

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF MEDICINAL MARIJUANA

Medicinal Marijuana

Proposed Readoption with Amendments: N.J.A.C. 8:64

Proposed Repeal and New Rule: N.J.A.C. 8:64-5.1

Proposed Repeal: N.J.A.C. 8:64-10.7

Authorized By: Shereef M. Elnahal, MD, MBA, Commissioner, Department of Health.

Authority: N.J.S.A. 24:6I-1 et seq., particularly 24:6I-3, 4, 7, and 16.

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

Proposal Number: PRN 2018-057.

Submit written comments by August 17, 2018, electronically to <http://www.nj.gov/health/legal/ecomments.shtml>, or by regular mail postmarked by August 17, 2018, to:

Joy L. Lindo, Director
Office of Legal and Regulatory Compliance
Office of the Commissioner
New Jersey Department of Health
PO Box 360
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The agency proposal follows:

Summary

N.J.A.C. 8:64 implements the New Jersey Compassionate Use Medical Marijuana Act (Act), P.L. 2009, c. 307 (approved January 18, 2010), codified at N.J.S.A. 24:6I-1 et seq. The Act finds and declares that marijuana has beneficial uses in treating or alleviating pain or other symptoms associated with certain debilitating medical conditions, N.J.S.A. 24:6I-2.e, and establishes a system by which patients and their primary caregivers may register with the Department of Health (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 medicinal and non-medicinal uses of marijuana and states as its purpose the protection of patients, who use marijuana to alleviate their suffering from debilitating medical conditions, and their physicians and primary caregivers, from arrest, prosecution, property forfeiture, and criminal and other penalties. N.J.S.A. 24:6I-2.e. The Act, at N.J.S.A. 24:6I-16, requires the Commissioner of the Department to promulgate rules to implement the Act.

Following the promulgation of the Act in early 2010, P.L. 2010, c. 36 (approved June 30, 2010), amended the Act to extend its effective date by 90 days, to October 1, 2010.

In late 2010, the Department proposed new rules to implement the Act and to establish the Medicinal Marijuana Program (MMP). 42 N.J.R. 2668(a). Shortly thereafter, the New Jersey Legislature issued a concurrent resolution declaring that portions of the proposed new rules at 42 N.J.R. 2668(a) were "not consistent with the intent of the Legislature as expressed in the [Act]." ACR 151 (2010).

In early 2011, in response to the concurrent resolution, the Department repropose new rules at N.J.A.C. 8:64 to implement the Act. 43 N.J.R. 340(a). The repropose new rules differed from the rules proposed at 42 N.J.R. 2668(a) by authorizing six alternative treatment centers (ATCs) to 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 requiring that the medical conditions originally named in the Act only be resistant to conventional medical therapy to qualify as “debilitating medical conditions” to qualify a patient as eligible to obtain a registry identification card. *Ibid.* In addition, the repropose new rules established a definition of the term, “medical advisory board,” to further describe this term that the original notice of proposal proposed at 42 N.J.R. 2668(a). *Ibid.* Following a March 7, 2011, public hearing, effective December 19, 2011, the Department adopted the repropose new rules without change. 43 N.J.R. 3335(a).

N.J.A.C. 8:64 establishes the process by which qualifying patients, their physicians, and their primary caregivers register with the Department to avail themselves of the Act’s protections against civil and criminal sanction. N.J.A.C. 8:64 also establishes procedures by which the Department issues ATC operating permits, and by which ATCs are to cultivate and dispense medicinal marijuana and related supplies.

P.L. 2013, c. 160 (approved September 10, 2013), at § 1, amended the Act by requiring the physician of a qualifying patient who is a minor to explain the risks and benefits of the use of medicinal marijuana to the minor’s parent or other legal

representative, and to document the occurrence of the explanation in the patient's medical record. P.L. 2013, c. 160, § 2, preempted N.J.A.C. 8:64-10.7, by prohibiting the imposition of a limit on the number of strains of medicinal marijuana that an alternative treatment center could offer. P.L. 2013, c. 160, § 2 expanded N.J.A.C. 8:64-10.8, which authorizes ATCs to package and dispense medicinal marijuana in dried form, oral lozenges, and topical formulations, by authorizing ATCs to package and dispense, in addition to those forms, medicinal marijuana in edible form, but only for the use of minor qualifying patients. The availability of medicinal marijuana in edible form was "intended as a means by which a minor, particularly one who is very young, could receive treatment." Senate Judiciary Comm. Statement to S. 2842 (June 6, 2013).

P.L. 2015, c. 158 (approved November 9, 2015), at § 1, established N.J.S.A. 18A:40-12.22, which requires those in charge of schools to establish policies for the administration of medicinal marijuana, by means other than smoking and inhalation, to students, if they are "qualifying patients" within the meaning of the Act, while they are on school grounds and buses, and at school-sponsored events. P.L. 2015, c. 158, § 2, established N.J.S.A. 30:6D-5b, which requires administrators of facilities offering services for persons with developmental disabilities to establish policies for the administration of medicinal marijuana to those persons, if they are facility clients and "qualifying patients" within the meaning of the Act, while they are on facility premises. P.L. 2015, c. 158, § 3, amended N.J.S.A. 2C:35-18, to include conduct that is consistent with §§ 1 and 2 as exempt from the State criminal liability that persons engaging in that conduct might otherwise incur. P.L. 2015, c. 158, § 4, amended the Act, at N.J.S.A. 24:6I-6, to include conduct consistent with §§ 1 and 2 as exempt from State civil or

administrative penalty, or disciplinary action, that persons engaging in that conduct might otherwise incur.

In mid-2016, pursuant to the Act and N.J.A.C. 8:64-5, the Department announced that it would accept petitions, during the month of August 2016, for the inclusion of additional medical conditions within the meaning of the Act's definition of the term, "debilitating medical condition," at N.J.S.A. 24:6I-3. See 48 N.J.R. 1395(a). The Department received 68 petitions, 45 of which the Department, after a completeness review pursuant to N.J.A.C. 8:64-5.3, accepted as eligible for consideration by the Medicinal Marijuana Program Review Panel (Review Panel), which then-Commissioner Cathleen D. Bennett assembled to consider and make recommendations on the petitions. Final Agency Decision: Petitions to Establish Additional Debilitating Medical Conditions under the New Jersey Medicinal Marijuana Program at 1-2 (March 22, 2016) ("Final Agency Decision"), available at <http://www.nj.gov/health/medicalmarijuana/review-panel> (Review Panel website).

During the petition process, P.L. 2016, c. 53 (approved September 14, 2016), amended the Act's definition of the term, "debilitating medical condition," at N.J.S.A. 24:6I-3, to include, within the meaning of that term, post-traumatic stress disorder, thereby mooted those petitions seeking the inclusion of this condition within the meaning of the term, "debilitating medical condition."

As described more fully in the Final Agency Decision, and in accordance with the process at N.J.A.C. 8:64-5, the Review Panel convened several sessions throughout 2017, during which it accepted and considered public comments on the 45 accepted petitions. On October 26, 2017, the Review Panel adopted its final recommendations,

which were that the Commissioner grant the petitions to establish, as “debilitating medical conditions,” chronic pain related to musculoskeletal disorders, migraine, anxiety, chronic pain of visceral origin, and Tourette syndrome, and deny the petitions to establish, as “debilitating medical conditions,” asthma and chronic fatigue.

On January 23, 2018, Governor Murphy issued Executive Order No. 6 (EO 6), in which he directed the Department and the Board of Medical Examiners to “undertake a review of all aspects of New Jersey’s medical marijuana program, with a focus on ways to expand access to marijuana for medical purposes.” The aspects of the MMP subject to review included, but were not limited to, a review of the current rules for operations and siting of dispensaries and cultivation facilities; conditions for participating physicians in the program; the list of debilitating medical conditions for which medical marijuana may be authorized pursuant to N.J.S.A. 24:6I-3; physician flexibility to make determinations about qualifying conditions; methods by which patients and caregivers obtain product; forms for medical marijuana to be ingested, taking into consideration the needs for different methods for different patients; and other aspects of the MMP within the Department’s discretion that hinder or fail to effectively achieve the statutory objective of ensuring safe access to medical marijuana for all patients in need. *Ibid.*

On March 22, 2018, then-Acting Commissioner Shereef M. Elnahal, MD, MBA (sworn in as Commissioner effective April 2, 2018), announced, in a Final Agency Decision, his determination to grant the petitions to add the following as “debilitating medical conditions” within the meaning of the Act: chronic pain related to musculoskeletal disorders, chronic pain conditions that are of a visceral origin, Tourette’s Syndrome, migraine, and anxiety under the MMP; and to deny the petitions

to add asthma and chronic fatigue syndrome as “debilitating medical conditions.” *Id.* at 5-21. Commissioner Elnahal noted in the Final Agency Decision that his determination was “consistent with the [Review] Panel’s recommendations.” *Id.* at 5.

