosecute physicians for violations of Federal law, such as certifying or authorizing patients to use medicinal marijuana and states should, therefore, avoid these words in order to protect physicians from Federal prosecution. N.J.A.C. 8:64-2.5(a)9, which requires physicians to inform patients that there exists a lack of scientific consensus for the use of medicinal marijuana, is more of a political statement than a medical statement and should be removed from the rules because it is an obtrusive interference with the physician-patient relationship. N.J.A.C. 8:64-3.4, which requires primary caregivers to execute a certification stating that they will comply with various conditions, including only purchasing medicinal marijuana from the designated ATC on his or her registry identification card, is not required by the Act and is unnecessarily and excessively intrusive. The requirement of approval of the local governing body where the ATC will be located is overly onerous and creates an unnecessary financial risk for ATCs. The restriction on consumption of food and beverages at ATCs is unique among medicinal marijuana states and is not justifiable. The complete ban on persons under the age of 18 in ATCs will present a hardship for patients and caregivers who need to pick up their medication but are unable to obtain child care. No such restriction applies to New Jersey pharmacies. The security requirements at N.J.A.C. 8:64-9, particularly the requirements to provide neighbors within 100 feet of the ATC with a phone number where they can reach an ATC employee after hours, the drug free school zone 1,000-foot location restriction, and the video monitoring requirements, are excessive. (23)

RESPONSE: N.J.S.A. 24:6I-3 defines "physician," in relevant part, as a person responsible for the ongoing treatment of a patient's debilitating medical condition, "provided, however, that such ongoing treatment shall not be limited to the provision of authorization for a patient to use medical marijuana or consultation solely for that purpose." The intent of the law is to prevent patients from simply consulting with a physician for the sole purpose of obtaining a patient registry identification card from the Department to use medicinal marijuana with no ongoing care or treatment from that physician. The definition of bona fide physician-patient relationship defined at N.J.A.C. 8:64-1.2 furthers the legislative intent through rulemaking, specifically by establishing what is meant by "ongoing" responsibility for the patient's care. The Department notes that the Board of Medical Examiners, which is the agency responsible for regulating physicians, proposed similar language to define "ongoing responsibility" at N.J.A.C. 13:35-7A.2. Accordingly, in the notice of reproposal dated February 22, 2011, the Department incorporates

the BME rule by reference. The word, “certification” is a defined term at N.J.S.A. 24:6I-3. The Department is bound by the language in the statute, which requires physicians to “certify” that they have a bona fide physician-patient relationship with a qualifying patient which attests to the physician’s authorization for the patient to apply for registration to the MMP. The Department disagrees that N.J.A.C. 8:64-2.5(a)9 is more of a political statement than a medical statement because the Department intends this rule to memorialize that the certifying physician has explained the possible risks of medicinal marijuana use to the patient. The Department intends N.J.A.C. 8:64-3.4 to be a valid exercise of rulemaking authority under N.J.S.A. 24:6I-16 that is consistent with the Act and that explains to primary caregivers, through reading and agreeing to the certification, that they are responsible to only purchase medicinal marijuana from an ATC, that they may not grow marijuana for their patient, that they are required to notify the Department if their patient wants to designate a new ATC, etc. The Department does not agree that requiring approval for the location of ATCs from local governments is overly restrictive. As a practical matter, ATCs and other businesses must generally locate in areas that local governments have zoned for their business activity. The restriction on the consumption of food and beverages at ATCs found at N.J.A.C. 8:64-9.2(b) is intended by the Department to foster a businesslike atmosphere at the ATC that is focused on providing the patient with medication. The general ban on persons under the age of 18 in ATCs at N.J.A.C. 8:64-9.2(d) does not apply to registered qualifying patients who are minors, as long as the minor is accompanied by his or her primary caregiver and is intended to limit the exposure of minors who are not registered qualifying patients to medicinal marijuana and paraphernalia. The Department believes that all of the security requirements are necessary in order to ensure a safe, adequate supply of medicinal marijuana to patients, to prevent diversion, and to instill public confidence in the integrity of the MMP.

62. COMMENT: The commenter states that he represents a business entity that sells medicinal marijuana patches, lozenges, etc. (24)

RESPONSE: The Department thanks the commenter for the comment.

63. COMMENT: The commenter represents an ATC applicant and testified that the rules are consistent with a medical model and are generally appropriate, especially for ATCs. (42)

RESPONSE: The Department thanks the commenter for his support of the rules.

64. COMMENT: The commenter states that the rule prohibiting a doctor who is on an ATC’s corporate board from serving on the medical advisory board and the rule that requires an ATC to affiliate with a hospital are restrictive. (43)

RESPONSE: The Department intends the definition of “medical advisory board” at N.J.A.C. 8:64-1.2 to establish an advisory body that can provide medical advice to an ATC without a conflict of interest that would be created if an owner or officer of the ATC were permitted to serve on the advisory board. The Department intends the rule requiring an ATC to affiliate with an acute care hospital to benefit the ATC by creating an association whereby the hospital would be in a position to provide the ATC with advice and consultation.

Federal Standards Statement

Existing Federal law prohibits the manufacture, possession, sale, or distribution of marijuana for any reason. 21 U.S.C. §§ 841 et seq. The Act provides at N.J.S.A. 24:6I-2d, “States are not required to enforce federal law or prosecute people for engaging in activities prohibited by federal law; therefore, compliance with [the Act] does not put the State of New Jersey in violation of federal law.”

The new rules conflict with Federal law, which prohibits marijuana cultivation, possession, sale, and distribution. The Department has determined that the only way to fulfill its obligation to implement the Act pursuant to N.J.S.A. 24:6I-1 et seq., particularly 24:6I-7 and 16, is to promulgate the new rules to establish standards governing the cultivation, possession, manufacture, sale, and use of medicinal marijuana.

On October 19, 2009, United States Attorney General Eric Holder announced formal guidelines for the exercise of investigative and prosecutorial discretion by Federal prosecutors in states that have enacted laws authorizing the use of marijuana for medical purposes (enforcement guidelines). The accompanying press release describes the enforcement guidelines as establishing, “that the focus of federal resources should not be on individuals whose actions are in compliance with existing state laws, while underscoring that the [United States] Department [of Justice] will continue to prosecute people whose claims of compliance with state and local law conceal operations inconsistent with the terms, conditions, or purposes of those laws.” “Attorney General Announces Formal Medical Marijuana Guidelines,” Press Release, October 19, 2009, available at <http://www.justice.gov/opa/pr/2009/October/09-ag-1119.html>. In announcing the guidelines, Attorney General Holder stated, “It will not be a priority to use federal resources to prosecute patients with serious illnesses or their caregivers who are complying with state laws on medicinal marijuana, but we will not tolerate drug traffickers who hide behind claims of compliance with state law to mask activities that are clearly illegal.” The enforcement guidelines are available at <http://www.justice.gov/opa/documents/medical-marijuana.pdf>.

The new rules articulate standards that are achievable under current technology.

Full text of the new rules follows:

TEXTCHAPTER 64

MEDICINAL MARIJUANA PROGRAM RULES

SUBCHAPTER 1. GENERAL PROVISIONS

8:64-1.1 Purpose and scope

(a) This chapter implements the New Jersey Compassionate Use Medical Marijuana Act, P.L. 2009, c. 307 (approved January 18, 2010), codified at N.J.S.A. 24:6I-1 et seq. (Act).

(b) This chapter is applicable to:

1. Persons seeking to register and/or who register with the Department of Health and Senior Services (Department) as qualifying patients and/or primary caregivers;
2. Physicians seeking to certify and/or who certify that a person has a debilitating medical condition;
3. Entities seeking to operate and/or operating alternative treatment centers, and their owners, directors, officers and employees; and
4. Persons seeking to petition the Department for identification of debilitating medical conditions not specified at N.J.S.A. 24:6I-3.

8:64-1.2 Definitions

The following words and terms, as used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise or another subchapter defines one of the following words or terms differently for the purposes of that subchapter.

“Act” shall mean the New Jersey Compassionate Use Medical Marijuana Act, P.L. 2009, c. 307 (approved January 18, 2010), codified at N.J.S.A. 24:6I-1 et seq.

“Adequate supply” shall mean not more than is reasonably necessary to assure the uninterrupted availability of marijuana to meet the needs of registered patients at a given ATC.

“Adulterated” or “adulteration” means made impure or inferior by adding extraneous ingredients.

“Alternative treatment center” or “ATC” means the permitted alternative treatment center authorized to grow and provide registered qualifying patients with usable marijuana and related paraphernalia in accordance with the provisions of the Act. This term shall include the organization’s officers, directors, board members and employees.

“ATC identification card” means a document issued by the Department that identifies a person as a principal officer, director, board member, owner or employee of an ATC.

“Bona fide physician-patient relationship” means a relationship in which the physician has ongoing responsibility for the assessment, care and treatment of a patient’s debilitating medical condition consistent with the requirements of the Act and N.J.A.C. 13:35-7A.

“Central region” means the counties of Hunterdon, Middlesex, Mercer, Monmouth, Ocean, Somerset and Union.

“Certification” means a statement signed by a physician with whom a qualifying patient has a bona fide physician-patient relationship, which attests to the physician’s authorization for the

patient to apply for registration for the medical use of marijuana and meets the requirements of N.J.A.C. 13:35-7A.

“Commissioner” means the Commissioner of the Department of Health and Senior Services.

“Cultivation” includes the planting, propagating, cultivation, growing, harvesting, labeling or manufacturing, compounding and storing of medicinal marijuana for the limited purpose of the Act and this chapter.

“Debilitating medical condition” means:

1. One of the following conditions, if resistant to, or if the patient is intolerant to, conventional medical therapy: seizure disorder, including epilepsy; intractable skeletal muscular spasticity; or glaucoma;
2. One of the following conditions, if severe or chronic pain, severe nausea or vomiting, cachexia or wasting syndrome results from the condition or treatment thereof: positive status for human immunodeficiency virus, acquired immune deficiency syndrome or cancer;
3. Amyotrophic lateral sclerosis, multiple sclerosis, terminal cancer, muscular dystrophy or inflammatory bowel disease, including Crohn’s disease;
4. Terminal illness, if the physician has determined a prognosis of less than 12 months of life; or
5. Any other medical condition or its treatment that is approved by the Department pursuant to N.J.A.C. 8:64-5.

“Department” means the Department of Health and Senior Services.

“Disqualifying conviction” means a conviction of a crime involving any controlled dangerous substance or controlled substance analog as set forth in Chapter 35 of Title 2C of the New Jersey Statutes except paragraph (4) of subsection a. of N.J.S.A. 2C:35-10, or any similar law of the United States or of any other state.

“Electronic signature” or “signature” means either the name of one written by oneself or an electronic code, sound, symbol or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

“Lozenge” means a solid oral dosage form that is designed to dissolve or disintegrate slowly in the mouth. They contain one or more active pharmaceutical ingredients that are slowly liberated from the flavored and sweetened base. Lozenges can be prepared by molding (gelatin and/or fused sucrose or sorbitol base) or by compression of sugar-based tablets.

“Marijuana” has the meaning given in section 2 of the “New Jersey Controlled Dangerous Substances Act,” P.L. 1970, c. 226 (N.J.S.A. 24:21-2).

“Mature plant” means a harvestable female marijuana plant that is flowering and either greater than 12 inches in height or greater than 12 inches in diameter.

“Medical advisory board” means a five-member panel appointed by the ATC for the purpose of providing advise to the ATC on all aspects of its business. The medical advisory board shall:

1. Be comprised of three New Jersey licensed health care professionals, at least one of whom shall be a physician; one patient registered with the ATC; and one business owner from the same region as the ATC.

- i. No ATC owners, employees, officers or board members shall serve on the medical advisory board; and

2. Meet at least two times per calendar year.

“Medical use of marijuana” means the acquisition, possession, transport or use of marijuana or paraphernalia by a registered qualifying patient as authorized by the Act.

“Medicinal Marijuana Program” or “MMP” means the program within the Department of Health and Senior Services, which is responsible for the administration and implementation of activities related to the New Jersey Compassionate Use Medical Marijuana Act.

