Filed May 2, 2019

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF MEDICINAL MARIJUANA

Medicinal Marijuana

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

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

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

Proposed: June 18, 2018, at 50 N.J.R. 1398(a).

Adopted: April 26, 2019, by Shereef M. Elnahal, MD, MBA, Commissioner, Department of Health.

Filed: April 26, 2019, as R.2019 d.049, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3), **and with the proposed amendment at N.J.A.C. 8:64-7.9 not adopted.**

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

Effective Dates: April 26, 2019, Readoption;

May 20, 2019, Amendments, New Rule, and Repeals.

Expiration Date: April 26, 2026.

Summary of Public Comments and Agency Responses:

The Department received comments from the following:

1. Justin Alpert, Livingston, NJ
2. Rebecca Barnes, Lawrence, NJ
3. Raul Barreiro, Livingston, NJ

4. Chris Beals, President and General Counsel, and Dustin McDonald, Dustin McDonald, Vice President, Government Relations, Weedmaps

5. Kate M. Bell, Esq., Marijuana Policy Project, Washington, DC

6. Mara Brough, Senior Manager of Advocacy, New Jersey and Pennsylvania, National Multiple Sclerosis Society, Woodbridge, NJ

7. Anthony Bennett, Monmouth Junction, NJ

8. Cristina Buccola, Esq., New York, NY

9. Patricia Cancelli, Pennsauken, NJ

10. Aubrey Conway, Parlin, NJ

11. Laurent Crenshaw, Senior Director of Government Affairs, Eaze Solutions Inc., San Francisco, CA

12. Robert Devine, Mount Laurel, NJ

13. Evelyn De-Souza, Linden, NJ

14. Hilary Downing, MAMMA (Mothers Advocating Medical Marijuana for Autism), Whitehouse Station, NJ

15. Nicholas J. Etten, Vice President, Government Affairs, Acreage Holdings, New York, NY

16. Nancy S. Fitterer, President and Chief Executive Officer, Home Care & Hospice Association of NJ, Cranford, NJ

17. Peter Furey, Executive Director, New Jersey Farm Bureau, Trenton, NJ

18. Agustin Garcia, President, Garcorp International, Inc., Miami, FL

19. David Green, East Brunswick, NJ

20. Patrick Haugh, North Brunswick, NJ

21. Andrew Holsman, Mount Laurel, NJ

22. Eric Karsh, Point Pleasant Borough, NJ

23. David L Knowlton, Chairman and President, Compassionate Care Foundation, Egg Harbor Township, NJ

24. Jeanne Van Duzer Lang, Chief of Staff, Patients Out of Time, Washington, NJ

25. Gaetano Lardieri, Newark, NJ

26. Charles Latini, American Planning Association — NJ, West Trenton, NJ

27. Scott Ledbetter, Glassboro, NJ

28. Giselle Marmolejos, Elizabeth, NJ

29. Danielle McBride, Voorhees, NJ

30. Deborah Miran, Lutherville, MD

31. Terry Morriken, Morris Plains, NJ

32. Hugh O'Beirne, President, New Jersey Cannabis Industry Association, Trenton, NJ

33. Lisa Parles, Glassboro NJ

34. Shiel Patel, Marlton, NJ

35. John W. Poole, MD, President, Board of Trustees, Medical Society of New Jersey, Lawrenceville, NJ

36. Oleg Rivkin, Ridgewood

37. Teri Roach, Vineland, NJ

38. Peter Rosenfeld, Coalition for Medical Marijuana—New Jersey, Collingswood, NJ

39. Jessica Rumer, New Jersey Cannabusiness Association, Westmont, NJ

40. George Schidlovsky, President, CuraleafNJ, Inc.

41. Alan Silber, Esq., Pashman Stein Walder Hayden, Hackensack, NJ

42. Laramie Silber, Patients Out of Time, Washington, NJ

43. Brett Stein, Toms River, NJ

44. David Stetser, Mantua, NJ

45. Michelle Tihanyi, Red Bank, NJ

46. Edward N. Tobias, Esq., East Brunswick, NJ

47. Bharat Vasan, Chief Executive Officer, PAX Labs, Inc., San Francisco, CA

48. Christian Velasquez, Sativa Cross, Dover, NJ

49. Ken Wolski, Coalition for Medical Marijuana — NJ, Trenton, NJ

Quoted, summarized, and/or paraphrased below, are the comments and the Department's responses. The numbers in parentheses following the comments below correspond to the commenter numbers above.

General Support

1. COMMENT: A commenter states, "[the] Murphy administration inherited a flawed [medicinal] marijuana program limited by an extremely small number of licensed businesses, leading to some of the highest prices for medical cannabis in the country, as well as severe restrictions on the types of cannabis and cannabis products available to patients. These and other factors, including the obvious hostility toward medical cannabis evinced by the previous administration, contributed towards extremely low participation in the program. [The commenter] commends the New Jersey Department of Health [(Department)] and Governor Murphy for their commitment to improving

patient access to the [medicinal] marijuana program and for the steps they have already taken toward that end. [The commenter] supports the regulatory changes being proposed [and the] additional changes suggested in the EO 6 [Report] that will require action by the legislature. [The] proposed [rulemaking is] a step forward in improving New Jersey's [medicinal] marijuana program." (5)

2. COMMENT: A commenter "supports the rights of people with [multiple sclerosis (MS)] to work with their healthcare providers to access marijuana for medical purposes in accordance with [State] law, where such use has been approved. The [Guideline Development Subcommittee of the] American Academy of Neurology [published a 2014 report stating] that some forms of marijuana may relieve MS-related symptoms such as … spasticity, pain[,] and urinary frequency. Additionally, individuals living with MS have personally reported that the use of [medicinal] marijuana has lessened many MS symptoms and provided pain relief … The [commenter] applauds New Jersey for moving forward with improving the [medicinal marijuana program]. [Many] of these changes are a start to making the program more accessible and affordable for New Jerseyans living with MS." (6)

3. COMMENT: A commenter notes the assertion in the proposed rulemaking that it is "designed 'to realize the goal of expanding patient access [(citation omitted).]' And many of the [proposed amendments, repeals, and new rule] are extremely pro-patient: N.J.A.C. 8:64-5.1 [would empower] the Commissioner to propose [and/or] adopt debilitating medical conditions … without requiring a lengthy petition process; N.J.A.C. 8:64-7.9 [would allow] ATCs to have satellite locations; the repeal of N.J.A.C. 8:64-10.7 [would enable] ATCs to produce [and/or] dispense multiple strains of [medicinal

marijuana] and [would eliminate] the limit on [tetrahydrocannabinol] in [medicinal marijuana] and [medicinal marijuana-containing] products." (8)

4. COMMENT: A commenter "[applauds] the [State's open-mindedness] to embrace something that has saved so many[;] was so very excited and almost relieved to know [the State] would be expanding the program for [patients'] ease of access[; is] very proud of this Administration and the steps [toward] progress regarding the [State medicinal marijuana program; and is] excited for the future of the program while the State is still hearing from the ones IN the program, not just politics and businesses." (10)

5. COMMENT: A commenter "[applauds] the Department's efforts to liberalize the [rules] regarding [medicinal] marijuana," and states that many patients and their families "have benefited from New Jersey's [medicinal] marijuana program." (16)

6. COMMENT: A commenter states that it is "pleased with the proposed repeal and new rule [at N.J.A.C. 8:64-5.1] and the proposed repeal [of N.J.A.C. 8:64-10.7 because these would] enhance the ability of [ATCs] to more adequately provide medicinal cannabis to appropriate, permitted New [Jerseyans]." The commenter states that the expansion of "the conditions for which medicinal marijuana can be authorized and the elimination of barriers to physicians authorizing such use are long-overdue." The commenter "[applauds] the change that the Department contemplates. The medicinal marijuana program in New Jersey suffered from unnecessary restrictions that hampered safe access to medical marijuana for all patients in need. The proposed changes go a long way toward changing those restrictions." (23)

7. COMMENT: A commenter states, “[although] cannabis has been legal medically in California and Oregon for over [two] decades (!) it has been very hazardous … to be a cannabis[-consuming patient] in [the State. Therefore, the commenter] was heartened when Governor Murphy issued Executive Order No. 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.’” (24)

8. COMMENT: A commenter “[thanks] the Department … for its work putting together the [proposed rulemaking].” (28)

9. COMMENT: A commenter is “very pleased with the fact that New Jersey is finally expanding its [medicinal marijuana program, which] has been a vital necessity since the program’s inception.” (31)

10. COMMENT: A commenter “[thanks] the Department for the proposed rule changes, which reflect best practices that are drawn from but also improve upon the experiences of other states. [The] regulatory context that will develop from the proposed rule changes will significantly improve the quality [and] increase [the] supply [of medicinal marijuana,] and further ease patient accessibility to New Jersey’s [medicinal] marijuana program. In particular, … the rule changes pertinent to industry architecture will enhance supply chain and market efficiencies, which will benefit patients through an increase in industry participants and result in fruitful competition.” (32)

11. COMMENT: A commenter states, “The proposed [rulemaking is] a major improvement and a good start.” (41)

12. COMMENT: A commenter states, “[medical] cannabis is a crucial tool in maintaining the health of so many; [medicinal marijuana in the State] needs to be run with an eye toward practicality, efficiency, and patient rights, [to] all of which the [Department] seems committed …” (42)

13. COMMENT: A commenter “supports the existing rules as an excellent base to be improved upon.” (40)

14. COMMENT: A commenter “[congratulates] the … Department … on its efforts to expand access to medical cannabis for qualified patients.” (47)

15. COMMENT: A commenter states that medicinal marijuana “patients greatly appreciate the obvious effort the personnel of the Department … expended in rescuing the Medicinal Marijuana Program (MMP) from the currently often cruel and counterproductive [rules, many of which] were designed to delay the program’s implementation and severely limit patient access. The [commenter] applauds the current proposal which resonates with a refreshing commitment to patient welfare … Based on the tenor of the … proposal, we have every confidence that the Department will give full and fair consideration to our comments and concerns in the interests of benefitting patients … The [EO] 6 Report … is clear and welcome.” (49)

16. COMMENT: A commenter states that the rulemaking is “already an excellent proposal and far superior to the existing [rules]. (49 and 31)

RESPONSE TO COMMENTS 1 THROUGH 16: The Department acknowledges the commenters’ support for the program and the rules.

Qualifying Patient Debilitating Medical Conditions (N.J.A.C. 8:64-1.2)

17. COMMENT: A commenter "[appreciates] the addition of new conditions. The reality is that many responsible members of the [cannabis community] personally partake as an important part of a wellness regimen. Welcome opportunity under the [Act] to recognize this reality and secure the [blessings] of [liberty] for good and free adult New Jersey citizens [sic]. Not all cannabis users are ill or wish to be forced by the State to identify as ill to comply with the law[,] especially when there is a natural right and they are already exercising the personal liberty anyway. Time for the [rules] to catch up to the reality as reflected through [the people] of [the] Garden State. Any good adult citizen should qualify for safe and legal access as part of a committed wellness regimen." (1)

18. COMMENT: A commenter states, "[the] Department should acknowledge ALL of the petitions recommended by the review panel and add them as debilitating conditions — including opiate use disorder and general chronic pain. [The commenter] supports the qualifying conditions being formally added in this rulemaking. However, the 2017 review panel's unusual decision to group petitions into categories appears to have resulted in confusion and many of its recommendations being ignored. Its recommendations included adding opiate use disorder and general chronic pain, yet the Department has not acted on those recommendations.

The EO 6 [Report] states …: 'The Commissioner concurs with the October 25, 2017[,] final recommendation of the Medicinal Marijuana Review Panel to grant the petitions *under the categories of* Chronic Pain Related to Musculoskeletal Disorders, Migraine, Anxiety, Chronic Pain of Visceral Origin, and Tourette's Syndrome (emphasis

added [by commenter]).' Those categories each contained many loosely related conditions, not just the conditions whose names form the titles of the category. For example, the petition for [opioid use disorder] was placed in the *category* "Chronic Pain Related to Musculoskeletal Disorders.' However, [opioid] use disorder was actually a broad petition; in no way was it limited to opioid use disorder that commenced solely as a result of a patient being prescribed opiates for that specific type of pain. Such a limitation would not appear to have any scientific basis.

[In its] recommendations[,] the review panel recommends the Health Commissioner 'GRANT those petitions listed under the categories Chronic Pain Related to Musculoskeletal Disorders, Migraine, Anxiety, Chronic Pain of Visceral Origin, and Tourette's Syndrome.' But again, … the *category '*Chronic Pain Related to Musculoskeletal Disorders,' on page four of the review panel's recommendations, … includes petitions to add both general chronic pain and opioid use disorder, among other things.

In the 'final agency decision' of March 22, [2017, to which] the EO 6 [Report refers], the Commissioner states:

> On May 11, 2017, the MMP Review Panel, which is a panel assembled by the Department to review and make recommendations on petitions seeking to add conditions to the MMP, met to review and hear public comments on the *forty-five* accepted petitions. At the meeting, the Panel acknowledged that they reviewed the material submitted with the petitions and that they also conducted their own

> independent analysis and *research for each condition*. During the meeting, the Panel also advised that it grouped the petitioned conditions into *seven categories*, namely chronic pain related to musculoskeletal disorders, chronic pain of a visceral origin, Tourette's Syndrome, migraine, anxiety, asthma and chronic fatigue. After offering a panel *discussion on each condition* and hearing public comments from two individuals, both of whom expressed support for the MMP, the Panel voted on *each petition*. Based upon a majority vote of the members who were present at the meeting, the Panel recommended that chronic pain related to musculoskeletal disorders, chronic pain of a visceral origin, Tourette's Syndrome, migraine, and anxiety be approved as debilitating conditions under the MMP and recommended denial of asthma and chronic fatigue.' [(Emphases added by commenter.)]

It is clear from this description, as well as the ultimate review panel recommendations themselves, that the review panel distinguished between *categories* and conditions, the latter of which were the subject of the petitions. Yet inexplicably, in the last sentence of the paragraph above, the Commissioner collapses the distinct terms 'category' and 'condition,' and treats the Panel's recommendations as if they did not recommend granting all petitions in each category. If the Commissioner intended to reject the review panel's recommendations to add all conditions listed in each category

— including opioid use disorder and the general category for chronic pain — … this should have been explicitly stated, along with an explanation.

Regardless of the past confusion generated by the categorization decision, however, current law and regulation puts the ultimate decision in the Commissioner's hands, subject of course to the ordinary standards governing administrative action. [The commenter urges] the Commissioner to reconsider this issue and add all of the qualifying conditions listed in the favorable categories in the review panel's report.

With respect to opioid use disorder …, [the commenter agrees] with Governor Murphy that medical cannabis can be 'an offensive weapon' in combatting the opioid crisis." The commenter provides two articles relating to this issue entitled, "Medical Marijuana Access Can Help Fight the Opioid Epidemic" and "Severe Pain and Medical Cannabis."

The commenter "supports streamlining the process for adding new conditions … but urges the Department to maintain transparency. While this administration has been very supportive of the [medicinal] marijuana program, that may not always be the case in the future, and transparency is an important tool to ensure that public officials are accountable for their actions. At the same time, … the existing process for adding conditions is excessively lengthy and onerous. [The commenter supports] the Commissioner being able to add qualifying conditions on his or her own, but would urge that, if the review panel does meet to consider a petition, or anything else the Commissioner requests that they consider, those meetings remain subject to the [Senator Byron M. Baer Open Public Meetings Act]." (5)

19. COMMENT: A commenter states, “the addition of six ‘debilitating medical conditions’: PTSD, by statutory enactment[,] and five new conditions (anxiety, chronic pain of visceral origin, chronic pain related to musculoskeletal disorders, migraines, and Tourette syndrome), by the State Health Commissioner’s March 22, 2018, petition decision[,] is a wonderful, welcome addition to the patient community. That so many will be able to access this therapy is amazing.” (10)

20. COMMENT: A commenter states, “autism should be a covered condition.” (14)

21. COMMENT: A commenter supports the proposed amendments, repeal and new rule, which would “[establish] review cycles to accept petitions to approve additional medical conditions or treatments thereof as qualifying for medical marijuana treatment [and define] the duties of the advisory review panel to evaluate those petitions.” (16)

22. COMMENT: A commenter states, “[physicians] should be permitted to recommend medical cannabis for any condition that they believe would be beneficially treated by cannabis. Physicians are entrusted with discretion when it comes to prescribing typical prescription drugs for off-label uses and New Jersey’s medical cannabis program should allow physicians to similarly use their medical expertise when recommending cannabis.” The commenter recommends that the Department add to the definition of the term, “debilitating medical condition,” the phrase, “other conditions as determined in writing by a registered qualifying patient’s registered healthcare professional.” The commenter states, with respect to proposed new N.J.A.C. 8:64-5.3(d), that 180 days “is too long to wait for the commissioner to make a final determination about a petition to add a new qualifying condition. Medicinal cannabis patients with rare conditions need

faster access and this timeline should be changed to 60 days to ensure efficient access for patients with severe and life-threatening conditions." (32)

23. COMMENT: A commenter "[wishes] that [patient authorization to use medicinal marijuana] didn't have any restrictions of medical conditions at all and it was up to a prescriber to make a decision if [a] patient would benefit from medical marijuana." (36)

RESPONSE TO COMMENTS 17 THROUGH 23: As several commenters note, the Medicinal Marijuana Review Panel (Review Panel), in the recommendation it issued following its May 11, 2017, meeting, and which it adopted as a final recommendation decision effective October 25, 2017, proposed to group the conditions, of which the petitioners' requested addition to the list of debilitating medical conditions, into broad categories, and then to approve (or deny) all petitions identifying conditions within those categories. See Review Panel's Recommendation at 2, and 4-5 (undated; marked "received," July 21, 2017), available at https://nj.gov/health/medicalmarijuana/review-panel/.

The Review Panel grouped the petitions to highlight the commonalities among the petitioned conditions for which it found evidence that medicinal marijuana could be an effective treatment. For example, chronic pain is both a condition and a symptom related to and resulting from all the musculoskeletal disorders cited in the petitions grouped under the category, "chronic pain related to musculoskeletal disorder." *Id.* at 4.

Likewise, in his March 22, 2018, Final Agency Decision (FAD) at 5, available at https://nj.gov/health/medicalmarijuana/review-panel/, consistent with the Review Panel's recommendation, the Commissioner approved those petitions that requested the addition to the list of debilitating medical conditions classifiable within the following five

categories (as listed in the Initial Recommendation at 4-5): chronic pain related to musculoskeletal disorder, chronic pain of visceral origin, migraine, Tourette syndrome, and anxiety.

Thus, contrary to the suggestion of a commenter, the Commissioner's approval of the broad categories to the list of debilitating medical conditions means that the Commissioner approved the individual petitions within each category. This serves to broaden the availability of medicinal marijuana to conditions within a category that petitions did not specifically identify. Again, using the example of "chronic pain related to musculoskeletal disorder," pursuant to the FAD and the proposed amendment at N.J.A.C. 8:64-1.2, a person who has chronic pain that is related to any musculoskeletal disorder, in addition to, or other than, the musculoskeletal disorders the petitions address, would qualify that person as having a debilitating medical condition for which physicians can recommend the use of medicinal marijuana. By recognizing the broader categories rather than the specific conditions the petitioners recommended, the FAD, as implemented through the proposed amendment to the existing definition of the term, "debilitating medical condition," at N.J.A.C. 8:64.1.2, would enhance physicians' ability to recommend medicinal marijuana for a broader range of conditions.

Pursuant to the FAD, as implemented through the proposed amendment at N.J.A.C. 8:64-1.2, opioid use disorder would qualify as a debilitating medical condition if it results from the treatment of chronic pain resulting from musculoskeletal disorder with opioids. Moreover, the Commissioner's January 23, 2019, Revised Final Agency Decision (RFAD) adds "opioid use disorder" as a standalone debilitating medical condition, conditioned on the patient's concurrent adherence to medication-assisted

therapy (MAT), that is, the use of medications such as buprenorphine and methadone, in combination with counseling and behavioral therapies, to treat substance use disorders.