On March 23, 2018, Commissioner Elnahal issued the “Executive Order 6 Report,” in which he announced the results of the Department’s review of the Medicinal Marijuana Program in accordance with EO 6, identified ways to expand access to marijuana for medical purposes through programmatic and regulatory changes, and statutory amendments to the Act. Department of Health, *Executive Order 6 Report* (March 23, 2018) (EO 6 Report), available at http://nj.gov/health/medicalmarijuana/documents/EO6Report_Final.pdf.

The programmatic and regulatory changes that the Commissioner recommends in the EO 6 Report are: reduction in qualifying patient and caregiver registration fees and expansion of the categories of qualifying patients and caregivers eligible for reduced fees; allowing satellite locations for original ATCs for the cultivation, manufacturing, or dispensing of medicinal marijuana; elimination of the physician registry and the establishment of protections for physicians authorizing the use of medicinal marijuana; streamlining of the process for the addition of debilitating conditions, including the establishment of authority in the Commissioner to review conditions outside of the Review Panel process and authority in the Review Panel to recommend debilitating conditions; elimination of the requirement for psychiatrist evaluation for minors prior to the authorization of medicinal marijuana; expansion of the number of caregivers per patient from one to two; elimination of the 10 percent limit on

the amount of delta-9-tetrahydrocannabinol (THC) in usable medicinal marijuana; and creation of a separate endorsement system for ATC permits.

The Commissioner has reviewed N.J.A.C. 8:64 and determined that, subject to the proposed amendments, new rule, and repeals described below, which would implement statutory changes to the Act since its initial promulgation and the EO 6 Report programmatic and regulatory changes described above, the existing rules remain necessary, adequate, reasonable, efficient, understandable, and responsive to the purposes for which the Department originally promulgated the chapter. Therefore, the Department proposes to readopt the chapter with the amendments, new rule, and repeals described below.

N.J.A.C. 8:64 was scheduled to expire December 19, 2018. Pursuant to N.J.S.A. 52:14B-5.1.c(2), the filing of this notice of proposal to readopt the chapter prior to its expiration operates to extend the expiration date 180 days to June 17, 2019.

As the Department provides a 60-day comment period for this notice of proposal, pursuant to N.J.A.C. 1:30-3.3(a)5, this notice is excepted from the rulemaking calendar requirement.

Following is a summary of the rules proposed for readoption with amendments, a new rule, and repeals.

The Department proposes technical changes throughout the chapter to reflect the change in the name of the Department pursuant to P.L. 2012, c. 17, § 93 (approved June 29, 2012), codified in part at N.J.S.A. 26:1A-2.1; to delete references to the MMP and to add in their place references to the Division of Medicinal Marijuana, thereby reflecting an administrative reorganization of the Department elevating the MMP to

division status; and to correct references to the Supplemental Nutrition Assistance Program (SNAP) to reflect its proper name. Other proposed technical changes would correct grammar and syntax, improve style and readability, eliminate the passive voice and the future tense, update contact information and internet website addresses, correct cross-references, and conform the text to New Jersey Administrative Code style and formatting conventions.

Subchapter 1 establishes general provisions.

N.J.A.C. 8:64-1.1 establishes the purpose and scope of the chapter.

N.J.A.C. 8:64-1.2 establishes definitions of the words and terms used throughout the chapter. The Department proposes to amend the definitions of the following terms:

“adequate supply,” to expand the intent of the term to mean to all forms of marijuana; “alternative treatment center,” to refer to the proposed endorsement process at N.J.A.C. 8:64-7.1; “cultivation,” to delete manufacturing and compounding from within the meaning of this term; “debilitating medical condition,” to add the conditions the Commissioner approved in the EO 6 Report and to reflect the amendment to the definition of the term in the Act to include post-traumatic stress disorder; “lozenge,” to remove limiting language; “primary caregiver,” to reflect that a qualifying patient can designate up to two caregivers; and “review panel,” to reflect its revised advisory role.

The Department proposes to add definitions of the following terms: “business day,” “cannabidiol,” “Division of Medicinal Marijuana,” “endorsement,” “manufacturing,” “military veteran,” “oil,” “original ATC,” “proof of New Jersey residency,” “reduced-fee eligible,” “satellite,” “senior citizen,” “utility bill,” and “vertical integration.”

The new term “reduced-fee eligible” would relocate the criteria that qualify an applicant for issuance, renewal, or replacement of a registry identification card at a reduced fee from existing N.J.A.C. 8:64-2.1 and 3.3, and would add senior citizens and military veterans to those eligible for reduced registration fees. The Department proposes corresponding amendments at existing N.J.A.C. 8:64-2.1 and 3.3 to delete the relocated criteria.

The new term “proof of New Jersey residency” would relocate the list of proofs that demonstrate an applicant’s status as a New Jersey resident from existing N.J.A.C. 8:64-2.2 and 2.3, require a New Jersey driver’s license that an applicant submits as proof of New Jersey residency to be in effect and good standing, and add approximately 30 days to the existing two-month lookback for a utility bill to qualify as proof of New Jersey residency. The Department proposes corresponding amendments at existing N.J.A.C. 8:64-2.2 and 2.3 to delete the relocated criteria. In addition, the new term would add additional types of proofs to the existing list of New Jersey residency proofs, to include correspondence from Federal or State taxation authorities; New Jersey Motor Vehicle Commission-issued non-driver identification cards that are in effect and good standing; Federal, State, or local government correspondence to the applicant’s address; and bank statements issued in each of the preceding three months.

Subchapter 2 establishes registration requirements for qualifying patients and primary caregivers.

N.J.A.C. 8:64-2.1 establishes registration and registration renewal fees, establishes the manner of payment, and establishes reduced fees for individuals who are reduced-fee eligible. The Department proposes to amend the section to reduce the

registration fee from \$200.00 to \$100.00; and to establish that a minor patient is reduced-fee eligible if the minor's designated caregiver is the minor's parent, guardian, or custodian, and is reduced-fee eligible.

N.J.A.C. 8:64-2.2 establishes patient registration procedures and specifies the information that applicants must submit to the Department to apply for a registry identification card. The rule establishes procedures by which a qualifying patient can name a primary caregiver and by which the parent, guardian, and custodian of a qualifying patient who is a minor can consent to the minor's use of medicinal marijuana. The Department proposes to amend this section to indicate that a qualifying patient can designate up to two caregivers.

N.J.A.C. 8:64-2.3 establishes primary caregiver registration procedures and specifies the information that a patient is to submit to the Department to apply for a primary caregiver registry identification card. The rule requires primary caregiver applicants to submit to a fingerprinting process as part of a criminal history background investigation. In addition, the rule establishes the factors that the Department is to consider in determining whether a primary caregiver applicant who has a disqualifying conviction has demonstrated his or her rehabilitation. The Department proposes to amend this section to reflect that if a qualifying patient designates more than one caregiver, each would be subject to the eligibility review process.

N.J.A.C. 8:64-2.4 requires physicians to register electronically with the Department as a prerequisite to their eligibility to certify persons as medically qualified to use medicinal marijuana. The Department proposes to amend this section to require physicians to create a portal account prior to submitting certifications authorizing the

medicinal use of marijuana; authorize physicians to opt out of inclusion on the Department's public list of participating physicians; and exclude participating physicians' names and other identifying information from being subject to public access as government records.