“Minor” means a person who is under 18 years of age and who has not been married or previously declared by a court or an administrative agency to be emancipated.

“Misbranded” means the term “misbranded” as defined in N.J.S.A. 24:5-16 and 17.

“Nonprofit entity” means corporations, associations or organizations not conducted for pecuniary profit of any private shareholder or individual, and established, organized or chartered without capital stock under the provisions of Titles 15, 15A, 16 or 17 of the Revised Statutes; or a special charter; or any similar general or special law of this or any other state, that are exempt from the tax imposed by the Corporation Business Tax Act, as set forth at N.J.S.A. 54:10A-3(e). A nonprofit entity is not required to be a tax-exempt organization under 26 U.S.C. §501(c)(3).

“Northern region” means the counties of Bergen, Essex, Hudson, Morris, Passaic, Sussex and Warren.

“Onsite assessment” means a visit by an employee of the Department to ensure compliance with the Act and this chapter to any site that has received a permit as an alternative treatment center.

“Organic” means the organic program standards as defined at N.J.A.C. 2:78.

“Paraphernalia” has the meaning given in N.J.S.A. 2C:36-1.

“Permit” means the document issued by the Department pursuant to this chapter granting the legal right to operate as an alternative treatment center for a specified time.

“Permitting authority” means the Medicinal Marijuana Program within the Department of which the mailing address is PO Box 360, Trenton, NJ 08625-0360.

“Petition” means a written request made by an individual submitted pursuant to this chapter to approve other medical conditions or the treatment thereof as a debilitating medical condition.

“Physician” means a person licensed to practice medicine and surgery

pursuant to Title 45 of the Revised Statutes with whom the patient has a bona fide physician-patient relationship and who is the primary care physician, hospice physician or physician responsible for the ongoing treatment of a patient’s debilitating medical condition, provided, however, that such ongoing treatment shall not be limited to the provision of authorization for a patient to use medicinal marijuana or consultation solely for that purpose.

“Primary caregiver” or “caregiver” means a resident of the State who:

1. Is at least 18 years old;

2. Has agreed to assist with a registered qualifying patient’s medical

use of marijuana, is not currently serving as primary caregiver for another qualifying patient and is not the qualifying patient’s physician;

3. Has never been convicted of possession or sale of a controlled dangerous substance, unless such conviction occurred after October 1, 2010, the effective date of the Act, N.J.S.A. 24:6I-1 et seq., and was for a violation of Federal law related to possession or sale of marijuana that is authorized under the Act;

4. Has registered with the Department pursuant to N.J.A.C. 8:64-2.3 and has satisfied the criminal history record background check requirement of N.J.A.C. 8:64-2.3(e); and

5. Has been designated as primary caregiver on the qualifying patient’s application or renewal for a registry identification card or in other written notification to the Department.

“Qualifying patient” or “patient” means a resident of the State who has

been provided with a certification by a physician pursuant to a bona fide physician-patient relationship.

“Region” means either the northern region, central region or southern region as defined in this section.

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

“Review panel” means a panel of health care professionals appointed by the Commissioner to review petitions and make recommendations for identification and approval of additional debilitating medical conditions.

“Security alarm system” means any device or series of devices, including, but not limited to, a signal system interconnected with a radio frequency method, such as cellular, private radio signals or other mechanical or electronic device, used to detect an unauthorized intrusion.

“Seedling” means a cannabis plant that has no flowers and that is less than 12 inches in height and less than 12 inches in diameter.

“Southern region” means the counties of Atlantic, Burlington, Camden, Cape May, Cumberland, Gloucester and Salem.

“THC” means delta-9-tetrahydrocannabinol.

“Topical formulation” means a transcutaneous therapeutic marijuana extract formulation comprising of water, short carbon chains, alcohol, dimethylsulfoxide, polyethylene glycol, polypropylene glycol, glycerin, mineral and mixtures thereof.

“Unusable marijuana” means marijuana seedlings, seeds, stems, stalks or roots.

“Usable marijuana” means the dried leaves and flowers of the female marijuana plant, and any mixture or preparation thereof, and does not include the seedlings, seeds, stems, stalks or roots of the plant.

SUBCHAPTER 2. REGISTRATION REQUIREMENTS FOR QUALIFYING PATIENTS AND PRIMARY CAREGIVERS

8:64-2.1 Fees for issuance and renewal of registration

(a) Registration and renewal fees are due upon filing of an application for issuance or renewal of registration as either a qualifying patient or a primary caregiver, and are non-refundable.

(b) An applicant for issuance of registration and registration renewal shall transmit to the Medicinal Marijuana Program a check or money order, or any other form of payment approved by the Medicinal Marijuana Program, that is made payable to the “Treasurer, State of New Jersey” in the amount of the required payment.

1. The Department shall place a 10-day hold on the issuance of a registry identification card for an application accompanied by a personal check.

(c) The fee to apply for issuance or renewal of a registry identification card is \$200.00.

1. If an applicant can demonstrate eligibility to receive services under the New Jersey Medicaid program, receipt of current food stamp benefits, receipt of current New Jersey Temporary

Disability Insurance benefits, Supplemental Security Income (SSI) benefits or Social Security Disability (SSD) benefits, then the fee to apply for a registry identification card is \$20.00.

(d) The Department shall not grant an application fee refund if an applicant demonstrates eligibility for a reduced application fee as provided (c)1 above on or after the date of issuance of the applicant's registry identification card.

(e) The Department shall notify an applicant who submits a reduced fee for which the applicant is not eligible and shall grant the applicant 30 days from the date of such notice to either:

1. Submit the correct fee to the Department; or
2. Demonstrate eligibility to receive services under the New Jersey Medicaid program, receipt of current food stamp benefits, New Jersey Temporary Disability Insurance benefits, Supplemental Security Income (SSI) benefits or Social Security Disability (SSD) benefits.

(f) The fee to apply for issuance or renewal of a primary caregiver identification card is \$200.00.

8:64-2.2 Application for registration as a qualifying patient

(a) A person applying for issuance or renewal of registration as a qualifying patient shall provide the following to the Department:

1. The patient's full name, address, date of birth, telephone number and signature;
2. The name, address and telephone number of the patient's physician;
3. The physician certification identification number obtained from the patient's physician;
4. The name, address and telephone number of the alternative treatment center with which the applicant would register.
 - i. A qualifying patient shall be registered to purchase usable marijuana from only one ATC at any given time;
5. The correct application fee as specified at N.J.A.C. 8:64-2.1;
6. Proof that the applicant is a New Jersey resident, consisting of one or more of the following:
 - i. A New Jersey driver's license;
 - ii. A government-issued identification card that shows the applicant's name and address; or
 - iii. A utility bill issued within the previous two months that shows the applicant's name and address; and

7. One recent passport-size color photograph, two inches by two inches, taken against a white background or backdrop with the applicant's face being not less than three quarters of an inch in width. The applicant shall not wear a hat, glasses or any other item that may alter or disguise the overall features of the face in the photograph and the applicant shall legibly print his or her name on the back of the photograph submitted. The photo shall have been taken not more than 30 days prior to the date of the application.

(b) The Department shall notify the applicant in writing, by electronic mail or by telephone, if an application is incomplete and shall explain what documents or information is necessary for the Department to deem the application complete.

1. An applicant shall have 30 days from the date of a notification issued pursuant to (b) above to submit the materials required to complete the application.

2. The Department shall not process incomplete applications.

3. The Department shall not accept and shall return applications to applicants who fail to submit materials necessary to complete an application within the 30 days provided pursuant to (b)1 above.

4. Applicants whose applications are not accepted pursuant to (b)3 above who seek to reapply for registration would need to submit a new application and the applicable fee in accordance with (a) above.

(c) Prior to issuing or renewing a registry identification card, the Department shall verify the information submitted by the applicant.

(d) The Department shall approve or deny an application to issue or renew a registration within 30 days of receipt of the completed application or renewal and shall issue a registry identification card within five business days of approving the application or renewal.

(e) A qualifying patient may designate a primary caregiver either on the application for issuance or renewal of registry identification card or in another written notification to the Department.

1. The Department shall not acknowledge a qualifying patient's designation of a primary caregiver unless and until the person designated as a primary caregiver successfully applies for primary caregiver registration in accordance with N.J.A.C. 8:64-2.3.

(f) As a condition of registration of a qualifying patient who is a minor, the minor's custodial parent, guardian or other legal custodian of the minor shall consent in writing in the application for issuance or renewal of registration to the minor's medical use of marijuana and shall acknowledge that the parent, guardian or custodian will control the acquisition and possession of the medicinal marijuana and any related paraphernalia dispensed by an alternative treatment center.

1. Upon the Department's issuance of a registry identification card to a qualifying patient who is a minor, the Department shall issue a primary caregiver registry identification card to the minor's custodial parent, guardian or other legal custodian of the minor, provided the custodial parent, guardian or other legal custodian has qualified as a primary caregiver pursuant to N.J.A.C. 8:64-2.3; however, no application fee required pursuant to N.J.A.C. 8:64-2.3(a)3 shall apply.

8:64-2.3 Primary caregiver registration

(a) A person who a qualifying patient designates as a primary caregiver pursuant to N.J.A.C. 8:64-2.2(e) shall submit the following to the Department to apply for issuance or renewal of primary caregiver registration:

1. The applicant's full name, address, date of birth, telephone number and signature;
 2. Written consent to submit to a criminal history record background check pursuant to N.J.S.A. 24:6I-4.
 - i. The applicant shall remit the fee for the criminal history record background check in compliance with the procedures established by the Division of State Police pursuant to N.J.A.C. 13:59;
 3. The correct application fee as specified in N.J.A.C. 8:64-2.1;
 4. A statement that the applicant agrees to assist the qualifying patient with the medical use of marijuana, is not currently serving as primary caregiver for another qualifying patient and is not the qualifying patient's physician;
 5. Proof that the applicant is a New Jersey resident, consisting of one or more of the following:
 - i. A New Jersey driver's license;
 - ii. A government-issued identification card that shows the applicant's name and address; or
 - iii. A utility bill issued within the previous two months that shows the applicant's name and address; and
 6. One recent passport-size color photograph, two inches by two inches, taken against a white background or backdrop with the applicant's face being not less than three quarters of an inch in width. The applicant shall not wear a hat, glasses or any other item that may alter or disguise the overall features of the face in the photograph and the applicant shall legibly print his or her name on the back of the photograph submitted. The photo shall have been taken not more than 30 days prior to the date of the application.
- (b) The Department shall notify the applicant in writing, by electronic mail or by telephone, if an application is incomplete and shall explain what documents or information is necessary for the Department to deem the application to be complete.

1. An applicant shall have 30 days from the date of a notification issued pursuant to (b) above to submit the materials required to complete the application.

2. The Department shall not process incomplete applications.

3. The Department shall not accept and shall return applications to applicants who fail to submit materials necessary to complete an application within the 30 days provided pursuant to (b)1 above.

4. Applicants whose applications are not accepted for processing pursuant to (b)3 above who seek to reapply for registration shall submit a new application and the applicable fee in accordance with (a) above.

(c) Prior to issuing or renewing a registry identification card, the Department shall verify the information submitted by the applicant.

(d) The Department shall approve or deny an application or renewal within 30 days of receipt of the completed application or renewal and shall issue a registry identification card within five business days of approving the application or renewal.

(e) Each applicant for issuance or renewal of registration as a primary caregiver shall submit to a fingerprinting process as part of the criminal history record background check and shall comply with procedures established by the Division of State Police pursuant to N.J.A.C. 13:59 for obtaining readable fingerprint impressions.

(f) The Department shall deny registration of a primary caregiver who:

1. Refuses to consent to, or cooperate in, the securing of a criminal history record background check; or

2. Fails to provide any of the information required by (a) above.

(g) Subject to (h) below, the Department shall deny an application for issuance or renewal of registration as a primary caregiver if the criminal history record background check of the applicant reveals a disqualifying conviction.