Autism would qualify as a debilitating medical condition if it results in anxiety secondary to autism.

N.J.S.A. 24:6I-5 authorizes physicians treating patients with whom they are in a "bona fide physician-patient relationship" to certify those patients as authorized to use medicinal marijuana, that is, eligible to register with the Medicinal Marijuana Registry as "qualifying patients." The definition of a "bona fide physician-patient relationship" at N.J.S.A. 24:6I-3 requires a physician to be treating a patient for a "debilitating medical condition," that is, a condition listed in the definition of that term at N.J.S.A. 24:6I-3, and/or that the Commissioner establishes through rulemaking. Therefore, the Department is without authority to eliminate through rulemaking, as one commenter suggests, the statutory requirement that a patient have a "debilitating medical condition." But, pursuant to N.J.A.C. 8:64-5, as proposed for readoption with amendment, and through rulemaking, the Department has authority to establish additional debilitating medical conditions, which it can articulate as broad categories and construe expansively, as it would through the proposed amendment to the definition of "debilitating medical condition" at N.J.A.C. 8:64-1.2, as described above.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

24. COMMENT: A commenter "[applauds] the expansion of qualifying conditions," and states, "some of the most compelling conditions highlighted in the literature are not included. In particular, … human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS)-related neuropathy and cachexia, chemotherapy-related nausea and vomiting, muscle spasticity related to multiple sclerosis, Crohn's disease, graft-versus-host disease, and pediatric epileptic conditions are excluded from the list. These patient classes are among the most vulnerable, and the scientific literature supports the efficacy of cannabis as a treatment option [(citations omitted)]. Additionally, published evidence indicates … that[,] at the population level, cannabis can reduce opioid overdose mortality [and] the intake of opioid analgesics [(citations omitted)]. [The] Department [should consider] how medical cannabis may serve as a [harm-reduction] measure in light of the national opioid epidemic … New York [State took this approach] earlier this year, through an emergency regulation [(citations omitted)]." The commenter provides "lists of qualifying conditions adopted by other states with well-regulated medical cannabis markets, including … Oregon and Massachusetts [(citations omitted)]. In … these states, medical cannabis markets have been maintained, while [adult-use] markets have been established in parallel." (47)

RESPONSE: The existing definition of the term, "debilitating medical condition," at N.J.S.A. 24:6I-3, which existing N.J.A.C. 8:64-1.2 reiterates, already includes many of the conditions that the commenter suggests are omitted from the definition of that term. The definition includes, intractable skeletal muscular spasticity; severe or chronic pain, severe nausea and vomiting, cachexia, or wasting syndrome resulting from HIV, AIDS, or cancer or the treatment thereof; muscular dystrophy; and inflammatory bowel

disease, including Crohn's disease. The definition does not specifically include pediatric epileptic conditions but it does include the more general term, seizure disorder (if resistant to conventional medical therapy). The Commissioner recommended, in the EO 6 Report at 6, that the statutory requirement that certain conditions be "resistant to conventional medical therapy" to qualify as debilitating medical conditions "should be deleted to permit the use of medicinal marijuana as a first-line treatment, rather than a last resort, for these conditions."

A commenter identifies "graft-versus-host" disease as a condition that might qualify as a debilitating medical condition. The condition was not the subject of a petition to add it as a debilitating medical condition, and accordingly was not considered, during the last petition round. The commenter can submit the condition, with appropriate supporting documentation, in accordance with the process at N.J.A.C. 8:64-5, as proposed for readoption with amendments.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

Qualifying Patient and Caregiver Registration Fees (N.J.A.C. 8:64-2.1)

25. COMMENT: A commenter states, "The [existing] fee for [qualifying patient] registration … is too high and unaffordable for many New Jerseyans living with MS. The estimated cost of living with MS is $70,000 per year, per person. MS may impact the ability to work and may generate significant out-of-pocket costs related to medical care, rehabilitation, home and auto modifications, and more. Paying a high registration fee before accessing [a recommended amount of medicinal marijuana], which also has

a high cost, can make [medicinal] marijuana unattainable. The [commenter] supports the proposed [amendment] to reduce the registration fee from $200 to $100 and provide a reduced fee of $20 for those receiving public assistance and encourages the State to find additional ways to make [medicinal] marijuana more affordable for New Jerseyans." (6)

26. COMMENT: A commenter supports the proposed amendments and new rules that would "[create] a 'reduced-fee' eligibility category[, reduce] the registration fee for a qualifying patient or a primary caregiver from $[200.00] to $[100.00, set] a reduced-fee registration of $[20.00] for qualified individuals[, and establish a $5.00] 'reduced-fee' price to replace a registry identification card." (16)

27. COMMENT: A commenter states that the Department should reduce the registration fee for parents of minor qualifying patients to $20.00 because these parents "experience high financial and medical cost when paying out of pocket [to participate in medicinal marijuana, and a reduced fee would] ease the burden of cost for many families in need." (40)

RESPONSE TO COMMENTS 25, 26, AND 27: Making medicinal marijuana more affordable is a priority for the Department. The Department acknowledges the commenters' support of the proposed amendment at N.J.A.C. 8:64-2.1 to reduce registration fees by 50 percent for all qualifying patients and to expand eligibility for the reduced fee of $20.00 to seniors and armed services veterans.

Children who are qualifying patients with debilitating medical conditions may qualify for the Federal- and State-funded Medicaid program, https://www.state.nj.us/humanservices/dmahs/clients/medicaid/families/index.html,

through the Medicaid-funded Children's Health Insurance Program (CHIP), known in New Jersey as NJ FamilyCare, http://www.njfamilycare.org, enrollment which would qualify those children for the reduced registration fee. NJ FamilyCare has more generous income eligibility criteria for children than it does for adults. Children qualify whose family income is up to 355 percent of the Federal poverty guidelines ($7,278 per month for a family of four), whereas adults qualify if their income is at or under 138 percent of the Federal poverty guidelines ($1,387/month for a single person and $1,868/month for a couple).

Based on the foregoing, the Department will make no change on adoption in response to the comments.

Qualifying Patient Residency and Multistate Reciprocity (N.J.A.C. 8:64-2.2)

28. COMMENT: A commenter states that the Department should amend N.J.A.C. 8:64-2.2 to authorize "[additional] methods of proving patients' New Jersey residency [and that the] limited forms of proof [at N.J.A.C. 8:64-2.2 as proposed for amendment would] not account for individuals who have relocated to New Jersey to live with family [and/or] friends and may not have these forms of identification. The patient residency requirement also ignores … patients who may be temporarily located in New Jersey for medical treatment." (8)

29. COMMENT: A commenter supports "[reciprocity] of other valid [out-of-State medicinal] marijuana cards. All states currently bordering [New Jersey] have a medical marijuana program along with 30 states total so it is only fair that those with a debilitating condition can safely visit New Jersey. There are many examples of why this

… is of utmost importance. For instance[,] a young child with an extremely debilitating and[,] if left untreated with medical marijuana[,] deadly seizure disorder, [might need] to visit New Jersey for a medical appointment with an epilepsy specialist. Some of the children with the most severe cases have upwards of [hundreds] of seizures per day. If the use of medicinal marijuana is the only effective treatment, as it is for countless patients, then abruptly halting the dispensation of their medication can prove to be dangerous if not [downright] fatal." (31)

30. COMMENT: A commenter states that reciprocity with other states that authorize medical cannabis use "is crucial" for registered qualifying patients and notes that 30 states now have medical cannabis programs. The commenter states that patients "need to be free to travel for business or leisure without fearing criminal penalties for possession and use. Reciprocity is a patient right to freedom of movement." (42)

31. COMMENT: A commenter states that the Department should amend N.J.A.C. 8:64-2.2 to "recognize current, valid [medicinal] marijuana [identification] cards that are issued by any other state in the country, and [that] patients [holding other states' identification cards would] not be subject to criminal penalties for possession and use of marijuana that is consistent with [N.J.A.C. 8:64 because] 30 states now have [medicinal] marijuana laws." (31 and 49)

RESPONSE TO COMMENTS 28 THROUGH 31: The proposed amendment at N.J.A.C. 8:64-1.2 would add a definition of the term, "proof of residency," and would establish several types of documents that can be used to establish New Jersey residency, in addition to the forms that the existing chapter recognizes as acceptable proofs. The

commenter does not suggest any other types of documents that might be appropriate to include as proofs of residency.

The definitions of the terms, “qualifying patient” or “patient,” and “primary caregiver,” at N.J.S.A. 24:6I-3, condition the eligibility of a person to register with the Medicinal Marijuana Registry in either capacity on New Jersey residency. N.J.S.A. 24:6I-6 affords immunity to civil liability and criminal prosecution under State law only to qualifying patients, primary caregivers, ATCs, and physicians acting in accordance with the Act. Therefore, the Department is without authority to extend, through rulemaking, as the commenters suggest, eligibility to persons who are not New Jersey residents to participate in the Medicinal Marijuana Registry, to have access to New Jersey ATCs, and to enjoy the State immunity that the Act affords.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

32. COMMENT: A commenter states that the residency requirements at existing N.J.A.C. 8:64-2.2(a)6 are redundant of the new term, “proof of New Jersey residency,” in N.J.A.C. 8:64-1.2, as proposed for amendment.

RESPONSE: The commenter is correct. Contrary to the Department’s intention, the rulemaking inaccurately omits to show the proposed deletion of some existing rule text at N.J.A.C. 8:64-2.2(a)6, and instead shows N.J.A.C. 8:64-2.2(a) as having been proposed for readoption without change. 50 N.J.R. 1398(a), 1407. In the notice of proposal Summary, the Department states, “[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 ... The Department proposes corresponding amendments at existing N.J.A.C. 8:64-2.2 and 2.3 to delete the relocated criteria." 50 N.J.R. at 1400. Because the notice of proposal Summary provides adequate advance notice of the proposed relocation of the residency criteria and there is no harm to the public in the change, the Department will make a non-substantial change on adoption to delete the redundant text at N.J.A.C. 8:64-2.2(a)6.

Qualifying Patient Designation of One ATC (N.J.A.C. 8:64-2.2 and 3.4)

33. COMMENT: A commenter opposes "the ongoing limitation of one ATC per patient [and/or] caregiver. This rule limits access to [medicinal] marijuana and is a [hindrance] to many. As New Jersey continues to expand the number of ATCs[,] patients should be able to choose at [any time from] which ATC they want to pick up their prescription." Referring to N.J.S.A. 17:48-6j(a)(2), the commenter states, "New Jersey enacted 'any willing provider' legislation[,] which allows New Jerseyans to have their prescriptions filled at any pharmacy in the [State and] requires insurers to accept any pharmacy [and/or] pharmacist into their [networks] as long as they agree to the contract. Yet, New Jersey continues to limit patients receiving medical marijuana to one ATC. [The State should] allow patients to have access to all ATCs and align the policy on this to the any willing provider statute." (6)

34. COMMENT: A commenter states, "Requiring patients and caregivers to obtain [medicinal marijuana] from only one designated ATC limits patient access to[,] and denies patient choice of[, medicinal marijuana … N.J.A.C. 8:64-3.4 [requires] primary caregivers [to] certify [that] they will only obtain [medicinal marijuana] from the ATC

selected by their patients [as] identified on [caregivers'] registry [cards ... N.J.A.C. 8:64-11.3 [requires] an ATC … to deny [medicinal marijuana] dispensary services to qualifying patents and/or primary caregivers who have not previously designated [that] ATC as their ATC. [These rules] chain patients to a single ATC, [eliminate] their ability to try different strains [and/or medicinal marijuana-containing] products from different ATCs and are distinctly anti-patient. When patients change their designated ATC, caregivers are required to surrender their cards and await new ones[. During] this time[,] patients' [medicinal marijuana courses] may be interrupted to the detriment of patients' health." (8)

35. COMMENT: A commenter states "that a patient has a right to choose more than one ATC and that the patient must not be limited to only one ATC. The [Department] should allow [patients] the right to change their ATC whenever [they] may need to do so. Limiting a primary caregiver to the ATC named on the card will hold that caregiver to said ATC." (40)

36. COMMENT: A commenter states that existing N.J.A.C. 8:64-3.4(c) "limits [a] caregiver to [obtaining medicinal] marijuana only from the ATC named on the registry [identification] card. This needs to be changed to allow flexibility for quick changes between ATCs, without the need for a new card. The reality is that caregivers report [that] they can already change their [ATCs] without getting a new ID card." (31 and 49)

RESPONSE TO COMMENTS 33, 34, 35, AND 36: N.J.S.A. 24:6I-10 at §d authorizes patients to be registered with only one ATC at a time. Therefore, the Department is without authority to eliminate this statutory requirement through rulemaking, as the commenters suggest. In the EO 6 Report at 18, The Commissioner stated that this

requirement, “limits patient access to product. The Department recommends that the statute be amended to allow patients to obtain product from any State ATC dispensary.”

The existing rules and Department practice allow patients and caregivers to change their ATCs as often, and as many times, as they would like in the online Medicinal Marijuana Registry, which updates immediately in real time. The Department has added mobile access to the Medicinal Marijuana Registry, allowing registrants even greater flexibility to make instantaneous changes “on the fly,” using their mobile phones.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

Qualifying Patient Designation of Additional Registered Caregivers (N.J.A.C. 8:64-2.2)

37. COMMENT: A commenter “supports allowing as many caregivers as a particular patient needs. In addition to picking up medications, many patients need assistance with the act of administering their medicine, including medical cannabis. It is important that [the rules] be crafted broadly enough to reflect the reality of patients’ situations, including those of patients with the most severe limitations. A patient with intractable seizures, muscular dystrophy, or [amyotrophic lateral sclerosis (ALS)] may have numerous people assist with administering medication in the course of a year — including parents or adult children as well as nurse aides and other medical professionals. Thus, [the commenter supports] allowing patients to designate two caregivers instead of just one, and [encourages] the Department to allow additional

caregivers if [a] patient demonstrates a need due to [the patient's] age or medical condition." (5)

38. COMMENT: A commenter "supports the rule to increase the number of caregivers each participant can have from one to two. Some individuals may require more regular care, or they may have multiple caregivers who work in rotation. Limiting access to one caregiver could be burdensome for some people living with MS. Expanding access to the second caregiver would give people more flexibility so they're not entirely reliant on one person to obtain their medicine from [an] ATC. The primary caregiver could get sick or have their own personal or health issues so having a second caregiver licensed to acquire medical marijuana from an ATC would ensure that access is not interrupted due to unforeseen events." (6)

RESPONSE TO COMMENTS 37 AND 38: The Department acknowledges the commenters' support for the proposed amendment at existing N.J.A.C. 8:64-2.2(e) that would to increase from one to two the number of caregivers that a qualifying patient can designate. The Commissioner stated, in the EO 6 Report at 17, that this would, "reduce the burdens on primary caregivers and further ensure that qualifying patients are able to continuously obtain product. In advance of the formal rulemaking process, the Department will lift the one-person limit on primary caregiver designation and allow two primary caregivers upon request."

The Department's experience with allowing two primary caregivers, since the Commissioner's issuance of the EO 6 in March 2018, has indicated thus far that two is a sufficient number of caregivers for qualifying patients to be "able to continuously obtain product." The Department will continue to monitor the adequacy of limiting the number

of caregivers to two based on client experience, and if it determines that qualifying patients generally need a larger number of caregivers, it will propose to amend the rulemaking accordingly. In the meantime, if qualifying patients experience hardship resulting from the two-caregiver limit, the Department would consider allowing additional caregivers for individual patients on a case-by-case basis following the submission of an application for waiver of the two-caregiver limit at N.J.A.C. 8:64-2.2(e), pursuant to the Department's waiver authority at N.J.A.C. 8:64-7.11.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

39. COMMENT: A commenter is "deeply concerned about the legal implications of marijuana in New Jersey, both for current medicinal use and potential adult/recreational use in the future. [The rules proposed for readoption and the proposed amendments, repeal, and new rule, at N.J.A.C. 8:64], well-meaning as they are, are inadequate to address the large population of patients … who [could] benefit from cannabis in all its forms but who do not wish to make their identities known to [the State] and [Federal governments] for a wide number of reasons [such as to avoid self-incrimination and interference with the physician-patient relationship]. The Department [should] consider ways to allow prospective patients … to anonymously take advantage of the benefits that medicinal marijuana can provide. HIPAA protections exist to keep the doctor-patient relationship confidential. The highly contentious political views regarding marijuana make this drug the sole exception to these protections." (46)

RESPONSE: N.J.S.A. 24:6I-4 at §f obliges the Department to maintain a confidential list of persons to whom it issues registry identification cards and exempts this information from public access and disclosure under the government records law, N.J.S.A. 47:1A-1 et seq., except as specified therein. Therefore, the Department is without authority to authorize through rulemaking a procedure to issue anonymous registration. Registration is the only means by which the State can implement the immunity from State civil liability and criminal prosecution that the Act affords qualifying patients and their caregivers. The Department is without authority to affect Federal liability for marijuana possession and use through rulemaking. At N.J.S.A. 24:6I-2, the Legislature found and declared that the medicinal marijuana use has beneficial value.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

Caregiver Eligibility Criteria (N.J.A.C. 8:64-2.3)

40. COMMENT: A commenter states, “[the] requirements to serve as a primary caregiver under N.J.A.C. 8:64-2.3 are unduly burdensome. Mandating that only New Jersey residents may serve as designated caregivers fails to acknowledge that [qualifying] patients may depend on family and friends who live close to, but not in, New Jersey as caregivers. If the residency requirement is maintained, the amount of time required proving residency should be reduced [so] that individuals who relocate to New Jersey and serve as caregivers [can qualify as State residents] as soon as possible. [The Department should clarify] the criminal background checks to be completed as part of a primary [caregiver’s] application, specifically what constitutes a ‘disqualifying

conviction.’ A criminal record should not automatically disqualify someone from serving as a caregiver. Certain criminal records ([that is], those involving cannabis) might even be related to a desired asset in caregivers — familiarity with the cannabis plant and its effects.” (8)

RESPONSE: The definition of the term, “primary caregiver” or “caregiver” at N.J.S.A. 24:6I-3 establishes the eligibility criteria to serve in this capacity. These are State residency, attainment of the 18 years of age, registration with the Department, satisfaction of a criminal history record background check, and not having “been convicted of possession or sale of a controlled dangerous substance.” Therefore, the Department is without authority to expand, through rulemaking, the statutory eligibility criteria that require persons seeking to serve as caregivers to be New Jersey residents.

Existing N.J.A.C. 8:64-1.2 provides a definition of the term, “disqualifying conviction,” which is consistent with the definition of that term at N.J.S.A. 24:6I-4 at c(2) and the definition of “primary caregiver” or “caregiver,” described above. Based on the foregoing, the Department disagrees with the assertion that the meaning of the term, “disqualifying conviction” is unclear.

Contrary to the commenters’ assertion, a conviction does not “automatically disqualify someone from serving as a caregiver.” N.J.S.A. 24:6I-4 at c(5) obliges the Commissioner to permit a person with a conviction to serve as a caregiver if the Commissioner finds, upon consideration of the factors therein listed, that the person has “affirmatively demonstrated … clear and convincing evidence of rehabilitation.”