N.J.A.C. 8:64-2.5 specifies standards for issuance of physician certifications, which are prerequisite to the registration of persons as qualifying patients. The rule also establishes procedures by which treating physicians are to issue written instructions to qualifying patients in the use of medicinal marijuana. The Department proposes to amend this section to delete the requirement for psychiatrist evaluation as a condition of the issuance of a certification authorizing the use of medicinal marijuana for qualifying minor patients.

N.J.A.C. 8:64-2.6 establishes grounds for denial of an application for, and/or revocation of, a registry identification card.

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

N.J.A.C. 8:64-3.1 establishes the content of registry identification cards and the period of registry identification card validity. The rule requires registrants to carry their registry identification cards whenever they possess medicinal marijuana, to produce their cards to Department staff upon demand, and to surrender their cards to the Department when the Department issues them new cards, and when it revokes, or declines to renew, their registrations.

N.J.A.C. 8:64-3.2 establishes procedures by which the Department is to issue temporary registry identification cards to primary caregivers pending the results of a

criminal history background investigation. The rule requires surrender of temporary registry identification cards to the Department upon the Department's issuance of either a permanent registry identification card or notice to the applicant of the Department's determination to deny the application.

N.J.A.C. 8:64-3.3 establishes procedures and fees for registry identification card replacement if the original card is lost, stolen, or destroyed, and establishes a reduced fee for persons who are reduced-fee eligible. The rule requires registrants to notify the Department within 24 hours of the loss of a registry identification card and, as a condition of issuance of a replacement registry identification card, to remit the applicable replacement fee.

N.J.A.C. 8:64-3.4 requires a primary caregiver to certify that he or she will only obtain medicinal marijuana from the permitted ATC named on the primary caregiver's registry certification card. In addition, the rule requires both the qualifying patient and the primary caregiver to surrender their registry identification cards to the Department if any of the information on the registry identification cards changes, and requires the Department to issue new registry identification cards reflecting the changed information.

Subchapter 4 establishes reporting requirements.

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

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

N.J.A.C. 8:64-4.3 establishes reporting requirements applicable to ATCs.

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

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

N.J.A.C. 8:64-5.1 establishes the review cycle for accepting petitions for determination of additional qualifying debilitating medical conditions. The Department proposes to repeal and replace this section to permit the Commissioner to propose and adopt additional debilitating medical conditions outside of the petition process.

N.J.A.C. 8:64-5.2 establishes standards for the constitution and operation of an advisory review panel to evaluate petitions to identify debilitating medical conditions and make recommendations to the Commissioner. The Department proposes to amend this section to revise the section heading to reflect proposed amendments to the section; to modify the role of the advisory review panel to allow it to recommend additional debilitating conditions to the Commissioner without the need for a petition; to reflect that the Commissioner may request the review panel's guidance related to the medicinal use of marijuana; to establish that members of the review panel are to be knowledgeable in the medicinal use of marijuana; to delete the requirement that the review panel convene annually to review petitions; and to establish that, upon the Commissioner's request, the review panel may examine scientific and medical research in providing the Commissioner guidance and recommendations.

N.J.A.C. 8:64-5.3 establishes standards for evaluating petitions to identify medical conditions, and/or the treatment thereof, as debilitating medical conditions. The Department proposes to amend this section to authorize the Commissioner to consider petitions outside of a formal advisory review panel petition process; and to delete the cumbersome list of deadlines for issuance of interim and final recommendations and repeated public hearings, processes to which an advisory review panel is to adhere in considering petitions at subsections (d) and (e) and most of subsection (f), while retaining the Commissioner's obligation at existing paragraph (f)2, which the Department proposes to recodify as new subsection (d), to issue, within 180 days, a final determination on a petition.

N.J.A.C. 8:64-5.4 establishes that decisions of the Commissioner on petitions are to be final agency actions.

Subchapter 6 establishes the standards and processes by which the Department is to issue requests for applications to operate ATCs, and evaluate applications.

N.J.A.C. 8:64-6.1 establishes the procedures by which the Department is to issue notices of requests for applications. The Department proposes to amend this section to add new subsection (e), which would require the Department to announce, in a request for applications, the number of permits and/or endorsements the Department plans to issue.

N.J.A.C. 8:64-6.2 establishes criteria that the Department is to consider in evaluating responses to a request for applications. The Department proposes to amend this section to delete the applicant's involvement with acute care hospitals from the existing list of criteria that the Department is to consider in evaluating applications for

ATC permits and endorsements, and to add the following criteria: an applicant's experience, and history of compliance, with government-regulated marijuana programs; competence to maintain marijuana supply; workforce and job creation plan, including plan to involve women, minorities, and military veterans in management and staffing and experience with collective bargaining in the cannabis and other industries.

N.J.A.C. 8:64-6.3 establishes procedures by which the Department is to verify information contained in an application.

N.J.A.C. 8:64-6.4 establishes the procedures by which the Department is to evaluate applications and issue award decisions. The Department proposes to amend this section to add requirements related to evaluation committee interests and experience and disclosure of committee composition after issuance of award decisions.

N.J.A.C. 8:64-6.5 establishes Department fees for review of applications. The Department proposes to amend this section to indicate that an application fee would apply to each endorsement sought; that application fees for endorsements sought and awarded would be non-refundable; and that applicants applying for ATC permits containing more than one endorsement in the same region may submit a single application.

Subchapter 7 establishes procedures and standards for permitting of ATCs.

N.J.A.C. 8:64-7.1 establishes procedures for submission and review of initial permit applications and for issuance of initial permits. The Department proposes to amend this section to reflect the change in the issuing authority for business and corporate-related certifications; include applicants' security interests as a required disclosure; and to require submission of evidence of community engagement and

minority, women, and veteran participation in an ATC's operations through ownership, management, and local hiring plans, and endorsements of community organizations; establish the new endorsement system for the cultivation, manufacturing, and dispensing of marijuana for medical use; and establish that the Department would issue permits and endorsements in a manner that ensures adequate qualifying patient access to medicinal marijuana.

N.J.A.C. 8:64-7.2 establishes procedures for the conduct of criminal history record background investigations of officers, directors, board members and employees of ATCs.

N.J.A.C. 8:64-7.3 establishes procedures the Department uses to verify information in a permit application.

N.J.A.C. 8:64-7.4 requires ATC 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.

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

N.J.A.C. 8:64-7.6 prohibits operation of an ATC without a permit, establishes that ATC permit holders are responsible for the management, operation, and financial viability of an ATC, establishes that a permit is effective for one year, and requires the permit holder to post the permit in a conspicuous location.

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

N.J.A.C. 8:64-7.8 establishes application procedures for permit amendments.

N.J.A.C. 8:64-7.9 establishes 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 is to identify the physical addresses of the ATC sites, that the Department is to conduct an onsite assessment of each proposed ATC site prior to permit issuance, and that this chapter does not prohibit a political subdivision of the State from limiting the number of ATCs that may operate within its borders. The Department proposes to amend this section to delete the prohibition on satellite locations for original ATCs, establish a fee for satellite location applications, include criteria for the submission and evaluation of satellite applications, and indicate that an ATC can only conduct the operations that its permit and endorsement authorize.

N.J.A.C. 8:64-7.10 establishes fees applicable to ATC permits.

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

Subchapter 8 establishes standards for ATC identification cards issued to officers, directors, board members and employees of ATCs.

N.J.A.C. 8:64-8.1 establishes procedures for issuance and expiration of identification cards and condition a person's participation in the operation of an ATC upon the prior issuance of an identification card.

N.J.A.C. 8:64-8.2 establishes standards for ATC notification to the Department of the separation of an ATC identification cardholder from employment or affiliation with

the ATC and establishes that ATC identification cards immediately expire when a person ceases employment or affiliation with an ATC.

N.J.A.C. 8:64-8.3 establishes a procedure through which an ATC identification cardholder may surrender his or her ATC identification card to the permitting authority.

Subchapter 9 establishes general administrative requirements for ATC organization and recordkeeping.

N.J.A.C. 8:64-9.1 establishes requirements for ATC operations manuals.

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

N.J.A.C. 8:64-9.3 establishes organization and recordkeeping requirements applicable to ATCs.

