

HEALTH AND SENIOR SERVICES

PUBLIC HEALTH SERVICES BRANCH

ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICES DIVISION

MEDICINAL MARIJUANA PROGRAM

Medicinal Marijuana Program Rules

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

Authorized By: Poonam Alaigh, MD, MSHCPM, FACP, Commissioner, Department of Health and Senior Services.

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

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN _____.

A **public hearing** on the proposed new rules will be held between 10:00 A.M.

and 12:00 P.M. on March 7, 2011 at the following address:

New Jersey Department of Health and Senior Services

First Floor Auditorium

Health and Agriculture Building

369 South Warren Street (at Market Street)

Trenton, New Jersey 08608

(This address is provided to assist interested persons in obtaining driving directions by means of computerized mapping programs: Do not mail comments to this address, as it is undeliverable.)

Submit written comments by April 23, 2011 to:

Devon L. Graf, Director
Office of Legal and Regulatory Compliance
Office of the Commissioner
New Jersey Department of Health and Senior Services
PO Box 360
Trenton, NJ 08625-0360

The agency proposal follows:

Summary

P.L. 2009, c. 307, approved January 18, 2010, codified at N.J.S.A. 24:6I-1 et seq., establishes the New Jersey Compassionate Use Medical Marijuana Act (the Act). The Act at N.J.S.A. 24:6I-16 requires the Commissioner of the Department of Health and Senior Services (Department) to promulgate rules to implement the Act. In satisfaction of that requirement, the Department proposes new rules at N.J.A.C. 8:64 to implement the Act.

The Act finds and declares that marijuana has beneficial uses in treating or alleviating pain or other symptoms associated with certain debilitating medical conditions, and establishes a system whereby patients and their primary caregivers may register with the Department so that qualifying patients may use medicinal marijuana and primary caregivers may obtain medicinal marijuana and assist such patients with its use according to instructions provided by the patient's physician. The Act makes a distinction between medical and non-medical uses of marijuana and sets forth as its purpose the protection of patients who use marijuana to alleviate suffering from

debilitating medical conditions and their physicians and primary caregivers from arrest, prosecution, property forfeiture and criminal and other penalties.

On November 15, 2010, the Department proposed rules for the establishment of the Medicinal Marijuana Program at 42 N.J.R. 2668(a). On December 13, 2010, the New Jersey Legislature passed SCR 130, which declared that portions of the rule proposal at 42 N.J.R. 2668(a) were inconsistent with the Act. Accordingly, the Department proposes new rules at N.J.A.C. 8:64 to implement the provisions of the Act. The proposed new rules differ from the rules proposed at 42 N.J.R. 2668(a) by providing for 6 alternative treatment centers (ATCs) that cultivate and dispense medicinal marijuana, combining the separate application processes for cultivating and dispensing permits into one application for an ATC permit, prohibiting ATC satellite dispensing locations, prohibiting home delivery, and only requiring that the medical conditions originally named in the Act be resistant to conventional medical therapy in order to qualify as debilitating medical conditions for purposes of a patient obtaining a registry identification card. In addition, the proposed new rules establish a definition for the term, "medical advisory board," to further define this requirement which was introduced in the rule proposal at 42 N.J.R. 2668(a).

The proposed new rules would establish the process by which qualifying patients, their physicians and their primary caregivers would register with the Department to avail themselves of the Act's protections against civil and criminal sanction. The proposed new rules would also establish procedures for the permitting, establishment and operation of alternative treatment centers to cultivate and dispense medicinal marijuana and related supplies.

Subchapter 1 would establish general provisions.

Proposed new N.J.A.C. 8:64-1.1 would establish the purpose and scope of the chapter.

Proposed new N.J.A.C. 8:64-1.2 would establish definitions of the following words and terms used throughout the chapter. The Department notes that under the Act, seizure disorders, including epilepsy, intractable skeletal muscular spasticity or glaucoma are deemed “debilitating medical conditions” if they are resistant to conventional medical therapy. The Department believes that a patient with such conditions should be able to use medicinal marijuana if he or she is unable to tolerate conventional therapy. Accordingly, under the rule definition, such conditions are deemed debilitating medical conditions if they are resistant to conventional medical therapy, or if the patient is unable to tolerate such therapy. The Department believes that this modification is reasonable and consistent with the statutory intent of the Act to permit persons who suffer from these conditions, who do not benefit from the use of conventional medical therapies, to avail themselves of the benefits associated with the medical use of marijuana.

Subchapter 2 would establish registration requirements for qualifying patients and primary caregivers.

Proposed new N.J.A.C. 8:64-2.1 would establish registration and registration renewal fees, establish the manner of payment and provide reduced fees for individuals who demonstrate eligibility for certain benefit programs.

Proposed new N.J.A.C. 8:64-2.2 would establish patient registration procedures and specify the information that a patient must provide the Department to submit a

complete application for a registry identification card. The proposed new rule would also establish procedures by which a patient could name a primary caregiver and by which the parent or guardian of a qualifying patient who is a minor would consent to the minor's use of medicinal marijuana.

Proposed new N.J.A.C. 8:64-2.3 would establish primary caregiver registration procedures and specify the information that a patient must provide the Department to submit a complete application for a primary caregiver registry identification card. The proposed new rule would require primary caregiver applicants to submit to a fingerprinting process as part of a criminal history background investigation. In addition, the proposed new rule would establish the factors that the Department would consider in determining whether a primary caregiver applicant who has a disqualifying conviction has demonstrated his or her rehabilitation.

Proposed new N.J.A.C. 8:64-2.4 would establish that a physician must first electronically register with the Department in order to be eligible to certify that a patient is medically qualified to use medicinal marijuana.

Proposed new N.J.A.C. 8:64-2.5 would specify standards for issuance of physician certifications needed to qualify patients to register as qualifying patients. The proposed new rule would also establish procedures by which treating physicians would issue written instructions to patients in the use of medicinal marijuana.

Proposed new N.J.A.C. 8:64-2.6 would specify the reasons for denial of an application for a registry identification card or for revocation of a registry identification card.

Subchapter 3 would establish standards for registry identification cards for qualifying patients and their primary caregivers.

Proposed new N.J.A.C. 8:64-3.1 would establish the content of registry identification cards and the period of registry identification card validity. The proposed new rule would require registrants to carry their registry identification card whenever the registrant possesses medicinal marijuana, to produce the card upon demand to Department staff and to surrender the card to the Department when the Department issues a new card or revokes or declines to renew a registrant's registration.

Proposed new N.J.A.C. 8:64-3.2 would establish procedures by which the Department would issue temporary registry identification cards to primary caregivers pending the results of a criminal history background investigation. The proposed new rule would require surrender of temporary registry identification cards to the Department upon the Department's issuance of a permanent registry identification card or notification to the applicant of the Department's determination to deny the application.

Proposed new N.J.A.C. 8:64-3.3 would establish procedures for registry identification card replacement in the event that the original card is lost, stolen or destroyed. The proposed new rule would require the registrant to notify the Medicinal Marijuana Program (MMP) of the loss of the card within 24 hours and to remit the appropriate replacement fee.

Proposed new N.J.A.C. 8:64-3.4 would require a primary caregiver to certify that he or she will only obtain medicinal marijuana from the permitted alternative treatment center (ATC) named on the primary caregiver's registry certification card. In addition, the proposed new rule would require both the qualifying patient and the primary

caregiver to surrender their registry identification cards to the Department in the event that any of the information on the registry identification cards changes. The proposed new rule would provide that the Department would issue new registry identification cards reflecting the changed information.