Existing N.J.A.C. 8:64-3.2, as proposed for amendment, would continue to facilitate provisional approval of caregivers and issuance to them of temporary registry

identification cards pending the completion of criminal background record reviews. This enables caregivers to assist qualified patients, “as soon as possible,” as the commenter requests.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

Qualifying Patient Authorized Amount (N.J.A.C. 8:64-2.5)

41. COMMENT: A commenter states, “limits should be set by physicians not limited by the [State]” [sic]. (2)

42. COMMENT: A commenter supports “raising the allotment limits not just for patients [who are minors] but also for those with terminal [illnesses who are] not capable of things like vaping.” (10)

43. COMMENT: A commenter states, “[the] amount of cannabis [that patients are] allowed to purchase should be increased to help with patient costs. If a particular strain works well for a patient, [the patient] should be able to purchase a full ounce of that strain at a reduced [cost], rather than buying [four] separate quarter-ounce packages at the quarter-ounce package price.” (12)

44. COMMENT: A commenter states that the requirement that “physicians … limit their recommendations to a [90-day] supply … is too short. Other states offer [six-month] and [one-year] supply amounts. Having a [90-day] supply [maximum] puts undue financial burden on … patients. Each doctor visit costs money that many people in this [State] don’t have [and] puts a physical strain on a person with a debilitating condition and/or disability. [It is hard for] many [qualifying] patients … to leave the house and the

number of patients with mobility issues will only grow since [the State] has approved chronic pain from musculoskeletal origins (arthritis, fibromyalgia …) [as a recognized debilitating medical condition]. [The Department should authorize physicians to recommend six-month or one-year supply options] to keep the program accessible to all whom could benefit from it …" (31)

45. COMMENT: A commenter states that the Department should eliminate the 90-day supply limit on the amount of medicinal marijuana a physician can recommend to a qualifying patient, because this limit "amounts to a needless expense for a number of patients who suffer from life-long debilitating medical conditions [and the limit] should be extended to … either a [six]-month supply, or better still, left up to the authorizing physician in consultation with the patient to determine when a return visit is appropriate." (31 and 49)

46. COMMENT: A commenter states that the Department should remove "restrictions on the amount of [medicinal marijuana strains containing both high cannabidiol and low THC levels that] a patient … can purchase in a month," because such "strains do not get a patient 'high.' A patient can consume any amount of [such strains] and not become … incapacitated in [any way]. [Cannabidiol] is completely non-psychoactive. It is impossible to get 'high' from [cannabidiol]. The high levels of [cannabidiol] in [such strains] completely mitigate any 'high' one would get from even a lower amount of THC. [Cannabidiol] has many medicinal benefits including anti-inflammatory and anti-seizure properties." (31)

RESPONSE TO COMMENTS 41 THROUGH 46: The Department agrees with the commenters' assertions that the limitations on dispensable amounts and certification

periods can impose undue burdens of expense and inconvenience to qualifying patients and their caregivers. However, N.J.S.A. 24:6I-10 establishes the maximum dispensable amount as two ounces in a 30-day period and the maximum certification period of 90 days. Therefore, the Department is without authority to expand, through rulemaking, these statutory limitations on the dispensable amount or the certification period.

The Commissioner made the following recommendations in the EO 6 Report at 6 and 16, "The Department strongly recommends that the statutory product limit for those receiving hospice care be eliminated. This recommendation reinforces the purpose established in the enabling legislation, which 'protects … those patients who use marijuana to alleviate suffering from debilitating medical conditions.' [The] Department recommends that the statutory limit be increased to four ounces. This recommendation is consistent with our neighboring states that have an active medicinal marijuana program. Both New York and Pennsylvania provide for a '30-day supply' without reference to amount and Delaware's program has a six-ounce limit. However, this proposed increase in medicinal marijuana supply limits would likely need reinforcement through the revision of N.J.S.A. 24:6I-6 to ensure that patients have adequate legal protection against criminal charges."

Based on the foregoing, the Department will make no change on adoption in response to the comments.

Physician Participation and Registration; Insurance Coverage for Physician Visits (N.J.A.C. 8:64-2.5)

47. COMMENT: A commenter states, “[insurance] coverage for [physician] visits” [sic]. (2)

48. COMMENT: A commenter “supports making the list of participating physicians opt-in [to encourage] more participation from physicians who … want to recommend cannabis for [only] a few of their existing patients, rather than making medical cannabis a significant part of their practice. They may not want to receive calls from people seeking medical cannabis recommendations who are not already their patients and therefore decline to issue any recommendations if they would be required to be publicly listed.” The commenter supports “eliminating the physician registry. This additional hurdle reduces physician — and thus patient — participation. However, the … proposed [rulemaking would] still require a physician to ‘enroll,’ and it is not clear how enrollment differs from registration. That said, [the commenter supports] anything that reduces the extra burden on busy physicians who want to recommend [medicinal] marijuana, beyond what they would have to do to prescribe other drugs, many of which are more dangerous than cannabis …” (5)

49. COMMENT: A commenter states, “[allowing] physicians to opt out of inclusion on a public list of participating physicians … is a step in the right direction … So many physicians were unjustly discriminated against both personally and professionally. However, … the [State needs] to step in when it comes to what some of these doctors are charging potential patients. [While] they are private businesses …, if [medicinal marijuana is regarded] as medication[,] how can [one’s] finances [be] the gatekeeper to

possibly saving a life[?]" The commenter does "not [suggest that the services of] participating physicians [should] be free of cost." The commenter describes a person who was eligible to be a qualifying patient "for many years [but] was not able to [enroll because] the only participating physician [to whom the person's] general practitioner referred [the patient] cost [$1,000] for ONE visit, without [the physician] ever having to see [the patient] again for the year. [The Department should] consider the pain felt by so many that want desperately to [abandon] harmful therapies like opiates, … but do not have the option to use medical cannabis due to the very first cost they incur. [While visits to] some participating physicians can run as low as [$175.00] for the initial visit[,] these are few and far between. It requires a lot of work and then in most cases, a lot of travel … to see one of those physicians. Again, what is [the] message to the residents of [the State] when [medicinal marijuana is said to be] effective, [lifesaving, and life-improving], while also qualifying it with a [physician's] appointment ranging from [$175.00 to $500.00] upfront [for an] appointment with doctor, [the State registration] fee ([the proposed reduction of] which is a much welcomed and intelligent improvement), [$300.00 and more] per ounce of medication, and to top it off[,] every 90 days the recertification will again have [one] reaching for [one's] wallet[, which tells New Jerseyans] that nothing has changed when it comes to [pharmaceuticals:] if [one cannot] afford it, [one does not] get to have these healthier options." (10)

50. COMMENT: A commenter supports the proposed amendments that would permit "physician enrollment through the [Department's] web portal [and] physicians to disenroll [from] the program." (16)

51. COMMENT: A commenter states, “[sadly,] I think sometimes we can’t see the forest for the trees. [Everyone] in the program is a patient. [Allowing physicians to] opt out of publicly asserting they prescribe [medicinal marijuana makes] it more difficult for [patients]. [If a rule] doesn’t benefit patients what good does [it] do[, at] least until we wake up and decide that the tax money is way more lucrative and more research needs to be done. [The industry has produced] great strides … in such a short time but [certainly] greed must not be allowed to be the crowning factor.” (27)

52. COMMENT: A commenter inquires, “Will there be an updated list of doctors who participate in the [medicinal marijuana system]?” (37)

53. COMMENT: A commenter inquires whether “the report [that Executive Order No. 6 requires] the New Jersey Board of Medical Examiners (BME) [to issue is] forthcoming?” The commenter states that the EO 6 Report says that there are 523 enrolled participating physicians throughout the State (as of February 15, 2018), while only 79 percent are actively writing patient statements and treating patients. The commenter states, “there are approximately 28,000 physicians in New Jersey, so less than [two percent of] New Jersey physicians are participating in the [medicinal marijuana system, which] is an unacceptable level of physician participation … that the BME and the Department must address. Currently patients must search the Department website for a physician to recommend marijuana for them. Typically, these physicians charge cash (usually over $[100.00]) for each visit as they contend that a patient’s health insurance does not cover [medicinal] marijuana. Additionally, patients are required to return to the participating physician every 30, 60 or 90 days for a renewal of [a medicinal] marijuana recommendation[, which] is an added and unnecessary expense for many of the New

Jersey [qualifying] patients who already have to contend with the most expensive [medicinal] marijuana in the [United States]." (31 and 49)

RESPONSE TO COMMENTS 47 THROUGH 53: N.J.S.A. 24:6I-14 states, in pertinent part, "Nothing in this act shall be construed to require a government medical assistance program or private health insurer to reimburse a person for costs associated with the medical use of marijuana …" The rules proposed for readoption and the proposed amendments, repeal, and new rule have had, and would continue to have, no bearing on whether health insurance products available to New Jersey residents cover patient visits to physicians who might authorize the use of medicinal marijuana for patients' debilitating medical conditions, as this is a matter within the jurisdiction of the New Jersey Department of Banking and Insurance. Likewise, the Department has no jurisdiction over the billing practices of physicians, because physician licensing and oversight is within the jurisdiction of the State Board of Medical Examiners in the Division of Consumer Affairs of the New Jersey Department of Law and Public Safety, and particularly as that Board establishes at N.J.A.C. 13:35-7A with respect to physicians' participation in authorizing their patients' use of medicinal marijuana. However, the Department is aware of no reason why a visit of this nature should be subject to any different coverage standards or physician billing practices than those associated with other routine diagnostic or follow-up office visits.

As discussed in response to a previous comment, the Department is without authority to expand through rulemaking the statutory maximum certification period of 90 days at N.J.S.A. 24:6I-10, but, as reflected in the EO 6 Report, the Commissioner

supports amendments to the statute to reduce the burdens associated with this requirement.

N.J.S.A. 24:6I-5 states that, to issue a certification authorizing a qualifying patient's use of medicinal marijuana, a physician must "be licensed and in good standing to practice in the State." The enrollment function at N.J.A.C. 8:64-2.4, as proposed for amendment, would facilitate the Department's physician license verification process and provide physicians electronic access to certify patients' authorization to use medicinal marijuana in the patient registry. To further distinguish enrollment from the existing physician "registration" process, as one commenter suggests, the Department will make a change on adoption to the section heading, which the Department inadvertently omitted in the notice of proposal, to indicate more accurately that the section addresses physician "enrollment" rather than "registration."

The Department acknowledges the commenters' support for proposed new N.J.A.C. 8:64-2.4(b), which would allow physicians to opt out of inclusion on the public list of participating physicians that the Department maintains.

The Commissioner has undertaken various efforts to increase physician participation in authorizing their patients' use of medicinal marijuana. For example, beginning in May 2018, and as of April 2019, the Commissioner has presented 12 "grand rounds" sessions throughout the State to over 1,000 New Jersey physicians to discuss evidence that supports marijuana as an appropriate or alternative treatment for patients with certain debilitating conditions and to describe the operation of the Medicinal Marijuana Registry. See

https://www.youtube.com/watch?time_continue=5&v=Mmq_X-9QAvo. In addition, the Commissioner has authorized the use of medicinal marijuana to reduce reliance on opioids to address chronic pain and treat opioid use disorder. See RFAD at 16-19, and 24. These and other Department initiatives to increase physician participation have been fruitful. Enrollment of participating physicians has increased by 80 percent over the course of the Murphy Administration. As one commenter notes, there were 513 physicians participating in the program as of January 2018. As of April 2019, there are 940 participating physicians, an increase of over 400 physicians.

Based on the foregoing, except for the non-substantial change described above, the Department will make no change on adoption in response to the comments.

Authorization of Health Care Providers Other Than Physicians to Recommend Medicinal Marijuana (N.J.A.C. 8:64-2.5)

54. COMMENT: A commenter states, "[N.J.A.C.] 8:64-2.5 still requires that only a physician who is licensed and in good standing to practice medicine in New Jersey is eligible to authorize the medical use of marijuana by a qualifying patient. [This] should be expanded to include all healthcare practitioners who are licensed and in good standing to provide healthcare services to a qualifying patient and who are authorized to prescribe controlled substances. This would include advanced practice nurses, dentists, and podiatrists. Such professionals are actively engaged in the care of patients and have demonstrated ability to prescribe controlled substances. Their patients should have access to [recommend] medicinal marijuana when, in the opinion of the professional, [a patient's] condition warrants it." (23)

55. COMMENT: A commenter states that EO 6 “contemplates, and the Administration has been on record [as stating,] that the need may create as many as 300,000 medical cannabis patients in the near term … To serve 300,000 patients for whom the medicine is helpful, the rules need to create a path for many health care professionals to be able to recommend cannabis to patients. Currently only [two percent] of New Jersey’s 28,000 doctors are participating in the [Medicinal] Marijuana Program. This is a profound bottleneck that the [rules] should address. The Board of Medical Examiners, [which Executive Order No. 6 requires] to create a report …, (but [which] inexplicably has not [created a report]), can authorize nurse practitioners to recommend cannabis. That should certainly be done.” (41)

56. COMMENT: A commenter states that the authority to recommend the use of medicinal marijuana should be broader and that “essentially anyone with prescribing privileges[, including advanced practice nurses, physician assistants, and veterinarians,] needs to be able to recommend cannabis to [the healthcare professional’s] patients. These professionals are already experienced in interfacing with substances far more dangerous than cannabis. If the [State] expects the program to expand to the extent anticipated, more healthcare professionals need to have the ability to recommend cannabis. In addition to simply creating more capacity, many patients will be more comfortable discussing comprehensive treatment options, including cannabis, with their existing primary care [providers], who in many cases [are advanced practice nurses] or other [types] of [high-level] healthcare [professionals] other than [physicians].” (42)

57. COMMENT: A commenter states, “the Department should allow anyone in New Jersey who has prescription privileges, including [advanced practice nurses, physician

assistants, dentists, and veterinarians], to recommend [medicinal] marijuana. Marijuana is part of mainstream medicine, despite the fact that 98 [percent] of New Jersey physicians have shown little or no interest in learning about the [endocannabinoid system, which] interacts with all the other systems in the body and … may well play a role in all disease processes affecting humans and animals." (31 and 49)

RESPONSE TO COMMENTS 54, 55, 56, AND 57: N.J.S.A. 24:6I-5 authorizes only physicians who are licensed and in good standing to practice in New Jersey to authorize their patients' use of medicinal marijuana through the issuance of a certification. The Department is without authority to expand by rulemaking the statutory authority to issue qualifying patient certifications to health care professionals other than New Jersey licensed physicians.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

Qualifying Patient Workplace Protection; Drug Testing (N.J.A.C. 8:64-9.6)

58. COMMENT: A commenter states, "work place protection" [sic]. (2)

59. COMMENT: A commenter has "spoken directly with Governor Murphy on television and Commissioner Elnahal on the phone at length about patients' rights in the workplace, and both … have been very receptive and open to suggestions …" (7)

60. COMMENT: With respect to N.J.A.C. 8:64-9.6, Drug testing, a commenter states, "Cannabis should be omitted from a qualifying patient's drug screen entirely, and all employees, not just those in ATCs, must be protected." (42)

61. COMMENT: Commenters state, “Work place protection [sic]. Please give the patients in this program have the power not the big business! Health over wealth.” (29 and 48)

62. COMMENT: A commenter states, “[the] Department wisely recommends no change to [N.J.A.C. 8:64-9.6,] the ‘Alcohol and drug-free workplace policy’ for ATCs … Indeed, this workplace protection for [medicinal] marijuana patients should become the standard for all businesses in New Jersey. It makes no sense to penalize a patient in the workplace for using the very physician-recommended medication that, in many cases, allows that employee to participate in the workplace in the first place.” (31 and 49)

RESPONSE TO COMMENTS 58 THROUGH 62: The Act does not confer jurisdiction to the Department to establish standards requiring employers to accommodate the use of medicinal marijuana in the workplace. In fact, N.J.S.A. 24:6I-14 states: “Nothing in this act shall be construed to require … an employer to accommodate the medical use of marijuana in any workplace.” However, the Department notes the recent decision of the Superior Court of New Jersey, Appellate Division, in *Wild v. Carriage Funeral Holdings, Inc.,* No. A-3072-17T3, 2019 *N.J. Super. LEXIS* 37 (App. Div. March 27, 2019), wherein the panel held that N.J.S.A. 24:6I-14 does not “immunize[ ] employers from obligations already imposed elsewhere,” such as by the New Jersey Law Against Discrimination (LAD); that is, the Act does not impact existing employment protections under the LAD where an employee with a covered disability seeks an accommodation to take medicinal marijuana off-site and during off-work hours.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

Qualifying Patient Federal and Affordable Housing Protection

63. COMMENT: A commenter states that the Department "needs to create a consumption license. Not all patients are able to consume [medicinal marijuana] in their homes. Patients who receive [Federal] housing subsidies, for example, risk losing their homes for at-home [medicinal marijuana] consumption. [The] Housing Affordability Impact Analysis [states that] the [Department does not anticipate] that the [rulemaking would] have an impact on the [affordability] of housing in New Jersey. But failure to provide [a] class of licenses that allow patients to consume [medicinal marijuana] in a safe space outside of their homes threatens the residency of thousands or patients and could cause living expenses for such patients to skyrocket." (8)

RESPONSE: The rules proposed for readoption, and the proposed amendments, repeals, and a new rule, at N.J.A.C. 8:64 would not establish the conditions attendant to acceptance of Federal housing subsidies that the commenter describes. To the extent a prohibition against the use of medicinal marijuana in Federally funded housing exists, it exists by operation of Federal law. The Department has no ability to contradict or supersede Federal housing subsidy mandates. The Department notes that Federal law also prohibits tobacco smoking in Federally funded housing (24 CFR Parts 965 and 966).

N.J.A.C. 8:64 as proposed for readoption with amendments, a new rule, and repeals, does not, and would not, limit patients exclusively to using medicinal marijuana

in their own homes. Nor does it limit patients to smokable forms of medicinal marijuana. Recodified N.J.A.C. 8:64-10.8, as proposed for readoption with amendment, would expand the forms of medicinal marijuana available to qualified patients to include "oil formulations," in addition to oral lozenges and topical formulations. In addition, the proposed amendments authorizing manufacturing permit endorsements would expand qualifying patients' access to non-smokable forms of medicinal marijuana.