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

N.J.A.C. 8:64-9.5 establishes training requirements for employees of ATCs.

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

N.J.A.C. 8:64-9.7 establishes security standards applicable to ATCs.

N.J.A.C. 8:64-9.8 establishes events that ATCs need to report to the Department.

N.J.A.C. 8:64-9.9 establishes medicinal marijuana inventory controls and requirements for ATCs.

N.J.A.C. 8:64-9.10 establishes procedures for destruction of marijuana and associated recordkeeping requirements.

Subchapter 10 establishes authorized conduct for plant cultivation by ATCs.

N.J.A.C. 8:64-10.1 establishes standards for marijuana cultivation and inventory limitation.

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

N.J.A.C. 8:64-10.3 establishes recordkeeping requirements for ingredients used in the manufacturing or processing of medicinal marijuana.

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

N.J.A.C. 8:64-10.5 establishes medicinal marijuana storage requirements.

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

N.J.A.C. 8:64-10.7 establishes standards for strain cultivation at Department-approved plant cultivation locations. The Department proposes to repeal this rule, thereby authorizing ATCs to produce and dispense multiple strains of marijuana for medicinal use and to eliminate the limit on THC in usable marijuana and marijuana-containing products.

N.J.A.C. 8:64-10.8 establishes standards for the processing and packaging of medicinal marijuana. The Department proposes to amend this section to indicate that ATCs are to manufacture only the listed forms and formulations of usable marijuana and marijuana-containing products, and to add oil formulations to this list.

N.J.A.C. 8:64-10.9 prohibits the use of pesticides in medicinal marijuana cultivation.

N.J.A.C. 8:64-10.10 establishes standards for the cultivation of organically certified medicinal marijuana.

N.J.A.C. 8:64-10.11 establishes standards for the secure transport of medicinal marijuana.

N.J.A.C. 8:64-10.12 prohibits home delivery of medicinal marijuana.

Subchapter 11 establishes authorized conduct standards by which ATCs are to dispense medicinal marijuana.

N.J.A.C. 8:64-11.1 requires ATCs to develop policies to provide educational information to registered qualifying patients, and identifies subject areas as to which ATCs are to provide informational and educational opportunities to their registered qualifying patients.

N.J.A.C. 8:64-11.2 requires ATCs to make available the educational materials identified at N.J.A.C. 8:64-11.1 to registered qualifying patients and their primary caregivers in an adequate supply, and requires each ATC to request approval for the ATC to contact registered qualifying patients and their primary caregivers with information concerning ongoing peer-reviewed clinical studies related to the use of medicinal marijuana.

N.J.A.C. 8:64-11.3 requires 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.

N.J.A.C. 8:64-11.4 establishes 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.

N.J.A.C. 8:64-11.5 establishes dispensing prohibitions applicable to ATCs.

N.J.A.C. 8:64-11.6 establishes operational inventory standards and limitations for ATCs.

Subchapter 12 establishes standards for marketing and advertising.

N.J.A.C. 8:64-12.1 establishes standards and prohibitions for marketing and advertising by ATCs.

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

N.J.A.C. 8:64-13.1 establishes standards for the Department's collection of information from physicians, ATCs, registered qualifying patients, primary caregivers, and minor patients' parents, guardians, and custodians, to monitor the impact and effectiveness of the Division.

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

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

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

N.J.A.C. 8:64-13.5 establishes standards for Department issuance of violation notices.

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

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

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

N.J.A.C. 8:64-13.9 establishes requirements for revocation of ATC permits.

N.J.A.C. 8:64-13.10 establishes appeal rights.

N.J.A.C. 8:64-13.11 reiterates 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.

Social Impact

There are currently 29 states with a medicinal marijuana program. In addition to New Jersey, the laws of Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Mexico, New York, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and West Virginia 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. Since the implementation of the New Jersey Compassionate Use Medical Marijuana Act in 2010, the number of states with a medicinal marijuana program has more than doubled.

The rules proposed for readoption with amendments, a new rule, and repeals would have the beneficial social impact of fully achieving the statutory objective of ensuring safe access to medicinal marijuana for those patients in need. EO 6 charges the Department with reducing bureaucratic barriers and expanding patient access to medicinal marijuana to achieve this objective. Governor Murphy stated in EO 6 that, “of New Jersey’s nine million residents, only approximately 15,000 are able to participate in the State’s medical marijuana program.” There is a significant disparity in New Jersey’s program participation compared to the programs of Michigan and Arizona. EO 6 states that, “the medical marijuana program in Michigan, a state with a similar population to New Jersey, currently serves over 218,000 patients, and the program in Arizona, a state with a similar population than New Jersey serves over 136,000 patients.” The rules proposed for readoption with amendments, a new rule, and repeals aim to realize the goal of expanding patient access.

Another beneficial social impact of the expansion of the medicinal marijuana program is to reduce patient reliance on opioids. Governor Christie declared the use of opioids to be a public health crisis in New Jersey in Executive Order No. 219. A study conducted by the Johns Hopkins Bloomberg School of Public Health and the Philadelphia Veterans Affairs Medical Center concluded that states with a medical marijuana law had about 1,700 fewer opioid painkiller overdose deaths in 2010 than would be expected based on trends before the laws were passed. Bachhuber, Marcus A., MD, et al., Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010, JAMA Internal Medicine (August 25, 2014), available at <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1898878>.

In addition, an October 2016 report noted that a 2015 review of 38 randomized controlled trials evaluating cannabinoids in pain management found that in “71 [percent] of the studies, cannabinoids had empirically demonstrable statistically significant pain-relieving effects.” National Cannabis Industry Association, Cannabis: A Promising Option for the Opioid Crisis (October 2016), available at <http://thecannabisindustry.org/wp-content/uploads/2016/10/NCIA-Cannabis-and-Opioids-Report.October-2016.pdf>, citing Baron, Eric P., DO, Comprehensive Review of Medicinal Marijuana, Cannabinoids, and Therapeutic Implications in Medicine and Headache: What a Long Strange Trip It's Been ..., Headache, the Journal of Head and Face Pain, 885-916 (May 25, 2015), available at <https://onlinelibrary.wiley.com/doi/abs/10.1111/head.12570>.

The rules proposed for readoption with amendments, a new rule, and repeals would expand access for current and future qualifying patients by adding to the list of accepted debilitating medical conditions the following five conditions that Commissioner Elnahal recently approved: chronic pain related to musculoskeletal disorders, migraine, anxiety, chronic pain of visceral origin, and Tourette syndrome, and, pursuant to P.L. 2016, c. 53, post-traumatic stress disorder (PTSD), by reducing the biennial registration fee for patients from \$200.00 to \$100.00, and by expanding eligibility for the reduced fee for registry identification cards to senior citizens and military veterans.

The rules proposed for readoption with amendments, a new rule, and repeals would revise the existing alternative treatment center permitting process, through the creation of separate endorsements for manufacturing, cultivating, and dispensing usable marijuana. This would increase the available supply of, and access to, usable

marijuana to mitigate patient supply issues. It would promote a more diverse workforce and industry dedicated to the provision of medicinal marijuana. The rules proposed for readoption with amendments, new rules, and repeals would establish new application criteria to ensure community support and evidence of minority, women, and veteran participation in ATC operations through ownership, management, and local hiring plans, and would prohibit conflicts of interest in the evaluation of applications. The proposed endorsement system, instead of continuing to require vertically integrated operations, would allow greater competition among applicants and promote a more inclusive community of permit holders. The proposed authorization of original ATCs to operate satellite locations would be subject to an application process for the equitable evaluation of such applications.

The Department anticipates that the rules proposed for readoption with amendments, a new rule, and repeals would have a positive social impact for physicians seeking to authorize the use of marijuana for their qualifying patients, by eliminating the requirement that participating physicians must appear on the Department's published list thereof, and by maintaining the confidentiality of participating physicians. The proposed deletion of the requirement of "written confirmation from a physician trained in the care of pediatric patients and from a psychiatrist" to authorize the use of medicinal marijuana for a minor would provide greater flexibility to treating physicians. A physician or patient who elects to consult with another health care provider can do this in the regular course of care, as there should be parity in the treatment of patients, regardless of age.