Subchapter 4 would establish reporting requirements.

Proposed new N.J.A.C. 8:64-4.1 would establish reporting requirements applicable to qualifying patients, primary caregivers and physicians.

Proposed new N.J.A.C. 8:64-4.2 would establish requirements applicable to the Department to report to the Governor and the Legislature pursuant to N.J.S.A. 24:6I-12.

Proposed new N.J.A.C. 8:64-4.3 would establish reporting requirements applicable to alternative treatment centers.

Proposed new N.J.A.C. 8:64-4.4 would articulate the Department's obligation to maintain the confidentiality of registered persons and would establish the exemption of registrant information from public access pursuant to N.J.S.A. 47:1A-1 et seq.

Subchapter 5 would establish standards and procedures for the identification of medical conditions and/or the treatment thereof as debilitating medical conditions within the meaning of the Act.

Proposed new N.J.A.C. 8:64-5.1 would establish the review cycle for accepting petitions for determination of additional qualifying debilitating medical conditions.

Proposed new N.J.A.C. 8:64-5.2 would establish standards for the constitution and operation of a review panel to evaluate petitions to identify debilitating medical conditions and make recommendations to the Commissioner.

Proposed new N.J.A.C. 8:64-5.3 would establish standards for evaluating petitions to identify medical conditions and/or the treatment thereof as debilitating medical conditions.

Proposed new N.J.A.C. 8:64-5.4 would establish that decisions of the Commissioner on petitions would be final agency actions.

Subchapter 6 would establish the standards and processes by which the Department would issue requests for applications to operate alternative treatment centers and evaluate applications.

Proposed new N.J.A.C. 8:64-6.1 would establish the procedure by which the Department would issue notices of requests for applications.

Proposed new N.J.A.C. 8:64-6.2 would establish criteria the Department would use to evaluate the responses to the Department's request for applications.

Proposed new N.J.A.C. 8:64-6.3 would establish procedures the Department would use to verify information contained in an application.

Proposed new N.J.A.C. 8:64-6.4 would establish the procedures by which the Department would evaluate applications and issue award decisions.

Proposed new N.J.A.C. 8:64-6.5 would establish Department fees for review of applications.

Subchapter 7 would establish procedures and standards for permitting of alternative treatment centers.

Proposed new N.J.A.C. 8:64-7.1 would establish procedures for submission and review of initial permit applications and for issuance of initial permits.

Proposed new N.J.A.C. 8:64-7.2 would establish procedures for the conduct of criminal history record background investigations of officers, directors, board members and employees of alternative treatment centers.

Proposed new N.J.A.C. 8:64-7.3 would establish procedures the Department would use to verify information in a permit application.

Proposed new N.J.A.C. 8:64-7.4 would establish a requirement for alternative treatment center principal officers, directors, owners and board members to submit to the jurisdiction of the courts of the State of New Jersey and to comply with all the requirements of the laws of the State of New Jersey pertaining to the Medicinal Marijuana Program.

Proposed new N.J.A.C. 8:64-7.5 would provide standards for permit issuance and that permits are non-transferable without Department approval.

Proposed new N.J.A.C. 8:64-7.6 would prohibit operation of an alternative treatment center without a permit, establish that permit holders would be responsible for the management, operation and financial viability of an ATC, establish that a permit would be effective for one year and require the permit to be posted in a conspicuous location.

Proposed new N.J.A.C. 8:64-7.7 would establish procedures for submission and review of permit renewal applications and for issuance of renewed permits.

Proposed new N.J.A.C. 8:64-7.8 would establish application procedures for permit amendments.

Proposed new N.J.A.C. 8:64-7.9 would establish that satellite ATC dispensary sites are prohibited, that an ATC may be authorized to cultivate marijuana at a separate

location from its dispensary site, that the ATC permit shall identify the physical address(es) of the ATC site(s), that the Department shall conduct an onsite assessment of each proposed ATC site prior to permit issuance, and that this chapter does not prohibit a political subdivision of this State from limiting the number of ATCs that may operate within its borders.

Proposed new N.J.A.C. 8:64-7.10 would establish fees applicable to alternative treatment center permits.

Proposed new N.J.A.C. 8:64-7.11 would establish criteria for the Commissioner or the Commissioner's designee to use in determining whether to waive a provision of this chapter.

Subchapter 8 would establish standards for alternative treatment center identification cards issued to officers, directors, board members and employees of alternative treatment centers.

Proposed new N.J.A.C. 8:64-8.1 would establish procedures for issuance and expiration of identification cards and would condition a person's participation in the operation of an alternative treatment center upon the prior issuance of an identification card.

Proposed new N.J.A.C. 8:64-8.2 would establish standards for ATC notification to the Department of the separation of an ATC identification cardholder from employment or affiliation with the ATC and would establish that ATC identification cards would immediately expire when a person ceases employment or affiliation with an ATC.

Proposed new N.J.A.C. 8:64-8.3 would establish a procedure whereby an ATC identification cardholder may surrender his or her ATC identification card to the permitting authority.

Subchapter 9 would establish general administrative requirements for ATC organization and recordkeeping.

Proposed new N.J.A.C. 8:64-9.1 would establish requirements for an ATC operations manual.

Proposed new N.J.A.C. 8:64-9.2 would establish prohibitions applicable to ATCs, including a prohibition on the consumption of marijuana on or near ATC premises.

Proposed new N.J.A.C. 8:64-9.3 would establish organization and recordkeeping requirements applicable to ATCs.

Proposed new N.J.A.C. 8:64-9.4 would establish the information that ATCs are to maintain in personnel records.

Proposed new N.J.A.C. 8:64-9.5 would establish training requirements for employees of ATCs.

Proposed new N.J.A.C. 8:64-9.6 would establish standards for ATCs to create and implement an alcohol-free, smoke-free and drug-free workplace policy.

Proposed new N.J.A.C. 8:64-9.7 would establish security standards applicable to ATCs.

Proposed new N.J.A.C. 8:64-9.8 would establish events that ATCs would need to report to the Department.

Proposed new N.J.A.C. 8:64-9.9 would establish medicinal marijuana inventory controls and requirements for ATCs.

Proposed new N.J.A.C. 8:64-9.10 would establish procedures for destruction of marijuana and recordkeeping requirements in connection therewith.

Subchapter 10 would establish authorized conduct for plant cultivation by ATCs.

Proposed new N.J.A.C. 8:64-10.1 would establish standards for marijuana cultivation and inventory limitation.

Proposed new N.J.A.C. 8:64-10.2 would establish standards for limitation of access to marijuana storage areas in Department approved plant cultivation locations.

Proposed new N.J.A.C. 8:64-10.3 would establish recordkeeping requirements for ingredients used in the manufacture or processing of medicinal marijuana.

Proposed new N.J.A.C. 8:64-10.4 would establish standards for security of and access to marijuana cultivation locations.

Proposed new N.J.A.C. 8:64-10.5 would establish medicinal marijuana storage requirements.

Proposed new N.J.A.C. 8:64-10.6 would establish standards for provision of information about provided strains of medicinal marijuana and establish standards for medicinal marijuana package labeling.

Proposed new N.J.A.C. 8:64-10.7 would establish standards for strain cultivation at Department approved plant cultivation locations.

Proposed new N.J.A.C. 8:64-10.8 would establish standards for the processing and packaging of medicinal marijuana.