The Department is without statutory authority to establish by rulemaking a standard for licensure of "safe spaces," at which qualifying patients could use medicinal marijuana.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

Qualifying Patient and Caregiver Home Cultivation for Patient Personal Use; Cost of Medicinal Marijuana

64. COMMENT: A commenter states, "home cultivation" [sic]. (2)

65. COMMENT: A commenter states, "A [medicinal] marijuana bill with no provisions for … patients growing their own or a caregiver growing it for them is a big mistake and is basically a [medicinal] marijuana program for the few that can afford it. This medicine needs to be universally accessible and available to all those who need it. People on fixed incomes and patients who are unable to work [cannot] afford dispensary prices for this medicine and they should have an alternative that they can access. [Many law-abiding] citizens and residents of New Jersey would be willing, [ready,] and able to grow this medicine for those who need it." (3)

66. COMMENT: A commenter states, “with the highest prices in the nation by about” three times, qualifying patients in the State “need to be able to grow their own plants. Let people grow organically if they choose. Allow the ATCs to sell clones or seeds. No patient would be opposed proper regulation and inspection, as well as a mandatory safety classes and … fees to be able to grow their own medicine [versus] buying improperly grown marijuana at a premium price.” (7)

67. COMMENT: A commenter states, “[to] be truly patient-focused, [the State] needs a home cultivation allowance. [Medicinal marijuana that is] grown at home for personal medical use is more cost effective than purchasing [medicinal marijuana] through ATCs. Home [growing affords] patients the easiest access to their medicine.” (8)

68. COMMENT: A commenter states the Department should authorize patients on fixed incomes to “be able to grow [medicinal marijuana for personal use] because it costs SO MUCH MONEY[.] Some persons in the dispensary system stated that [patients] would be able to buy [medicinal marijuana] for less than it would cost for [patients] to grow [their] own, which of course was an OUTRIGHT LIE. Please allow again the freedoms that should be inherent within humanity, to take charge of [patients’] own health and medicine. Who [is a patient] going to injure growing [medicinal marijuana] in [the patient’s] secured basement or garage? When [the patient] is no longer [able to afford purchasing medicinal marijuana], [the patient will] have to go … back to … pharmaceuticals, which will kill [the patient] faster, but at least [pharmaceuticals are] covered by [the Pharmaceutical Assistance to the Aged and Disabled (PAAD) program] to a point. It’s all about [a patient’s] quality of the life. [A patient should] have that RIGHT to grow and have earned some respect. Unless money lining the pockets of the

legislators and dispensary agents is more important to [the State] than … fellow humans, please allow homegrow for patients." (9)

69. COMMENT: A commenter states that the price of medicinal marijuana "is overwhelming and suffocating [for a patient on a fixed income who has children with special needs]. [The] price … is too much. [A patient] can't always afford [the amount needed to relieve symptoms]. [Some] strains that … dispensaries [in the State] offer … cause … anxiety and don't always help with sleep[. Because] of the limited [number] of strains available[, allowing] patients to grow a small number of cannabis plants [for] their own [use would enable them] to know the exact strain that helps with their needs … The cost of medical cannabis in New Jersey is equivalent to [renting] a studio apartment — [more than $900.00 per month]. [Not] allowing patients to grow [takes] away their access to affordable medicine[. While] the opioid crisis is being paid for by insurance companies, [medicinal] marijuana patients are bleeding and struggling to pay for what little [amounts] they can afford. [Hopefully,] one day cannabis [patients] can be taken into consideration when it comes to their OWN medicine." (13)

70. COMMENT: A commenter states, "it is extremely important to allow … limited home cultivation for patients to help reduce medicine costs. The current costs at dispensaries are far too high and patients are being forced to go without their medicine at times because they cannot afford it. [The] current rates for medical cannabis are very expensive and [cost-prohibitive] to patients." (12)

71. COMMENT: A commenter states, "[the] program is too expensive; we need patient co-ops and home cultivation …" (14)

72. COMMENT: A commenter states that the cost of medicinal “marijuana is too much for most patients. Because insurance companies do not cover [medicinal marijuana], patients are forced to pay out of pocket, sometimes over [$1,000] a month for medicine they need to … live a relatively normal life.” (19)

73. COMMENT: A commenter states, “the price of [medicinal marijuana] should not be so expensive considering many patients cannot work or qualify for discounts. There should be … lower prices … We are sick [and] we are being robbed while suffering and this must end … Enough … robbing us.” (20)

74. COMMENT: A commenter states, “Patients must be allowed to grow or the discounts provided to the disabled need to be increased … At [$400.00] per ounce, [a patient who has income of under $1,000 per month for all expenses has] never been able to fill [a] prescription and barely [has] been able to even cover the cost of one ounce … of … medicine.” The commenter emphasizes the term, “medicine,” because use of medicinal marijuana has enabled a patient to approach “remission for the first time in eight years …, stop all opiates [and] steroids, [and] dramatically decrease the [use of] antianxiety and anti-depressant medications. [A patient] could become a productive member of society if able to medicate on a more consistent basis … as needed … like any other maintenance medication for [a qualifying condition].” (21)

75. COMMENT: A commenter states that the “cost of [medicinal marijuana] is way too high. This is a program for the rich and not the sick. It’s not fair. [Patients do not] want to have to take pills again. Please let [patients] grow [their] own [medicinal marijuana] at home. [It is] vital to [patients’] survival.” (22)

76. COMMENT: “[The] elaborate and highly restrictive regulatory structure developed [is] the opposite of expanding access. [There are] many [rules] regarding ATCs, but [there are no patient-centered rules]. [What] is missing … is most egregious[, paramount of [which] the lack of home cultivation.

[Cannabis] works with our own bodies’ endocannabinoid system … Cannabis [is a botanical] herbal medicine, which is different from Western medicine where part of a plant is extracted and made into a pharmaceutical, like Valerian root into Valium.

Herbal medicines are full spectrum and are quite efficiently regulated and tested when they are made into oils or capsules and sold in health stores. But all botanical medicines, by definition, grow. [One] could buy or forage white willow bark, the basis for aspirin, or grow [St. John’s] wort and make an antidepressant. People have grown their own cannabis for centuries, millennia, [and] patients could do so here, in the Garden [State]. It is the height of hypocrisy for the … Act … to state that ‘Modern medical research has discovered a beneficial use for marijuana in treating of alleviating the pain or other symptoms associated with certain debilitating medical conditions, as found by the National Academy of Sciences’ Institute of Medicine in March 1999,’ [N.J.S.A.] .24:6I-2a, coupled with [EO No. 6, which emphasizes] making access easier — and home cultivation is not mentioned.

When New Jersey legalized [medicinal] use, it was the 14th state to do so (now there are 30) and the first state to not have specific provisions for home cultivation. The Senate’s version of the Act (Feb 2009) did indeed have home cultivation and won overwhelming support in both committee and floor votes. Governor Corzine was not comfortable with the Senate version and signed the House’s version which came out a

few months later — with no mention of home cultivation. Anything not specifically prohibited could be allowed — by a simple regulation. It would be the right thing to do to include home growing. [Almost] all states [that have legalized medicinal marijuana] allow patients and their caregivers to grow and no skies have fallen. Prices have fallen though and as … ATC [prices for medicinal marijuana in New Jersey are] about [four to six] times more costly than [in other states, such as] Oregon[. That] is nothing but good for patients. [The] Governor's exceedingly cautious stance made sense to him at the time, but [the State is] nearly a decade down the road: 16 more states have passed medical cannabis laws, [and] enough both scientific and anecdotal research exists now that even [CNN health news reporter] Sanjay Gupta admits he was wrong and has become a passionate advocate. The prices are also lower out West because the number of licenses issued is not so severely limited as is in [the State]. Understandably, as competition for a license is so incredible and therefore costly, with some applicants spending millions for a license, and often not receiving one, and with the [rules] regarding ATCs so complicated and restrictive, costs are high and [ATCs'] investors want to see a profit.

And, for some patients, an ATC may be their best option. For other patients though, home grown may be their only option. For some patients, paying ATC prices of $[400.00 to $600.00 per] ounce … is not possible. In [the commenter's experience working with the entity, most] patients with a severe condition use about [two] ounces of cannabis a month. [The entity was] founded by Navy Veterans and [its] President is a Navy Veteran nurse [and many of the entity's clients are] patients [who are United States Military Veterans]. Many were on a cocktail slew of strong pharmaceuticals and

were able to give them up by using cannabis. They often use an ounce a week (which they often make into concentrate so that they don't have to smoke all … day long). For either class of patient — those using [two to four] ounces a month, at $[400.00 to $600.00 per] ounce — those prices are not sustainable[. That is] much more than a [Social Security] disability check or rent and car and food[, with the bottom] line being, they would not … be able to get their medication.

Many states for many years … have allowed caregivers to grow for their patients if they are unable (and all this without fingerprints or background checks). New Jersey cannot stay so needlessly stuck with policies that have not worked for nearly a decade. New Jersey, the Garden [State], allowing home growing [would] not eliminate [ATCs'] profits; people still buy tomatoes in various forms in various stores even though they could — and do — grow their own. But, do ATCs have to make all the profit, all the high margins — from patients, for their medication[?] That is not fair at all and is counterintuitive to the spirit of the Act and … Executive Order [No. 6]. This law and subsequent [rules] were not touted to be written so that investors could make a lot of money, but it sometimes appears to patients, as they are left out of being able to safely access their needed medication, that that is exactly the outcome — [especially] as 'owners' compete for[,] collect[,] and trade licenses in nearby states and then fix their prices accordingly, at such a high level [that] it is difficult to not be cynical.

Without home cultivation for patients, the gray market will never be curbed, and New Jersey may unwittingly be creating another gangster organization by keeping the price and profit margins so high. Worse, the patients are the ones who suffer and the aim of the Act and EO6 will remain unrealized. [The entity] is the only national

organization calling for descheduling of cannabis. Our very own Senator Booker has taken up the descheduling cause, because until cannabis is removed from the 'drug schedules,' it is … impossible to make sensible [rules] that work and fulfill legislative … and the people's intent." (24)

77. COMMENT: A commenter states, "the price of [medicinal] marijuana in New Jersey is still extremely high and often too expensive for patients to participate in the program. Being able to grow their own medical marijuana would allow … a much more cost-effective solution. [There] are only [six] ATCs in New Jersey[,] the last of which … only [opened] in the last few months. [This] can make it extremely difficult for a patient to … physically go to a dispensary. As an example[,] a patient and/or caregiver who resides in … Sussex County [has] to travel [up to] an … hour and a half or more (depending on time of day traveled) and [a] minimum of 58 miles one way to reach [the] closest dispensary … If that dispensary [does not] have the [needed product or strain], which often happens … then [the patient or caregiver might then] have to travel [up to or over another three] hours and … 175 miles one way to [reach a dispensary with the needed product or strain, which over the course of a year could] total … 72 hours equaling three … days and over [4,200] miles … That is an extreme unjust burden to place on a patient with a debilitating medical condition. Forcing a patient with limited mobility or a debilitating medical condition of musculoskeletal origins to travel distances that are too much for them can be extremely dangerous. The liability lies in the fact of a patient with perhaps arthritis in the hips who is forced to travel hours in a cramped car every month[, which could then cause more inflammation in their hips and a worsening of their musculoskeletal disorder[, and] result in a broken hip and subsequent fall. That is just

one example of how a patient who does not have adequate access to the medicine that they need at a dispensary could have a worsening of their condition from being a part of the [existing medicinal] marijuana [system]. Patients should be allowed after receiving permission from the [Department] to grow up to six mature plants [that] have adequate [State-issued] tags [(to indicate the plants' legality to law enforcement officials) and are] only … allowed to grow indoors in a lockable room and/or enclosure. There is no need for outdoor grow. New Jersey's climate only allows for roughly one growing season a year and an outdoor grow cannot be as easily contained. Having an outdoor grow might cause neighbor conflicts over smell [and the like]. Allowing indoor grow only would also prevent theft of crop." (31)

78. COMMENT: A commenter states, "The number one [issue among] patients … is the affordability of cannabis. About [half] of [qualifying patients in New Jersey] are on disability income. If they were to purchase two ounces a month from the ATCs, this would cost over half their disability income. Increased competition will help lower price, but not nearly enough for these patients. [If] insurance started paying for it, that would go a long way to helping. But for now, the quickest and easiest way to help make cannabis affordable for many patients is to allow home cultivation of small number of plants. This desperately needs to be added to the [rules]." (38)

79. COMMENT: A commenter states, "Include homegrow" [sic]. (39)

80. COMMENT: A commenter "fully supports a laissez-faire approach to regulation [of] regarding product pricing. This allows [ATCs] to price competitively and offer a variety of discounts, including but not limited to deals and volume discounts within the regulated purchase limits." (40)

81. COMMENT: A commenter states, “The cost of medical cannabis (as well as the quality of the medicine) has been criticized. It is widely reported that the cannabis currently available in New Jersey dispensaries is more expensive that what is available on the unregulated market. The variety of strains available has not been equal to medical cannabis programs in many other state programs. There needs to be a price cap set by the [State] to [ensure] that the cost to patients is not prohibitive. [Low-income] families need access to quality medicine at prices that are affordable. Allowing home grow is one of the most effective ways to achieve reasonable pricing. Moreover, in many instances, allowing the patients to grow a specific number of plants is the only way for home bound patients to access the necessary medicine. When home grown is allowed, a necessary component should be ‘walk up’ inexpensive testing labs to [ensure] safety … If something like 300,000 patients are to benefit from this effective and non-dangerous medicine, the [rules] require more flexibility with an emphasis on making this truly remarkable medicine easily available (it is not as dangerous as aspirin) to all in medical need, but especially for [low-income] patients. [The rules] must support meeting the medical needs of the [people of] New Jersey.” (41)

82. COMMENT: A commenter states that allowing patients to grow medicinal marijuana for their own use is “[one] of the most crucial rights of patient access,” and that “there is no rationale for denying New Jersey patients this benefit. Most other states with medical cannabis programs allow patients to grow (or designate a caregiver to do so) and there have been no noted repercussions or fallout. Rather, patient growing provides a number of important benefits. It allows patients to access the specific varieties most suited to treating their [conditions] (the dispensaries simply cannot stock

every type) and will smooth any shortfall in supply at the ATCs due to increase in the patient base. It allows [low- and fixed-income] patients to afford their medicine[. ATC prices in the State] are among the highest in the country … It also allows patients to use cannabis in its raw form, as many with chronic autoimmune conditions, such as lupus, find relief with juicing cannabis." (42)

83. COMMENT: A commenter states, "[we] need home growing for medical patients [who live] in poverty, that [cannot] afford to buy from the dispensaries. Home growing will allow almost everyone to get the medicine they need [and would help a patient who has very painful] neuropathy [for whom] doctors have prescribed opiates for over 10 years [to get] off the opiates." (44)

84. COMMENT: Commenters state, "[patients] should be allowed to grow [their] own medicine so [they] can actually afford it and have access to specific strains that better [their] conditions. [Dispensaries] should give [patients] the option to have [home-cultivated product] tested when [harvested]." (29 and 48) "Home [cultivation] was in the [Act] in 2010 and passed in the senate. Sadly[,] it was taken out right before they signed it into law. Please bring back patient home cultivation." (48)

85. COMMENT: A commenter states that the Department should establish a permit program to authorize patient and/or caregiver "home cultivation under stringent controls" of "up to [six] marijuana plants" because "there are an insufficient number of ATCs to serve … existing patients … there is a greatly expanding patient need for [medicinal] marijuana … ATC prices for medicinal marijuana exceed what many patients can afford (as well as what the illegal market charges) … the Act [authorizes] patient access from ATCs but does not prohibit patient growing … there is a greater need for stringent

control over growers for general consumption, [which need does] not [apply to] individual patients growing for themselves … not all strains necessary for patients are available from ATCs when needed by … patients … the very act of cultivating medical marijuana may itself provide therapeutic benefit to patients … the majority of states that have [medicinal] marijuana programs in the country allow home cultivation by patients; and … the [State] is moving toward legalization of marijuana for recreational use." The commenter suggests rule text to implement the suggested cultivation permit standard. (31 and 49)

RESPONSE TO COMMENTS 64 THROUGH 85: The Department is without statutory authority to establish standards, by rulemaking, that would allow patients and/or caregivers to engage in home-based cultivation of medicinal marijuana. N.J.S.A. 24:6I confers neither jurisdiction to the Department to regulate, nor legal immunity from civil liability and criminal prosecution under State law to patients and caregivers to engage in, the home-based cultivation of medicinal marijuana.

The Department anticipates that its ongoing efforts to increase the number of ATCs in the State might result in a corresponding increase in competition among ATCs with respect to product offering and pricing. This, in turn, might result in patients realizing greater choice and lower costs.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

Caregivers in Institutions; Administration of Medicinal Marijuana in Residential and Day Facilities Funded by the Division of Developmental Disabilities (DDD) within the New Jersey Department of Human Services

86. COMMENT: A commenter states, "[it] is necessary that 'qualifying patients' with developmental disabilities have access to their medicinal marijuana in the same manner that they have access to all other prescribed medications. [The Department should] allow all 'qualifying patients' to have access to [medicinal] marijuana. In particular, [the rules should] facilitate the administration of medicinal marijuana to developmentally disabled individuals who live in DDD-funded residential programs and attend DDD-funded day programs who are incapable of 'self-administering' their medicinal marijuana. Residential and day program providers should be permitted to administer validly prescribed medicinal marijuana to 'qualifying patients' in the same way as [they administer] other necessary prescription medications." The commenter describes an adult qualifying patient "who lives in a DDD-funded residential program and attends a DDD-funded day program." The commenter has applied to be the qualifying patient's authorized caregiver to purchase and administer medicinal marijuana to the patient, because the patient is unable to self-administer, and "it is extremely unlikely that [the patient's] residential/day provider will agree to administer [the patient's] medicinal marijuana, even though [the provider] administers multiple prescription medications to [the patient] daily. This will make it extraordinarily difficult for [the patient] to receive … medicinal marijuana in accordance with the prescribed frequency [and] will impair [the patient's] health and well-being. [The patient's] situation is anything but unique. Individuals … with developmental disabilities who reside in residential programs and

attend day programs are most unlikely to be capable of self-administering. Since many such individuals reside in residences that are far from where their parents or family members live, they will be reliant on their providers to administer their medicinal marijuana. The situation is the same for individuals who are without living family members. Absent additional [rules] that authorize and streamline the ability of residential providers to administer medicinal marijuana to 'qualifying patients,' a significant portion of the population who require this medication will be precluded from receiving it. The failure to adopt [rules] and guidelines that allow such patients the same access to their medicinal marijuana as they have to their other prescribed medications will have a discriminatory effect upon this vulnerable and protected class. If the legislature has seen fit to recognize marijuana as a medication it should be readily available to all qualifying patients, be [they] disabled or not. It is essential that the legislature recognize the need to empower residential and day program providers to administer medication to their persons served and codify [rules] as part of its readoption of N.J.A.C. 8:64." (33)

87. COMMENT: A commenter quotes a paragraph from the notice of proposal Summary that provides the statutory and regulatory history of medicinal marijuana laws and rules in New Jersey, 50 N.J.R. 1398(a) at 1399 (June 18, 2018), specifically the paragraph describing N.J.S.A. 18A:40-12.22 and 30:6D-5b (addressing the administration of medicinal marijuana to qualifying patients in schools and programs for persons with developmental disabilities), and states that this paragraph "is missing is an evaluation of how this law is working. How many patients in schools and facilities for the developmentally disabled qualify for medical marijuana? How many of these patients

are actually receiving medical marijuana as a result of this law? Are caregivers actually able to come to these facilities one or more times a day to administer [medicinal] marijuana to qualifying patients? Families of patients typically report that these patients are not getting the medical marijuana that they require in order to control their serious medical conditions (seizures, chronic pain, anxiety, etc.). Thus, the clear intent of this law is being frustrated by the inability of caregivers [and/or] family members to report to these facilities one or more times a day to administer [medicinal marijuana. On the other hand, staff at these facilities are trained to safely administer and account for other controlled substances. The staff of these facilities should be empowered to administer medical marijuana as well, to relieve the families of this burden while meeting the needs of the patients, in compliance with the intent of the law." (31 and 49)

RESPONSE TO COMMENTS 86 AND 87: The Department is without authority to establish requirements applicable to schools and programs for people with developmental disabilities. These facilities are, respectively, within the jurisdiction of the Departments of Education and Human Services.

N.J.S.A. 18A:40-12.22 requires a "board of education or chief school administrator of a nonpublic school [to] develop a policy authorizing parents, guardians, and primary caregivers to administer medical marijuana to a student while the student is on school grounds, aboard a school bus, or attending a school-sponsored event." Likewise, N.J.S.A. 30:6D-5b requires the "chief administrator of a facility that offers services for persons with developmental disabilities [to] develop a policy authorizing a parent, guardian, or primary caregiver authorized to assist a qualifying patient with the use of medical marijuana pursuant to [the Act] to administer medical marijuana to a

person who is receiving services for persons with developmental disabilities at the facility."

The proposed amendment at existing N.J.A.C. 8:64-2.2(e) would authorize qualifying patients to designate up to two caregivers. This might alleviate some of the practical difficulties the commenters describe attendant to administration of medicinal marijuana to persons who are clients of the DDD and school children.

Neither the Act nor the rules proposed for readoption with amendments, repeals, and a new rule, would prohibit staff at these facilities from serving as caregivers for their students and clients. However, the definition of a "primary caregiver" or "caregiver" at N.J.S.A. 24:6I-3 prohibits a person from serving as a caregiver for more than one qualifying patient at a time, thereby impeding a facility's ability to repose caregiver status in one or two persons, such as a school nurse or a responsible staff member for a group home, for all students or clients of a facility, if the facility serves more than one qualifying patient. The Department is without authority to modify by rulemaking this statutory requirement.

In addition, many facilities receive Federal funding for their operations, which can cause their administrators to be reluctant to engage in activities that might jeopardize that funding, such as the possession or administration of medicinal marijuana on the premises, as this is an illegal activity under Federal law.