Additionally, the rules proposed for readoption with amendments, a new rule, and repeals would streamline the process for adding debilitating medical conditions by allowing the Commissioner to propose, review, and adopt additional debilitating medical conditions outside of the current petition and review panel process, and by authorizing the advisory review panel to recommend additional debilitating medical conditions to the Commissioner without the need for a petition process. This would allow the addition of debilitating medical conditions more quickly to fulfill the Act's objectives. The review panel would also be authorized to develop educational and other guidance materials related to medicinal marijuana for the benefit of participating and interested physicians.

The rules proposed for readoption with amendments, a new rule, and repeals would promote consistent product quality among ATCs. The proposed deletion of the 10 percent THC limit and maximum number of strains that ATCs can offer would expand patient access to more effective treatment of the debilitating medical conditions covered under the State's program.

Economic Impact

The rules proposed for readoption with amendments, a new rule, and repeals would continue to 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.

The rules proposed for readoption with amendments, a new rule, and repeals would continue to require applicants to retain the services of professionals and applicants might elect to retain the services of other kinds of professionals. The types of professionals that the rules might cause an applicant to retain include experts and professionals in one or more 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 costs to retain these professionals would vary depending on such factors as the type of professional, the professional's relative education and experience, the nature and extent of the services the professional is to provide, and the location and size of the entity and its operations.

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; \$10,000 for the opening of a satellite location; \$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 Department has proposed to reduce the fee to register or renew as a qualifying patient or a primary caregiver from \$200.00 to \$100.00 and expand the eligibility for reduced fees to military veterans and senior citizens. Those receiving certain forms of public assistance already are eligible for the \$20.00 reduced fee. Registrations would have an effective period of two years; thus, applicants would incur these fees every two years. Those seeking to register as caregivers would also incur fees to the State Police to conduct a fingerprinted criminal history background check. Patients and caregivers who register with the program would incur costs associated with the purchasing of medicinal marijuana; however, the Department does not regulate the prices that ATCs establish.

The Department would continue to incur costs associated with the operation of the Division of Medicinal Marijuana. N.J.S.A. 24:6I-11 requires the Department to offset costs of the Division using fees collected from ATC permit applicants, ATC permit holders, qualifying patients, and caregivers.

The Department has incurred and would continue to incur costs associated with the salaries, benefits, and other costs associated with existing and future personnel to administer the program, respond to consumer inquiries, and conduct compliance and enforcement activities, and costs associated with ongoing information technology infrastructure maintenance and upgrading.

Federal Standards Statement

The Act obliges the Department to promulgate rules establishing Department-approved “debilitating medical conditions,” see the definition of that term at N.J.S.A. 24:6I-3 subparagraph 1; criteria and procedures for the registration of qualifying patients and their primary caregivers and the content of registry identification cards, N.J.S.A. 26:6I-4.a and d; criteria and procedures by which it will accept applications and grant permits to operate, and regulating the operation of, alternative treatment centers, see N.J.S.A. 24:6I-7.b and i; and general implementing standards, see N.J.S.A. 24:6I-16. Therefore, the Act requires the Department to promulgate rules governing the regulated community’s cultivation, possession, manufacture, sale, distribution, and use of marijuana for medicinal purposes.

The Controlled Substances Act, 21 U.S.C. §§ 801 et seq., prohibits the cultivation, distribution, and possession of marijuana, for any reason, including medicinal purposes. 21 U.S.C. §§ 841 et seq. The rules proposed for readoption with amendments, a new rule, and repeals anticipate that members of the regulated community would cultivate, distribute, and possess marijuana, and may engage in certain financial activities that are ancillary to cultivation, distribution, and possession of

marijuana. These ancillary financial activities may constitute prohibited conduct under other Federal criminal and civil laws, such as the money laundering statutes, the unlicensed money transmitter statute, and the Bank Secrecy Act (BSA). 18 U.S.C. §§ 1956 through 1957, and 1960; and 31 U.S.C. § 5318.

Therefore, the rules proposed for re-adoption with amendments, a new rule, and repeals would continue to conflict with Federal law. Members of the regulated community who engage in activities contemplated by the Act and N.J.A.C. 8:31B might incur Federal civil and criminal liability. N.J.S.A. 24:6I-2.d notes that “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.”

Between October 2009 until October 2014, the United States Department of Justice (Justice Department) issued a series of formal memoranda to United States Attorneys to guide their exercise of investigative and prosecutorial discretion in states enacting laws authorizing the cultivation, distribution, and possession of marijuana, for medicinal and/or recreational purposes. David W. Ogden, Deputy Att’y Gen., Memorandum for Selected United States Attorneys: Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana (October 19, 2009); James M. Cole, Deputy Att’y Gen., Memorandum for United States Attorneys: Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use (June 29, 2011); James M. Cole, Deputy Att’y Gen., Memorandum for All United States Attorneys: Guidance Regarding Marijuana Enforcement (August 29, 2013); James M. Cole, Deputy Att’y Gen., Memorandum for All United States Attorneys: Guidance Regarding

Marijuana[-]Related Financial Crimes (February 14, 2014); and Monty Wilkinson, Director of the Executive Office for United States Att'ys, Policy Statement Regarding Marijuana Issues in Indian Country (Oct. 28, 2014).

While noting the Justice Department's commitment to enforcing the Controlled Substances Act, these guidance memoranda instructed United States Attorneys to focus on the following eight enforcement interests in prioritizing the prosecution of Federal laws criminalizing marijuana-related activity in states that have enacted laws authorizing marijuana-related conduct:

1. Preventing the distribution of marijuana to minors;
2. Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
3. Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
4. Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
5. Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
6. Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
7. Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
8. Preventing marijuana possession or use on federal property.

Cole (August 29, 2013), *Id.*, at 1-2.

The memoranda encouraged United States Attorneys to continue to rely on states that have enacted laws authorizing marijuana-related conduct to address marijuana-related activity through enforcement of state narcotics laws, if those states “provide the necessary resources and demonstrate the willingness to enforce their laws and regulations in a manner that ensures they do not undermine” the eight Federal enforcement priorities, *Id.* at 2-3, and “implement clear, strong and effective regulatory and enforcement systems in order to minimize the threat posed” to the eight Federal enforcement priorities. Cole (February 14, 2014), *Id.*, at 3. The memoranda noted that persons and entities engaged in marijuana-related activities “are more likely to risk entanglement with conduct that implicates the eight [Federal] enforcement priorities” in states that lack “clear and robust” regulatory schemes and enforcement systems. *Ibid.*

In guidance issued concurrently with Deputy United States Attorney General Cole’s February 14, 2014, memorandum on marijuana-related financial crime enforcement priorities, *Id.*, the Financial Crimes Enforcement Network (FinCEN) of the United States Department of the Treasury (Treasury Department) issued a companion guidance document that “clarifies how financial institutions can provide services to marijuana-related businesses consistent with their BSA obligations, and aligns the information provided by financial institutions in BSA reports with [Federal] and state law enforcement priorities. This FinCEN guidance should enhance the availability of financial services for, and the financial transparency of, marijuana-related businesses.” FinCEN, United States Department of the Treasury, [Guidance FIN-2014-G001: BSA](#)

Expectations Regarding Marijuana-Related Businesses (February 14, 2014) (FinCEN Guidance).

The FinCEN guidance emphasizes that financial institutions' exercise of thorough due diligence is critical to their assessment of the risk of providing services to marijuana-related businesses, and specifies tasks financial institutions should perform as part of their due diligence, noting that as "part of its customer due diligence, a financial institution should consider whether a marijuana-related business implicates one of the [eight Federal enforcement] priorities or violates state law." *Id.* at 2-3. The FinCEN Guidance identifies the types of required "Suspicious Activity Report" and "Currency Transaction Report" filings that financial institutions are to make attendant to their engagement with marijuana-related businesses, and provides a non-exhaustive list of "red flags" or indicia that could give rise to a financial institution's suspicion, or actual or constructive knowledge, "that a marijuana-related business may be engaged in activity that implicates one of the [eight Federal enforcement] priorities or violates state law," thereby triggering the financial institution's obligations to perform additional due diligence investigation and/or file a "Marijuana Priority" Suspicious Activity Report. *Id.* at 3-7.