Proposed new N.J.A.C. 8:64-10.9 would prohibit the use of pesticides in medicinal marijuana cultivation.

Proposed new N.J.A.C. 8:64-10.10 would establish standards for the cultivation of organically certified medicinal marijuana.

Proposed new N.J.A.C. 8:64-10.11 would establish standards for the secure transport of medicinal marijuana.

Proposed new N.J.A.C. 8:64-10.12 would provide that home delivery of medicinal marijuana is prohibited.

Subchapter 11 would establish authorized conduct standards for dispensing of medicinal marijuana by ATCs.

Proposed new N.J.A.C. 8:64-11.1 would establish requirements for ATCs to develop policies to provide educational information to registered qualifying patients and would identify subject areas as to which ATCs are to provide informational and educational opportunities to their registered qualifying patients.

Proposed new N.J.A.C. 8:64-11.2 would require that the educational materials identified at N.J.A.C. 8:64-11.1 be made available to registered qualifying patients and their primary caregivers in an adequate supply and would further require each ATC to request approval for the ATC to contact registered qualifying patients and their primary caregivers with information concerning ongoing peer review clinical studies related to the use of medicinal marijuana.

Proposed new N.J.A.C. 8:64-11.3 would require an ATC to sell medicinal marijuana only to registered qualifying patients that have designated that ATC as their registered ATC, as reflected on the registry identification card of the registered qualifying patient and/or his or her primary caregiver.

Proposed new N.J.A.C. 8:64-11.4 would establish standards by which an ATC-dispensary is to develop a system to document a registered qualifying patient's self-assessment of pain and/or qualifying symptom using a pain rating scale upon commencement of treatment with medicinal marijuana and at three-month intervals thereafter.

Proposed new N.J.A.C. 8:64-11.5 would establish dispensing prohibitions applicable to alternative treatment centers.

Proposed new N.J.A.C. 8:64-11.6 would establish operational inventory standards and limitations for ATCs.

Subchapter 12 would establish standards for marketing and advertising.

Proposed new N.J.A.C. 8:64-12.1 would establish standards and prohibitions for marketing and advertising by ATCs.

Subchapter 13 would establish standards for monitoring, enforcement actions appeal rights and establish exemptions from prosecution.

Proposed new N.J.A.C. 8:64-13.1 would establish the standards for the Department's collection of information from physicians, ATCs, registered qualifying patients, primary caregivers, parents, guardians and custodians of minor patients for the purpose of monitoring the impact and effectiveness of the MMP.

Proposed new N.J.A.C. 8:64-13.2 would establish standards for State inspections of ATCs to ensure compliance with the Act and the chapter.

Proposed new N.J.A.C. 8:64-13.3 would establish standards for onsite assessment of ATCs and ATC permit applicants.

Proposed new N.J.A.C. 8:64-13.4 would establish standards for Departmental quality control activities through sample collection from ATCs.

Proposed new N.J.A.C. 8:64-13.5 would establish standards for Department issuance of violation notices.

Proposed new N.J.A.C. 8:64-13.6 would establish prohibitions on the cultivation and dispensing of medicinal marijuana not authorized by the Act or the chapter.

Proposed new N.J.A.C. 8:64-13.7 would establish standards for the revocation of registry identification cards, ATC identification cards and ATC permits.

Proposed new N.J.A.C. 8:64-13.8 would establish requirements for corrective action by permittees following onsite inspection and notice of a violation by the Department.

Proposed new N.J.A.C. 8:64-13.9 would establish requirements for revocation of ATC permits.

Proposed new N.J.A.C. 8:64-13.10 would establish appeal rights.

Proposed new N.J.A.C. 8:64-13.11 would reiterate N.J.S.A. 24:6I-6, which establishes an exemption from State criminal and civil penalties for the use or possession of medicinal marijuana in conformance with the Act and the chapter.

The Department has provided a comment period of 60 days on this notice of proposal. Therefore, pursuant to N.J.A.C. 1:30-3.3(a)5, this notice is not subject to the rulemaking calendar requirements at N.J.A.C. 1:30-3.1 and 3.2.

Social Impact

The Act made New Jersey the 14th state to authorize the use of medicinal marijuana by qualifying patients. The laws of Alaska, California, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Mexico, Oregon, Rhode Island, Vermont and Washington permit the use of marijuana for medical purposes. In addition, the District of Columbia and the United States Territory of Puerto Rico have established medicinal marijuana programs.

By implementing the Act, the proposed new rules would have the beneficial social impact of establishing orderly mechanisms and procedures by which entities could apply to the Department for authorization to operate alternative treatment centers for the cultivation and dispensing of medicinal marijuana, the Department could evaluate those applications, physicians could register their patients as qualifying patients, qualifying patients could designate primary caregivers to assist them with obtaining and assisting the qualifying patient's use of medicinal marijuana and the Department could perform assessment, oversight and enforcement activities with respect to registrants and ATCs. By virtue of the exemption the Act affords them, physicians, patients, caregivers and ATCs could engage in these activities while being protected from arrest, prosecution, property forfeiture and criminal and other penalties under State law.

The Department anticipates that the Act and these rules would provide additional opportunities for cooperation with the Board of Medical Examiners in the development of educational opportunities related to medicinal marijuana. Inasmuch as this is a new treatment modality in New Jersey, the Department is unable to estimate physician and

patient interest in and demand for medicinal marijuana services, except by conjecture in comparison to the demand in other states. Therefore, the Department makes no representation or estimate as to the number of certifying physicians, qualifying patients and primary caregivers whom the proposed new rules would affect.

The Department anticipates that the proposed standards establishing security requirements for ATC premises would have a beneficial social impact by protecting the staff, affiliates, patrons and neighbors of ATCs from criminal activity. The Department anticipates that the proposed standards prohibiting ATC satellite sites would have the beneficial social impact of concentrating security efforts at a single dispensing site for each permitted ATC, thereby reducing opportunities for theft or diversion.

The Department anticipates that the proposed standards establishing requirements for investigation of the backgrounds of ATC staff and primary caregivers would provide additional assurances against the unlawful use or distribution of medicinal marijuana.

The Department anticipates that the proposed standards establishing requirements for inventory controls and limitation of access to marijuana storage areas would have a beneficial social impact by inhibiting the opportunity for theft or other diversion of marijuana.

The Department anticipates that the proposed standards for secure transport of medicinal marijuana would have a beneficial social impact in inhibiting the opportunity for theft or other diversion of marijuana during transport by a permitted ATC.

The Department anticipates that the proposed standards for Department oversight and enforcement activities would have a beneficial social impact in deterring

unauthorized conduct and enhancing public confidence in the lawfulness, safety and integrity of the program.

The Department anticipates that the proposed standards establishing a mechanism by which the Commissioner would identify additional conditions and/or their associated treatments as “debilitating medical conditions” would provide applicants with a fair opportunity for due consideration of non-frivolous applications while preventing abuse of the Act’s protections against criminal and civil sanction.

The Department anticipates that the proposed standards requiring ATCs to provide patient, caregiver and staff training opportunities would help to ensure that patients safely use medicinal marijuana in accordance with their physicians’ instructions. The Department anticipates that the proposed standards requiring ATCs to provide substance abuse prevention programs and referral services to patients, caregivers and staff would ensure that these persons have resources to address addictive behavior in themselves or others.