1. If an applicant has a disqualifying conviction, the Department shall issue written notice to the applicant identifying the conviction that constitutes the basis for the denial of the application.

(h) The Department shall not deny an application for issuance or renewal of registration as a primary caregiver of an applicant who has a disqualifying conviction if the applicant affirmatively demonstrates to the Department by clear and convincing evidence that the applicant is rehabilitated.

1. In determining whether an applicant has demonstrated clear and convincing evidence of rehabilitation, the Department shall consider the following factors:

- i. The nature and responsibility of the position that the convicted individual would hold, has held or currently holds;
- ii. The nature and seriousness of the crime or offense;
- iii. The circumstances under which the crime or offense occurred;
- iv. The date of the crime or offense;
- v. The age of the individual when the crime or offense was committed;
- vi. Whether the crime or offense was an isolated or repeated incident;
- vii. Any social conditions that may have contributed to the commission of the crime or offense; and
- viii. Any evidence of rehabilitation, including good conduct in prison or in the community, counseling or psychiatric treatment received, acquisition of additional academic or vocational schooling, successful participation in correctional work-release programs or the recommendation of those who have had the individual under their supervision.

8:64-2.4 Physician registration

To be eligible to submit a certification pursuant to N.J.A.C. 8:64-2.5, a physician shall register using the secure Department web page at http://www.nj.gov/health/med_marijuana.shtml.

8:64-2.5 Physician certification

(a) A physician who is licensed and in good standing to practice medicine in this State and who is registered pursuant to N.J.A.C. 8:64-2.4 is eligible to authorize the medical use of marijuana by a qualifying patient pursuant to a certification the physician issues pursuant to N.J.A.C. 13:35-7A that contains:

1. The physician's name, address and telephone number;
2. The physician's license number as issued by the New Jersey Board of Medical Examiners;
3. A statement that the physician is licensed and in good standing to practice medicine in this State and possesses an active controlled dangerous substances registration issued by the Division of Consumer Affairs;
4. A statement that the physician has an ongoing responsibility for the assessment, care and treatment of the patient's debilitating medical condition;
5. The patient's name, address and telephone number;

6. The patient's diagnosis;

7. A statement that the patient's diagnosis qualifies as a debilitating medical condition that authorizes the patient to use medicinal marijuana pursuant to N.J.S.A. 24:6I-1 et seq.;

8. Written instructions to a registered qualifying patient and/or the patient's primary caregiver concerning the total amount of usable marijuana that may be dispensed to the patient, in weight, in a 30-day period, which amount shall not exceed two ounces.

i. If the physician does not specify an amount, the maximum amount that may be dispensed at one time is two ounces; and

9. The physician's certification that the physician has explained the potential risks and benefits of the medical use of marijuana to the qualifying patient and has documented the explanation in the patient's medical record.

i. The certification shall include the following statement:

"I have completed a comprehensive history and physical on this patient and have documented an assessment and treatment plan. I have provided education to the patient on the lack of scientific consensus for the use of medicinal marijuana, its sedative properties and the risk of addiction. The patient has provided informed consent. I will continue to follow this patient at a minimum of every three months and reassess the patient's debilitating medical condition and responses to treatment options."

(b) Prior to complying with (a) above, a registered physician seeking to authorize the medicinal use of marijuana by a patient who is a minor shall:

1. Obtain written confirmation from a physician trained in the care of pediatric patients and from a psychiatrist establishing, in their professional opinions, following review of the minor patient's medical record or examination of the minor patient, that the minor patient is likely to receive therapeutic or palliative benefits from the medical use of marijuana to treat or alleviate symptoms associated with his or her debilitating medical condition.

i. If the certifying physician is trained in the care of pediatric patients, he or she shall only be required to obtain written confirmation from a psychiatrist; and

2. Explain the potential risks and benefits of the medical use of marijuana to the minor patient and to the minor patient's parent, guardian or another person having legal custody of the minor patient. Such explanation shall be documented in the minor patient's medical record.

(c) A physician may issue multiple written instructions at one time authorizing the patient to receive a total of up to a 90-day supply, provided that the following conditions are met:

1. Each separate set of instructions shall be issued for a legitimate medical purpose by the physician, as provided in the Act and this chapter;

2. Each separate set of instructions shall indicate the earliest date on which an ATC may dispense the marijuana, except for the first dispensation if it is to be filled immediately; and

3. The physician has determined that providing the patient with multiple instructions in this manner does not create an undue risk of diversion or abuse.

(d) A physician may provide written instructions for the medical use of marijuana by electronic or other means directly to an alternative treatment center on behalf of a registered qualifying patient.

8:64-2.6 Application denial and/or revocation of a registry identification card

(a) The Department shall deny an application for a registry identification card that:

1. Contains false information, including, but not limited to, a false name, address, physician certification, date of birth, signature or photo identification; or

2. Fails to provide any of the information required by N.J.A.C. 8:64-2.2(a).

(b) The Department shall revoke a registry identification card upon finding that a registered individual:

1. Submitted false information to the Department;

2. Has a disqualifying conviction; or

3. Ceases to have his or her debilitating condition.

SUBCHAPTER 3. REGISTRY IDENTIFICATION CARDS FOR QUALIFYING PATIENTS AND PRIMARY CAREGIVERS

8:64-3.1 Registry identification cards

(a) Subject to N.J.A.C. 8:64-3.2, each registry identification card shall be valid for two years from its effective date unless revoked or surrendered.

(b) Each person to whom the Department has issued a registry identification card shall possess the registry identification card whenever he or she is in possession of medicinal marijuana.

(c) Registry identification cards shall contain:

1. The name, address, date of birth and Department-issued registry identification number of the qualifying patient;

2. If the qualifying patient has designated a registered primary caregiver, the name, address, date of birth and Department-issued registry identification number of the primary caregiver;

3. If the qualifying patient is a minor, the name, address, date of birth and Department-issued registry identification number of the parent, guardian or person who has legal custody of a qualifying patient who is a minor;

4. An indication as to whether the cardholder is the qualifying patient, a primary caregiver, a minor who is a qualifying patient or the parent, guardian or person who has legal custody of a qualifying patient who is a minor;

5. A photograph of the cardholder;

6. The effective date and expiration date of the registry identification card; and

7. The telephone number and web address of the Medicinal Marijuana Program of the Department, so that the authenticity of the registry identification card can be validated.

(d) Each person to whom the Department issues a registry identification card shall produce it to Department staff for inspection upon demand or pursuant to N.J.A.C. 8:64-4.4(b).

(e) Registry identification cards shall not be transferable.

(f) Registry identification cards are the property of the Department and shall be surrendered to Department staff upon issuance of a new registry identification card or following the revocation or denial of renewal of registration of the registrant.

1. The temporary registry identification card may be surrendered by United States mail to the Medicinal Marijuana Program or in person.

(g) A person may voluntarily surrender a registry identification card with a written notice stating that the person wishes to voluntarily surrender the registry identification card pursuant to N.J.A.C. 8:64-3.1(f)1.

1. The Department shall deem a voluntarily surrendered registry identification card to be null and void on the date the Department receives it.

8:64-3.2 Provisional approval of primary caregiver and temporary registry identification card

(a) Notwithstanding N.J.A.C. 8:64-3.1(a) above, the Department shall issue a temporary registry identification card to an applicant for issuance or renewal of registration as a primary caregiver pending the results of the applicant's criminal history record background check, provided the applicant otherwise satisfies the requirements for registration as a primary caregiver.

(b) A temporary registry identification card issued pursuant to this section shall be valid for no more than 30 days from its effective date.

(c) The primary caregiver shall surrender the temporary registry identification card to the Department within 10 days following the date that the Department approves or denies the primary caregiver's application.

i. The temporary registry identification card may be surrendered by United States mail to the Medicinal Marijuana Program or in person pursuant to N.J.A.C. 8:64-3.1(f)1.

8:64-3.3 Registry identification card replacement

If a qualifying registered patient or registered primary caregiver becomes aware of the theft, loss or destruction of his or her registry identification card, he or she shall notify the MMP in writing or by telephone within 24 hours after the discovery of the occurrence of the theft, loss or destruction.

The Department shall deem the initial registry identification card null and void and issue a replacement registry identification card with a new random identification number within five business days of the request provided the applicant continues to satisfy the requirements for registration.

(c) An applicant for issuance of a registration replacement card shall transmit to the Medicinal Marijuana Program a check or money order, or any other form of payment approved by the Medicinal Marijuana Program, that is made payable to the "Treasurer, State of New Jersey" in the amount of the required payment.

1. The Department shall place a 10-day hold on the issuance of a registry identification card for an application accompanied by a personal check.

(d) The fee to apply for issuance of a registry identification card replacement is \$10.00.

1. If an applicant can demonstrate eligibility to receive services under the New Jersey Medicaid program, receipt of current food stamp benefits, receipt of current New Jersey Temporary Disability Insurance benefits, Supplemental Security Income (SSI) benefits or Social Security Disability (SSD) benefits, then the fee to apply for a registry identification card replacement is \$5.00.

8:64-3.4 Marijuana obtained from designated ATC

(a) As a condition of issuance of a primary caregiver registration card, a primary caregiver shall execute a certification in which the primary caregiver agrees to comply with (b) and (c) below.

(b) The registered primary caregiver shall only obtain medicinal marijuana for the qualifying patient from the alternative treatment center designated on his or her registry identification card and shall not:

1. Grow or cultivate medicinal marijuana for the qualifying patient;

2. Purchase medicinal marijuana through non-permitted alternative treatment centers or vendors;
or

3. Obtain medicinal marijuana from or for other qualifying patients and/or primary caregivers.

(c) If the qualifying patient changes his or her designation of alternative treatment center, or makes a change to the information set forth on his or her registry identification card, both the qualifying patient and the primary caregiver shall surrender their registry identification cards to the Department and obtain new registry identification cards reflecting the change.

SUBCHAPTER 4. REPORTING REQUIREMENTS

8:64-4.1 Reporting requirements for qualifying patients, primary caregivers and physicians

(a) A qualifying patient or primary caregiver shall notify the Department of any change in the qualifying patient's name, address, alternative treatment center or physician within 10 days of such change.

(b) Each primary caregiver to whom the Department issues a registry identification card shall notify the Department of any change in the primary caregiver's name or address within 10 days of such change.

(c) A physician shall report a change in status of a qualifying patient's debilitating medical condition that may affect the continued eligibility of that patient as a qualifying patient within 10 days of such change.

(d) A qualifying patient or primary caregiver shall notify the Department of the theft, loss or destruction of his or her registry identification card within 24 hours after the discovery of the occurrence of the theft, loss or destruction.

(e) Failure of a registrant to make a notification required pursuant to this section shall result in the Department deeming the registration of the registrant to be null and void.

(f) Such other information as may be required by the Department in the administration and enforcement of this chapter.

8:64-4.2 Reporting requirements of the Department

(a) The Commissioner shall report to the Governor, and to the Legislature pursuant to section 2 of P.L. 1991, c. 164 (N.J.S.A. 52:14-19.1):

1. No later than October 1, 2011, one year after the effective date of N.J.S.A. 24:6I-1 et seq., on the actions taken to implement the provisions of the New Jersey Compassionate Use Medical Marijuana Act; and

2. Annually thereafter on the number of applications for registry identification cards, the number of qualifying patients registered, the number of primary caregivers registered, the nature of the debilitating medical conditions of the patients, the number of registry identification cards revoked, the number of alternative treatment center permits issued and revoked and the number of physicians providing certifications for patients.

(b) The reports shall not contain any identifying information of patients, caregivers or physicians.

8:64-4.3 Alternative treatment center reporting requirements

(a) The ATC shall collect and submit to the Department for each calendar year at least the following statistical data:

1. The number of registered qualified patients and registered primary caregivers;
2. The debilitating medical conditions of qualified patients;
3. Patient demographic data;
4. Program costs;
5. A summary of the patient surveys and evaluation of services; and
6. Such other information as the Department may require in the administration and enforcement of this chapter.

8:64-4.4 Confidentiality

(a) The Department shall maintain a confidential list of the persons to whom it issues registry identification cards.