On January 4, 2018, the Justice Department issued a memorandum to all United States Attorneys, instructing them that, in "deciding which marijuana activities to prosecute under [applicable Federal] laws with the [Justice] Department's finite resources[, to] follow the well-established principles that govern all [Federal] prosecutions ... as reflected in ...the United States Attorneys' Manual. These principles require [Federal] prosecutors deciding which cases to prosecute to weigh all relevant

considerations, including [Federal] law enforcement priorities set by the Attorney General, the seriousness of the crime, the deterrent effect of criminal prosecution, and the cumulative impact of particular crimes on the community. Given the Department's well-established general principles, previous nationwide guidance specific to marijuana enforcement is unnecessary and is rescinded, effective immediately." Jefferson B. Sessions, III, Att'y Gen., Memorandum for All United States Attorneys: Marijuana Enforcement (January 4, 2018) (Sessions Memorandum) (specifically listing, at n.1, the 2009 through 2014 Justice Department Memoranda, discussed above, as rescinded).

The Sessions Memorandum neither identified the "law enforcement priorities set by the Attorney General" that United States Attorneys were to consider instead of the eight Federal enforcement priorities announced in the rescinded Justice Department Memoranda, nor did it explain whether and how those sets of priorities might differ. However, the press release accompanying its issuance characterized the Sessions Memorandum as, "announcing a return to the rule of law," and quoted Attorney General Sessions as saying that the Sessions Memorandum, "simply directs all [United States] Attorneys to use previously established prosecutorial principles that provide them all the necessary tools to disrupt criminal organizations, tackle the growing drug crisis, and thwart violent crime across our country." Office of Public Affairs, Justice Department, Press Release No. 18-8: Justice Department Issues Memo on Marijuana Enforcement (January 4, 2018).

The Treasury Department did not issue guidance, concurrent with the issuance of the Sessions Memoranda or thereafter, rescinding its FinCEN Guidance. Therefore, the FinCEN Guidance appears to remain extant.

Despite the Sessions Memoranda guidance, existing Federal statutes protect and safeguard state-administered legal medicinal marijuana programs. The Rohrabacher-Blumenauer amendment (previously known as the Rohrabacher-Farr amendment), most recently sponsored by United States Representatives Dana Rohrabacher (R-CA) and Earl Blumenauer (D-OR), prevents the Justice Department from using Federal funds to prosecute state-compliant medical marijuana operators in states that have legal cannabis programs. It was first approved in 2014, approved or renewed by Congress 11 times since, and most recently renewed on March 23, 2018, as part of the most recent omnibus spending bill, the Consolidated Appropriations Act (Pub. L. 115-141), which is in effect through September 30, 2018.

Jobs Impact

The Department anticipates that the rules proposed for re adoption with amendments, a new rule, and repeals would result in the creation of jobs.

The Department anticipates that the creation of the endorsement system and the planned expansion of the alternative treatment center business community through the issuance of future requests for application and approval of satellite locations for original ATCs would lead to the creation of jobs to perform administrative, cultivating, manufacturing, 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.

In addition, enhancing public participation and access and increasing the number of ATCs would require the Division of Medicinal Marijuana to retain additional staff to

discharge its duties. The Department estimates that it would require up to 20 positions to accommodate the expansion of the program, including agency service representatives, investigators, field monitors, public health representatives, and administrative staff.

Agriculture Industry Impact

The Department anticipates that the rules proposed for readoption with amendments, a new rule, and repeals would have an impact on the agriculture industry in New Jersey in that it would create additional 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. The creation of the endorsement system will allow permit holders to specialize in activities such as cultivation, which may spark agricultural innovation. The extent of the impact on the agriculture industry in New Jersey will depend on factors such as patient demand for medicinal marijuana and the business decisions of the ATCs.

Regulatory Flexibility Analysis

The rules proposed for readoption with amendments, a new rule, and repeals would continue to establish reporting, recordkeeping, and compliance requirements applicable to qualifying patients, primary caregivers, certifying physicians, ATCs, minor qualifying patients' custodial parents, guardians, and other custodians, and persons and entities seeking to apply to be any of the foregoing, and the Department. Of these, only physicians, ATCs, and applicants to become ATCs could qualify as small businesses

within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The Department is unable to estimate how many of these would be small businesses within the meaning of the Regulatory Flexibility Act.

The Summary above describes the reporting, recordkeeping, and compliance requirements that the rules proposed for readoption with amendments, a new rule, and repeals would impose on physicians who may elect to participate in registering their patients, the entities that may apply to be ATCs, and the ATCs that the Department would authorize.

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

The rules proposed for readoption with amendments, a new rule, and repeals would not require certifying physicians to retain the services of professionals to comply. The Department anticipates that patients and/or their health insurance carriers, rather than referring physicians, would bear the costs of participation.

The rules proposed for readoption with amendments, a new rule, and repeals would require entities applying to the Department to be ATCs to complete an application process that addresses the various minimum requirements for eligibility and compliance. The Economic Impact above describes the nature and types of professionals that the rules might cause applicants for ATC permits to retain, and their associated retention costs.

The Department has determined that the rules proposed for readoption with amendments, a new rule, and repeals would establish the minimum standards necessary to ensure the health and safety of qualifying patients and their primary

caregivers, the employees, and neighbors of ATCs, 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.

Housing Affordability Impact Analysis

The Department anticipates that the rules proposed for readoption with amendments, a new rule, and repeals would not have an impact on the affordability of housing in New Jersey and would not evoke a change in the average costs associated with housing because the rules proposed for readoption with amendments, a new rule, and repeals would establish procedures and fees associated with registering as a qualifying patient or primary caregiver and obtaining permits to operate ATCs, and would not have any bearing on housing costs.

Smart Growth Development Impact Analysis

The rules proposed for readoption with amendments, a new rule, and repeals 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 rules proposed for readoption with amendments, a new rule, and repeals would establish procedures and fees associated with registering as a qualifying patient or primary caregiver and obtaining permits to operate ATCs, and would not have any bearing on housing production.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:64.

Full text of the rules proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:64-5.1 and 10.7.

Full text of the proposed amendments follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

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. – 4. (No change.)

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] means 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] means not more than is reasonably necessary to [assure] **ensure** the uninterrupted availability of marijuana, **in all forms**, to meet the needs of registered patients at a given ATC.

...

“Alternative treatment center” or “ATC” means the permitted alternative treatment center authorized **by endorsements described at N.J.A.C. 8:64-7.1** to [grow and provide] **cultivate, manufacture, and/or dispense medicinal marijuana and related paraphernalia** to registered qualifying patients [with usable marijuana and related paraphernalia] in accordance with the provisions of the Act. This term [shall] includes the [organization’s] **ATC’s** officers, directors, board members, and employees.

...

“**Business day**” means any day other than **Saturday, Sunday, or a State-recognized holiday**.

“**Cannabidiol**” means a nonpsychoactive constituent of marijuana, **C₂₁H₃₀O₂**.

...

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

“Cultivation” includes the planting, propagating, [cultivation] **cultivating**, 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. – 3. (No change.)

4. Anxiety, chronic pain associated with a musculoskeletal disorder, chronic pain of a visceral origin, migraines, Tourette syndrome, and post-traumatic stress disorder (PTSD);

Recodify existing 4.-5. as **5.-6.** (No change in text.)

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

...

“Division of Medicinal Marijuana” or “Division” means the division within the Department of Health responsible for the administration and implementation of activities related to the Act.

...

“Endorsement” means a designation set forth on the permit of an ATC that authorizes the ATC to cultivate, manufacture, or dispense medicinal marijuana for the benefit of qualifying patients.

“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.]

“Manufacturing” means compounding, making, and processing medicinal marijuana in all forms.

...

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

1. – 2. (No change.)

...

[“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.]

“Military veteran” means a person who served in any branch of the active or reserve component of the United State military and/or the National Guard of any state military service and who was discharged or released under conditions other than dishonorable.

...

“Oil” means a viscous liquid substance containing cannabinoids, such as THC and cannabidiol, which are extracted from the marijuana plant.