Economic Impact

The proposed new rules would have an economic impact on entities that apply to operate ATCs. These entities would incur a permit application fee of \$20,000, \$2,000 of which would be nonrefundable in the event an application is unsuccessful. Applicants would incur other costs associated with identifying proposed site locations, developing site plans and security measures, obtaining local approvals and identifying personnel to serve as officers, directors and staff. Applicants would probably elect to retain the services of professionals to assist them in this process. The Regulatory Flexibility

Analysis below identifies the types of professionals with which an applicant might elect to consult.

Upon the Department granting a permit to a successful applicant for an ATC, the grantee would incur costs associated with finalizing site construction and development, obtaining necessary local approvals, purchasing lighting, irrigation and ventilation systems, hiring and training staff, procuring and installing equipment and obtaining startup inventory. Permitted ATCs would also incur fees associated with obtaining criminal history record reviews for principal officers, directors, owners, board members, staff and affiliates, in accordance with the fee schedule the State Police establishes. Permitted ATCs would incur initial and ongoing costs associated with security and safety requirements, research activities, staff salaries and record retention. The cost of recordkeeping would vary depending on such factors as whether the ATC permit holder opts for paper-based or electronic storage methods and the quantity of records generated and retained.

The Department would charge a fee of \$20,000 to renew an ATC permit; \$2,000 for a permit to modify or construct an addition to an ATC; and \$20,000 to transfer ownership of a permit. Permits would have an effective period of one year, thus, applicants would incur renewal fees every year.

Persons who register as qualifying patients and primary caregivers would incur initial registration fees and registration renewal fees. The fee to register or renew as a qualifying patient or a primary caregiver would be \$200.00 except that the fee payable by patients or caregivers who demonstrate eligibility for certain benefit programs would be \$20.00. Registrations would have an effective period of two years, thus, applicants

would incur these fees every two years. Applicants for registration as primary caregivers would also incur fees the State Police assess to conduct a fingerprinted criminal history record review. Patients and primary caregivers who elect to register with the program would incur costs associated with purchasing medicinal marijuana, the pricing of which the proposed new rules would require to be reasonable. ATCs would establish prices not as a function of the proposed new rules, except that ATCs would need to develop policies and procedures for consistent pricing that are subject to Department review.

The Department would incur costs associated with the establishment and operation of the Medicinal Marijuana Program to implement the Act and the proposed new rules, as described below. The Act at N.J.S.A. 24:6I-11 requires the Department to off-set costs of the Medicinal Marijuana Program. The fees described above that are applicable to ATC permit applicants, ATC permit holders, qualifying patients and primary caregivers would address that obligation. Initially, the Department will absorb the burden of its startup expenses, because the program receives no budget appropriation. The Department anticipates that the fees it would collect associated with patient and caregiver registration and ATC permits, and the fines it may collect through enforcement activities would help the Department to offset the program costs described below.

The Department anticipates incurring certain costs in the first year of program implementation, some of which it may not incur in subsequent years. In the first year of program implementation, the Department estimates that it would incur nearly \$400,000 in costs associated with retaining information technology consultants to perform, and

staff personnel to oversee and to develop the registry and costs associated with obtaining software licenses. In the first year of program implementation, the Department estimates that it would incur infrastructure and equipment costs of more than \$300,000 associated with telecommunications, computers, vehicles, information technology support services and vehicle maintenance. Whether and the extent to which the Department would continue to incur these types of costs in subsequent years of program operation would depend on such factors as public demand for the program, equipment depreciation, inflation and the economy.

In the first and in subsequent years of program operation, the Department anticipates that it would incur costs associated with the salaries and benefits of personnel to administer the program, respond to consumer inquiries and conduct compliance and enforcement activities. In the first year of program operation, the Department estimates these costs at approximately \$2.5 million. These costs could increase or decrease in subsequent years, depending on such factors as program demand, salary and staff changes, benefit costs and the economy.

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 proposed new rules would 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 at 24:6I-7 and 16, is to promulgate the proposed 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 proposed new rules articulate standards that are achievable under current technology.

Jobs Impact

The Department anticipates that the proposed new rules would result in the creation of jobs.

The Department anticipates that ATCs would require personnel to perform administrative, cultivation, dispensary and security activities. The Department is unable to estimate the number of positions ATCs would need to fill to perform these functions as this will depend on patient demand for medicinal marijuana.

The Department would need to retain staff to implement the program. The Department estimates that the number of positions required to implement the proposed new rules would be approximately 30, depending on patient demand.

Agriculture Industry Impact

The Department anticipates that the proposed new rules would have an impact on the agriculture industry in New Jersey in that it would create demand for personnel to cultivate and process medicinal marijuana, and agricultural supplies and equipment to aid ATCs in the performance of cultivation and processing activities. Implementation of the program could also create a demand for the services of the Department of Agriculture to ensure compliance with applicable laws that the Department of Agriculture administers, such as ATC compliance with organic growing practices and good

agricultural practices. The extent of the impact on the agriculture industry in New Jersey will depend on factors such as patient demand for medicinal marijuana.

Regulatory Flexibility Analysis

The proposed new rules would impose reporting, recordkeeping and compliance requirements on qualifying patients, primary caregivers, certifying physicians, alternative treatment centers, custodial parents, guardians or other legal custodians of minor qualifying patients, persons and entities seeking to apply to be any of the foregoing and the Department. Of these, only physicians, alternative treatment centers and applicants to become alternative treatment centers could qualify as small businesses within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. Among the physicians who may elect to participate in registering their patients, the entities that may apply to be alternative treatment centers and the alternative treatment centers that the Department would authorize, the Department is unable to estimate how many would be small businesses within the meaning of the Regulatory Flexibility Act, inasmuch as this is a new care model in New Jersey and the Department is uncertain at this point as to the level of demand for participation in any capacity.

The Summary above describes the reporting, recordkeeping and compliance requirements that the proposed new rules would impose on physicians who may elect to participate in registering their patients, the entities that may apply to be alternative treatment centers and the alternative treatment centers that the Department would authorize.

The Economic Impact above describes the costs to these entities to participate in the program.

The proposed new rules would not require certifying physicians to retain the services of professionals to comply, except that certifying physicians would need to assist the families of qualifying patients who are minors to obtain the additional professional opinions necessary to certify that a minor qualifies for registration. The Department anticipates that the costs of this retention would be borne by patients and/or their health insurance carriers, and not by the referring physicians.

The proposed new rules would require entities applying to the Department to be alternative treatment centers to complete an application process that addresses the various minimum requirements for eligibility and compliance. To assist applicants to complete an application, applicants may elect to retain the services of experts and professionals in some or all of the following fields: medicine, premises security, horticulture, agriculture, agribusiness, engineering, architecture, construction, lighting, packaging, transportation, waste disposal, employee substance abuse assistance and education. Successful applicants likewise may elect to continue to engage the services of these types of professionals to assist them in ongoing compliance. Moreover, successful applicants would need to enter into a consulting arrangement with an entity that provides employee assistance services. The Economic Impact above describes these costs, however, the costs to each entity would vary depending on the types of professionals retained and the location and size of the entity and its operations.

The Department has determined that the proposed new rules would establish the minimum standards necessary to ensure the health and safety of qualifying patients and

their primary caregivers, the employees and neighbors of alternative treatment centers, and the public generally; to prevent abuse and ensure compliance with applicable law; and to maintain public confidence in the fiscal and legal integrity of the program.

Smart Growth Impact

The Department does not anticipate that the proposed new rules would have an impact on smart growth in New Jersey or on the implementation of the New Jersey State Development and Redevelopment Plan.