(b) Individual names and other identifying information on the list, and information contained in any application form, or accompanying or supporting document shall be confidential, and shall not be considered a public record under P.L. 1963, c. 73 (N.J.S.A. 47:1A-1 et seq.) or P.L. 2001, c. 404 (N.J.S.A. 47:1A-5 et seq.) and shall not be disclosed except to:

1. Authorized employees of the Department and the Division of Consumer Affairs in the Department of Law and Public Safety as necessary to perform official duties of the Department and the Division, as applicable; and
2. Authorized employees of State or law enforcement agencies, only as necessary to verify that a person who is engaged in the suspected or alleged medical use of marijuana is lawfully in possession of a registry identification card.

SUBCHAPTER 5. ESTABLISHMENT OF ADDITIONAL DEBILITATING MEDICAL CONDITIONS

8:64-5.1 Review cycle for accepting petitions for additional qualifying debilitating medical condition

(a) The Commissioner shall take no action concerning the acceptance of petitions to approve other medical conditions or the treatment thereof as debilitating medical conditions pursuant to (b) below, before completing at least two annual reports required pursuant to N.J.A.C. 8:64-4.2.

1. The Department shall publish notice of an open period to accept petitions in the New Jersey Register.

(b) The process for review of petitions to approve other medical conditions or the treatment thereof as debilitating medical conditions pursuant to the definition at N.J.S.A. 24:6I-3 of “debilitating medical condition” at paragraph (5) shall include one review cycle each year, subject to (a) above.

(c) The beginning of each cycle shall be the first business day of the month.

(d) The Department shall accept petitions on the first business day of each cycle.

(e) The Department shall return to the petitioner a petition submitted in any month outside of the review cycle as not accepted for processing.

8:64-5.2 Panel to review petitions and make recommendations for identification and approval of additional debilitating medical conditions; membership; responsibilities

(a) The Commissioner shall appoint a review panel (panel) to make recommendations to the Commissioner regarding approval or denial of a petition submitted pursuant to this subchapter.

(b) The panel shall consist of not more than 15 health care professionals, among whom shall be:

1. The President of the Board of Medical Examiners or the President’s designee; and

2. Other physicians and non-physicians who are knowledgeable about the condition as to which the petition seeks approval;

i. Each physician appointed to the review panel shall be nationally board-certified in his or her area of specialty; and

3. At least three physicians appointed to the review panel shall have expertise in pain and symptom management.

(c) The majority of the panel shall be physicians.

(d) The Department shall convene the panel at least once per year to review petitions.

1. The panel may examine scientific and medical evidence and research pertaining to the petition, and may gather information, in person or in writing, from other parties knowledgeable about the addition of the debilitating medical conditions being considered.
2. The petitioner shall be given the opportunity to address the panel in person or by telephone.
3. The petitioner may request that his or her individual identifiable health information remain confidential.
4. The Department shall provide staff support to the panel and other administrative support.
5. The meetings will be considered open public meetings.

(e) The panel shall make a written recommendation to the Commissioner regarding approval or denial of the addition of a qualifying debilitating medical condition.

1. A quorum of the panel shall concur with the recommendation in order to be considered a final recommendation of the panel.
 - i. For purposes of this subsection, a majority of the members appointed and serving on the panel constitute a quorum.

8:64-5.3 Addition of qualifying debilitating medical condition

(a) In order for the petition to be accepted for processing, the petitioner shall send a letter by certified mail to the Medicinal Marijuana Program that contains the following information:

1. The extent to which the condition is generally accepted by the medical community and other experts as a valid, existing medical condition;
2. If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition;
3. The extent to which the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on activities of daily living;
4. The availability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition and/or the treatment thereof;
5. The extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition and/or the treatment thereof; and

6. Letters of support from physicians or other licensed health care professionals knowledgeable about the condition.

(b) Upon review of materials submitted pursuant to (a) above, the Commissioner shall make a final determination as to whether:

1. The petition is frivolous and, if so, to deny a petition without further review; or
2. The petition is bona fide and, if so, to accept the petition for further review.

(c) If the petition is accepted, the Department shall refer the written petition to the review panel established pursuant to N.J.A.C. 8:64-5.2.

(d) Within 60 days of the receipt of the petition, the review panel shall consider the petition in view of the factors identified in (a) above and shall issue an initial written recommendation to the Commissioner as to whether:

1. The medical condition and/or the treatment thereof is/are debilitating;
2. Marijuana is more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition and/or the treatment thereof; and
3. Other matters that the panel recommends that the Commissioner consider that are relevant to the approval or the denial of the petition.

(e) Upon receipt of the panel's recommendation, the Department shall:

1. Post the review panel's recommendations on the Department's website for 60-day public comment period;
2. Post notice of a public meeting no fewer than 10 days prior to the public meeting; and
3. Hold a public hearing within the 60-day public comment period.

(f) After the public hearing, the Department shall forward the comments made during the public hearing to the review panel for its consideration.

1. If, based on a review of the comments, the panel determines substantive changes should be made to its initial recommendation, the Commissioner shall deny the petition and the Department shall provide the petitioner with a copy of the initial recommendation and an explanation of the substantive changes and the petitioner may resubmit the petition to the Department at any time.
2. If, based on a review of the comments, the panel determines to recommend no changes to its initial recommendation, the initial recommendation shall be deemed a final recommendation and the Commissioner will make a final determination on the petition within 180 days of receipt of the petition.

8:64-5.4 Denial of a petition considered final agency action subject to judicial review

(a) If a condition in a petition is the same as, or is, as determined by the Commissioner, substantially similar to a condition of which the Commissioner has issued a previous determination denying approval as a debilitating medical condition pursuant to N.J.A.C. 8:64-5.3, the Commissioner may deny the new petition unless new scientific research supporting the request is brought forward.

(b) A decision of the Commissioner issued pursuant to N.J.A.C. 8:64-5.3 or this section is a final agency decision, of which jurisdiction and venue for judicial review are vested in the New Jersey Superior Court, Appellate Division.

SUBCHAPTER 6. ALTERNATIVE TREATMENT CENTER; PROCESS FOR DEPARTMENT REQUEST FOR APPLICATIONS

8:64-6.1 Notice of request for applications

(a) The Department may periodically request applications for the entities that seek authority to apply for a permit to operate an alternative treatment center.

(b) The Department shall announce a request for applications for entities that seek authority to apply for a permit to operate an alternative treatment center by publishing a notice of request for applications in the New Jersey Register, which notice shall:

1. Include eligibility criteria and a statement of the general criteria by which the Department shall evaluate applications; or

2. Identify such criteria by reference to the provisions of the Act and this chapter.

(c) A notice of request for applications shall establish weights for the criteria the Department shall use to evaluate applications and select successful applicants, and shall identify the process for obtaining application materials and the deadline for receipt of applications.

(d) The Department shall not consider an application that is submitted after the due date specified in, or that is not submitted in response to, a published notice of request for applications.

8:64-6.2 Criteria for identifying alternative treatment centers

(a) A selection committee shall evaluate applications on the following general criteria:

1. Submission of mandatory organizational information;

2. Documented involvement of a New Jersey acute care general hospital in the ATC's organization;

3. Ability to meet overall health needs of qualified patients and safety of the public;

4. Community support and participation; and
5. Ability to provide appropriate research data.

(b) The applicant's failure to address all applicable criteria and measures, to provide requested information or to present truthful information in the application process shall result in the application being considered non-responsive and shall be considered an unsuccessful application pursuant to N.J.A.C. 8:64-6.4.

8:64-6.3 Verification of applicant information

(a) The Department may verify information contained in each application and accompanying documentation by:

1. Contacting the applicant by telephone, mail or electronic mail;
2. Conducting an onsite visit; and
3. Requiring a face-to-face meeting and the production of additional identification materials if proof of identity is uncertain.

8:64-6.4 Award decisions

(a) The Department shall convene a selection committee to evaluate and score each application.

1. The selection committee shall evaluate and score each application based on the quality of the applicant's submission, and its conformity to the notice of request for applications published in the New Jersey Register.

(b) The Department shall issue a written notice of its award decision to successful applicants.

1. A written notice of denial of an application (non-selection) is a final agency decision, of which jurisdiction and venue for judicial review are vested in the New Jersey Superior Court, Appellate Division.

(c) The record for review shall be the application and any attached supporting documents excluding information deemed exempt pursuant to N.J.S.A. 47:1A-1 et seq.

8:64-6.5 Request for application; fee

(a) As a condition of Department consideration of an application submitted in response to a request for applications issued pursuant to N.J.A.C. 8:64-6.1, applicants shall submit a fee of \$20,000 for each application.

1. The applicant shall submit the fee with the application, in the form of two checks payable to the “Treasurer, State of New Jersey,” one of which is for \$2,000 and the other of which is for \$18,000.

2. If an application is unsuccessful, the Department shall retain the \$2,000 fee and shall destroy the other check for \$18,000.

3. Application fees of successful applicants are non-refundable.

(b) Applicants may submit an application for an ATC permit for one or more regions, but must submit a separate application for each region.

SUBCHAPTER 7. GENERAL PROCEDURES AND STANDARDS APPLICABLE TO ALTERNATIVE TREATMENT CENTERS

8:64 -7.1 Permit application procedures and requirements for alternative treatment centers

(a) An applicant for an ATC permit shall submit an application form and the fees required by N.J.A.C. 8:64-6.5, as well as all other required documentation on forms obtained from the permitting authority or on the Department’s website at www.state.nj.us/health.

(b) In addition to the application, the documentation shall include the following:

1. The legal name of the corporation, a copy of the articles of incorporation and by-laws, evidence that the corporation is in good standing with the New Jersey Secretary of State and a certificate certified under the seal of the New Jersey State Treasurer as to the legal status of the business entity; and

2. Each applicant, including the information for each subcontractor or affiliate to the entity named in the application shall submit:

i. Documentation of a valid Business Registration Certificate on file with the New Jersey Department of the Treasury, Division of Revenue;

ii. A list of the names, addresses and dates of birth of the proposed alternative treatment center’s employees, principal officers, directors, owners and board members, including service on any other ATC board;

iii. A list of all persons or business entities having direct or indirect authority over the management or policies of the ATC;

A list of all persons or business entities having five percent or more ownership in the ATC, whether direct or indirect and whether the interest is in profits, land or building, including owners of any business entity that owns all or part of the land or building;

The identities of all creditors holding a security interest in the premises, if any;

- vi. The by-laws and a list of the members of the ATC's medical advisory board;
 - vii. Evidence of compliance with N.J.A.C. 8:21-3A.18 with regards to inspection and auditing of the ATC;
 - viii. Evidence of the principals, directors, board members, owners and employees to cooperate with a criminal history record background check pursuant to N.J.A.C. 8:64-7.2, including payment of all applicable fees associated with the criminal history record background check, which shall be paid by the ATC or the individual;
 - ix. The mailing and physical addresses of the proposed alternative treatment center;
 - x. Written verification of the approval of the community or governing body of the municipality in which the alternative treatment center is or will be located;
 - xi. Evidence of compliance with local codes and ordinances including, but not limited to, the distance to the closest school, church, temple or other places used exclusively for religious worship or a playground, park or child day care facility from the alternative treatment center;
 - xii. A legible map or maps of the service areas by zip code to be served by the alternative treatment center showing the location of the alternative treatment center; and
 - xiii. Text and graphic materials showing the exterior appearance of the ATC and its site compatibility with commercial structures already constructed or under construction within the immediate neighborhood.
- (c) The applicant's failure to provide requested information or to present truthful information in the application process shall result in a decision to not accept the application for processing. The Department shall notify the applicant of this decision and the filing fee shall be nonrefundable.

8:64-7.2 Criminal history record background checks for principals, directors, board members, owners and employees

- (a) Each principal, director, board member, owner and employee shall provide written consent to submit to a criminal history record background check pursuant to N.J.S.A. 24:6I-4 and shall comply with procedures established by the Division of State Police pursuant to N.J.A.C. 13:59 for obtaining readable fingerprint impressions.
- (b) The Department shall deny registration of a principal, director, board member, owner and employee who:
 - 1. Refuses to consent to, or cooperate in, the securing of a criminal history record background check; or
 - 2. Fails to provide any of the information required by (a) above.