1. **An ATC may manufacture oil for use in preloaded cartridges, or in topical or oral formulations.**

...

“Original ATC” means one of the first six ATCs to which the Department issued a permit pursuant to the Act.

...

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

...

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

1. – 4. (No change.)

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

“**Proof of New Jersey residency**” means **one or more of the following:**

1. A New Jersey driver’s license that is in effect and good standing;

2. A Federal, State, or local government-issued identification card that shows the applicant’s name and New Jersey address;

3. A utility bill issued within the 90 days preceding the application date that shows the applicant’s name and New Jersey address;

4. Correspondence from the Internal Revenue Service or the New Jersey Division of Taxation issued within the year preceding the application date that shows the applicant’s name and New Jersey address;

5. A non-driver identification card issued by the New Jersey Motor Vehicle Commission that is in effect and good standing;

6. Federal, State, or local government correspondence issued to the applicant within the 90 days preceding the application date that shows the applicant’s name and New Jersey address; or

7. Bank statements issued within each of the three months preceding the application date that show the applicant’s name and New Jersey address.

...

“Reduced-fee eligible” means a person is:

- 1. A senior citizen or a military veteran; or**
- 2. A beneficiary or recipient of:**
 - i. New Jersey Medicaid;**
 - ii. Supplemental Nutrition Assistance Program (SNAP);**
 - iii. New Jersey Temporary Disability Insurance (TDI);**
 - iv. Supplemental Security Income (SSI); or**
 - v. Social Security Disability (SSD).**

...

“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] about the medicinal use of marijuana.

“Satellite” means an additional site that an original ATC operates to conduct one of the following activities: the cultivation, manufacturing, or dispensing of usable marijuana to qualifying patients.

...

“Senior citizen” means a person age 65 and older.

...

“Utility bill” means a bill for one or more of the following services: gas, electric, water, sewer, cellular or landline telephone, internet, or cable or satellite television.

“Vertical integration” means the co-location or combination of two or more of the following activities related to the production of usable marijuana for qualifying patients in one location: cultivation, manufacturing, and dispensing.

SUBCHAPTER 2. REGISTRATION REQUIREMENTS FOR QUALIFYING PATIENTS AND PRIMARY CAREGIVERS

8:64-2.1 Fees for issuance and renewal of registration **of qualifying patients and primary caregivers**

(a) (No change.)

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

1. (No change.)

(c) The fee to apply for issuance or renewal of a registry identification card **as either a qualifying patient or a primary caregiver** 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] **\$100.00, unless the**

applicant is reduced-fee eligible, in which case, the fee to apply for **issuance or renewal of** a registry identification card is \$20.00.

2. A minor who applies for issuance or renewal of a registry identification card as a qualifying patient is reduced-fee eligible, if the minor's designated primary caregiver is:

i. The minor's parent, guardian, or custodian; and

ii. Reduced-fee eligible.

(d) The Department shall not [grant] **refund** an application fee [refund] if an applicant demonstrates **reduced-fee** 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] **without demonstrating reduced-fee eligibility, that** the applicant **has** 30 days from the date of such notice to either:

1. (No change.)

[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.]

2. Demonstrate reduced-fee eligibility.

[(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) - (d) (No change.)

(e) A qualifying patient may designate [a] **up to two** primary caregivers, either on the application for issuance or renewal of **a** registry identification card or in another written notification to the Department.

1. (No change.)

(f) (No change.)

8:64-2.3 Primary caregiver registration

(a) A person [who] **whom** 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. – 4. (No change.)

5. Proof [that the applicant is a] **of** 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]**residency**; and

6. (No change.)

(b) – (h) (No change.)

(i) If a qualifying patient proposes to designate more than one person as a primary caregiver, each applicant for registration as the qualifying patient's primary caregiver is subject to this section.

8:64-2.4 Physician registration

(a) 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] **enroll to participate as an authorizing physician through the website** at [http://www.nj.gov/health/med_marijuana.shtml] **<http://www.nj.gov/health>, thereby creating a portal account.**

(b) Physicians who enroll or who have previously enrolled, can opt out of inclusion in the public list of participating physicians that the Department maintains at any time by contacting the Division.

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] **enrolls** 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. – 9. (No change.)

(b) Prior to complying with (a) above, [a registered] **an enrolled** 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] **the physician's** professional

opinion[s], 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] **the minor’s** debilitating medical condition[.]; **and**

[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. (No change.)

(c) – (d) (No change.)

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

8:64-3.1 Registry identification cards

(a) – (b) (No change.)

(c) Registry identification cards shall contain:

1. – 6. (No change.)

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

(d) – (e) (No change.)

(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] **Division** or in person.

(g) (No change.)

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

(a) – (b) (No change.)

(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.] 1. The temporary registry identification card may be surrendered by United States mail to the [Medicinal Marijuana Program] **Division** 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] **Division** in writing or by telephone within 24 hours after the discovery of the occurrence of the theft, loss, or destruction.

(b) (No change.)

(c) An applicant for issuance of a [registration] replacement **registry identification** card shall transmit to the [Medicinal Marijuana Program] **Division** a check or money order, or any other form of payment approved by the [Medicinal Marijuana Program] **Division**,

that is made payable to the “Treasurer, State of New Jersey,” in the amount of the required payment.

1. (No change.)

(d) The fee to apply for issuance of a **replacement** registry identification card [replacement] is \$10.00, **unless the applicant is reduced-fee eligible, in which case the fee to apply for issuance of a replacement registry identification card is \$5.00.**

[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.]

SUBCHAPTER 4. REPORTING REQUIREMENTS

8:64-4.4 Confidentiality

(a) (No change.)

(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 **agencies** or **local** law enforcement agencies, only as necessary to verify that a person who is engaged in the suspected or alleged [medical] **medicinal** 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 conditions

(a) The Department shall announce the establishment of review cycles during which, and procedures by which, it will accept petitions to approve other medical conditions or the treatment thereof as “debilitating medical conditions,” pursuant to paragraph 5 of the definition of that term at N.J.S.A. 24:6I-3, by publishing a notice in the New Jersey Register.

(b) Nothing in this section shall prevent the Commissioner from establishing, pursuant to the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., additional “debilitating medical conditions,” notwithstanding the absence or existence of a pending review cycle announced pursuant to (a) above.

1. The Commissioner may consult with a review panel established pursuant to N.J.A.C. 8:64-5.2 in determining to establish additional “debilitating medical conditions.”

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

(a) The Commissioner shall appoint [a] **an advisory** review panel (panel) to make recommendations to the Commissioner regarding [approval or denial of a petition submitted pursuant to this subchapter] **the addition of debilitating medical conditions that should qualify for medicinal marijuana and, upon the Commissioner's request, to provide guidance and recommendations regarding the medicinal use of marijuana.**

1. In response to the Commissioner's request for its guidance and recommendations, the advisory review panel may examine scientific and medical evidence and research and may gather information, in person or in writing, from persons and entities who are knowledgeable about the medicinal use of marijuana.

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

1. (No change.)

2. Other physicians and non-physicians who are knowledgeable about the [condition as to which the petition seeks approval] **medicinal use of marijuana**;

i. (No change.)

[3.] ii. (No change in text.)

[(c)] **3.** [The] **Physicians shall comprise 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] **For a** petition to be accepted for processing, [the] **a** petitioner shall send a letter by certified mail to the [Medicinal Marijuana Program] **Division** that contains the following information:

1. – 6. (No change.)

(b) (No change.)

(c) If the petition is accepted, the Department [shall] **may** 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]

(d) The Commissioner will make a final determination on the petition within 180 days of receipt of the petition.

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

8:64-6.1 Notice of request for applications

(a) – (d) (No change.)

(e) The Department, in its published notice of request for applications, shall announce the number of permits and endorsements it intends to issue.

8:64-6.2 Criteria for identifying alternative treatment centers

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

1. (No change.)

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

[3.] **2.** (No change in text.)

3. Experience in cultivating, processing, or dispensing marijuana in compliance with government-regulated marijuana programs;

4. History of compliance with regulations and policies governing government-regulated marijuana programs;

5. Ability and experience of the applicant in ensuring adequate supply of marijuana;

6. Workforce and job creation plan, including plan to involve women, minorities, and military veterans in ATC ownership, management, and experience with collective bargaining in the cannabis and other industries;

Recodify existing 4. and 5. as **7. and 8.** (No change in text.)