Another difficulty that these facilities encounter is the prohibition against smoking in indoor public places and workplaces at N.J.S.A. 26:3D-55 et seq., the "New Jersey Smoke-Free Air Act," which applies to the smoking of medicinal marijuana in these facilities. While smoking outside is generally permissible, some facilities might have

established “smoke-free campuses” and others might have impediments related to lack of exterior grounds and client security concerns. The proposed amendment at recodified N.J.A.C. 8:64-10.7, proposed for amendment, at subsection (e), authorizing ATCs to produce and dispense an additional form of medicinal marijuana, could help these facilities to administer medicinal marijuana to their clients and students without violating the Smoke-Free Air Act.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

Review Panel Role (N.J.A.C. 8:64-5.2 and 5.3)

88. COMMENT: A commenter states, “rather than just … assist with approving new qualifying conditions,” the “review panel should review and recommend additional conditions [so] that physicians [are] encouraged to consider cannabis” and “should … help to direct any excess revenues from medical cannabis patient fees towards furthering research into the palliative effects of medical cannabis on recommended conditions.” (32)

89. COMMENT: A commenter “has always sought for New Jersey’s [medicinal] marijuana program to rely on scientific data as much as possible. In 2011, [the commenter] commended the Department for establishing safeguards to ensure that the use of [medicinal] marijuana is limited to therapeutic treatment for specific debilitating medical conditions [and] supported the creation of the [review panel] to consider and approve of any addition to the list of … debilitating medical conditions. As such, [the commenter is] concerned with the reduction of the [review panel’s] role in reviewing new

[debilitating] medical conditions." The commenter requests that the Department not adopt the proposed amendments at N.J.A.C. 8:64-5.3, "particularly the change allowing the Commissioner to consider petitions outside of the [review panel's] process. Having already gone through the petition process, the [review panel] holds expertise in the detailed consideration necessary for the addition of conditions to the program. Any additional debilitating medical conditions should be considered and recommended by physicians. Given that the Commissioner of the Department of Health is not always a physician, this part of the process should not be removed. The [review panel], [comprising] a majority of physicians, should maintain authority to make recommendations 'regarding approval or denial of a petition submitted pursuant to [Subchapter 5]. Without robust, legal scientific studies of the effectiveness of marijuana in the treatment of medical conditions, physician review is essential to ensure patient safety. Unlike other medications, marijuana is not subject to scientific review or to the FDA's rigorous approval process. In medicine, what some may consider cumbersome processes within the State's medical marijuana program are more accurately described as routine and necessary steps needed for patient safety."

The commenter "[appreciates] the [Department's] acknowledgement of the [review panel's] expertise [by] the proposed [amendment at existing N.J.A.C.] 8:64-5.2(a)1 [and the proposed amendment at N.J.A.C. 8:64-5.2(b)3, which restates] the requirement that physicians must comprise the majority of the [review panel]. Given that the [review panel] has such expertise, it should continue to carefully review the enumerated criteria in [N.J.A.C.] 8:64-5.3(d)[. The Department should reverse the proposed deletion of the review panel's] required powers [at N.J.A.C.] 8:64-5.3(d) and

[should not adopt the proposed deletion of the word, “shall,” and addition of the word, “may,” at N.J.A.C.] 8:64-5.3(c)....” (35)

RESPONSE TO COMMENTS 88 AND 89: The proposed amendments at existing N.J.A.C. 8:64-5.2 and 5.3 would streamline the process by which to add to the list of debilitating medical conditions. The proposed amendments would maintain the review panel’s critical role in advising the Commissioner as to the clinical benefits of medicinal marijuana use for additional debilitating medical conditions under consideration as debilitating medical conditions and authorize the Commissioner to act outside of the petition process to add debilitating medical conditions at the Commissioner’s own initiative upon determining that clinical evidence support such additions.

Contrary to the commenter’s assertion, pursuant to N.J.S.A. 26:1A-3, either the Commissioner or the Deputy Commissioner for Public Health Services (DC for PHS) is always a physician. The existing rules at N.J.A.C. 8:64, even without the proposed amendments, authorize the review panel to make only nonbinding recommendations to the Commissioner. If the Commissioner is not a physician, then the existing rules contemplate that a non-physician could reject the review panel’s nonbinding recommendations and make a different final decision. The commenter inaccurately suggests that a non-physician is incapable of independently reviewing and understanding clinical evidence or reports, and might make an unadvised decision, that is, without seeking informed counsel, if needed, from either qualified Department personnel or external advisors.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

ATC Eligibility Criteria and Selection (N.J.A.C. 8:64-6.2)

90. COMMENT: A commenter "supports opening the New Jersey market to meaningful competition. While it is encouraging that so many more patients are enrolling in the medical marijuana program, the [State's] artificial oligopoly cannot meet the increasing demand. The supply shortage has already been causing long lines and a lack of availability of some strains, leaving patients without the medication that works best for them [(citation omitted)], and it will likely get worse as patient numbers continue to increase. [The commenter] thanks the administration for already moving forward with licensing new businesses while this regulatory change is pending and supports the changes that will end mandatory vertical integration and allow more licensees. Increasing competition should bring prices down to a more reasonable level, which will greatly benefit patients. Because New Jersey does not allow home cultivation, patients who cannot afford to shop at the dispensaries — or who are unable to travel to them — are forced to either ignore the ban on cultivation and risk becoming felons or purchase their medicine in the illicit market, where untested and unregulated products could expose them to mold or harmful pesticides.

[The commenter] supports ending mandatory vertical integration [at proposed N.J.A.C. 8:64-7.1]. Few businesses have the skills and expertise necessary to provide excellent customer service at the retail level, manufacture a wide range of innovative products that must meet [State] standards for laboratory testing, *and* engage in specialized agriculture. Allowing companies to specialize in operating a dispensary, processing cannabis into a particular type of product, or cultivation will allow for better

patient experiences and a much wider variety of options in terms of types of products, as well as strains. Each type of product, such as topicals, lozenges, and different kinds of extracts, requires specialized knowledge and equipment. Many states, such as Connecticut, D.C., Illinois, Maryland, Nevada, Pennsylvania, and West Virginia, license cultivators, producers, and dispensaries separately.

It is a belief fundamental to American society and our system of government that a free market is preferable to a planned economy. Yet … limiting the medical cannabis industry to a tiny number of companies forced to be vertically integrated essentially amounts to [the latter: a planned economy]. The tremendous negative impact this system had on the medical program in New York, which until recently was one of the worst in the country [(citation omitted)], is a further illustration of this problem.

Another basic economic principal is that monopolies (and oligopolies) are bad for consumers because they inflate prices and can reduce innovation — in fact, they can be so bad for consumers that the [Federal] government will interfere with the free market via the [United States] Department of Justice's Antitrust Division (which obviously is not currently regulating the cannabis industry) to ensure a particular industry does not become unduly concentrated. Medical cannabis, while a new industry, is not fundamentally different from all other industries, such as pharmaceuticals, which are subject to antitrust laws [(citation omitted)]."

Referring to N.J.A.C. 8:64-7.9 as proposed for amendment, the commenter states, "Satellite locations improve convenience for patients (although not price or access to more types of medicine). [The commenter does] not oppose allowing existing ATCs to open satellite locations, because additional locations will reduce travel time for

many patients and make it more convenient for them to obtain their medicine. However, … this will not address the problem of extremely high prices and limited product offerings due to lack of competition.

Adding multiple criteria on the license applications that can only be met by out-of-[State] companies licensed elsewhere limits competition and hurts New Jersey residents. The proposed [rules] contemplate adding three new criteria that can only be met by applicants if they, or their principals, have been licensed to operate marijuana businesses in other states. [Proposed N.J.A.C.] 8:64-6.2, "Criteria for identifying alternative treatment centers," [at paragraphs (a)3, 4, and 5, relates] specifically to past experience operating a marijuana business, which only the six existing ATCs have among New Jersey residents. Thus, … these provisions benefit out-of-[State] companies at the expense of New Jerseyans. The provisions will also suppress diversity, given the lack of diversity in the existing industry.

Applicants can demonstrate their ability to comply with [N.J.A.C. 8:64] in other ways. For example, they could be asked to describe their experience in any heavily regulated industry. [At proposed new N.J.A.C. 8:64-6.2(a)5], 'ability and experience of the applicant in ensuring adequate supply of marijuana,' is also confusingly worded and unnecessary. It could instead provide for experience in botany or with cultivating crops (which need not be cannabis to be relevant), if that was the intent. It is the market that ensures an adequate supply of a good or service, not the output of a particular company." (5)

91. COMMENT: A commenter states that the Department should amend the criteria the Department is to consider in identifying ATCs at N.J.A.C. 8:64-6.2(a) to add an

applicant's "[experience] with inventory tracking or compliance[,] financial regulatory compliance, insurance or healthcare compliance[,] and other applicable highly regulated industries[, in addition to applicants'] history of medical cannabis regulatory compliance." (32)

RESPONSE TO COMMENTS 90 AND 91: The Department acknowledges the commenters' support of the proposed amendments at N.J.A.C. 8:64-6 and 7 that would establish an endorsement system as part of the permitting process. An endorsement system would allow ATCs to specialize in one part of the supply chain rather than be obliged to integrate cultivation, manufacturing, and dispensing under one business entity.

The proposed amendments to the criteria for selecting ATCs at N.J.A.C. 8:64-6.2 would give the Department greater flexibility to judge potential applicants across a range of qualifications, and thereby establish a diverse and representative pool of ATCs to serve New Jersey's qualifying patients. The Department can incorporate these criteria into ATC application requests that identify the relative weight and importance of each factor, depending on the State's unmet needs at the time of the call for applications. This, in turn, would support the goals of the Act and the Department's mandate pursuant to EO 6 to "expand access to marijuana for medical purposes" and to eliminate program aspects that "hinder or fail to effectively achieve the statutory objective of ensuring safe access to medical marijuana for patients in need."

Based on the foregoing, the Department will make no change on adoption in response to the comments.

ATC Management and Staffing Diversity; Participation of People with Disabilities (N.J.A.C. 8:64-6.2)

92. COMMENT: A commenter states, “the diversity provision has no enforcement mechanism. Creating a meaningful equity program for licensing additional cannabis businesses may have to be done by statute — and is even more critical when New Jersey legalizes and regulates cannabis for adult [use.] The proposed [rule] requiring consideration of the applicant’s ‘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’ is a small step in the right direction. But it does not … specify that there must be diversity in ownership, [and] does [not] meet the rigorous constitutional requirements to take race into account in making licensing decisions.

The provision also lacks any type of enforcement mechanism. This problem is not unique to New Jersey, but unfortunately states generally have not followed up with licensees to ensure they have kept the promises they made in their applications … to get licensed. A strong local hiring or diversity plan may well be abandoned once the business gets its license — unless there is the prospect of meaningful enforcement. [The rules] should explicitly state that the Department … can and will revoke a business’ license for failure to demonstrate (at the very least reasonable efforts towards) compliance with the plans set forth in its application. The statute explicitly permits the Department to revoke applications for cause, and the failure to live up to the promises that pushed [an] application to the top of the list should provide that cause. The

Department could also require proof of compliance prior to issuing license renewals." (5)

93. COMMENT: A commenter states that the Department "needs to ensure that in awarding the next round of ATC licenses, the [Department] helps to create an inclusive [medicinal marijuana] community. The participation of women, minorities, and military veterans in the new ATCs must include real equity opportunities." With respect to proposed N.J.A.C 8:64-6.2 and 7.1, the commenter states, "While employment opportunities for women, minorities, and military veterans are important, such opportunities cannot be at the expense of these groups having equity interests in the new ATCs. An ATC applicant that simply creates a plan for women, [minorities], and military veterans to staff or manage a facility without any path to ownership is insufficient. A truly inclusive [medicinal marijuana] industry warrants the participation of women, minorities, and military veterans at the ownership level of the ATCs." (8)

94. COMMENT: A commenter "[appreciates] and [commends] the Department [for] taking steps to ensure that the New Jersey medicinal marijuana program is inclusive and poised to empower the diverse communities that exist in our State. Among the proposed revisions to N.J.A.C. 8:64-6.2 … are criteria related to the potential workforce and job creation plan by the applicant, and specific reference to 'including plan to involve women, minorities, and military veterans in management and staffing.'" The commenter proposes that, "in addition to women, minorities and military veterans, [that] N.J.A.C. 8:64-6.2 also [should refer] specifically [to] disabled people. There is a large community of disabled people in New Jersey that could be valuable assets in the management and staffing of ATCs and, to every extent possible, applicants should be

encouraged to involve this community of people as well. Consistent with the above, we request that N.J.A.C. 8:64-7.1 similarly specifically include disabled people as a category of people referenced in future applications." (18)

95. COMMENT: A commenter states, with respect to proposed new N.J.A.C. 8:64-6.2(a)6, that the Department should require an applicant's "workforce and job creation plan" to address the applicant's plan to involve individuals with disabilities, in addition to women, minorities, and military veterans, and the applicant's plan "to engage with or have contracts with labor unions for collective bargaining agreements" in addition to the applicant's "experience with collective bargaining." (32)

96. COMMENT: A commenter states, "[it] is obvious … that the Department is seeking to have an expansive and inclusive medical marijuana program in New Jersey. In particular, N.J.A.C. 8:64-[7.1(b)2xiii] requires ATC applicants to provide '[evidence] of minority, women, and veteran participation in ATC operations through ownership, management, and local hiring plans.' Inclusion and diversification within the medicinal marijuana program can be further increased if [the Department would revise this section to include reference to participation in ATC operations by] people with recognized disabilities. [The] Department [should] consider amending the criteria for identifying ATCs in N.J.A.C. 8:64-[6.2(a)6] to [state, 'workforce] and job creation plan, including plan to involve women, minorities, people with disabilities and military veterans in ATC ownership, management, and experience with collective bargaining in the cannabis and other industries.' [Medicinal marijuana can provide] tremendous potential benefits … both as an effective medicine for a variety of conditions, but also as an opportunity [for disabled persons] to get involved in a new and exciting industry. By amending the

[rules as suggested], people in the [medicinal] marijuana industry will be encouraged to include people with disabilities[, who in turn] will be [encouraged] to investigate ways in which they can participate. [This] will truly make this new industry something [of which] New Jersey can be proud …" (28)

97. COMMENT: A commenter states that the rules "should include a [set-aside] for [people with disabilities] to have an equal opportunity to be involved with the ATC [license], ownership[,] or working in the dispensary. It will be a great social impact, allowing [people with disabilities] to join the [medicinal marijuana] industry … Obviously, they should follow the proper guidelines for the application process or employment guidelines. [With] New Jersey being a very unique, innovative [State,] this will be great to see." (34)

RESPONSE TO COMMENTS 92 THROUGH 97: The Department agrees with the commenters' assertions that diversity in an ATC applicant's ownership plan is as important as diversity in an applicant's staffing and job creation plan. The Department acknowledges the commenters' support for proposed new N.J.A.C. 8:64-6.2(a)6, which would include, among ATC selection criteria, the applicant's workforce and job creation plan, including a plan to involve women, minorities, and military veterans in ATC ownership, management, and staffing, and proposed new N.J.A.C. 8:64-7.1(b)2xiii, which would require applicants to submit evidence of their commitment, in respect to this diversity, "through ownership, management, and local hiring plans." The proposed amendments at N.J.A.C. 8:64-6.2 and 7.1, described above, would reflect the Department's goal of selecting ATCs that demonstrate commitment to diversity in ownership, management, and staffing.

The Department disagrees with a commenter's assertion that the diversity standards, which the proposed amendments at N.J.A.C. 8:64-6.2 and 7.1 would establish, would be unenforceable. An ATC applicant must submit a sworn statement as to the accuracy of the representations the applicant makes in an application. Existing N.J.A.C. 8:64-7.1 authorizes the Department to reject applications if applicants fail "to provide requested information," which include diversity plans, "or to present truthful information." As part of its routine oversight and inspection activities, and upon an ATC permittee's annual submission of an application for ATC permit renewal, the Department would evaluate a permittee's compliance with representations contained in its diversity plan and, if the Department assesses the permittee to be noncompliant with the plan, the Department has authority to take progressive enforcement action to secure compliance therewith, such as requiring permittees to implement a plan of correction or, if a permittee's correction efforts are deficient, to revoke the ATC permit.

The Department agrees with the commenters' assertion that an ATC applicant's diversity plan should include the applicant's plan to involve people with disabilities. Applicants can include a plan to involve people with disabilities in support of the existing criterion at N.J.A.C. 8:64-6.2(a)4, proposed for recodification as new paragraph (a)7, that applicants demonstrate "community support and participation," and as proposed new N.J.A.C. 8:64-7.1(b)2xii would require, as evidence of "community engagement or participation in the ATC's operations through ownership, management, and local hiring plans, and support of community organizations." The Department would view favorably an ATC applicant's demonstration of commitment to involve people with disabilities in their operations and encourages ATC applicants and existing ATC permittees to take

advantage of the many resources to encourage, and assist in, the hiring of people with disabilities, including training services and financial incentives, that the Division of Vocational Rehabilitation Services within the New Jersey Department of Labor and Workforce Development offers. See https://careerconnections.nj.gov/careerconnections/hire/hiring/disable/connecting_jobseekers_with_disabilities_to_employment.shtml.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

ATC Selection Team Conflict of Interest Policy (N.J.A.C. 8:64-6.4)

98. COMMENT: A commenter "supports the addition of a conflict of interest policy for people who are reviewing applications [for ATC permits]. There have been significant problems with merit-based licensing systems for cannabis businesses across the country, particularly with respect to allegations of conflict of interest or corruption. Not only does this undermine public trust in the program, but it also forces [states] to spend millions of taxpayer dollars defending the inevitable lawsuits challenging the licensing process, often resulting in lengthy delays [(citation omitted)].

First, individuals signing a conflict of interest disclosure should do so under penalty of perjury. Second … there are now numerous businesses that operate in multiple states across the country. They are frequently structured in such a way that each state's operation is technically a different company. However, if someone works for, is invested in, or otherwise financially benefits from, an affiliated or parent company of an applicant, that person has a clear conflict of interest in evaluating applications in

New Jersey. Yet because ‘applicant’ is not a defined term in either the statute or the existing [rules], it is presumably limited to the legal entity applying — so these conflicts would not need to be disclosed under the proposed [rule].” The commenter suggests that the Department amend proposed N.J.A.C. 8:64-6.4 to require participants on the selection committee to disclose, and be without, conflicts of interest under the penalty of perjury; to define “applicants” to “include any parent, subsidiary, or affiliated entity of the entity applying; to define “financial interest” to “mean any investment in, ownership of, current or anticipated employment by, or current or anticipated independent contractor or other financially beneficial relationship with, an applicant, or the solicitation of such a relationship”; to define “familial interest” to “mean that if any individual to whom the proposed selection committee member is related by blood or marriage within two degrees of consanguinity is disqualified, they are also disqualified.” The commenter states that these changes would make N.J.A.C. 8:64-6.4 “much clearer, which protects not only the public and the Department, but also the committee member, so that they have a clear understanding of what they must and what they need not disclose. Without clear definitions, the individual being considered for committee membership cannot make a truthful disclosure.” (5)

RESPONSE: The Department anticipates that the Commissioner would appoint only State employees to serve as members of committees it convenes to review ATC permit applications. State employees are subject to the existing ethics and conflicts of interest standards applicable to all State employees pursuant to the New Jersey Conflicts of Interest Law, N.J.S.A. 52:13D-12 et seq., the rules of the State Ethics Commission at N.J.A.C. 19:61, and the Uniform Ethics Code promulgated by the State Ethics

Commission pursuant to N.J.S.A. 52:13D-23. Moreover, the Department anticipates requiring members of each selection committee to attend a specialized ethics training, in addition to the training that State employees routinely receive, to emphasize members' ethical obligations.