(c) Subject to N.J.A.C. 8:64-7.1, in considering any application for a permit for an ATC, the Department shall consider, at a minimum, the following factors in reviewing the qualifications of principals, directors, board members and owners applying for a permit as an alternative treatment center:

1. Any convictions of the applicant under any Federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of a controlled substance;
2. Any felony conviction under Federal laws, or the equivalent conviction under state or local laws;
3. The applicant's past experience in the manufacturing or distribution of drugs or controlled substances;
4. The furnishing of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;
5. Suspension or revocation by Federal, state or local government of any registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
6. Compliance with license and/or registration requirements under any previously granted license or registration, if any;
7. Compliance with requirements to maintain and/or make available to the Department or Federal or law enforcement officials those records required by this subchapter; and
8. Any other factors or qualifications the Department considers relevant to and consistent with ensuring public health and safety.

(d) In considering any application for a permit for an ATC, the Department shall consider, at a minimum, the factors at (f) below in reviewing the qualifications of an employee who has a disqualifying conviction. The Department shall issue written notice to the employee identifying the conviction that constitutes the basis for the denial of the application.

(e) The Department shall not disqualify an applicant from serving as an officer, director, board member or employee of an alternative treatment center as a result of a disqualifying conviction if the applicant affirmatively demonstrates to the Department by clear and convincing evidence that the applicant is rehabilitated.

(f) In determining whether an applicant has demonstrated clear and convincing evidence of rehabilitation, the Department shall consider the following factors:

1. The nature and responsibility of the position that the convicted individual would hold, has held or currently holds;

2. The nature and seriousness of the crime or offense;
3. The circumstances under which the crime or offense occurred;
4. The date of the crime or offense;
5. The age of the individual when the crime or offense was committed;
6. Whether the crime or offense was an isolated or repeated incident;
7. Any social conditions that may have contributed to the commission of the crime or offense;
and
8. Any evidence of rehabilitation, including good conduct in prison or in the community, counseling or psychiatric treatment received, acquisition of additional academic or vocational schooling, successful participation in correctional work-release programs or the recommendation of those who have had the individual under their supervision.

(g) In accordance with the provisions of the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq., and the Uniform Administrative Procedures Rules, N.J.A.C. 1:1, any individual disqualified from owning or operating an alternative treatment center shall be given an opportunity to challenge the accuracy of the disqualifying criminal history record prior to being permanently disqualified from participation.

8:64-7.3 Verification of applicant information

(a) The Department may verify information contained in each selected application and accompanying documentation by:

1. Contacting the applicant by telephone, mail or electronic mail;
2. Conducting an onsite visit;
3. Requiring a face-to-face meeting and the production of additional identification materials if proof of identity is uncertain; and
4. Requiring additional relevant information as the Department deems necessary.

8:64-7.4 Submission to the jurisdiction of the State

(a) Prior to the issuance of any permit to an ATC, every principal officer, owner, director and board member of the ATC must execute a certification stating that he or she submits to the jurisdiction of the courts of the State of New Jersey and agrees to comply with all the requirements of the laws of the State of New Jersey pertaining to the Medicinal Marijuana Program. Copies of such certifications shall be maintained by the ATC at the ATC's principal office, which shall be located within the State of New Jersey.

(b) Failure to establish or maintain compliance with the requirements of this section shall constitute sufficient cause for the denial, suspension or revocation of any permit issued to an ATC.

8:64-7.5 Permit issuance; nontransferability of permit

(a) Upon approval of the application for an ATC permit and payment of the required fee, the permitting authority may conduct an onsite assessment of the alternative treatment center to determine if the facility adheres to the Act and this chapter.

(b) An ATC permit is not assignable or transferable without Department approval, and it shall be immediately null and void if the alternative treatment center ceases to operate, if the alternative treatment center's ownership changes or if the alternative treatment center relocates.

(c) This chapter does not prohibit a political subdivision of this State from limiting the number of alternative treatment centers that may operate in the political subdivision or from enacting reasonable local ordinances applicable to alternative treatment centers.

8:64-7.6 Permit required; term; posting

(a) No person shall operate an alternative treatment center without a Department-issued permit.

(b) The permit holder shall have responsibility for the management, operation and financial viability of the alternative treatment center.

(c) A permit shall be in effect for a period of one year and shall be renewable thereafter subject to N.J.A.C. 8:64-7.7.

(d) The permit holder shall post the permit in a conspicuous location on the premises of each permitted alternative treatment center.

8:64-7.7 Renewal of alternative treatment center permit

(a) 60 days prior to the expiration of an ATC permit, an ATC that seeks to renew the permit shall submit to the permitting authority an application for renewal of the permit with all required documentation and the required fees pursuant to N.J.A.C. 8:64-7.10.

1. An ATC shall update and ensure the correctness of all information submitted in previous applications for a permit or otherwise on file with the Department.

2. Failure to provide correct and current up-to-date information is grounds for denial of application for renewal of the permit.

(b) The permit period for an alternative treatment center shall be from January 1st (or the date of approval of the application, if later) through December 31st of a given year.

(c) The Department may deny the application for renewal of the permit if the applicant is noncompliant with applicable local rules, ordinances and/or zoning requirements, or if the Department determines that the facility is in violation of the Act or this chapter.

(d) The Department may issue and/or renew a permit subject to conditions set forth in this chapter.

8:64-7.8 Amendments to alternative treatment center permit

(a) An ATC shall submit to the Department an application for an amended permit, together with fees, if applicable, pursuant to N.J.A.C. 8:64-7.10, prior to any:

1. Change of the alternative treatment center's location;
2. Change of the alternative treatment center's ownership;
3. Change of the alternative treatment center's name;
4. Change in the alternative treatment center's capacity; or
5. Modification of or addition to the alternative treatment center's physical plant.

(b) The alternative treatment center shall submit the application to the permitting authority no later than 30 business days prior to the change.

8:64-7.9 ATC location; satellite sites prohibited

(a) An ATC shall conduct all operations authorized by the Act at the address(es) identified on the permit issued by the Department. The Department shall not authorize or permit dispensing operations at any satellite locations. However, an ATC, as approved by the Department, may cultivate marijuana at a location separate from the location where the ATC shall dispense the marijuana, but both locations shall be within the same region.

1. The ATC permit shall identify the physical address(es) of the ATC site(s).
2. The Department shall conduct an onsite assessment of each proposed ATC site prior to permit issuance.

(b) This chapter does not prohibit a political subdivision of this State from limiting the number of ATCs that may operate in the political subdivision or from enacting reasonable local ordinances applicable to ATCs.

8:64-7.10 Fees

(a) The following fees apply:

1. The annual fee for the review of a permit renewal application for an alternative treatment center is \$20,000;
2. The fee for a change of location of the alternative treatment center is \$10,000;
3. The fee for a change of capacity or any physical modification or addition to the facility is \$2,000; and
4. The fee for the transfer of ownership of a permit is \$20,000.

(b) Fees shall be paid by certified check, money order or any other form of payment approved by the Medicinal Marijuana Program, and made payable to the “Treasurer, State of New Jersey.”

8:64- 7.11 Waiver

The Commissioner, or the Commissioner's designee, in accordance with the general purposes and intent of N.J.S.A. 24:6I-1 et seq. and this chapter, may waive a requirement regarding the operations of the ATC, if in the Commissioner's, or the Commissioner's designee's, determination, such a waiver is necessary to achieve the purpose of the Act and provide access to patients who would otherwise qualify for the use of medicinal marijuana to alleviate suffering from debilitating medical conditions, and does not create a danger to the public health, safety or welfare.

SUBCHAPTER 8. ALTERNATIVE TREATMENT CENTER IDENTIFICATION CARDS

8:64-8.1 Department issuance of identification cards; expiration

(a) The Department shall issue each qualified principal officer, director, owner, board member and employee of an alternative treatment center an ATC identification card within 10 business days of the date the Department receives a completed Department-approved application form with required documents including a copy of a New Jersey driver’s license or other State-issued photo identification.

(b) Principal officers, directors, owners, board members and employees shall not begin working at the registered ATC before the Department issues an ATC identification card and the card is in the registrant’s physical possession.

(c) ATC identification cards issued to principal officers, directors, owners, board members and employees of an alternative treatment center expire one year after the date of issuance.

(d) ATC identification cards shall contain:

1. The name of the individual;
2. The name of the ATC;

3. The date of issuance and expiration; and
4. A photograph of the cardholder.

8:64-8.2 Notice to Department when employment or affiliation ceases; expiration of an ATC identification card

(a) The alternative treatment center shall notify the permitting authority within 10 business days of the date that a principal officer, director, board member or employee ceases to work at or be affiliated with the alternative treatment center.

1. The alternative treatment center identification card of a principal officer, director, board member or employee expires immediately when a person ceases to work at or be affiliated with the alternative treatment center.

8:64-8.3 Surrender of ATC identification cards

(a) The alternative treatment center shall surrender to the permitting authority the ATC identification card of any principal officer, director, board member or employee who is no longer eligible to validly use or possess the card for any reason.

(b) The alternative treatment center shall document the reason the person is no long eligible to validly use or possess the card in the alternative treatment center's personnel files and shall submit a copy of the documentation to the permitting authority.

SUBCHAPTER 9. ALTERNATIVE TREATMENT CENTER GENERAL ADMINISTRATIVE REQUIREMENTS FOR ORGANIZATION AND RECORDKEEPING

8:64-9.1 Alternative treatment centers policies, procedures and records

(a) Each alternative treatment center shall develop, implement and maintain on the premises an operations manual that addresses, at a minimum, the following:

1. Procedures for the oversight of the alternative treatment center;
2. Procedures for safely growing and dispensing medicinal marijuana;
3. Procedures to ensure accurate recordkeeping, including inventory protocols to ensure that quantities cultivated do not suggest redistribution;
4. Employee security policies;
5. Safety and security procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;

6. Personal safety and crime prevention techniques;
 7. The alternative treatment center's alcohol, smoke and drug-free workplace policies; and
 8. A description of the ATCs:
 - i. Hours of operation and after hour contact information;
 - ii. Fee schedule and availability of sliding fee scales based on income;
 - iii. Expectations of onsite personnel in maintaining confidentiality and privacy of the operations and clients of the ATC;
 - iv. Criteria for involuntary disenrollment from the ATC's list of qualifying patients pursuant to unacceptable behavior and appeal process; and
 - v. Registered qualifying patient's assumption of risk in complying with ATC registration policies.
- (b) The permit holder shall ensure that the operating manual of the alternative treatment center is available for inspection by the Department, upon request.

8:64-9.2 Prohibitions applicable to alternative treatment centers

- (a) Consumption of marijuana and/or alcohol on, or public areas in the vicinity of, the premises of an ATC is prohibited.
- (b) Consumption of food and/or beverages by qualifying patients and primary caregivers on the premises of an ATC is prohibited.
- (c) Sales of food, beverages, alcohol or tobacco on the premises of an ATC is prohibited.
- (d) Entry onto the premises of an ATC by a person who is under the age of 18 is prohibited unless he or she is a registered, qualifying patient accompanied by his or her primary caregiver and both are in possession of a registry identification card.

8:64-9.3 Organization and recordkeeping requirements applicable to alternative treatment centers

- (a) The ATC shall maintain the following administrative records, as applicable:
 1. Organization charts consistent with the job descriptions in N.J.A.C. 8:64-9.4(a)6;
 2. A general description of any facilities to be used as an ATC and a floor plan identifying the square footage available and descriptions of the functional areas of the ATC;

3. If applicable, a projection of the number of qualified patients to be served by the ATC;
4. Projections by the ATC for a two-year period of the ratio of registered qualifying patients-to-demand for usable marijuana and procedures by which the ATC shall periodically review these ratios for consistency with actual patient demand ratios;
5. Procedures by which the ATC shall ensure the availability of medicinal marijuana in accordance with projected and actual demand ratios;
6. The name, medical license number, résumé and contact address of the medical director of the ATC, if applicable;
7. The name, résumé and address of the chief administrative officer of the ATC; and
8. The standards and procedures by which the ATC determines the price it charges for usable marijuana and a record of the prices charged.