Housing Affordability Impact

The Department anticipates that the proposed new rules would not have an impact on affordable housing in New Jersey and would not evoke a change in the average costs associated with housing because the proposed new rules would establish procedures and fees associated with registering as a qualifying patient or primary caregiver and obtaining permits to operate alternative treatment centers, and would not have any bearing on housing costs.

Smart Growth Development Impact

The proposed new rules would have no impact on smart growth and would not evoke a change in housing production in Planning Areas 1 or 2 or within designated centers under the State Development and Redevelopment Plan in New Jersey because the proposed new rules would establish procedures and fees associated with registering

as a qualifying patient or primary caregiver and obtaining permits to operate alternative treatment centers, and would not have any bearing on housing production.

Full text of the proposed new rules follows:

CHAPTER 64

MEDICINAL MARIJUANA PROGRAM RULES

SUBCHAPTER 1. GENERAL PROVISIONS

8:64-1.1 Purpose and scope

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

(b) This chapter is applicable to:

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

8:64-1.2 Definitions

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

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

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

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

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

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

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

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

“Certification” means a statement signed by a physician with whom a qualifying patient has a bona fide physician-patient relationship, which attests to the physician’s authorization for the patient to apply for registration for the medical use of marijuana and meets the requirements of N.J.A.C. 13:35-7A.

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

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

“Debilitating medical condition” means:

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

5. Any other medical condition or its treatment that is approved by the Department pursuant to N.J.A.C. 8:64-5.

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

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

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

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

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

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

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

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

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

2. Meet at least two times per calendar year.

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

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

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

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

“Nonprofit entity” means corporations, associations or organizations not conducted for pecuniary profit of any private shareholder or individual, and established, organized or chartered without capital stock under the provisions of Titles 15, 15A, 16 or 17 of the Revised Statutes; or a special charter; or any similar general or special law of this or any other state, that are exempt from the tax imposed by the Corporation

Business Tax Act, as set forth at N.J.S.A. 54:10A-3(e). A nonprofit entity is not required to be a tax-exempt organization under 26 U.S.C. §501(c)(3).

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

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

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

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

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

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

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

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

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

1. Is at least 18 years old;
2. Has agreed to assist with a registered qualifying patient’s medical use of marijuana, is not currently serving as primary caregiver for another qualifying patient and is not the qualifying patient’s physician;
3. Has never been convicted of possession or sale of a controlled dangerous substance, unless such conviction occurred after October 1, 2010, the effective date of the Act, N.J.S.A. 24:6l-1 et seq., and was for a violation of Federal law related to possession or sale of marijuana that is authorized under the Act;
4. Has registered with the Department pursuant to N.J.A.C. 8:64-2.3 and has satisfied the criminal history record background check requirement of N.J.A.C. 8:64-2.3(e); and
5. Has been designated as primary caregiver on the qualifying patient’s application or renewal for a registry identification card or in other written notification to the Department.

“Qualifying patient” or “patient” means a resident of the State who has been provided with a certification by a physician pursuant to a bona fide physician-patient relationship.

“Region” means either the northern region, central region or southern region as defined herein.

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

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

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

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

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

“THC” means delta-9-tetrahydrocannabinol.

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

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

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

SUBCHAPTER 2. REGISTRATION REQUIREMENTS FOR QUALIFYING PATIENTS AND PRIMARY CAREGIVERS

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

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

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

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

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

1. If an applicant can demonstrate eligibility to receive services under the New Jersey Medicaid program, receipt of current food stamp benefits, receipt of current New Jersey Temporary Disability Insurance benefits, Supplemental Security Income (SSI) benefits or Social Security Disability (SSD) benefits, then the fee to apply for a registry identification card is \$20.00.

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

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

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

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

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

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

1. The patient's full name, address, date of birth, telephone number and signature;
2. The name, address and telephone number of the patient's physician;
3. The physician certification identification number obtained from the patient's physician;
4. The name, address and telephone number of the alternative treatment center with which the applicant would register.
 - i. A qualifying patient shall be registered to purchase usable marijuana from only one ATC at any given time;

5. The correct application fee as specified at N.J.A.C. 8:64-2.1;
6. Proof that the applicant is a New Jersey resident, consisting of one or more of the following:
 - i. A New Jersey driver's license;
 - ii. A government-issued identification card that shows the applicant's name and address; or
 - iii. A utility bill issued within the previous two months that shows the applicant's name and address; and
7. One recent passport-size color photograph, two inches by two inches, taken against a white background or backdrop with the applicant's face being not less than three quarters of an inch in width. The applicant shall not wear a hat, glasses or any other item that may alter or disguise the overall features of the face in the photograph and the applicant shall legibly print his or her name on the back of the photograph submitted. The photo shall have been taken not more than 30 days prior to the date of the application.

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

1. An applicant shall have 30 days from the date of a notification issued pursuant to (b) above to submit the materials required to complete the application.
2. The Department shall not process incomplete applications.

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

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

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

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

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

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

(f) As a condition of registration of a qualifying patient who is a minor, the minor's custodial parent, guardian or other legal custodian of the minor shall consent in writing in the application for issuance or renewal of registration to the minor's medical use of marijuana and shall acknowledge that the parent, guardian or custodian will control the

acquisition and possession of the medicinal marijuana and any related paraphernalia dispensed by an alternative treatment center.

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

8:64-2.3 Primary caregiver registration

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

1. The applicant's full name, address, date of birth, telephone number and signature;
2. Written consent to submit to a criminal history record background check pursuant to N.J.S.A. 24:6I-4.
 - i. The applicant shall remit the fee for the criminal history record background check in compliance with the procedures established by the Division of State Police pursuant to N.J.A.C. 13:59;
3. The correct application fee as specified in N.J.A.C. 8:64-2.1;

4. A statement that the applicant agrees to assist the qualifying patient with the medical use of marijuana, is not currently serving as primary caregiver for another qualifying patient and is not the qualifying patient's physician;

5. Proof that the applicant is a New Jersey resident, consisting of one or more of the following:

i. A New Jersey driver's license;

ii. A government-issued identification card that shows the applicant's name and address; or

iii. A utility bill issued within the previous two months that shows the applicant's name and address; and

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

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

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

2. The Department shall not process incomplete applications.

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

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

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

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

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

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

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

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

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

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

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

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

- i. The nature and responsibility of the position that the convicted individual would hold, has held or currently holds;
- ii. The nature and seriousness of the crime or offense;
- iii. The circumstances under which the crime or offense occurred;
- iv. The date of the crime or offense;
- v. The age of the individual when the crime or offense was committed;
- vi. Whether the crime or offense was an isolated or repeated incident;
- vii. Any social conditions that may have contributed to the commission of the crime or offense; and
- viii. Any evidence of rehabilitation, including good conduct in prison or in the community, counseling or psychiatric treatment received,

acquisition of additional academic or vocational schooling, successful participation in correctional work-release programs or the recommendation of those who have had the individual under their supervision.