If the Commissioner elects to appoint to an ATC selection committee a person who is not an existing State employee, that person likewise would be subject to the applicable laws, rules, and standards that the State Ethics Commission routinely applies to non-employees serving on boards and commissions. In addition, the Department would require these non-employee committee members to participate in the specialized ethics training described above that the Department requires committee members who are employees to receive.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

ATC Ownership and Financial Disclosure (N.J.A.C. 8:64-7.1)

99. COMMENT: A commenter states that the Department should amend "ownership … disclosure requirements … to reduce unnecessary burdens that cause operational delays and increased costs to operators and patients. In particular[, the Department should bring these] requirements [in] line with the 10 [percent] ownership reporting requirement thresholds of the Canadian securities markets[, which provide] the only significant public liquidity opportunity for [United States] cannabis operators[. An inconsistent reporting threshold will increase costs and barriers to entry to New Jersey for public companies and may impair New Jersey entities' ability to become publicly

listed companies … The requirement to submit information for each subcontractor or affiliate named in the application should only apply to individuals that will be present in the facility and exercise some degree of control over activities in the facility. There are likely to be many subcontractors or affiliates that will not enter the ATC and will just provide expertise remotely. Requiring all individuals named to provide extensive information will likely just result in the applicant naming fewer subcontractors or affiliates on the application and hiring them after the fact." (32)

RESPONSE: Existing N.J.A.C. 8:64-7.1(b)2iv requires ATC permit applicants to submit with their applications "a list of all persons or business entities having five percent or more ownership in the ATC" and to include the same information as to each owner's "subcontractor or affiliate." The commenter does not explain how the disclosure of entities with ownership interests would result in operational delays and increased costs. Transparency in ownership is critical to the Department being able to meet the requirements of N.J.S.A. 24:6I-7 and N.J.A.C. 8:64-7.2.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

ATC Endorsements and Satellites (N.J.A.C. 8:64-7.1 and 7.9)

100. COMMENT: A commenter supports the proposed amendments and new rules that would "[authorize] several categories of endorsement[, allow] ATC applicants for several endorsements in a single region to do so with one application[, and establish, define, and set fees for,] satellite sites." (16)

RESPONSE: The Department acknowledges the commenter's support of the proposed rulemaking.

101. COMMENT: A commenter states, "[to] avoid potential litigation from patients or applicants that feel the Department is not fulfilling its regulatory obligations," the Department should amend proposed new N.J.A.C. 8:64-7.1(f) to provide that the Department shall issue endorsements in a manner that the Department *reasonably believes would ensure* adequate patient access to medicinal marijuana." (32)

RESPONSE: The Department has an implicit obligation to exercise its authority with reasonableness and in adherence to principles of fundamental fairness and due process. See, for example, *Communications Workers of Am., AFL-CIO v. New Jersey Civ. Serv. Comm'n (In re Job Banding for Software Dev. Specialist 1 & 2),* 234 *N.J.* 483, 514-515 (2018). This obligation would apply to the Department's exercise of authority with respect to the issuance of endorsements. Therefore, the change the commenter suggests is redundant of this implicit obligation.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

102. COMMENT: A commenter states that the Department should amend the proposed definition of the term, "cultivation," at N.J.A.C. 8:64-1.2, "to include drying and processing," and that the Department should establish a definition of the term, "processing," that would "include activities such as grinding cannabis, rolling joints, and separating resin through non-chemical means such as a sieve method" because these

changes would “allow ATCs with a [cultivation] endorsement to roll joints at their [facilities].” (32)

RESPONSE: A cultivation endorsement would include authorization for the medicinal marijuana drying and rolling activities. Proposed new N.J.A.C. 8:64-7.1(e)1 would allow an ATC with a cultivation endorsement “to possess, cultivate, plant, grow, harvest, and package *usable marijuana* (*including in prerolled forms*) [(emphasis added)].” The existing definition of the term, “usable marijuana,” at N.J.A.C. 8:64-1.2, states that the term “means the *dried* leaves and flowers of the female marijuana plant, and any mixture or preparation thereof, and does not include the seedlings, seeds, stems, stalks, or roots of the plant [(emphasis added)].” Thus, by these provisions, a cultivation endorsement would authorize an ATC to engage in these activities to produce usable marijuana: drying the flowers of female plants, and separating flowers from seeds, stems, stalks, and roots, and would not distinguish between hand or mechanical trimming. Moreover, ATCs are subject to the standards for processing and packaging of marijuana at existing N.J.A.C. 8:64-10.8, proposed for recodification with amendment as new N.J.A.C. 8:64-10.7, which also address these activities.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

103. COMMENT: A commenter states that the proposed definition of the new term, “manufacturing,” at N.J.A.C. 8:64-1.2, “may need to be more comprehensive to ensure that it covers all activities that ordinarily occur within a cannabis [product] manufacturing facility, such as extraction and infusions … Products should not have to be pre-

approved by the Department as this will delay the process of product development and hinder access for patients requiring alternative forms of medical cannabis. Instead, the Department should set guidelines and regulations for the permissible forms and packaging of products and enforce against product manufacturers that violate those regulations." (32)

RESPONSE: N.J.S.A. 24:6I-7 obliges the Commissioner to authorize the forms of medicinal marijuana that ATCs can dispense to qualifying patients. Recodified N.J.A.C. 8:64-10.7, proposed for amendment, provides at subsection (e) the list of the authorized forms of medicinal marijuana products that an ATC with a manufacturing endorsement can manufacture. Moreover, existing N.J.A.C. 8:64-10.3, proposed for readoption, obliges the Department to evaluate each proposed product with respect to the sources of every ingredient to be used in manufacturing the product, the recordkeeping to be maintained for each ingredient, and the ATC's plan for adherence to good manufacturing practices. Likewise, existing N.J.A.C. 8:64-10.6, proposed for readoption, obliges the Department to evaluate the informational material proposed for dissemination to consumers with each new product, the security of the product proposed packaging, and the accuracy of labeling, with each new product. In addition, pursuant to N.J.A.C. 8:64-13.4, the Department might require laboratory testing of new products. Therefore, the Department declines to discontinue the new product pre-approval process, because it is an important and necessary means by which the Department ensures ATCs' compliance with applicable requirements and verifies the safety and quality of medicinal marijuana products offered to qualifying patients.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

104. COMMENT: A commenter states, “[the] clear intent of the [Act] and [EO 6] is to create and foster a level playing field between original ATCs and new market entrants. However, the proposed rule appears to create two unequal classes of ATC permits — one for the existing six or ‘original’ ATCs and one for all other ATCs — with the original ATCs at a … disadvantage. The proposed rule appears to allow new market entrants to expand their footprints as needed under the endorsement system … but imposes a total cap on the number of facilities an original ATC can have … N.J.A.C. [8:64-7.1, as proposed for amendment, appears to confer upon the Department absolute] discretion over how many endorsements to award an applicant … representing no cap on new market entrants. In … contrast, [N.J.A.C. 8:64-7.9(a)3 as proposed for amendment would prohibit] original ATCs [from having] ‘more than a total of two additional satellite sites.’ [The proposed amendments would disadvantage] the original ATCs [by establishing] a permanent and absolute cap on the expansion of original ATCs [that would] not [be] placed on any other ATC and [would exclude] the original ATCs from participating in the newly created endorsement system. Did the Department intend to permanently and exclusively cap the growth of the original ATCs and exclude them from the endorsement system?

[With] limited exceptions, [N.J.A.C. 8:64-7, as proposed for amendment, would] allow new market entrants to open and operate facilities [Statewide] but [would impose] a regional restriction on all original ATCs’ satellites and additional sites. [N.J.A.C. 8:64-

7.1, as proposed for amendment, appears to confer upon the Department absolute] discretion over the location of permits and endorsements … creating a [Statewide] marketplace for new market entrants. In … contrast, [N.J.A.C. 8:64-7.9(c), as proposed for amendment, would require] 'satellite locations [to] be within the same region as the original permitted ATC.' [This would impose a disadvantage on] the original ATCs [by establishing] a geographical constraint on their expansion [that would] not [apply to] any other ATC. The Department's continued insistence that the … Act … imposes geographical boundaries on any ATCs — including the existing six — is incorrect and requires additional discussion. New Jersey should allow existing and new ATCs to open dispensaries in all regions. The policy adopted by the Christie Administration of regional restrictions was an incorrect interpretation of the [Act] and was merely another contrivance by the prior Administration to stifle this program and its patients. The policy is not supported either by the [Act] or subsequent [court] interpretations. In fact, overturning this Christie-era contrivance is consistent with the Murphy Administration's laudable strategy of expanding access for patients throughout the State.

[The] Department … continues to interpret [N.J.S.A.] 24:6I-7(a) … as the Christie Administration did by limiting the available geographic scope of [an ATC's] operations to [its] permitted region. This interpretation is erroneous and seriously curtails the mandate of the Act[, which is to ensure] the availability of ATCs to patients throughout the State. Under an interpretation more consistent with the Act … and the [Department's] own interpretation of its mandate, the State could immediately increase patient access as well as the resiliency and competitiveness of the [State medicinal marijuana system,] to patients' great benefit.

The Act issues several directives for the siting of ATCs. It states[, 'the Department] shall seek to ensure the availability of a sufficient number of [ATCs] *throughout the State*, pursuant to need, including at least two each in the northern, central, and southern regions of the State.['] N.J.S.A. 24:6I-7(a) (emphasis added [by commenter]). The Act charges the [Department] with ensuring a minimum level of access for patients throughout the State. To facilitate [Statewide] access, the [Act fixes] a … minimum number of ATCs: 'at least two each in the northern, central, and southern regions of the State.' *Id.* Once [this minimum is] satisfied, ['the Department has discretion to determine how many] ATCs [are] 'needed to meet the demand for medicinal marijuana and whether the issuance of a permit to a particular applicant would be consistent with the purposes of the Act.' *Natural Med., Inc. v. New Jersey Dept. of Health and Senior Services,* 428 *N.J. Super.* 259, 263 (App. Div. 2012).

Contrary to the Christie Administration's interpretation, with these regional minimums the [Act facilitates Statewide] access to medicinal marijuana, not to restrict the ATCs' operations to a limited geographical region. Understanding that without such minimums, the northern region would attract most or all applicants because of its population, confirms that the [Department-]mandated minimum was designed not to limit [Statewide] access, but to foster it. Importantly, the [Department's] explanation of the award process in decision letters to applicants following the January 14, 2011[,] RFA supports this reading as it espoused the benefit to patients of a geographically diverse market. The [Department] stated [in those letters]: ['since geographic diversity would help ensure an adequate supply of medicinal marijuana through accessibility, [the Department] determined that it would be imprudent to issue permits to applicants who

intended to locate in or near the same city[']; and] in a subsequent Final Agency Decision [explained] that it did not believe that limited geographical diversity '[was] in the best interest of the public.' [*In re Inst. for Health Research and Abunda Life Ctr.,* 2013 N.J. Super. Unpub. LEXIS 2085 at *10-*11; 2013 WL 4458982 at *3-*4 (App. Div. Aug. 22, 2013).] While the topic of these letters was different than that at hand — namely why the [Department chose] an applicant with a lower score than the appellant — the principle espoused by the [Department] is perfectly relevant.

Similarly, allowing patients access to all [12] ATCs' dispensaries throughout the [State would] create diversity, resiliency, and competition that helps ensure the availability of medical marijuana to patients throughout the State. By allowing all ATCs to open dispensaries outside their regions, patients throughout the State [would] have greater access to much needed medicine. Patients [would] also benefit from a resilient marketplace with built-in cultivation and dispensary redundancy that maintains supply despite the inevitable production problems incumbent to agriculture production. Likewise, the competition attendant such an open marketplace will reduce prices and increase the level of service required to compete for patients.

[N.J.A.C. 8:64-7, as proposed for amendment, would appear] to allow vertical integration of new market entrants' facilities under the new endorsement system, but explicitly [would prohibit] vertical integration at all original ATCs' satellites or additional sites. [The] definition of 'ATC' [at] N.J.A.C. 8:64-1.2 and [proposed] new [N.J.A.C. 8:64-7.1(d) would allow] applicants [to] apply for and be awarded endorsements authorizing [them] to cultivate usable marijuana, manufacture usable marijuana, *'and/or'* dispense usable marijuana, signaling the allowance of vertical integration for new market

entrants. In … contrast, [N.J.A.C. 8:64-7.9(a), as proposed for] amendment[, would state,] 'satellite sites shall not be vertically integrated.' [The proposed amendment would impose a disadvantage on] the original ATCs … by prohibiting vertical integration at original ATCs' satellite or additional sites, while allowing it at all other ATC facilities. Did the Department intend to permanently and exclusively prohibit original ATCs from vertically integrating future facilities, while allowing the practice at all other ATCs?

[It] is unclear how the proposed [rulemaking at N.J.A.C. 8:64], once adopted, will impact the six new ATCs [that are] the subject of the July 18, 2018 RFA. The RFA application and the presentation at the mandatory August 9, 2018, Pre-Application Conference strongly suggest that the new ATCs cannot apply for satellites under the [rulemaking] proposal because they are not original ATCs. This presents an apparent advantage for the original ATCs until one considers that the proposed [rulemaking at N.J.A.C. 8:64] also permanently and exclusively caps the number of facilities an original ATC can have, effectively excluding them from the endorsement system. Furthermore, the proposed [rulemaking at N.J.A.C. 8:64] appears to permit, as part of the new endorsement system, all ATCs except the original ATCs to locate sites outside the permitted region and to vertically integrate those sites. [The proposed rulemaking at N.J.A.C. 8:64 would impose a disadvantage] exclusively [on] the original ATCs … by blocking them from participating in the endorsement system and asking them to compete against vertically integrated *for-profit* ATCs engaged in a [Statewide] market. Did the Department intend to [disadvantage] so heavily … original non-profit ATCs as compared to all other *for-profit* ATCs?

The [Act] and [EO 6] clearly intend to create a fair and level playing field amongst all ATCs. [The] proposed [rulemaking at N.J.A.C. 8:64] appears to deviate from this guiding principle through distinct, permanent, and serious disadvantages exclusively foisted upon original ATCs. Serious concerns will be raised if the original ATCs are precluded from expanding and participating in the endorsement system due to the numerical cap on growth[;] opening satellites or additional sites outside of the originally permitted regions[; or] vertically integrating satellite or additional sites. [The commenter requests] clarification regarding [these issues]." (15)

105. COMMENT: A commenter states, "[proposed N.J.A.C.] 8:64-7.9(a)3 [would prohibit] an original ATC from having more than a total of two additional satellite sites. [As] the medicinal marijuana program expands in New Jersey, the Commissioner should reserve discretion in permitting more than two additional satellite sites[,] especially [for] cultivation. Supply has been a problem and … the [ATC the commenter represents has] a … facility [that is] awaiting approval and an additional … facility [that is] currently operational. [The] Commissioner should have the discretion to allow both facilities to be operational if the Commissioner believes that applying this restriction would hinder or fail to effectively achieve the … objective of [EO 6 of] ensuring safe access to [medicinal] marijuana for all patients in need. [This] dual operation will also be necessary as an ATC transitions from one grow facility to another. However, … proposed [N.J.A.C. 8:64-7.9(a)3 would] not seem to allow the Commissioner discretion in this regard.

[Proposed new N.J.A.C.] 8:64-7.1(d) [would establish] separate endorsements for the cultivation, manufacturing and dispensing of usable marijuana and products

containing marijuana. [Existing ATCs that were] endorsed under current law [as the first ATCs] to provide all three of these activities … should be deemed to have all three endorsements at their existing or expansion [ATCs because they invested in that capacity]. To do otherwise … would waste invested capital resources, slow the expansion of the medicinal marijuana program and be unfair to those who have been actively engaged in all three endorsement activities. [Proposed new N.J.A.C.] 8:64-7.9(a)4 [would provide] that satellite sites cannot be vertically integrated. [This] creates a financial hardship [if] an ATC [wants] to dispense at the same location [at which] it cultivates. [This] was the operating premise of the original ATC permits and … should be continued at least for [the] original [ATC permit holders]. [The] Commissioner should have the discretion to waive this restriction [if] applying it would hinder or fail to effectively achieve the [Executive Order No. 6] objective of ensuring safe access to medical marijuana for all patients in need." (23)

106. COMMENT: A commenter states, "satellite sites are an additional location to an existing vertically integrated ATC license, and as such the business would already be vertically integrated. If [the Department intends proposed new N.J.A.C. 8:64-7.9(a)4] to prohibit other commercial cannabis activity at the satellite site that is not explicitly permitted, then [the Department should clarify and reword proposed new N.J.A.C. 8:64-7.9(a)4]." (32)

107. COMMENT: A commenter states that the Department should allow ATCs to have "access and the ability to locate in all areas of the [State]." (40)

RESPONSE TO COMMENTS 104, 105, 106, AND 107: The Department disagrees with the commenter's assertion that proposed new N.J.A.C. 8:64-7.9(a)3, which would limit

to two the number of additional satellite sites that an original ATC can have, would impose a disadvantage on the original ATCs. N.J.A.C. 8:64-7.1, as proposed for amendment, would not prohibit the original ATCs from applying for and receiving endorsements in addition to establishing the two satellite locations for their existing permitted ATCs. N.J.A.C. 8:64-7.1 and 7.9, as proposed for amendment, would distinguish between satellite locations and endorsements in that satellite locations would be available only to the original ATCs, and could not be vertically integrated, whereas permits to establish new ATCs and to obtain endorsements associated therewith would be available to all applicants, including the original ATCs, subject to the competitive process that Subchapter 6, as proposed for amendment, would establish, and subject to an eligibility standard that the Department might establish in a particular request for applications round. In contrast, all other potential market participants would be eligible to participate only in applying for new ATC permits in accordance with the competitive process that Subchapter 6, as proposed for amendment, would establish. Proposed new N.J.A.C. 8:64-7.9(a)3, while limiting the number of satellite locations that an original ATC could establish, would not limit the number of permits or endorsements that an ATC could obtain. However, as a matter of practice, in the two requests for ATC permit applications that the Department has issued to date, the Department has made it a condition of application that no single entity could have more than one ATC permit while there exist only a limited number of ATCs.

Given that additional ATC permittees have been selected following the 2018 request for applications, upon reconsideration, the Department finds that proposed new N.J.A.C. 8:64-7.9(a)3 would impose a disadvantage on new ATC permittees by allowing

the original ATCs to obtain new ATC permits and attendant endorsements and, at the same time, open satellite locations for their existing ATCs, the latter being a privilege that would be unavailable to new ATC permittees. Therefore, the Department will not adopt the proposed amendments at N.J.A.C. 8:64-7.9 and will readopt the section without change. In addition, the Department will not adopt the proposed amendment at existing N.J.A.C. 8:64-1.2 that would add definitions of the new terms, "original ATC" and "satellite," as the chapter would not use these terms. Likewise, the Department will not adopt the proposed amendment at N.J.A.C. 8:64-7.10(a)2 that would add fees for satellite applications. The Department would review satellite location applications pursuant to its waiver authority at existing N.J.A.C. 8:64-7.11 and any related guidance. The Department anticipates engaging with stakeholders and developing future rulemaking regarding satellite locations that provides a consistent approach across all ATCs.

The Department disagrees with a commenter's assertion that the proposed limit on the number of satellite locations that an original ATC could establish pursuant to proposed new N.J.A.C. 8:64-7.9(a)3 would limit the ability of the Department to increase supply. The Department has been accepting and processing ATC satellite site applications since April 2018, and yet no satellite locations have been opened as of April 2019. Thus, it appears that the original ATCs' business capacities, and not the number of satellites they can establish, are the real impediments to their ability to maintain medicinal marijuana supplies commensurate with demand. Nonetheless, the issue is moot, because the Department has determined to not adopt the proposed amendments to N.J.A.C. 8:64-7.9.

Existing N.J.A.C. 8:64-7.9, proposed for readoption, would continue to authorize ATCs, with Department approval, to cultivate marijuana at a location separate from the location of its dispensary, but requires both locations to be within the same region. The Department's coordination of ATCs by region is consistent with the mandate at N.J.S.A. 24:6I-7, obliging the Department to evaluate and grant permits pursuant to a regional needs assessment that ensures the availability of medicinal marijuana Statewide. If an ATC receives a regional permit with an accompanying endorsement, then the permit approval implicitly reflects the Department's assessment of the need, in that region, for an ATC to conduct the activity that the endorsement authorizes.

ATC Location and Zoning; Number of Facilities (N.J.A.C. 8:64-7.9)

108. COMMENT: A commenter states, "Having access to [medicinal] marijuana is beneficial to people with MS, yet [medicinal marijuana] in New Jersey is inaccessible and unaffordable. Allowing … only six … ATCs… has presented a significant barrier to access for patients. [To] receive their medication, many New Jerseyans have to travel great distances and wait in long lines once they arrive. For individuals living with a chronic illness, like MS[,] traveling a great distance and waiting in line to get their prescription is incredibly burdensome. There is no cure for MS and patients who use [medicinal] marijuana to relieve the symptoms of [the disease … do so regularly. In addition, many individuals living with MS have mobility issues or may rely on family, friends[,] or public transportation to get their prescriptions."