(b) ATCs shall maintain business records including, manual or computerized records of assets and liabilities, monetary transactions, various journals, ledgers and supporting documents, including agreements, checks, invoices and vouchers that the ATC keeps as its books of accounts.

(c) Business records include sales records that indicate the name of the qualifying patient or primary caregiver to whom marijuana is distributed, the quantity, strength and form and the cost of the product.

(d) The bylaws of the ATC and its affiliates or sub-contractors shall contain provisions relative to the disposition of revenues and receipts as may be necessary and appropriate to establish and maintain its nonprofit status, as applicable.

8:64-9.4 Personnel records

(a) Each alternative treatment center shall maintain a personnel record for each employee, principal officer, director, board member, agent or volunteer that includes, at a minimum, the following:

1. An application for employment or to volunteer;
2. A copy of his or her current ATC identification card and a copy of his or her driver's license or other State-issued photo identification card;
3. Documentation of the certification of each principal officer, director or board member stating that he or she submits to the jurisdiction of the courts of the State of New Jersey and agrees to comply with all the requirements of the laws of the State of New Jersey pertaining to the Medicinal Marijuana Program;

4. Documentation of verification of references;
5. Documentation of background checks;
6. The job description or employment contract that include duties, authority, responsibilities, qualifications and supervision;
7. Documentation of all required training, including training regarding privacy and confidentiality requirements, and the signed statement of the individual indicating the date, time and place he or she received said training and the topics discussed, including the name and title of presenters;
8. Documentation of periodic performance evaluations;
9. A record of any disciplinary action taken; and
10. Documentation of the results of drug tests authorized pursuant to this chapter.

(b) The permit holder shall maintain personnel records for at least 12 months after termination of the individual's affiliation with the alternative treatment center, for the purposes of this rule.

1. Permit holders are responsible for maintaining personnel records for all other business purposes in accordance with their business practice.

8:64-9.5 Alternative treatment center employee training

(a) Each alternative treatment center shall either:

1. Develop, implement and maintain on the premises an onsite training curriculum; or
2. Enter into contractual relationships with outside resources capable of meeting employee, agent and volunteer training needs.

(b) Each employee, agent or volunteer, at the time of his or her initial appointment, shall receive, as a minimum, training in the following:

1. Professional conduct, ethics and State and Federal laws regarding patient confidentiality;
2. Informational developments in the field of medical use of marijuana;
3. The proper use of security measures and controls that have been adopted; and
4. Specific procedural instructions for responding to an emergency, including a robbery or workplace violence.

8:64-9.6 Alcohol and drug-free workplace policy and smoke free workplace policy; employee assistance program

(a) The ATC shall establish, implement and adhere to a written alcohol, drug-free and smoke-free workplace policy.

(b) The permit holder shall ensure that the policy is available to the Department upon request.

(c) The policy shall address the following:

1. The policy's inapplicability if an employee, who is also a qualifying patient, fails the drug test solely because of the presence of marijuana in a confirmed positive test result;

2. The ATC's policy providing for probable cause substance abuse testing consistent with applicable State and Federal law; and

3. Opportunities for assistance of an employee with a substance abuse problem.

(d) The ATC shall maintain a contract with an approved New Jersey employee assistance program.

8:64-9.7 Security

(a) Each alternative treatment center shall provide effective controls and procedures to guard against theft and diversion of marijuana including, when appropriate, systems to protect against electronic records tampering.

(b) At minimum, each alternative treatment center shall:

1. Install, maintain in good working order and operate a safety and security alarm system at its authorized physical address(es) that will provide suitable protection 24 hours a day, seven days a week against theft and diversion and that provides, at a minimum:

i. Immediate automatic or electronic notification to alert State or local police agencies to an unauthorized breach of security at the alternative treatment center; and

ii. A backup system that activates immediately and automatically upon a loss of electrical support and that immediately issues either automatically or electronic notification to State or local police agencies of the loss of electrical support;

2. Implement appropriate security and safety measures to deter and prevent the unauthorized entrance into areas containing marijuana and the theft of marijuana;

3. Implement security measures that protect the premises, registered qualifying patients, registered primary caregivers and principal officers, directors, board members and employees of the alternative treatment center;

4. Establish a protocol for testing and maintenance of the security alarm system;
5. Conduct maintenance inspections and tests of the security alarm system at the ATC's authorized location at intervals not to exceed 30 days from the previous inspection and test and promptly implement all necessary repairs to ensure the proper operation of the alarm system;
6. In the event of a failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours:
 - i. Notify the Department pursuant to N.J.A.C. 8:64-9.8; and
 - ii. Provide alternative security measures approved by the Department or close the authorized physical addresses impacted by the failure or malfunction until the security alarm system is restored to full operation;
7. Keep access from outside the premises to a minimum and ensure that access is well controlled;
8. Keep the outside areas of the premises and its perimeter well lighted.
 - i. Exterior lighting must be sufficient to deter nuisance and criminal activity and facilitate surveillance and must not disturb surrounding businesses or neighbors;
9. Provide law enforcement and neighbors within 100 feet of the ATC with the name and phone number of a staff person to notify during and after operating hours to whom they can report problems with the establishment;
10. Equip interior and exterior premises with electronic monitoring, video cameras and panic buttons.
 - i. A video surveillance system shall be installed and operated to clearly monitor all critical control activities of the ATC and shall be in working order and operating at all times. The ATC shall provide two monitors for remote viewing via telephone lines in State offices. This system shall be approved by the MMP prior to permit issuance.
 - ii. The original tapes or digital pictures produced by this system shall be stored in a safe place with a 30-day archive;
11. Limit entry into areas where marijuana is held to authorized personnel;
12. Consistently and systematically prevent loitering, that is, the presence of persons who are not on-duty personnel of the ATC and who are not ATC registrants engaging in authorized ATC-dispensary activity; and
13. Provide onsite parking.

8:64-9.8 Reportable events

(a) An ATC, upon becoming aware of a reportable loss, discrepancies identified during inventory, diversion or theft, whether or not the medicinal marijuana, funds or other lost or stolen property is subsequently recovered and/or the responsible parties are identified and action taken against them, shall:

1. Immediately notify appropriate law enforcement authorities by telephone; and
2. Notify the permitting authority immediately but no later than three hours after discovery of the event.

(b) The ATC shall notify the permitting authority within 24 hours by telephone at (609) 826-4935, followed by written notification within 10 business days, of any of the following:

1. An alarm activation or other event that requires response by public safety personnel;
2. A breach of security;
3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and
4. Corrective measures taken, if any.

(c) An ATC shall maintain documentation in an auditable form for a period of at least two years after the reporting of an occurrence that is reportable pursuant to this section.

8:64-9.9 Inventory

(a) Each alternative treatment center, at a minimum, shall:

1. Conduct an initial comprehensive inventory of all medicinal marijuana, including marijuana available for cultivation and usable marijuana available for dispensing, seedling to mature marijuana plants and unusable marijuana, at the authorized location on the date the alternative treatment center first engages in the production or dispensing of medicinal marijuana;

i. If an alternative treatment center commences business with no medicinal marijuana on hand, the ATC shall record this fact as the initial inventory;

ii. Marijuana is deemed to be “on hand” if it is in the possession of or under the control of an ATC;

iii. An inventory shall include damaged, defective, expired or adulterated marijuana awaiting disposal, including the name, the quantity and the reasons for which the ATC is maintaining the marijuana;

2. Establish inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of cultivating, stored, usable and unusable marijuana;

3. Conduct a monthly inventory of cultivating, stored, usable and unusable marijuana;
 4. Conduct a comprehensive annual inventory at least once every year from the date of the previous comprehensive inventory;
 5. Promptly transcribe inventories taken by use of an oral recording device; and
 6. If marijuana is disposed of, maintain a written record of the date, the quantity disposed of, the manner of disposal and the persons present during the disposal, with their signatures;
 - i. ATCs shall keep disposal records for at least two years.
- (b) The record of an inventory conducted pursuant to this section shall include, at a minimum, the date of the inventory, a summary of the inventory findings and the name, signature and title of the individuals who conducted the inventory.

8:64-9.10 Destruction of marijuana; recordkeeping

(a) If a permit to operate an alternative treatment center expires without being renewed or is revoked, the permit holder shall:

1. Destroy or dispose of all unused marijuana or surplus inventory in its possession by providing it to the New Jersey State Police for destruction;
2. Create and maintain a written record of the disposal of marijuana that is identified for disposal by the alternative treatment center and weigh and inventory prior to destruction; and
3. Discontinue production of marijuana.

(b) Within 10 business days after destroying the marijuana, the holder of the permit shall notify the Department, in writing, of the amount of marijuana destroyed.

(c) A qualifying patient or a primary caregiver in possession of unused, unadulterated marijuana that is no longer needed for the qualifying patient's medical use shall dispose of the marijuana by:

1. Returning it to an alternative treatment center; or
 2. Transporting it or arranging for pickup by State or local police;
- i. The person or entity submitting marijuana for disposal pursuant to this section shall present a valid registry identification card and a New Jersey driver's license or other State-issued photographic identification to the ATC or the police, as applicable.

SUBCHAPTER 10. PLANT CULTIVATION AUTHORIZED CONDUCT

8:64-10.1 Indoor cultivation site; limitation of inventory

(a) An alternative treatment center shall:

1. Produce marijuana only at the indoor cultivation site and area authorized in the permit;
2. Sell marijuana with a consistent unit price and label and without volume discounts;
3. Limit its inventory of usable marijuana and seeds to reflect current patient needs as identified by the number of patients registered with the alternative treatment center;
4. Comply with applicable laws and rules of the New Jersey Department of Agriculture and attendant inspection and enforcement activities; and
5. Comply with N.J.A.C. 8:21-3A.8 and 9.

8:64-10.2 Accessibility of marijuana storage areas

(a) An ATC shall limit access to medicinal marijuana storage areas to the absolute minimum number of specifically authorized employees.

1. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests or visitors to be present in or pass through medicinal marijuana storage areas, the ATC shall provide for adequate observation of the area by an employee whom the permit holder specifically authorized by policy or job description to supervise the activity.

(b) Each alternative treatment center shall ensure that the storage of usable marijuana prepared for dispensing to patients is in a locked area with adequate security.

1. For purposes of this section, “adequate security,” at a minimum, shall be assessed, established and maintained based on:

- i. The quantity of usable marijuana kept on hand;
- ii. The alternative treatment center’s inventory system for tracking and dispensing usable marijuana;
- iii. The number of principal officers, directors, board members, agents, volunteers or employees who have or could have access to the usable marijuana;
- iv. The geographic location of the alternative treatment center and its associated environmental characteristics, such as the remoteness of the facility from local populations and the relative level of crime associated with the area;
- v. The scope and sustainability of the security alarm system; and

vi. The findings of root cause analyses of any breaches of security and/or inventory discrepancies for usable marijuana at that location.

8:64-10.3 Recordkeeping

(a) An ATC shall maintain records identifying the source of each ingredient used in the manufacture or processing of marijuana.

1. Records identifying the source of each ingredient shall include the date of receipt of the ingredient, vendor's name and address, the name of the ingredient and the vendor's batch number, lot number and control number or other identifying symbol, if any, used by the vendor to identify the ingredient, as well as the grade and quantity of said ingredient;

(b) An alternative treatment center shall meet good manufacturing practices at N.J.A.C. 8:21 for the production of marijuana lozenges or topical formulations;

(c) An alternative treatment center shall maintain a system of recordkeeping that will permit the identification for purposes of recall of any lot or batch of medicinal marijuana from registered qualifying patients when such is found to be unsafe for use.

1. As part of this system, the alternative treatment center shall ensure that the container of any drug at any stage in the process of manufacture and distribution bears an identifying name and number, commonly known as a "lot" or "control" number, to make it possible to determine the complete manufacturing history of the package of the marijuana.