8:64-2.4 Physician registration

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

8:64-2.5 Physician certification

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

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

6. The patient's diagnosis;

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

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

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

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

i. The certification shall include the following statement:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Submitted false information to the Department;

2. Has a disqualifying conviction; or

3. Ceases to have his or her debilitating condition.

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

8:64-3.1 Registry identification cards

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

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

(c) Registry identification cards shall contain:

1. The name, address, date of birth and Department-issued registry identification number of the qualifying patient;
 2. If the qualifying patient has designated a registered primary caregiver, the name, address, date of birth and Department-issued registry identification number of the primary caregiver;
 3. If the qualifying patient is a minor, the name, address, date of birth and Department-issued registry identification number of the parent, guardian or person who has legal custody of a qualifying patient who is a minor;
 4. An indication as to whether the cardholder is the qualifying patient, a primary caregiver, a minor who is a qualifying patient or the parent, guardian or person who has legal custody of a qualifying patient who is a minor;
 5. A photograph of the cardholder;
 6. The effective date and expiration date of the registry identification card;
- and
7. The telephone number and web address of the Medicinal Marijuana Program of the Department, so that the authenticity of the registry identification card can be validated.

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

(e) Registry identification cards shall not be transferable.

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

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

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

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

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

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

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

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

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

8:64-3.3 Registry identification card replacement

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

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

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

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

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

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

8:64-3.4 Marijuana obtained from designated ATC

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

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

1. Grow or cultivate medicinal marijuana for the qualifying patient;
2. Purchase medicinal marijuana through non-permitted alternative treatment centers or vendors; or
3. Obtain medicinal marijuana from or for other qualifying patients and/or primary caregivers.

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

identification cards to the Department and obtain new registry identification cards reflecting the change.

SUBCHAPTER 4. REPORTING REQUIREMENTS

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

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

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

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

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

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

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

8:64-4.2 Reporting requirements of the Department

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

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

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

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

8:64-4.3 Alternative treatment center reporting requirements

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

1. The number of registered qualified patients and registered primary caregivers;

2. The debilitating medical conditions of qualified patients;

3. Patient demographic data;

4. Program costs;
5. A summary of the patient surveys and evaluation of services; and
6. Such other information as the Department may require in the administration and enforcement of this chapter.

8:64-4.4 Confidentiality

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

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

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

SUBCHAPTER 5. ESTABLISHMENT OF ADDITIONAL DEBILITATING MEDICAL CONDITIONS

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

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

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

(b) The process for review of petitions to approve other medical conditions or the treatment thereof as debilitating medical conditions pursuant to the definition at N.J.S.A. 24:61-3 of "debilitating medical condition" at paragraph (5) shall include one review cycle each year, subject to (a) above.

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

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

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

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

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

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

1. The President of the Board of Medical Examiners or the President's designee; and
2. Other physicians and non-physicians who are knowledgeable about the condition as to which the petition seeks approval;
 - i. Each physician appointed to the review panel shall be nationally board-certified in his or her area of specialty; and
3. At least three physicians appointed to the review panel shall have expertise in pain and symptom management.

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

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

1. The panel may examine scientific and medical evidence and research pertaining to the petition, and may gather information, in person or in writing, from other parties knowledgeable about the addition of the debilitating medical conditions being considered.

2. The petitioner shall be given the opportunity to address the panel in person or by telephone.

3. The petitioner may request that his or her individual identifiable health information remain confidential.

4. The Department shall provide staff support to the panel and other administrative support.

5. The meetings will be considered open public meetings.

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

1. A quorum of the panel shall concur with the recommendation in order to be considered a final recommendation of the panel.

i. For purposes of this subsection, a majority of the members appointed and serving on the panel constitute a quorum.

8:64-5.3 Addition of qualifying debilitating medical condition

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

1. The extent to which the condition is generally accepted by the medical community and other experts as a valid, existing medical condition;

2. If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition;

3. The extent to which the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on activities of daily living;

4. The availability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition and/or the treatment thereof;

5. The extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition and/or the treatment thereof; and

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

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

1. The petition is frivolous and, if so, to deny a petition without further review; or

2. The petition is bona fide and, if so, to accept the petition for further review.

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

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

1. The medical condition and/or the treatment thereof is/are debilitating;

2. Marijuana is more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition and/or the treatment thereof; and

3. Other matters that the panel recommends that the Commissioner consider that are relevant to the approval or the denial of the petition.

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

1. Post the review panel's recommendations on the Department's website for 60-day public comment period;

2. Post notice of a public meeting no fewer than 10 days prior to the public meeting; and

3. Hold a public hearing within the 60-day public comment period.

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

1. If, based on a review of the comments, the panel determines substantive changes should be made to its initial recommendation, the Commissioner shall deny the petition and the Department shall provide the petitioner with a copy of the initial recommendation and an explanation of the substantive changes and the petitioner may resubmit the petition to the Department at any time.

2. If, based on a review of the comments, the panel determines to recommend no changes to its initial recommendation, the initial recommendation shall be deemed a final recommendation and the Commissioner will make a final determination on the petition within 180 days of receipt of the petition.

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

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

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

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

8:64-6.1 Notice of request for applications

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

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

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

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

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

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

8:64-6.2 Criteria for identifying alternative treatment centers

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

1. Submission of mandatory organizational information;
2. Documented involvement of a New Jersey acute care general hospital in the ATC's organization;
3. Ability to meet overall health needs of qualified patients and safety of the public;
4. Community support and participation; and
5. Ability to provide appropriate research data.

(b) The applicant's failure to address all applicable criteria and measures, to provide requested information or to present truthful information in the application

process shall result in the application being considered non-responsive and shall be considered an unsuccessful application pursuant to N.J.A.C. 8:64-6.4.

8:64-6.3 Verification of applicant information

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

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

8:64-6.4 Award decisions

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

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

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

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

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

8:64-6.5 Request for application; fee

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

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

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

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

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

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

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

(a) An applicant for an ATC permit shall submit an application form and the fees required by N.J.A.C. 8:64-6.5, as well as all other required documentation on forms

obtained from the permitting authority or on the Department's website at www.state.nj.us/health.

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

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

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

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

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

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

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

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

- vi. The by-laws and a list of the members of the ATC's medical advisory board;
- vii. Evidence of compliance with N.J.A.C. 8:21-3A.18 with regards to inspection and auditing of the ATC;
- viii. Evidence of the principals, directors, board members, owners and employees to cooperate with a criminal history record background check pursuant to N.J.A.C. 8:64-7.2, including payment of all applicable fees associated with the criminal history record background check, which shall be paid by the ATC or the individual;
- ix. The mailing and physical addresses of the proposed alternative treatment center;
- x. Written verification of the approval of the community or governing body of the municipality in which the alternative treatment center is or will be located;
- xi. Evidence of compliance with local codes and ordinances including, but not limited to, the distance to the closest school, church, temple or other places used exclusively for religious worship or a playground, park or child day care facility from the alternative treatment center;
- xii. A legible map or maps of the service areas by zip code to be served by the alternative treatment center showing the location of the alternative treatment center; and

xiii. Text and graphic materials showing the exterior appearance of the ATC and its site compatibility with commercial structures already constructed or under construction within the immediate neighborhood.

(c) The applicant's failure to provide requested information or to present truthful information in the application process shall result in a decision to not accept the application for processing. The Department shall notify the applicant of this decision and the filing fee shall be nonrefundable.

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

(a) Each principal, director, board member, owner and employee shall provide written consent to submit to a criminal history record background check pursuant to N.J.S.A. 24:6I-4 and shall comply with procedures established by the Division of State Police pursuant to N.J.A.C. 13:59 for obtaining readable fingerprint impressions.

(b) The Department shall deny registration of a principal, director, board member, owner and employee who:

1. Refuses to consent to, or cooperate in, the securing of a criminal history record background check; or
2. Fails to provide any of the information required by (a) above.