(b) (No change.)

8:64-6.4 Award decisions

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

1. The members of the selection committee shall have no personal, financial, or familial interest in any of the applicants, or principals thereof, to be evaluated.

[1.] **2.** (No change in text.)

(b) – (c) (No change.)

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 **endorsement sought in the** application.

1. The applicant shall submit the fee **for each endorsement sought** 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. (No change.)

3. Application fees [of successful applicants] **for endorsements sought and awarded** are non-refundable.

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

1. An applicant for an ATC permit for more than one endorsement in the same region may submit a single application.

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 [\[www.state.nj.us/health\]](http://www.state.nj.us/health) <http://www.nj.gov/health>.

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

1. The legal name of the [corporation] **business entity applying for a permit**, a copy of the [articles of incorporation] **entity's organizational documents** and by-laws, evidence that the [corporation] **business entity** is in good standing with the New Jersey [Secretary of State] **Department of the Treasury**, 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 **and**

Enterprise Services;

ii. — iv. (No change.)

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

vi. — xi. (No change.)

xii. Evidence of community engagement or participation in the ATC's operations through ownership, management, and local hiring plans, and support of community organizations;

xiii. Evidence of minority, women, and veteran participation in ATC operations through ownership, management, and local hiring plans;

xiv. Evidence of experience and ability related to the activities associated with the endorsement(s) sought, determined by proposed

operations, workforce, capital, management systems, business plan, safety, and security;

Recodify existing xii.-xiii. as new **xv.-xvi.** (No change in text.)

(c) (No change.)

(d) An entity seeking to engage in one or more of the following activities, associated with providing registered qualifying patients with usable marijuana and related supplies, shall apply for a permit endorsement authorizing it to:

- 1. Cultivate usable marijuana;**
- 2. Manufacture usable marijuana; and/or**
- 3. Dispense usable marijuana.**

(e) The endorsements issued by the Department shall authorize the following specific activities:

1. A cultivation endorsement allows an ATC to possess, cultivate, plant, grow, harvest, and package usable marijuana (including in prerolled forms); and display, transfer, transport, distribute, supply, or sell marijuana to other ATCs, but not directly to registered qualifying patients.

2. A manufacturing endorsement allows an ATC to possess and process usable marijuana; purchase usable marijuana from other ATCs possessing a cultivating endorsement; manufacture products containing marijuana approved by the Department; conduct research and develop products containing marijuana for approval by the Department; and to display, transfer, transport, distribute, supply, or sell marijuana and products containing marijuana to other ATCs, but not directly to registered qualifying patients.

3. A dispensary endorsement allows an ATC to purchase usable marijuana and products containing marijuana from other ATCs authorized to cultivate or manufacture usable marijuana or products containing marijuana; and possess, display, supply, sell, and dispense, usable marijuana and/or products containing marijuana, to registered qualifying patients.

(f) The Department shall issue endorsements in a manner that ensures adequate patient access to medicinal marijuana.

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] **Division**. [Copies] **An ATC shall maintain 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) (No change.)

8:64-7.9 ATC location; satellite sites [prohibited] **for original ATCs**

(a) An ATC shall conduct all operations authorized by the Act at the address(es) identified on the permit issued by the Department.

1. The Department [shall not] **may** authorize or permit **original ATCs to conduct** dispensing operations at any satellite locations. [However, an]

2. An original ATC, as approved by the Department, may cultivate and manufacture marijuana at a location separate from the location where the ATC shall dispense the marijuana, but both locations shall be within the same region.

3. Notwithstanding the original dispensary and cultivation sites permissible in this section, an original ATC may not have more than a total of two additional satellite sites.

4. Satellite sites shall not be vertically integrated.

(b) The fee to apply for a permit to establish a satellite location application is \$10,000.

1. An applicant shall submit the fee for each satellite location sought 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 \$8,000.

(c) Satellite locations must be within the same region as the original permitted ATC.

(d) The Department will evaluate applications for satellite locations based on the following criteria:

1. Demonstrated basis and need for the satellite location, including, but not limited to, current product supply, patient access or enrollment, or location of current alternative treatment centers;

2. Demonstrated ability of the applicant, upon review of the applicant’s operations, workforce, capital, management systems, business plan, safety, and security, to support the satellite location;

3. The potential of the proposed satellite location to contribute to expanding patient access to usable marijuana for medicinal use;

4. The potential of the proposed satellite location to contribute to the development of novel products containing marijuana for medicinal use by qualifying patients; and

5. Evidence of the applicant's past, current, and intended future compliance with the Act and this chapter, and all security, safety, and inventory management requirements.

(e) An application for a satellite location shall include the following:

1. A list of the names, addresses, and dates of birth of the proposed satellite location's employees, and principal officers, directors, owners, and board members, if different than the original ATC permitted location;

2. Evidence of the proposed employees and principals, directors, board members, and owners, if different than those of the original ATC, 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;

3. The mailing and physical addresses of the proposed satellite location;

4. Written verification of the approval of the community or governing body of the municipality in which the satellite location will be located;

5. Evidence of compliance with local codes and ordinances including, but not limited to, the distance from the satellite location to the closest school,

church, temple, or other places used exclusively for religious worship, and playground, park, and child care facility;

6. A legible map or maps of the service areas by zip code that the proposed ATC satellite location is to serve that shows the proposed satellite location; and

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

(f) The Department shall issue a determination on an application for a satellite location within 30 days of receipt.

1. The Department shall issue a written notice of its decision.

2. 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.

3. 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.

[1.] **(g)** [The] **An** ATC permit shall identify the physical address[(s)] of the ATC site[(s)] **and each satellite location, if applicable.**

[2.] **(h)** The Department shall conduct an onsite assessment of each proposed ATC site **and satellite location, if applicable,** prior to permit issuance.

[(b)] **(i)** (No change in text.)

8:64-7.10 Fees

(a) The following fees apply:

1. (No change.)
2. The fee **to apply** for a change of location of the alternative treatment center **or the addition or renewal of a satellite location** is \$10,000;
3. The fee **to apply** for a change of capacity or any physical modification or addition to the facility is \$2,000; and
4. The fee **to apply** 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] **Division**, and made payable to the "Treasurer, State of New Jersey."

SUBCHAPTER 9. ALTERNATIVE TREATMENT CENTER GENERAL

ADMINISTRATIVE REQUIREMENTS FOR ORGANIZATION AND RECORDKEEPING

8:64-9.4 Personnel records

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

1. – 2. (No change.)
3. Documentation of the certification of each principal officer, director, or board member stating that he or she submits to the jurisdiction of the courts of the State of New Jersey and agrees to comply with all the requirements of the laws of the State of New Jersey pertaining to the [Medicinal Marijuana Program] **Division**;

4. – 10. (No change.)

(b) (No change.)

8:64-9.7 Security

(a) (No change.)

(b) At minimum, each [alternative treatment center] **ATC** shall:

1. – 9. (No change)

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] **Division** prior to permit issuance.

ii. (No change.)

11. – 13. (No change.)

SUBCHAPTER 10. PLANT CULTIVATION AUTHORIZED CONDUCT

8:64-[10.8]10.7 Processing and packaging of marijuana

(a) – (d) (No change.)

(e) An ATC shall package, **manufacture**, 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.]; **or**

4. Oil formulations.

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

Recodify existing N.J.A.C. 8:64-10.9, 10.10, and 10.11 as **8:64-10.8, 10.9, and 10.10**

(No change in text.)

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

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] **The holding of an ATC permit or employment at 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) (No change.)

(c) Any person who makes a fraudulent representation to a law enforcement officer about the person's [participation in the Medicinal Marijuana Program] **status as a qualifying patient** 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) – (e) (No change.)

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 **local** law enforcement.

1. (No change.)

(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. (No change.)

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] **If the Department requires an audit of an ATC's financial records, the** 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] **Division**.

3. (No change.)

(c) – (i) (No change.)

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

(a) – (f) (No change.)