8:64-10.4 Physical plant

(a) All cultivation of marijuana shall take place in an enclosed, locked facility.

(b) Access to the enclosed, locked facility is limited to a cardholder who is a principal officer, director, board member or employee of an ATC when acting in his or her official capacity.

8:64-10.5 Storage of marijuana

Medicinal marijuana that is prepared for distribution shall be stored securely in compliance with 21 CFR 1301.72.

8:64-10.6 Informational policies; labeling

(a) An ATC shall establish and implement policies that require the ATC to maintain information about the different potencies, effects and forms for each usable marijuana package that the ATC prepares to dispense to registered qualifying patients and their caregivers.

(b) The ATC shall place a legible, firmly affixed label containing the information specified in (c) below on each package of medicinal marijuana it prepares to dispense and shall not dispense medicinal marijuana if the package does not bear the label.

(c) The label required pursuant to (b) above shall contain the following:

1. The name and address of the alternative treatment center that produced the medicinal marijuana;
2. The quantity of the medicinal marijuana contained within the package;
3. The date that the ATC packaged the content;
4. A sequential serial number, lot number and bar code to identify lot associated with manufacturing and processing;
5. The cannabinoid profile of the medicinal marijuana contained within the package, including THC level not to exceed 10 percent;
6. Whether the medicinal marijuana is of the low, medium or high strength strain;
7. A statement that the product is for medical use by a qualifying patient and not for resale;
8. A list of any other ingredients besides medicinal marijuana contained within the package;
9. The date of dispensing to the qualifying patient or primary caregiver; and
10. The qualifying patient's name and registry identification card number.

(d) Labeling shall be clear and truthful in all respects and shall not be false or misleading.

1. A label containing any statements about the product other than those specified in this chapter shall contain the following statement prominently displayed, and in boldface type: **“This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”**

(e) The ATC shall file the form of label with the permitting program.

8:64-10.7 Strains of marijuana

- (a) An ATC shall cultivate no more than three strains of medicinal marijuana.
- (b) Strains of marijuana authorized for cultivation shall be labeled as one of the following strengths: low, medium or high.
- (c) The maximum THC content of any sold product shall not exceed 10 percent.

8:64-10.8 Processing and packaging of marijuana

(a) An ATC shall process marijuana in a safe and sanitary manner to protect registered qualifying patients from adulterated marijuana and shall process the dried leaves and flowers of the female marijuana plant only, which shall be:

1. Well cured and free of seeds and stems;
2. Free of dirt, sand, debris or other foreign matter; and
3. Free of mold, rot or other fungus or bacterial diseases.

(b) Medicinal marijuana shall be packaged in a secure area connected to the production area.

1. The dried product shall be handled on food grade stainless steel benches (tables).
2. Proper sanitation shall be maintained.
3. Proper rodent/bird exclusion practices shall be employed at all times.

(c) Each package of usable marijuana, at a minimum, shall:

1. Contain no more than ¼ ounce of marijuana or equivalent dose dependent on form;
2. Bear a label that complies with N.J.A.C. 8:64-10.7; and
3. Be in a closed container that holds no more than ¼ ounce and sealed, so that the package cannot be opened, and the contents consumed, without the seal being broken.

(d) Once a package is sealed, the ATC shall not open the package except for quality control. Once the seal is broken at an ATC, the marijuana is deemed unusable.

(e) An ATC shall package or dispense medicinal marijuana only in:

Dried form for direct dispensing to qualifying patients;

Oral lozenges for direct dispensing to qualifying patients; or

Topical formulations for direct dispensing to qualifying patients.

(f) The ATC shall submit the label to the MMP for approval and record. The MMP shall provide a copy of the label to authorized employees of State or law enforcement agencies, as necessary to perform official duties of that department and that division.

8:64-10.9 Pesticide use prohibited

Inasmuch as there are no pesticides authorized for use on marijuana, and the unauthorized application of pesticides is unlawful, an ATC shall not apply pesticides in the cultivation of marijuana.

8:64-10.10 Organic certification

Marijuana for medical use may be labeled “organic” if the registered dispensary is certified as being in compliance with the United States Department of Agriculture certification requirements applying to organic products.

8:64-10.11 Secure transport

(a) An ATC that is authorized by permit to cultivate medicinal marijuana at one location and to dispense it at a second location shall transport only usable marijuana from the cultivation site to the dispensing site according to a delivery plan submitted to the Department.

(b) An ATC shall staff each transport vehicle with a delivery team consisting of at least two registered ATC employees.

1. At least one delivery team member shall remain with the vehicle at all times that the vehicle contains medicinal marijuana.

2. Each delivery team member shall have access to a secure form of communication with the ATC, such as a cellular telephone, at all times that the vehicle contains medicinal marijuana.

3. Each delivery team member shall possess his or her ATC employee identification card at all times and shall produce it to Department staff or law enforcement officials upon demand.

(c) Each transport vehicle shall be equipped with a secure lockbox or locking cargo area, which shall be used for the sanitary and secure transport of medicinal marijuana.

(d) Each ATC shall maintain current commercial automobile liability insurance on each vehicle used for transport of medicinal marijuana in the amount of one million dollars per incident.

(e) Each ATC shall ensure that vehicles used to transport medicinal marijuana bear no markings that would either identify or indicate that the vehicle is used to transport medicinal marijuana.

(f) Each ATC shall ensure that transports are completed in a timely and efficient manner. A transport vehicle shall proceed from the departure point where the medicinal marijuana is loaded directly to the destination point where the medicinal marijuana is unloaded without intervening stops or delays.

(g) Each ATC shall maintain a record of each transport of medicinal marijuana in a transport logbook. For each transport, the logbook shall record:

1. The date and time that the transport began and ended;

2. The names of the ATC employees comprising the delivery team;
3. The weight of the medicinal marijuana transported;
4. The lot number of the medicinal marijuana, the name of the strain and whether it is high, medium or low potency; and
5. The signatures of the ATC employees comprising the delivery team.

(h) An ATC shall report any vehicle accidents, diversions, losses, or other reportable events that occur during transport to the permitting authority in accordance with N.J.A.C. 8:64-9.8.

8:64-10.12 Home delivery prohibited

An alternative treatment center shall not deliver marijuana to the home or residence of a registered qualifying patient or primary caregiver.

SUBCHAPTER 11. DISPENSING AUTHORIZED CONDUCT

8:64-11.1 Education policies

(a) Each ATC shall establish and implement policies describing its plans for providing information to registered qualifying patients and primary caregivers as to:

1. Limitations of the right to possess and use marijuana pursuant to the Act and this chapter;
2. Potential side effects of marijuana use and how this shall be communicated to registered qualifying patients and primary caregivers;
3. The differing strengths of products dispensed;
4. Safe techniques for use of medicinal marijuana and paraphernalia;
5. Alternative methods and forms of consumption or inhalation by which one can use medicinal marijuana;
6. Signs and symptoms of substance abuse;
7. Opportunities to participate in substance abuse programs; and
8. Information on tolerance, dependence and withdrawal.

8:64-11.2 Patient informational materials

(a) Each ATC shall maintain, and make available for distribution to registered qualifying patients and their primary caregivers, an adequate supply of up-to-date informational materials addressing the matters identified in the policies developed pursuant to N.J.A.C. 8:64-11.1.

(b) Informational materials must be available for inspection by the Department upon request.

(c) Each ATC shall provide registered qualifying patients and their primary caregivers with a notice requesting approval for the ATC to contact registered qualifying patients and their primary caregivers with information concerning ongoing peer reviewed clinical studies related to the use of marijuana.

8:64-11.3 Notice of and adherence to ATC designation

(a) The Department shall maintain a list of the qualified patients who have designated each ATC to provide medicinal marijuana for the patient's medical use.

(b) An alternative treatment center shall maintain, and make available for Department inspection upon request, a copy of the registry identification card and New Jersey driver's license or other State-issued photographic identification of each current qualifying patient and his or her primary caregiver, if any.

(c) The Department shall issue written notice to each affected ATC each time a registered qualifying patient and/or his or her primary caregiver designates or ceases his or her designation of the ATC.

1. Upon receipt of a notice issued pursuant to (c) above, the ATC shall update its records to reflect the content of the notice.

(d) An ATC shall not provide dispensary services to qualifying patients and/or their primary caregivers who have not previously designated the ATC as their registered ATC, as reflected on the registry identification card of the qualifying patient and/or his or her primary caregiver.

8:64-11.4 Pain and/or primary qualifying symptom assessment records

(a) An alternative treatment center shall formulate a system for documenting a patient's self-assessment of pain and/or primary qualifying symptom using a pain rating scale.

1. An alternative treatment center serving different patient populations shall make more than one pain scale available for patient use, as appropriate.

(b) An alternative treatment center shall document a patient's self-assessment of pain or primary qualifying symptom upon commencement of the dispensing of medicinal marijuana to the patient and thereafter at three-month intervals.

1. The ATC shall maintain the record for the patient's use and information in consulting with his or her physician as to the use of medicinal marijuana to address the patient's qualifying debilitating condition.

(c) ATCs shall provide "log books" to registered qualifying patients and registered primary caregivers who request them to keep track of the strains used and their effects.

8:64-11.5 Prohibitions

(a) An ATC shall not furnish usable marijuana to a registered patient or primary caregiver if the ATC suspects or has reason to believe that the person is abusing marijuana or other substances or unlawfully redistributing usable marijuana.

(b) An ATC shall dispense medicinal marijuana only in the forms authorized pursuant to N.J.A.C. 8:64-10.8(e) directly to registered qualifying patients and their registered primary caregivers.

8:64-11.6 Inventory

(a) An alternative treatment center is authorized to possess two ounces of usable marijuana per registered qualifying patient plus an additional supply, not to exceed the amount needed to enable the alternative treatment center to meet the demand of newly registered qualifying patients, consistent with actual demand ratios calculated pursuant to N.J.A.C. 8:64-9.3(a)3, 4 and 5.

(b) During the first 60 days after commencement of operations, an alternative treatment center is authorized to possess a reasonable supply of usable marijuana to build initial inventory, without the ATC having been designated for use by any registered qualifying patients or primary caregivers.

(c) When there is a decrease in the number of registered qualifying patients and primary caregivers who have designated the alternative treatment center as their dispensary, the alternative treatment center shall have 10 business days to adjust the inventory.

(d) Two alternative treatment center employees shall weigh, log-in and sign-out quantities of packaged usable marijuana to perform dispensing.

SUBCHAPTER 12. MARKETING AND ADVERTISING

8:64-12.1 Marketing and advertising

(a) Alternative treatment centers shall restrict signage to black text on a white background on external signage, labeling and brochures for the alternative treatment center.

(b) Alternative treatment center signage shall not be illuminated at any time.

(c) Alternative treatment centers shall not display on the exterior of the facility advertisements for medicinal marijuana or a brand name except for purposes of identifying the building by the permitted name.

(d) Alternative treatment centers shall not advertise the price of marijuana, except that:

1. An ATC can provide a catalogue or a printed list of the prices and strains of medicinal marijuana available at the alternative treatment center to registered qualifying patients and primary caregivers.

(e) Marijuana and paraphernalia shall not be displayed or clearly visible to a person from the exterior of an alternative treatment center.

(f) Alternative treatment centers shall not produce any items for sale or promotional gifts, such as T-shirts or novelty items, bearing a symbol or references to marijuana. This prohibition shall not pertain to paraphernalia sold to registered qualifying patients or their primary caregivers.

SUBCHAPTER 13. MONITORING, ENFORCEMENT ACTIONS, APPEAL RIGHTS AND EXEMPTION FROM STATE CRIMINAL AND CIVIL PENALTIES FOR THE MEDICAL USE OF MARIJUANA

8:64-13.1 Monitoring

The Department may request information from physicians, ATCs, registered qualifying patients, primary caregivers, the parents, guardians or custodians of registered qualifying patients who are minors in order to assess the impact and effectiveness of the New Jersey Compassionate Use Medical Marijuana Act, N.J.S.A. 24:6I-1 et seq.