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

1. Any convictions of the applicant under any Federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of a controlled substance;

2. Any felony conviction under Federal laws, or the equivalent conviction under state or local laws;

3. The applicant's past experience in the manufacturing or distribution of drugs or controlled substances;

4. The furnishing of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;

5. Suspension or revocation by Federal, state or local government of any registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

6. Compliance with license and/or registration requirements under any previously granted license or registration, if any;

7. Compliance with requirements to maintain and/or make available to the Department or Federal or law enforcement officials those records required by this subchapter; and

8. Any other factors or qualifications the Department considers relevant to and consistent with ensuring public health and safety.

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

notice to the employee identifying the conviction that constitutes the basis for the denial of the application.

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

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

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

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

8:64-7.3 Verification of applicant information

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

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

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

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

ATC at the ATC's principal office, which shall be located within the State of New Jersey.

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

8:64-7.5 Permit issuance; nontransferability of permit

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

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

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

8:64-7.6 Permit required; term; posting

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

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

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

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

8:64-7.7 Renewal of alternative treatment center permit

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

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

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

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

(c) The Department may deny the application for renewal of the permit if the applicant is noncompliant with applicable local rules, ordinances and/or zoning

requirements, or if the Department determines that the facility is in violation of the Act or this chapter.

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

8:64-7.8 Amendments to alternative treatment center permit

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

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

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

8:64-7.9 ATC location; satellite sites prohibited

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

location where the ATC shall dispense the marijuana, but both locations shall be within the same region.

1. The ATC permit shall identify the physical address(es) of the ATC site(s);

2. The Department shall conduct an onsite assessment of each proposed ATC site prior to permit issuance.

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

8:64-7.10 Fees

(a) The following fees apply:

1. The annual fee for the review of a permit renewal application for an alternative treatment center is \$20,000.

2. The fee for a change of location of the alternative treatment center is \$10,000;

3. The fee for a change of capacity or any physical modification or addition to the facility is \$2,000; and

4. The fee for the transfer of ownership of a permit is \$20,000.

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

8:64- 7.11 Waiver

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

SUBCHAPTER 8. ALTERNATIVE TREATMENT CENTER IDENTIFICATION CARDS

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

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

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

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

(d) ATC identification cards shall contain:

1. The name of the individual;
2. The name of the ATC;
3. The date of issuance and expiration; and
4. A photograph of the cardholder.

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

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

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

8:64-8.3 Surrender of ATC identification cards

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

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

SUBCHAPTER 9. ALTERNATIVE TREATMENT CENTER GENERAL

ADMINISTRATIVE REQUIREMENTS FOR ORGANIZATION AND RECORDKEEPING

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

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

1. Procedures for the oversight of the alternative treatment center;
2. Procedures for safely growing and dispensing medicinal marijuana;
3. Procedures to ensure accurate recordkeeping, including inventory protocols to ensure that quantities cultivated do not suggest redistribution;
4. Employee security policies;
5. Safety and security procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;
6. Personal safety and crime prevention techniques;
7. The alternative treatment center's alcohol, smoke and drug-free workplace policies; and
8. A description of the ATCs:
 - i. Hours of operation and after hour contact information;
 - ii. Fee schedule and availability of sliding fee scales based on income;
 - iii. Expectations of onsite personnel in maintaining confidentiality and privacy of the operations and clients of the ATC;

iv. Criteria for involuntary disenrollment from the ATC's list of qualifying patients pursuant to unacceptable behavior and appeal process; and

v. Registered qualifying patient's assumption of risk in complying with ATC registration policies.

(b) The permit holder shall ensure that the operating manual of the alternative treatment center is available for inspection by the Department, upon request.

8:64-9.2 Prohibitions applicable to alternative treatment centers

(a) Consumption of marijuana and/or alcohol on, or public areas in the vicinity of, the premises of an ATC is prohibited.

(b) Consumption of food and/or beverages by qualifying patients and primary caregivers on the premises of an ATC is prohibited.

(c) Sales of food, beverages, alcohol or tobacco on the premises of an ATC is prohibited.

(d) Entry onto the premises of an ATC by a person who is under the age of 18 is prohibited unless he or she is a registered, qualifying patient accompanied by his or her primary caregiver and both are in possession of a registry identification card.

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

(a) The ATC shall maintain the following administrative records, as applicable:

1. Organization charts consistent with the job descriptions in N.J.A.C. 8:64-9.4(a)6;
2. A general description of any facilities to be used as an ATC and a floor plan identifying the square footage available and descriptions of the functional areas of the ATC;
3. If applicable, a projection of the number of qualified patients to be served by the ATC;
4. Projections by the ATC for a two-year period of the ratio of registered qualifying patients-to-demand for usable marijuana and procedures by which the ATC shall periodically review these ratios for consistency with actual patient demand ratios;
5. Procedures by which the ATC shall ensure the availability of medicinal marijuana in accordance with projected and actual demand ratios;
6. The name, medical license number, résumé and contact address of the medical director of the ATC, if applicable;
7. The name, résumé and address of the chief administrative officer of the ATC; and
9. The standards and procedures by which the ATC determines the price it charges for usable marijuana and a record of the prices charged.

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

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

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

8:64-9.4 Personnel records

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

1. An application for employment or to volunteer;
2. A copy of his or her current ATC identification card and a copy of his or her driver's license or other State-issued photo identification card;
3. Documentation of the certification of each principal officer, director board member stating that he or she submits to the jurisdiction of the courts of the State of New Jersey and agrees to comply with all the requirements of the laws of the State of New Jersey pertaining to the Medicinal Marijuana Program;
4. Documentation of verification of references;
5. Documentation of background checks;
6. The job description or employment contract that include duties, authority, responsibilities, qualifications and supervision;

7. Documentation of all required training, including training regarding privacy and confidentiality requirements, and the signed statement of the individual indicating the date, time and place he or she received said training and the topics discussed, including the name and title of presenters;

8. Documentation of periodic performance evaluations;

9. A record of any disciplinary action taken; and

10. Documentation of the results of drug tests authorized pursuant to this chapter.

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

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

8:64–9.5 Alternative treatment center employee training

(a) Each alternative treatment center shall either:

1. Develop, implement and maintain on the premises an onsite training curriculum; or

2. Enter into contractual relationships with outside resources capable of meeting employee, agent and volunteer training needs.