Referring to N.J.A.C. 11:24-6.2, the commenter states, "New Jersey has passed network adequacy standards to ensure that New Jerseyans have extensive access to

healthcare providers and pharmacies[, which] require health networks to have two physicians within 10 miles or 30 minutes average driving time or public transit (if available), whichever is less, of 90 percent of the enrolled population[, and specialists to] be within 45 miles or one hour driving time, whichever is less, of 90 percent of members within each county. [ATCs] should be within a reasonable distance to patients[. The commenter] supports the proposed rule to increase the number of ATCs [and suggests] that New Jersey use existing network adequacy standards to assess the ongoing need for ATCs." (6)

109. COMMENT: A commenter supports the creation of "an endorsement system for cultivation, manufacturing, and dispensing marijuana for medicinal purposes, which would increase the available supply of, and patient access to, usable marijuana." (10)

RESPONSE TO COMMENTS 108 AND 109: The Department acknowledges the commenters' support for the rulemaking with respect to the proposed establishment of an endorsement system.

The Department concurs with a commenters' assertion that the demand for medicinal marijuana in the State far exceeds the existing ATCs capacity, and that allocation of permits throughout the State should take into consideration ease of patient access with respect to travel times. The Department already conducts, as a commenter recommends, periodic assessments of the adequacy of the State network of ATCs. For example, the Biennial Report of the Division of Medicinal Marijuana (April 1, 2019), available at https://nj.gov/health/medicalmarijuana, at 4, evaluates the adequacy of the existing ATCs to serve the State's need, according to four measures. Measure 3 therein provides the result of the Department's network adequacy drive time analysis

and concludes that less “than half the [State] is within 30 minutes of an ATC under a best-case drive time scenario. The drive time analysis supports the need for additional ATCs.” *Id.*

Based on the foregoing, the Department will make no change on adoption in response to the comments.

110. COMMENT: A commenter, representing an entity “that provides assistance and resources for over 9,000 farm families and agribusinesses [in the State; and advocates] for agriculture in the [State],” and which has “been paying close attention to the expansion of the medical marijuana program as a potential forerunner to legislation enabling the production, sale and use of recreational marijuana,” states “that all cannabis needs to continue to be grown indoors only, as is now the case for medicinal marijuana. In a [State that is] so densely populated, it is essential to contain all growing and production to secured, indoor facilities, for security and safety reasons. Additionally, as New Jersey contemplates the authorization of growing industrial hemp, outdoor marijuana cultivation would pose the risk of crosspollination to the hemp crop.” (17)

RESPONSE: Existing N.J.A.C. 8:64-10.1(a)1, proposed for readoption, requires ATCs to produce medicinal marijuana “only at the indoor cultivation site and area authorized in the permit.” Similarly, existing N.J.A.C. 8:64-10.4(a), proposed for readoption, states, “all cultivation of marijuana shall take place in an enclosed, locked facility.” Thus, as the commenter acknowledges, the existing rules require all cultivation activity to occur in enclosed indoor, locked facilities. The Department takes no position on the applicability

of these standards to recreational marijuana, the proposed legalization of which in New Jersey being the subject of various pending bills, because the subject exceeds the scope of the proposed rulemaking and is not within the Department's jurisdiction.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

111. COMMENT: A commenter states, "[the] rules are overly biased toward a product that has been determined to be legal. While recreational dispensaries should be tightly controlled, medical facilities are amply secure. Notwithstanding, the rule could treat [dispensing] differently from cultivation [and] manufacturing, especially as cultivation [and] manufacturing facilities are highly restricted. Accordingly, local zoning has the ability to control this. Also, a hard and fast [1,000-foot] rule severely hampers access in urban areas." (26)

RESPONSE: While the Act makes legal the possession and use of medicinal marijuana under State law, Federal law continues to identify medicinal marijuana as a Schedule 1 controlled substance that has potential for abuse and diversion pursuant to the Controlled Substances Act, 21 U.S.C. §§ 801 et seq. Moreover, the Act obliges the Commissioner to promulgate rules to "ensure adequate security of all facilities 24 hours per day, including production and retail locations, and security of all delivery methods to registered qualifying patients." N.J.S.A. 24:6I-7.i(3). The rules proposed for readoption at N.J.A.C. 8:64, and the proposed amendments, repeals, and new rule, would continue to fulfill this obligation to ensure that ATCs maintain adequate security and thereby reduce the risks of diversion and/or abuse.

In referring to a “1,000-foot rule,” the commenter appears to refer to existing N.J.A.C. 8:64-13.6(b)1, proposed for readoption, which states that “ATCs shall not be located within a drug-free school zone.” Consistent with the commenter’s suggestion, to date, the Department has routinely deferred to, and relied on, local municipalities as to the determination of whether the situation of an ATC would be within 1,000 feet of school property.

N.J.S.A. 2C:35-7 of the Comprehensive Drug Reform Act of 1987 (CDRA), N.J.S.A. 2C:35-1 et seq., makes “distributing, dispensing or possessing with intent to distribute a controlled dangerous substance or controlled substance analog while on any school property used for school purposes which is owned by or leased to any elementary or secondary school or school board, or within 1,000 feet of such school property or a school bus, or while on any school bus,” a crime of the third degree. However, N.J.S.A. 2C:35-18 exempts from criminal liability conduct that the CDRA would otherwise prohibit if the Act authorizes the conduct. Likewise, N.J.S.A. 24:6I-6 expressly includes qualifying patients, their caregivers, ATCs, and physicians, among entities eligible for the exemption from criminal liability that N.J.S.A. 2C:35-18 establishes. Thus, the prohibition at N.J.A.C. 8:64-13.6(b)1 is unnecessary to ensure ATCs’ compliance with the CDRA and the Act.

However, “distributing, possessing with intent to distribute, or manufacturing a controlled substance in or on, or within one thousand feet of, the real property comprising a public or private elementary, vocational, or secondary school or a public or private college, junior college, or university, or a playground, or housing facility owned by a public housing authority, or within 100 feet of a public or private youth center,

public swimming pool, or video arcade facility," remains a Federal criminal offense. 21 U.S.C. § 860. The Act notes, "States are not required to enforce [Federal] law or prosecute people for engaging in activities prohibited by [Federal] law …" N.J.S.A. 24:6I-2.d. Moreover, the Act and N.J.A.C. 8:64 would continue to prohibit conduct that would violate State laws prohibiting smoking in indoor public places and workplaces, and "in a school bus or other form of public transportation, in a private vehicle unless the vehicle is not in operation, on any school grounds, in any correctional facility, at any public park or beach, at any recreation center, or in any place where smoking is prohibited pursuant to [N.J.S.A.] 2C:33-13." N.J.S.A. 24:6I-8.b; N.J.A.C. 8:64-9.6.

Based on these considerations, the Department will maintain the prohibition on ATCs within drug-free school zones at N.J.A.C. 8:64-13.6(b)1, even though ATCs are not subject to N.J.S.A. 2C:35-18. The Department will continue to defer to, and rely on, municipal zoning to determine the suitability of a given site for an ATC in relation to schools and to ensure that medicinal marijuana is not dispensed in drug-free school zones.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

112. COMMENT: A commenter states that the Department should allow ATC permittees to establish facilities in multiple regions of the State so they can "provide high quality medicine to all counties within the [State]" because this "will benefit patients by saving them time and money traveling from [other] parts of New Jersey." (40)

113. COMMENT: A commenter states, “The proliferation of additional ATCs is important for patient health, but it is critical that Legislators pay attention to location selection. Today, some patients must drive one to two hours to visit an ATC. It is critical to consider incentives for counties [and] towns to establish ATCs that may not otherwise. Ocean and Monmouth [Counties] do not have an ATC and still may not after the addition of new facilities. It’s imperative that these patients have local access to medicine.” (43)

114. COMMENT: A commenter states that, just as there is no limit to the number of pharmacies in the State, there should be no limit to the number of “dispensaries in the [State,] to make medical cannabis more easily accessible to patients,” and that “medical cannabis should be treated like any other form of medicine as it is medicine.” (45)

RESPONSE TO COMMENTS 112, 113, AND 114: The Act obliges the Commissioner, in granting ATC permits, to “seek to ensure the availability of a sufficient number of alternative treatment centers throughout the State, pursuant to need, including at least two each in the northern, central, and southern regions of the State.” N.J.S.A. 24:6I-7.a.

Subchapter 6 of the rules proposed for readoption, and the proposed amendments thereto, would establish the process by which the Department is to evaluate ATC permit applications to ensure Statewide access to ATCs, consistent with the mandate at N.J.S.A. 24:6I-7.a. The Act indicates that the Department’s permitting mandate, at least at the outset of its implementation of the Act, was to coordinate, by region, its needs assessments to ensure Statewide ATC access. The Department, following the conduct of regional needs assessments, is likely to issue future requests for ATC permit applications that would authorize existing ATC permittees to compete for

ATC permits in regions other than those in which they presently operate. However, the Department disagrees with the commenter's suggestion that the Department should authorize existing ATC permittees to expand to regions, other than those in which the Department authorized them by permit to establish operations, outside of the competitive ATC permit application process. To allow this would contravene the regional needs assessment determinations upon which the Department bases each request for applications it issues and could be counterproductive to the fulfillment of the Department's obligation to ensure Statewide ATC access.

The Department takes no position as to a commenter's suggestion that, "Legislators [should] pay attention to location selection," except to note that the Department strives to ensure that it conducts the ATC application review process apolitically, without conflict of interest, and in a manner that fulfills its obligation to ensure Statewide ATC access based on regional needs assessment.

The Department concurs with the commenters' assertions that, even upon the commencement of operations by the six additional ATCs selected in the 2018 call for applications, Statewide need for the establishment of additional ATCs is likely, particularly as the Department continues to recognize additional debilitating medical conditions. The Department anticipates that the establishment of the endorsement system at Subchapters 6 and 7, as proposed for readoption with amendments, would give the Department greater flexibility to facilitate the expansion of ATCs' service capacities in accordance with regional needs. For example, it is likely that more dispensaries than cultivation sites are necessary to improve patient access. The

issuance of regional need-specific endorsements would enable the Department to address existing barriers to Statewide access.

Contrary to a commenter's assertion, neither the Act nor the rules proposed for readoption with amendments, repeals, and a new rule, at N.J.A.C. 8:64, would limit the number of dispensaries in the State. The commenter might be misinterpreting N.J.S.A. 24:6I-7.a, which required the Department to ensure at the outset of its implementation of the Act that there were at least two ATCs in each of the northern, central, and southern regions of the State, that is, six ATCs. The Department met this obligation upon its issuance of permits to the original ATCs.

However, as described above, the Act authorizes the Department to issue "a sufficient number" of ATC permits "throughout the State, pursuant to need." N.J.S.A. 24:6I-7.a. This obliges the Department to conduct assessments to determine the number of ATC permits that are "sufficient" to serve the State's needs.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

ATC Application Fees (N.J.A.C. 8:64-7.10)

115. COMMENT: A commenter states that the Department should clarify the meaning of the term, "physical modification," which N.J.A.C. 8:64-7.10(a)3 uses, "to avoid confusion as to what type of material changes an ATC is required to apply for [Department approval]," and recommends that the Department consider another state's regulation as a model of "how to clarify the types of physical modifications that should require an application and approval from the Department." (32)

RESPONSE: The commenter is correct in noting that N.J.A.C. 8:64-7.10(a)3, as proposed for amendment, does not address what would constitute the physical modification of an ATC as the section only establishes the fees associated with the various applications one might submit to the Department for review. N.J.A.C. 8:64-7.8(a)5 obliges ATC permittees to apply to the Department for an amended permit prior to "modification of or addition to the [ATC's] physical plant." The Department's experience with the existing ATC permittees has indicated no confusion among them as to the meaning of this provision.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

116. COMMENT: A commenter states that the Department should amend proposed N.J.A.C. 8:64-7.10(a)4 to provide that "the $20,000 application fee for transfers of ownership only [applies] in instances when greater than 50 [percent] of a license is transferred or interest in a license is transferred to individual(s) who do not already hold an interest in a New Jersey cannabis license. In all other instances[,] the application fee for transfer of ownership should be substantially reduced. For instance, if an ATC is undergoing internal ownership changes and a 20 [percent] owner is buying out an interest from another owner of the same license and becoming a 30 [percent] owner the Department does not need to undergo the same length of review as if a completely new entity buys 80 [percent] of an ATC license." (32)

RESPONSE: When an ATC applies for approval of a change in ownership, regardless of the percentage of ownership that changes, the Department incurs administrative

costs associated with the review of criminal background checks pursuant to N.J.A.C. 8:64-7.2, the verification of information submitted by proposed new owners pursuant to N.J.A.C. 8:64-7.3, and the issuance of a new or revised ATC permit pursuant to N.J.A.C. 8:64-7.8. The fees at N.J.A.C. 8:64-7.10 help the Department offset those administrative costs. The Department is without authority to waive, based on percentage of ownership change, its review of new owners' criminal record history background checks and verification of other information owners provide. N.J.S.A. 24:6I-7.d(1) obliges the Department to conduct a review of "any owner, director, officer, or employee of an" ATC.

Based on the foregoing, the Department will make no changes upon adoption.

ATC Employee Transferability (N.J.A.C. 8:64-8.2)

117. COMMENT: A commenter states, "[while] allowing patients to shop at whichever ATCs they wish to will require a statutory change, nothing in the existing law addresses whether ATC *employees* can transfer their [ATC identification cards] from one ATC to another if they get a new job. [Existing N.J.A.C. 8:64-8.2 keeps] lower level employees locked into one ATC[. This] is likely to depress wages and working conditions, because it makes it harder for the employee to change jobs if they have to go through the hassle and expense of redoing a background check and getting a card reissued. This in effect insulates businesses from competing with one another to attract the best workers. Given that the employee has already gone through a background check, there is no reason they should not be allowed to change jobs." The commenter suggests that the Department address this in a future rulemaking. (5)

RESPONSE: The Act obliges the Department to require persons applying to be ATC employees to undergo criminal history record background checks, and to disapprove the applications of persons who have disqualifying convictions, unless the Commissioner finds that the applicant has demonstrated clear and convincing evidence of rehabilitation. N.J.S.A. 24:6I-7.d.

The requirement at existing N.J.A.C. 8:64-8.2 proposed for readoption that ATC identification cards expire immediately upon cessation of a person's employment at an ATC is necessary to maintain the security of ATC premises, to enable ATCs to fulfill the obligation to limit access to ATC premises only to "on-duty personnel," and registered qualifying patients and their caregivers who are engaging in authorized ATC dispensary activity, pursuant to existing N.J.A.C. 8:64-9.7(b)12 proposed for readoption, and to prevent abuse of the immunity from civil liability and criminal prosecution under State law that the Act confers on persons acting in accordance therewith, pursuant to N.J.S.A. 24:6I-6.

In the EO 6 Report at 8, the Commissioner stated that the "Department recognizes that the current process to obtain an ATC permit and open a dispensary is lengthy, which can have an effect on supply. This effect will be magnified by the anticipated influx of new participating patients resulting from the addition of new debilitating conditions. The Department is mindful of the balance between conducting thorough due diligence on ATC applicants while ensuring that potential permit holders are not mired down in an overly complex or burdensome application process. To strike this balance, the Department will work with the Department of Law and Public Safety to conduct a review of the current permit and background check process to create

efficiencies, with the anticipated goal of implementing the new review process in the upcoming Request for Applications."

The Department maintains records of applicants' criminal history record background checks, and, if applicable, the Commissioner's findings of applicants' rehabilitation. If an employee ceases employment at an ATC to work at a different ATC, the Commissioner would not readjudicate a previously issued finding of the applicant's rehabilitation for a known disqualifying crime but would simply refer to the prior adjudication of rehabilitation. The Act obliges the Department to require applicants to undergo a criminal history record background check as a precondition to the issuance of a registry identification card. Consistent with the Commissioner's stated goal of streamlining these administrative processes, as expressed in the EO 6 Report quoted above, the Department would endeavor to expedite the criminal history record background check investigation of employees transitioning from one ATC to another, for example, by requiring the evaluation of only the period between a prior criminal history record background check investigation and a pending application.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

ATC Disposal Practices (N.J.A.C. 8:64-9.9)

118. COMMENT: A commenter states that the Department "should allow [ATCs] to dispose of waste plant material by … means [other than] incineration [such as] composting, shredding[,] and mixing with soil to render unusable or allowing [a third-party] waste disposal company to take the waste." (40)

RESPONSE: The rules proposed for readoption and the proposed amendments, repeals, and new rule, at N.J.A.C. 8:64 are silent as to the procedures for disposal of waste products associated with medicinal marijuana production. Existing N.J.A.C. 8:64-9.9 requires ATCs to maintain inventory controls and records as to cultivating, stored, usable, and unusable marijuana and to maintain disposal records. Waste disposal is within the jurisdiction of the New Jersey Department of Environmental Protection (DEP). However, the Department issued guidance to ATCs in August 2018, indicating that ATC can shred and mix waste material to render it unusable and then dispose of it as solid waste.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

ATC Number of Strains; Tetrahydrocannabinol (THC) Potency (N.J.A.C. 8:64-10.7)

119. COMMENT: A commenter "[fully supports] the elimination of THC limits in all medicinal products." (40)

120. COMMENT: A commenter states, "10 [percent] THC limit [should] be removed." (45)

121. COMMENT: A commenter "supports removing the THC cap, [and] allowing cultivators to produce as many strains of cannabis as help patients … All of these measures are common sense changes that help patients get the medicine they need. Regarding lifting the THC cap … there are two prescription drugs that have been given FDA approval that contain synthetic THC as their sole active ingredient. One of these, [MARINOL® (dronabinol)], is pure (synthetic) THC in pill form, which is listed in

Schedule III under [Federal] law, allowing it to be freely prescribed by medical professionals. The other is [SYNDROS® (dronabinol)], THC in an oral solution, which is listed in Schedule II under [Federal] law, meaning it can be prescribed but with slightly more restrictions. There is also a THC analogue called [CESAMET® II (nabilone)] that is a prescription drug. None of these drugs are separately scheduled under New Jersey law. Allowing patients to take pure THC, which has more negative side effects than cannabis, while placing an artificial THC limit on medical cannabis, has no scientific or logical basis. [MARINOL® (dronabinol)] is not well tolerated by some patients. Without any other cannabinoids, pure THC can be too intoxicating. It is safer and more effective when THC is part of a treatment created from natural marijuana where other cannabinoids can provide a vital counter to the negative side effects of THC. Studies have shown that [cannabidiol (CBD)] has a neuroprotectant effect that helps to counteract the intoxicating effect of the THC [(citation omitted)]. Studies have also shown that patients find relief from cannabis with greater amounts of THC than are currently allowed in New Jersey. For example, a recent study from Israel using a cannabis strain containing 23 [percent] THC found that it eased symptoms in 10 out of 11 patients, with five patients experiencing complete remission [(citation omitted)]." (5)

122. COMMENT: A commenter "[agrees] with the [proposed repeal of existing N.J.A.C. 8:64-10.7] to remove the 10 [percent] THC limit for cannabis products. Nevertheless … the logic of regulating dosage is sound. Rather than focusing on an absolute cap on concentration, [rules addressing] potency … for cannabis preparations other than raw cannabis flower [should focus] on the size of an individual dose, rather than on the

average potency of the product." The commenter provides citations to other states' laws addressing potency limits (citations omitted).