8:64-13.2 Inspections

When a permit application is approved and an ATC is ready for operation, representatives of the Department or any other State agency, as applicable, shall conduct an inspection to determine if the facility complies with applicable laws and rules.

8:64-13.3 Onsite assessment

(a) An ATC is subject to onsite assessment by the Department at any time.

(b) The Department may enter an ATC without notice to carry out an onsite assessment in accordance with the Act and this chapter.

1. All ATCs shall provide the Department or the Department's designee immediate access to any material and information.

(c) Submission of an application for an ATC permit constitutes permission for entry and onsite assessment of an ATC.

(d) Failure to cooperate with an onsite assessment and or to provide the Department access to the premises or information may be grounds to revoke the permit of the ATC and to refer the matter to State law enforcement agencies.

(e) An onsite assessment may include, but not be limited to:

1. The review of all ATC documents and records and conferences with qualifying patients and primary caregivers and other persons with information, and the making and retaining of copies and/or extracts;

2. The use of any computer system at the ATC to examine electronic data;

3. The reproduction and retention of any document and/or electronic data in the form of a printout or other output;

4. The examination and collection of samples of any marijuana found at the ATC; and

5. The seizure and detention of any marijuana or thing believed to contain marijuana found at the ATC.

i. If the Department makes a seizure, it shall take such measures as are reasonable in the circumstances to give to the owner or other person in charge of the place where the seizure occurs notice of the seizure.

ii. If the Department determines that the detention of the substance or thing seized is no longer necessary to ensure compliance with applicable law and the ATC permit, the Department shall notify in writing the ATC permit holder of that determination and shall return the substance or thing to the permit holder, upon the permit holder issuing a receipt to the Department for the return of the substance or thing.

iii. The Department shall maintain documentation of the chain of custody of seized substances or things, in accordance with N.J.A.C. 8:64-13.4.

(f) During an onsite assessment, if the Department identifies violations of the Act or this chapter, the Department shall provide written notice of the nature of the violations to the ATC.

1. The ATC shall notify the Department in writing, with a postmark date that is within 20 business days of the date of the notice of violations, of the corrective actions the ATC has taken to correct the violations and the date of implementation of the corrective action.

8:64-13.4 Quality control; sample collection; chain of custody

(a) To ensure the safety of registered qualifying patients, an ATC shall provide samples to the Department during announced and unannounced inspections for product quality control.

(b) To implement the requirement in (a) above, the Department shall:

1. Collect soil and plant samples and samples of products containing marijuana cultivated and/or dispensed, as applicable, by the ATC;
2. Place the permit number of the ATC on each sample container;
3. Label the sample containers with a description and the quantity of its content;
4. Seal the sample containers; and
5. Have ATC and Department staff initial each sample container.

(c) The Department shall maintain documentation of the chain of custody of samples taken.

1. The Department shall provide a receipt for the collected samples to the ATC's authorized representative.
2. The Department shall maintain an accounting of all collected sample containers for control purposes.
3. The Department shall test samples.

i. Sample testing may include tests for, among other things, the presence of pests, mold, mildew, heavy metals and pesticides and the accuracy of labeling.

4. The Department shall issue written reports of the results of its testing to the ATC.
5. The ATC shall pay the expenses for the testing.

8:64-13.5 Notice of violations and enforcement actions

The Department shall issue a written notice to an ATC permit holder of a proposed assessment of civil monetary penalties, suspension or revocation of a permit, setting forth the specific violations, charges or reasons for the action, by transmitting the notice by certified mail to the ATC.

8:64-13.6 Prohibitions, restrictions and limitations on the cultivation or dispensing of medicinal marijuana and criminal penalties

(a) Participation in the Medicinal Marijuana Program by an ATC, or the employees of an ATC, does not relieve the ATC or its employees from criminal prosecution or civil penalties for activities not authorized by the Act, this chapter or the ATC permit.

(b) Distribution of medicinal marijuana to qualified patients or their primary caregivers shall take place at the Department approved location identified on the ATC's permit.

1. ATCs shall not be located within a drug-free school zone.

(c) Any person who makes a fraudulent representation to a law enforcement officer about the person's participation in the Medicinal Marijuana Program to avoid arrest or prosecution for a marijuana-related offense is guilty of a petty disorderly persons offense and shall be sentenced in accordance with applicable law.

(d) A person who knowingly sells, offers or exposes for sale or otherwise transfers or possesses with the intent to sell, offer or expose for sale or transfer a document that falsely purports to be a registry identification card or an ATC identification card issued pursuant to the Act, or a registry identification card or an ATC identification card issued pursuant to the Act that has been altered, is guilty of a crime of the third degree. A person who knowingly presents to a law enforcement officer a document that falsely purports to be a registry identification card or an ATC identification card issued pursuant to the Act, or a registry identification card or an ATC identification card that has been issued pursuant to the Act that has been altered, is guilty of a crime of the fourth degree. The provisions of this section are intended to supplement current law and shall not limit prosecution or conviction for any other offense.

(e) If an ATC or employee of an ATC sells, distributes, dispenses or transfers marijuana to a person not approved by the Department pursuant to the Act and this chapter, or obtains or transports marijuana outside New Jersey in violation of Federal law, the ATC or employee of the ATC shall be subject to arrest, prosecution and civil or criminal penalties pursuant to State law.

8:64-13.7 Revocation of registry identification card, ATC identification card, ATC permit

Violation of any provision of this chapter may result in the immediate revocation of any privilege granted under the Act and this chapter.

8:64-13.8 Onsite inspection and corrective actions

(a) Any failure to adhere to the Act and this chapter documented by the Department during monitoring may result in sanctions, including suspension, revocation, non-renewal or denial of permit and referral to State or law enforcement.

1. The Department shall refer complaints involving alleged criminal activity made against an ATC to the appropriate New Jersey State or local authorities.

(b) An ATC shall maintain detailed confidential sales records in a manner and format approved by the Department pursuant to N.J.A.C. 8:64-9.

1. The Department or its agents shall have complete access to the sales and other financial records of an ATC and shall be granted immediate access to those records upon request.

2. The Department may, within its sole discretion, periodically require the audit of an ATC's financial records by an independent certified public accountant approved by the Department.

i. An ATC that is required to be audited shall bear all costs related to such audit. A requested audit shall be concluded within a reasonable period, as determined by the Department. Results of a required audit shall be forwarded to the Medicinal Marijuana Program coordinator or designee.

3. An ATC shall submit reports on at least a quarterly basis, or as otherwise requested, by the Department.

(c) If violations of requirements of the Act or this chapter are cited as a result of inspection or review of financial records, the ATC shall be provided with an official written report of the findings within seven business days following the inspection.

1. Unless otherwise specified by the Department, the ATC shall correct the violation within 20 calendar days of receipt of the official written report citing the violation(s).

2. The violation shall not be deemed corrected until the Department verifies in writing within seven calendar days of receiving notice of the corrective action that the corrective action is satisfactory.

3. If the violation has not been corrected, the Department may issue a notice of contemplated action to revoke the ATC permit.

(d) Pursuant to N.J.S.A. 24:6I-7, the Commissioner may order the summary suspension of a ATC permit upon a finding that violations pose an immediate threat to the health, safety and welfare of the public, qualified patients or primary caregivers including, but not limited to:

1. Failure to comply with or satisfy any provision of this chapter;

2. Failure to allow a monitoring visit by authorized representatives of the Department;

3. Falsification of any material or information submitted to the Department;

4. Diversion of marijuana, as determined by the Department;

5. Threatening or harming a patient, a medical practitioner or an employee of the Department.

(e) Upon a finding described in (d) above, the Commissioner or the Commissioner's authorized representative shall serve notice by certified mail to the ATC or its registered agent of the nature of the findings and violations and the proposed order of suspension.

1. Except in the case of a life-threatening emergency, the notice shall provide the ATC with 72 hours from receipt to correct the violations and provide proof to the Department of such correction.

(f) If the Department determines the violations have not been corrected, and the facility has not filed notice requesting a hearing to contest the notice of suspension within 48 hours of receipt of

the Commissioner's notice pursuant to (g) below, then the ATC permit shall be deemed suspended.

1. Upon the effective date of the suspension, the ATC shall cease and desist the operations and cooperate with the Department as necessary in the orderly transfer of registrations of qualifying patients and primary caregivers to another ATC.

(g) If the facility requests a hearing within 48 hours of receipt of a notice of proposed suspension of permit, the Department shall arrange for an immediate hearing to be conducted by the Commissioner and a final agency decision shall be issued within 48 hours by the Commissioner. If the Commissioner affirms the proposed suspension of the permit, the order shall become final. The ATC may apply for injunctive relief against the Commissioner's order in the New Jersey Superior Court, Appellate Division.

(h) Notwithstanding the issuance of an order for proposed suspension of a permit, the Department may concurrently or subsequently impose other enforcement actions pursuant to the Act and this chapter.

(i) The Department may rescind the order for suspension upon a finding that the ATC has corrected the conditions that were the basis for the action.

8:64-13.9 Revocation of a permit

(a) The Department may issue a notice of the proposed revocation of an ATC permit in the following circumstances:

1. The ATC has failed to comply with administrative requirements related to an ATC permit, posing an immediate and serious risk of harm or actual harm to the health, safety and welfare of qualifying patients, primary residents or employees and the ATC has not corrected such violations in accordance with an approved plan of correction or subsequent to imposition of other enforcement remedies issued pursuant to these rules;

2. The ATC has exhibited a pattern and practice of violating permit requirements posing a serious risk of harm to the health, safety and welfare of qualifying patients, primary residents or employees. A pattern and practice may be demonstrated by the repeated violation of identical or substantially-related permit standards during three consecutive inspections or the issuance of civil monetary penalties pursuant to the Act or other enforcement actions for unrelated violations on three or more consecutive onsite assessments;

3. Failure of an ATC to correct identified violations that led to the issuance of an order for suspension of a permit; or

4. Continuance of an ATC on conditional permit status for a period of 12 months or more.

(b) The notice shall be served in accordance with this subchapter.

(c) The ATC has a right to request a hearing pursuant to this subchapter.

8:64-13.10 Appeal rights

(a) Denial of an application or revocation of a registry identification card shall constitute a final agency decision subject to review by the Superior Court, Appellate Division.

1. An individual has the right to appeal a final agency decision within 45 days to the New Jersey Superior Court, Appellate Division, Richard J. Hughes Justice Complex, PO Box 006, Trenton, NJ 08625-0006.

8:64-13.11 Exemption from State criminal and civil penalties for the medical use of marijuana

(a) The provisions of N.J.S.A. 2C:35-18 shall apply to any qualifying patient, primary caregiver, alternative treatment center, physician or any other person acting in accordance with the provisions of the Act and this chapter.

(b) A qualifying patient, primary caregiver, alternative treatment center, physician or any other person acting in accordance with the provisions of the Act shall not be subject to any civil or administrative penalty or denied any right or privilege, including, but not limited to, civil penalty or disciplinary action by a professional licensing board, related to the medical use of marijuana as authorized under the Act and this chapter.

(c) Possession of, or application for, a registry identification card shall not alone constitute probable cause to search the person or the property of the person possessing or applying for the registry identification card or otherwise subject the person or his or her property to inspection by any governmental agency.

(d) The provisions of section 2 of P.L.1939, c. 248 (N.J.S.A. 26:2-82), relating to destruction of marijuana determined to exist by the Department, shall not apply if a qualifying patient or primary caregiver has in his or her possession a registry identification card and no more than the maximum amount of usable marijuana that may be obtained in accordance with N.J.S.A. 24:6I-10 and this chapter.

(e) No person shall be subject to arrest or prosecution for constructive possession, conspiracy or any other offense for simply being in the presence or vicinity of the medical use of marijuana as authorized under the Act and this chapter.

(f) No custodial parent, guardian or person who has legal custody of a qualifying patient who is a minor shall be subject to arrest or prosecution for constructive possession, conspiracy or any other offense for assisting the minor in the medical use of marijuana as authorized under the Act and this chapter.

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