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

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

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

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

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

(c) The policy shall address the following:

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

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

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

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

8:64-9.7 Security

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

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

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

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

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

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

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

4. Establish a protocol for testing and maintenance of the security alarm system;

5. Conduct maintenance inspections and tests of the security alarm system at the ATC's authorized location at intervals not to exceed 30 days from the previous inspection and test and promptly implement all necessary repairs to ensure the proper operation of the alarm system;

6. In the event of a failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours:

i. Notify the Department pursuant to N.J.A.C. 8:64-9.8; and

ii. Provide alternative security measures approved by the Department or close the authorized physical addresses impacted by the failure or malfunction until the security alarm system is restored to full operation;

7. Keep access from outside the premises to a minimum and ensure that access is well controlled;

8. Keep the outside areas of the premises and its perimeter well lighted.

i. Exterior lighting must be sufficient to deter nuisance and criminal activity and facilitate surveillance and must not disturb surrounding businesses or neighbors;

9. Provide law enforcement and neighbors within 100 feet of the ATC with the name and phone number of a staff person to notify during and after operating hours to whom they can report problems with the establishment;

10. Equip interior and exterior premises with electronic monitoring, video cameras and panic buttons.

i. A video surveillance system shall be installed and operated to clearly monitor all critical control activities of the ATC and shall be in working order and operating at all times. The ATC shall provide two monitors for remote viewing via telephone lines in State offices. This system shall be approved by the MMP prior to permit issuance.

ii. The original tapes or digital pictures produced by this system shall be stored in a safe place with a 30-day archive;

11. Limit entry into areas where marijuana is held to authorized personnel;

12. Consistently and systematically prevent loitering, that is, the presence of persons who are not on-duty personnel of the ATC and who are not ATC registrants engaging in authorized ATC-dispensary activity; and

13. Provide onsite parking.

8:64-9.8 Reportable events

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

1. Immediately notify appropriate law enforcement authorities by telephone; and

2. Notify the permitting authority immediately but no later than three hours after discovery of the event.

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

1. An alarm activation or other event that requires response by public safety personnel;

2. A breach of security;

3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and

4. Corrective measures taken, if any.

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

8:64-9.9 Inventory

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

1. Conduct an initial comprehensive inventory of all medicinal marijuana, including marijuana available for cultivation and usable marijuana available for dispensing, seedling to mature marijuana plants and unusable marijuana, at the

authorized location on the date the alternative treatment center first engages in the production or dispensing of medicinal marijuana;

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

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

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

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

3. Conduct a monthly inventory of cultivating, stored, usable and unusable marijuana;

4. Conduct a comprehensive annual inventory at least once every year from the date of the previous comprehensive inventory;

5. Promptly transcribe inventories taken by use of an oral recording device; and

6. If marijuana is disposed of, maintain a written record of the date, the quantity disposed of, the manner of disposal and the persons present during the disposal, with their signatures;

i. ATCs shall keep disposal records for at least two years.

(b) The record of an inventory conducted pursuant to this section shall include, at a minimum, the date of the inventory, a summary of the inventory findings and the name, signature and title of the individuals who conducted the inventory.

8:64–9.10 Destruction of marijuana; recordkeeping

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

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

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

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

1. Returning it to an alternative treatment center; or
2. Transporting it or arranging for pickup by State or local police;
 - i. The person or entity submitting marijuana for disposal pursuant to this section shall present a valid registry identification card and a New

Jersey driver's license or other State-issued photographic identification to the ATC or the police, as applicable.

SUBCHAPTER 10. PLANT CULTIVATION AUTHORIZED CONDUCT

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

(a) An alternative treatment center shall:

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

8:64-10.2 Accessibility of marijuana storage areas

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

1. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests or visitors to be present in or pass through medicinal marijuana storage areas, the ATC shall provide for

adequate observation of the area by an employee whom the permit holder specifically authorized by policy or job description to supervise the activity.

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

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

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

8:64-10.3 Recordkeeping

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

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

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

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

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

8:64-10.4 Physical plant

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

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

8:64-10.5 Storage of marijuana

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

8:64-10.6 Informational policies; labeling

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

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

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

1. The name and address of the alternative treatment center that produced the medicinal marijuana;
2. The quantity of the medicinal marijuana contained within the package;
3. The date that the ATC packaged the content;
4. A sequential serial number, lot number and bar code to identify lot associated with manufacturing and processing;
5. The cannabinoid profile of the medicinal marijuana contained within the package, including THC level not to exceed 10 percent;
6. Whether the medicinal marijuana is of the low, medium or high strength strain;

7. A statement that the product is for medical use by a qualifying patient and not for resale; and

8. A list of any other ingredients besides medicinal marijuana contained within the package.

9. The date of dispensing to the qualifying patient or primary caregiver; and

10. The qualifying patient's name and registry identification card number.

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

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

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

8:64-10.7 Strains of marijuana

(a) An ATC shall cultivate no more than three strains of medicinal marijuana.

(b) Strains of marijuana authorized for cultivation shall be labeled as one of the following strengths: low, medium or high.

(c) The maximum THC content of any sold product shall not exceed ten percent.

8:64-10.8 Processing and packaging of marijuana

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

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

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

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

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

1. Contain no more than $\frac{1}{4}$ ounce of marijuana or equivalent dose dependent on form;
2. Bear a label that complies with N.J.A.C. 8:64-10.7; and
3. Be in a closed container that holds no more than $\frac{1}{4}$ ounce and sealed, so that the package cannot be opened, and the contents consumed, without the seal being broken.

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

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

1. Dried form for direct dispensing to qualifying patients;
2. Oral Lozenges for direct dispensing to qualifying patients; or
3. Topical formulations for direct dispensing to qualifying patients.

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

8:64-10.9 Pesticide use prohibited

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

8:64-10.10 Organic certification

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

8:64-10.11 Secure transport

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

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

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

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

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

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

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

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

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

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

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

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

8:64-10.12 Home delivery prohibited

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

SUBCHAPTER 11. DISPENSING AUTHORIZED CONDUCT

8:64-11.1 Education policies

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

1. Limitations of the right to possess and use marijuana pursuant to the Act and this chapter;

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

8:64-11.2 Patient informational materials

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8:64-11.5 Prohibitions

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

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

8:64-11.6 Inventory

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

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

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

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

SUBCHAPTER 12. MARKETING AND ADVERTISING

8:64–12.1 Marketing and advertising

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

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

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

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

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

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

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

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

8:64-13.1 Monitoring

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

8:64-13.2 Inspections

When a permit application is approved and an ATC is ready for operation, representatives of the Department or any other State agency, as applicable, shall

conduct an inspection to determine if the facility complies with applicable laws and rules.

8:64-13.3 Onsite assessment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. The Department shall provide a receipt for the collected samples to the ATC's authorized representative.

2. The Department shall maintain an accounting of all collected sample containers for control purposes.

3. The Department shall test samples.

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

4. The Department shall issue written reports of the results of its testing to the ATC.

5. The ATC shall pay the expenses for the testing.

8:64-13.5 Notice of violations and enforcement actions

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

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

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

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

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

(c) Any person who makes a fraudulent representation to a law enforcement officer about the person's participation in the medicinal marijuana program to avoid

arrest or prosecution for a marijuana-related offense is guilty of a petty disorderly persons offense and shall be sentenced in accordance with applicable law.

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

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

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

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

8:64-13.8 Onsite inspection and corrective actions

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

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

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

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

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

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

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

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

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

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

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

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

1. Failure to comply with or satisfy any provision of this chapter;
2. Failure to allow a monitoring visit by authorized representatives of the Department;
3. Falsification of any material or information submitted to the Department;
4. Diversion of marijuana, as determined by the Department;
5. Threatening or harming a patient, a medical practitioner or an employee of the Department.

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

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

(f) If the Department determines the violations have not been corrected, and the facility has not filed notice requesting a hearing to contest the notice of suspension within 48 hours of receipt of the Commissioner's notice pursuant to (g) below, then the ATC permit shall be deemed suspended.

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

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

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

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

8:64-13.9 Revocation of a permit

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

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

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

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

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

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

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

8:64-13.10 Appeal rights

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

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

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

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

(b) A qualifying patient, primary caregiver, alternative treatment center, physician or any other person acting in accordance with the provisions of the Act shall not be subject to any civil or administrative penalty or denied any right or privilege, including,

but not limited to, civil penalty or disciplinary action by a professional licensing board, related to the medical use of marijuana as authorized under the Act and this chapter.

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

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

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

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