

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: _____ Mary E. O'Dowd, MPH,

Commissioner, Department of Health and Senior Services.

Filed: November 23, 2011 as R._____ d._____, **with no changes.**

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 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 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

The official version of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* or *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

reviewing and responding to the written comments submitted on the first notice of proposal dated November 15, 2010 at 42 N.J.R. 2668(a) and the second notice of proposal 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 from the first notice of proposal dated November 15, 2010 at 42 N.J.R. 2668(a), the second notice of proposal dated February 22, 2011 at 43 N.J.R. 340(a), and 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, and published at 42 N.J.R. 2668(a). The second part provides a summary of the public comments and agency responses bearing on the notice of proposal dated February 22, 2011, and published at 43 N.J.R. 340(a). Persons commenting at the public hearing testified exclusively with regard to the notice of proposal dated February 22, 2011, and published at 43 N.J.R. 340(a).

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 Portuguez, 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 N.J.A.C. 8:64-10.7(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, 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 Medicinal Marijuana Program (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 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 Subchapter 5 of N.J.A.C. 8:64 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 Proposal dated February 22, 2011, and published at 43 N.J.R. 340(a), 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 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. (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 second rule proposal dated February 22, 2011 at 43 N.J.R. 340(a).

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 Subchapter 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. Two commenters (21, 32) stated that a one day wait for home delivery was cruel since it could cause a patient to suffer without his or her medicine. (17, 19, 21, 22, 26, 32, 36, and 38)

RESPONSE: A bi-partisan agreement between Governor Chris Christie and Assemblyman Reed Gusciora, one of the prime 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. Accordingly, the Department removed the option of home delivery by ATCs from Subchapter 12 of N.J.A.C. 8:64 in the second rule proposal dated February 22, 2011 at 43 N.J.R. 340(a).

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 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, the cost to New Jersey registered qualifying patients and primary caregivers is reduced over time and 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 Subchapter 5 of N.J.A.C. 8:64. 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 which 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 1 gram in a smoked form at one time. Since the New Jersey statute limits the quantity of marijuana to 2 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 N.J. 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 a 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 Subchapter 5 of N.J.A.C. 8:64 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.

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 1000 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 Notice of Rule Proposal dated November 15, 2010 at 42 N.J.R. 2668(a), 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 rule proposal), 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 rule proposal) 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 amend 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. Inasmuch as the comment calls for

substantive changes to the rules, the Department will consider the commenter's suggestions for amendments to N.J.A.C. 8:64-5.3, N.J.A.C. 8:64-9.6(a), N.J.A.C. 8:64-11.1(a)4, and N.J.A.C. 8:64-12.1(a) in future rulemaking actions.

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 "New Jersey Compassionate Use Medical Marijuana Act" (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. 8:64-1.1 et seq. 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 rule proposal), 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 1000 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 rule proposal) 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 rule proposal), 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 rule proposal) 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 rule proposal) 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 which 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 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. The Department notes the comment concerning qualifications for selection committee members at N.J.A.C. 8:64-6.2 and will consider the comment in future rulemaking. The Department notes the comment concerning a time frame within which the Department shall review and issue a decision on an ATC application and will consider the comment in future rulemaking. 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 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 second notice of proposal dated February 22, 2011 at 43 N.J.R. 340(a) 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 rule proposal) 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 rule proposal was not contained in the February 22, 2011 rule proposal; therefore, this specific issue is moot. The rules at N.J.A.C. 8:64-11.1 and N.J.A.C. 8:64-11.2(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 N.J.A.C. 8:64-13.7 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 Subchapter 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 second notice of proposal dated February 22, 2011 at 43 N.J.R. 340(a), 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 will consider the statement concerning N.J.A.C. 8:64-2.5(a)9 in future rulemaking. 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 DEA 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 comment and will consider the comment, particularly that portion of the comment addressing access, in future rulemaking decisions. 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.

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 Subchapter 5 of N.J.A.C. 8:64.

37. COMMENT: The commenter is an internal medicine physician with an interest in the Act. The comment 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 $Dose = Potency \times Quantity$. 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 Alaigh 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 6 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 NJ 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, and will consider the comments in future rulemaking decisions.

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 the comments and will consider the comments in future rulemaking decisions.

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 second rule proposal dated February 22, 2011, and published at 43 N.J.R. 340(a) 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 Portuguez (address not listed)
38. Rafael Portuguez (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 N.J.A.C. 8:64-10.7(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 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 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, 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 Medicinal Marijuana Program

(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 Subchapter 5 of N.J.A.C. 8:64 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 (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.

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) 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. (3)

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."

47. COMMENT: A number of commenters stated that proposed N.J.A.C. 8:64 Subchapter 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. One commenter (4) 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, 14, 16, 23, 27, 33, and 34)

RESPONSE: A bi-partisan agreement between Governor Chris Christie and Assemblyman Reed Gusciora, one of the prime 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 Subchapter 12 of N.J.A.C. 8:64 in the second rule proposal dated February 22, 2011 at 43 N.J.R. 340(a).

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, the cost to New Jersey registered qualifying patients and primary caregivers is reduced over time 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 and will consider the comments in future rulemaking decisions.

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 tramador, 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 Subchapter 5 of N.J.A.C. 8:64.

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 will consider the comment in future rulemaking deliberations.

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 comment 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. The Department will consider the comment in future rulemaking actions.

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 re-write 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(5) in the February 22, 2011 rule proposal), 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 rule proposal) 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 rule proposal) 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 which 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 notes the comment concerning qualifications for selection committee members at N.J.A.C. 8:64-6.2 and will consider the comment in future rulemaking. The Department notes the comment concerning a time frame within which the Department shall review and issue a decision on an ATC application and will consider the comment in future rulemaking. 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 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 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 rule proposal was not contained in the February 22, 2011 rule proposal; therefore, this specific issue is moot. The rules at N.J.A.C. 8:64-11.1 and N.J.A.C. 8:64-11.2(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 N.J.A.C. 8:64-13.7 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 makeup 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 will consider the need to home delivery in future rulemaking. 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 thanks the commenter for the comments and will consider them in future rulemaking decisions.

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 Subchapter 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 (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 second notice of proposal dated February 22, 2011 at 43 N.J.R. 340(a), 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 will consider the statement concerning N.J.A.C. 8:64-2.5(a)9 in future rulemaking. 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.A.C. 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 can be found in the New Jersey Administrative Code at N.J.A.C. 8:64.