"With respect to vaporizable cannabis concentrates, it is not uncommon to see cannabis concentrates with THC concentrations of over 70 [percent]. In spite of these higher concentrations, vaporizable concentrates can be titrated with relative accuracy, ensuring that a dose does not exceed a given threshold, such as [five milligrams] or 10 [milligrams]. This distinguishes vaporizable concentrates from combustible forms of cannabis, which cannot be dosed accurately, with the result that a patient may inadvertently take a larger-than-intended dose, regardless of the relative potency of the material consumed." (47)

RESPONSE TO COMMENTS 119, 120, 121, AND 122: The Department acknowledges the commenters support for the proposed repeal of N.J.A.C. 8:64-10.7. The Commissioner stated in the EO 6 Report at 17-18 that the Department established the 10 percent THC limit upon the inception of the Department's implementation of the Act, "to ensure that doctors and their patients had a reliable and standardized choice of potency options from which to choose and to provide patients with effective medicine to start. The Department committed to evaluate the THC limit as the program evolved. Minnesota conducted an analysis of the effects of THC doses to treat conditions approved for medicinal marijuana under its program, finding that higher potency THC treatments provided effective treatment for a number of conditions." The Department proposed to repeal the THC limit at existing N.J.A.C. 8:64-10.7 to give qualifying patients "more effective treatment of the debilitating medical conditions covered under the State's program." EO 6 Report at 18.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

ATC Packaging and Dispensing, Alternative Forms, Alternative Administration Methods (Recodified N.J.A.C. 8:64-10.7)

123. COMMENT: Commenters state, "When patients go to [dispensaries] they should be able to smell and see the product before they buy. Right now[,] the cannabis can only be seen through display cases and you can't open the medicine in the building so essentially you don't really know what you bought until you leave the dispensary!" (29 and 48)

RESPONSE: EO 6 at § 1g charges the Department to effectively achieve the statutory objective of "ensuring safe access" to medicinal marijuana for patients in need. Recodified amended N.J.A.C. 8:64-10.7(a) would continue to require ATCs to "process medicinal marijuana in a safe and sanitary manner to protect registered qualifying patients from adulterated marijuana," and, at subsection (c), to maintain usable marijuana in a closed, sealed container, "so that the package cannot be opened, and the contents consumed, without the seal being broken." Subsection (d) would continue to prohibit ATCs from opening sealed packages except for quality control, as breaking a seal renders unusable the marijuana therein. Because many qualifying patients have debilitating medical conditions that compromise their immune systems, ATCs must handle and dispense usable marijuana this way to avoid contamination and thereby protect vulnerable patients from harm that can result from the use of impure products. However, the Department has allowed ATCs to maintain display containers of product,

which is not for dispensing or sale, to enable patients, with ATC personnel assistance and direct supervision, to securely observe and smell product samples.

Based on the foregoing, the Department will make no change upon adoption in response to the comment.

124. COMMENT: A commenter states that the rules require ATCs to package medicinal marijuana “limited to structures within the retail sale of 1/8 ounce and 1/4 ounce only[, which] limits patients’ ability to choose their medicines individually and forces limited sales of various products,” and that the Department should restructure “these limits [by] providing patients the opportunity to mix and match smaller amounts of a wider variety of medicine should they choose including flower and extracts. For example, [the rules should allow] the sale of grams of flower and the sale of [half-gram] or [one-gram] increments of marijuana oil with no potency caps.” (40)

RESPONSE: Recodified amended N.J.A.C. 8:64-10.7(c) would continue to require ATCs to package usable marijuana in containers holding “no more than 1/4 ounce or equivalent dose dependent on form.” The rule does not prohibit ATCs from dispensing usable marijuana in packages of under 1/4 ounce, subject to Department labeling approval pursuant to subsection (f). However, the existing patient registry is capable of tracking only amounts dispensed in 1/8- and 1/4-ounce increments, which is why the Department has historically limited dispensing to those amounts. The Department is unable to make the change before the new patient registry is fully operational. Because the limitation is technological and not imposed by regulation, the Department will make no change on adoption in response to the comment.

Based on the foregoing, the Department will make no change upon adoption in response to the comment.

125. COMMENT: A commenter notes that recodified amended N.J.A.C. 8:64-10.7(f) would continue to require ATCs to submit medicinal marijuana packaging labels to the Department “for approval and record,” copies of which the Department, in turn, provides “to authorized employees of State agencies or local law enforcement agencies, as necessary to perform their official duties.” The commenter states, “[pre-approval] of medical cannabis product labels is unnecessary [because] the label requirements in [the rules] are explicit and detailed. Requiring pre-approval will only create additional work for the [Department] and slow down the process of providing new medicinal cannabis product options for patients.” (32)

RESPONSE: Absent extraordinary circumstances, the Department promptly processes requests for label “approval and record.” Prior approval of packaging labels enables ATCs to avoid costs associated with repackaging and relabeling items that the Department might later determine to have been improperly labelled. Dissemination of labels to State agencies and local law enforcement authorities protects qualifying patients and their caregivers in possession of products, bearing labels that are known to law enforcement agencies, from civil liability and criminal prosecution under State law that otherwise might attend the possession. Therefore, the Department disagrees with the commenter’s assertions that prior approval and dissemination of packaging labels imposes unreasonable delays or is unnecessary.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

126. COMMENT: A commenter states, “tincture, edibles” [sic]. (2)

127. COMMENT: A commenter supports authorizing “manufacturing and dispensing of medicinal marijuana in non-topical forms. [Some] parents make edibles for their sick children because there is only so much infused oil from the dispensaries that a little [body’s] stomach can handle day-to-day before it creates other digestion issues. [On] behalf of [parents whose] allotments run out because they somehow ruined or burnt it in an attempt to administer their children’s medication just a bit easier, [the commenter begs the Department] to allow edibles and other forms of cannabis besides what is allowed now. [Other] states are able to regulate things like edibles[. New Jersey patients] NEED edibles. [The commenter makes] the same plea [with respect to] products like patches [and] concentrates. [Terminal], elderly … and minor … patients should be and MUST be put first when we are using words like compassion in our laws and regulations.” (10)

128. COMMENT: A commenter states, “[regarding] the manufacturing of oil … in preloaded cartridges, or in topical or oral formulations[, the commenter imagines that the term, ‘oral formulations,’ includes] oils [that one vaporizes] outside of a cartridge[,] which are extremely necessary for some patients [needing] a fast heavy dose of medication [The commenter requests that the] definition [of the term, ‘oil,’] be cleared up if possible.” (12)

129. COMMENT: Commenters state, “[make] ‘FECO’ [full] extraction cannabis oil available to patients.” (29 and 48)

130. COMMENT: A commenter quotes from the Act, which lists the authorized forms of dispensable marijuana as, “dried form, oral lozenges, topical formulations, or edible form, or any other form as authorized by the commissioner.” N.J.S.A. 24:6I-7.a. The commenter states that the Commissioner “should greatly expand the number of listed product formulations permitted and establish a process whereby an ATC may produce a product that is not listed by applying to the Department for an exemption waiver.”

The commenter states, “[to] expand the types of infused product options for patients,” the Department should define “[oil] forms … as ‘concentrates’ or ‘concentrated cannabis extracts,’” delete paragraph 1 from the definition of the term, “oil,” at N.J.A.C. 8:64-1.2, as proposed for amendment, and add a definition of the term, “concentrates,” to mean “a viscous liquid substance containing cannabinoids, such as THC and cannabidiol, which are extracted from the marijuana plant….” The commenter states that the Department should change the term, “oil formulations,” to “concentrates” or “concentrated cannabis extracts,” consistent with the commenter’s recommendation for the definition of “oil.” The commenter states, “[the term, ‘concentrates,’] is the term most often used in other medical cannabis programs and will reduce potential confusion [because] the ‘oil’ produced from cannabis plants often refers to non-psychoactive [hemp oil, which] is [exempt] from many states’ criminal definitions of cannabis.”

The commenter supports the proposed amendment to the existing definition of the term, “lozenge,” at N.J.A.C. 8:64-1.2, because the text proposed for deletion “unnecessarily [restricts] the [types] of ‘lozenges’ that can be produced.” The

commenter states, “[until] legislation eliminates the requirement that edible products be limited to minors,” that the Department should further amend the definition to state that a lozenge is designed to dissolve, disintegrate, “or be chewed in the mouth,” because this would “permit many more types of orally active medical cannabis products and will further patient access for those who prefer smokeless options.” (32)

131. COMMENT: A commenter “[fully supports] the addition of oil formulations to be manufactured by ATCs for vaporizing and for oral administration and suggests the addition of marijuana infused edibles.” The commenter states that surveys of its existing patients indicate “that patients are reducing their use of opiates by using cannabis. In … 2017, 49 [percent] of … patients reported ‘not taking’ opioid pain killers anymore; 43 [percent] reported ‘currently taking less than before.’ It would be beneficial for patients to have the option to obtain a variety of cannabis products instead of receiving opioids for beneficial treatment and a better quality of life. [The Department should authorize] “a high concentration THC percentage (30 [to] 90 [percent]) with possible different consistencies of [cannabis] oil ([shatter, live resin, hash]) extracts. Offering a wider variety of potencies in the extracted products will [enable] patients looking to medicate to a higher dosage than 10 [milligrams] to address various [severities] of ailments. Products offering lower dosages ([of five to] 10 [milligrams]) will still be beneficial for new patients and patients in need of micro dosing[;] however, providing [higher-potency] products [would] open up opportunities for patients in need of high doses of THC and other cannabinoids. [As] to manufacturing full-spectrum extract products, [hash products are] a favorable option for patients looking for potent medicine with a full spectrum of cannabinoids [because they are high-THC extracts] with … little

or some plant matter (pigments, waxes, protectants, and such) … that can be used topically, ingested, and vaporized [and offer] various [plant-based] phytocannabinoids such as [cannabigerol, cannabinol, and cannabidiol]. Because hash products are minimally processed they are highly beneficial in all forms. [Cannabinol in tincture or topical form] is great for neurological conditions such as [multiple sclerosis, and Parkinson's and Alzheimer's diseases, and] is known to be a great sleep aid and pain reliever … Ingested products are favorable among [patients] that do not vaporize or combust medicine. Edible products are a perfect way to micro dose with a longer duration of effects [and relieve] pain … and nausea. [In] states with a more developed and integrated cannabis infrastructure, edible cannabis has become the primary means of consumption and medication for many patients. [The commenter supports the authorization of] sublingual products [such as] lozenges and spearmints[,] baked goods[, and] non-perishable items [to] take the burden of production off … patients, ensure exact dosages across a product, allow patients to have access to [laboratory-tested] products and provide a regulated space to safely and legally produce food products. [The commenter supports the authorization of viscous] substances [in] a variety of oil consistencies such as 'shatter,' 'crumble,' [and] 'live resin' [because including] these consistencies [would] give patients a wider array of products to target specific symptom relief." (40)

132. COMMENT: A commenter states, "All other forms of medical cannabis [should] be allowed (edible, oil, tinctures, vape oil cartridges, and others)." (45)

133. COMMENT: With respect to the proposed definition of the new term, "oil," at N.J.A.C. 8:64-1.2, a commenter states that in "mature cannabis markets … cannabis oil

and derivative products account for a large proportion of legal cannabis products sold [(citations omitted);] therefore[,] the Department [should revise the proposed definition of the term, "oil," to] take into account the following distinctions [and nuances]:

Although the primary constituents of cannabis oil are cannabinoids, they also include terpenes and flavonoids, both of which are believed to work in concert with the cannabinoids to deliver cannabis's therapeutic effects. Terpenes deserve special mention, as they account for a significant portion of the sensory experience of cannabis, and are currently used as additives to cannabis oil, to reduce the cannabis oil's high viscosity. [The] Department [also should] define the term, 'cannabis concentrate,' … as [have] states with mature medical cannabis markets [(citations omitted)]. Depending on the intended mode of administration — oral or inhaled — … the Department [should] distinguish between cannabis oils and cannabis concentrates. [While] vegetable oils such as olive oil and butter may be mixed with cannabis oil for oral ingestion, they should not be used in formulations intended for inhalation, as these pose the risk of serious pulmonary complications …

With respect to pre-loaded cartridges, the [rule] should specify their intended use. Two distinct types of cartridges may be imagined: syringes filled with a pre-determined amount of cannabis, with no specification of the intended mode of administration; and pre-filled vaporizer cartridges, to be used with an electronic device to heat and aerosolize the oil, for pulmonary administration. [The Department should define the terms, 'pre-loaded syringe,' and 'pre-loaded vaporizer cartridge,' and authorize] pre-filled vaporizer cartridges … Among modes of pulmonary administration … vaporizer

cartridges pre-filled with concentrates offer the patient the most control over dose titration.

[With] respect to oral administration, [paragraph 1 of the proposed definition of the term, 'oil,' is ambiguous] with respect to oral oil formulations. [One could interpret the] term 'oral' as [meaning] enteral (ingestible), or sublingual (absorbed through the mucosa of the mouth). Because of the manner in which the body processes cannabis, enteral and sublingual administration are substantially different, notably with respect to the patient's ability [to] self-titrate. Sublingually administered cannabis can easily be measured into the desired dosage by means of a graduated eyedropper … and reaches peak plasma levels (therefore peak effect) within minutes. By contrast, enterically administered cannabis can take hours to reach peak plasma concentrations … and tends to be significantly more intoxicating as a result of THC's metabolism into 11-OH-THC before entering the bloodstream. [The Department should authorize sublingually] administered cannabis [because it] is the only form appropriate for patients who cannot ingest food orally[. The proposed definition of the term, 'oil,'] implies that only oil may be used in such formulations. [The Department should amend the definition] to specify that cannabis oil intended for oral administration may be mixed with non-oil excipients, provided they form a homogenous solution and are safe for human consumption."

The commenter is "pleased … that … patients [would] have access to non-smokable forms of cannabis [under the proposed rulemaking]. [The] Department [should] encourage patients to choose non-combustible modes of administration, including sublingual tinctures, edibles, and vaporization. With respect to vaporization … the Department [should] differentiate between vaporization and combustion. Numerous

studies have demonstrated vaporization's suppression of harmful pyrolytic degradation products found in smoke, leading to the conclusion that vaporization is likely a less harmful alternative to smoking [(citations omitted)]. [The Department should include] vaporizers [for] both … cannabis flowers and concentrates … in the … definition of the term, 'paraphernalia.' Additionally, while the technology used to vaporize cannabis bears similarities with that used in electronic nicotine delivery systems (ENDS, 'e-cigarettes'), [the rules should] distinguish between nicotine delivery devices, and those used to deliver cannabis. This is … not just a semantic point, but one with significant regulatory implications, as ENDSs are [Federally] regulated, while cannabis vaporizers are not. Should [State] law regulate cannabis vaporizers as ENDSs, their manufacturers and retailers could be caught between two mutually exclusive legal frameworks, and patient access could be restricted. As vaporization is believed to be a less harmful mode of administration than combustion, [this] would be [a] detriment [to] public health." (47)

RESPONSE TO COMMENTS 126 THROUGH 133: The Department acknowledges the commenters' support for the proposed addition of "oil formulations" at recodified amended N.J.A.C. 8:64-10.8(e)4. The Department disagrees with the assertion that the term, "oil formulations," is unclear. A proposed amendment at existing N.J.A.C. 8:64-1.2 would add a definition of the term, "oil," to mean "a viscous liquid substance containing cannabinoids … extracted from the marijuana plant." This definition would recognize the extraction and production methods that ATCs would use to create oil formulations.

ATCs can submit new product proposals as waiver applications pursuant to existing N.J.A.C. 8:64-7.11, proposed for readoption, which establishes the conditions under which the Commissioner "may waive a requirement regarding the operations of the ATC." For example, pursuant to his waiver authority at N.J.A.C. 8:64-7.11, on August 30, 2018, the Commissioner granted a waiver to allow all ATCs to produce and dispense oil cartridges. Recodified amended N.J.A.C. 8:64-10.7(e)4 would implement this prior waiver authorization as part of the rules of general applicability to all ATCs. The Department anticipates that, if the Commissioner elects to permit ATCs to dispense medicinal marijuana in new forms, the Commissioner would authorize this activity through rulemaking, but the Department would continue to accept new product proposals as waiver applications in advance of formal rulemaking.

The Department acknowledges the commenters' support of the proposed amendment to the definition of the term "lozenge," at existing N.J.A.C. 8:64-1.2, proposed for readoption with amendment. A commenter correctly acknowledges that the Act limits the availability of edible forms "only to qualifying patients who are minors." N.J.S.A. 24:6I-7.a.

The Department acknowledges the commenter's support of the use of non-combustible forms of medicinal marijuana over smoking, including lozenges, oils, and oil cartridges that can be vaporized. During his Grand Rounds sessions, described above, the Commissioner discourages physicians from recommending the use of combustible forms of medicinal marijuana, and encourages them to favor instead, the use of oral, topical, and oil formulations.

The Act defines the term, “paraphernalia,” as having the meaning given in the definition of that term at N.J.S.A. 2C:36-1. N.J.S.A. 24:6I-3. The definition is broad and would include, “cannabis vaporizers,” as the commenter describes these devices. Therefore, ATCs are authorized to dispense, and qualifying patients are authorized to possess and use, cannabis vaporizers as “paraphernalia,” as used in the definition of the term, “medical use of marijuana” at N.J.S.A. 24:6I-3, and as “related supplies” at N.J.S.A. 24:6I-7.a. ATCs are prohibited from selling electronic nicotine delivery systems and nicotine products of any kind, as these are neither “paraphernalia” nor supplies related to the dispensing of medicinal marijuana.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

ATC Product Quality; Laboratory Testing (N.J.A.C. 8:64-10.9, 10.10, and 13.4)

134. COMMENT: A commenter notes the statement in the EO 6 Report that, “‘[with] the anticipated addition of ATCs and the influx of new patients, the Department is researching the feasibility of using external laboratories to provide the required testing, with the Department acting as a secondary testing source.’ Unfortunately, [the notice of proposal does] not address incorporating independent [laboratory] testing. The proposed rules show that the number of ATC cultivation facilities will increase. An increase in both supply and [demand] has the possibility of burdening already strained [State-run laboratories]. The longer it takes for test results to be processed, the longer [patients have] to wait for their medication. A lag in testing could also artificially constrict available supply causing a rise in price passed onto patients.

[The Department should] sanction independent [third-party] testing as a way to ensure that patients can receive their tested, safe medicine in a timely manner while the [State medicinal] marijuana [system] continues to expand. [Independent third-party] testing [laboratories are] not affiliated with the cultivator, the manufacturer, the consumer, or the brand, and have no interest in the outcome of the testing. They are authorized to collect samples of their choosing to test for potency, terpenes, residual solvents, pesticides[,] and microbial contamination. These reports are then shared with … the business and can be filed with the [Department] as well. Independent laboratories are an essential feature of a functioning legal cannabis marketplace … and have been authorized in nearly every legal access state across the country.

Licensing independent laboratories will also be critical in ensuring sufficient legal cannabis and cannabis products are available to consumers, and that consumers and commercial cannabis businesses are safeguarded from product shortages or severe market challenges such as those threatening the viability of the California system right now [(citation omitted)]. California's dual licensure system failed to license a sufficient number of independent [laboratories] to test the volume of cannabis being produced by [Californian] cultivators and manufacturers to meet consumer demand. The result of this oversight has been a very limited number of cannabis products available at legal retail locations, which is driving consumers to patronize illegal providers and forcing medical patients to drive for hours in search of retailers that carry products to treat their conditions. The product bottleneck is also threating the viability of the very [California]-licensed businesses that [California] is depending on to produce tax revenue. In the first quarter of 2018, California captured only 20 percent of the tax revenue [it]

anticipated flowing from establishing a legal commercial cannabis industry [(citation omitted)].

Integral to … successful independent [third-party] testing is the ability for [laboratories] to collect random samples, [conform] to industry best practices and upload all results to [the government] for maximum compliance. The language used by the Michigan Department of Licensing and Regulatory Affairs (LARA) to address independent lab testing has successfully held up an industry currently serving over 200,000 patients as of 2017 [(citation omitted)]. [The] Department [should] adopt [rules similar to those promulgated] by LARA." The commenter provides LARA regulatory text. (4)

135. COMMENT: A commenter, "who has worked in the State … as a grower in an ATC, [and] who has also grown medical marijuana in Colorado and California," claims to have witnessed "owners telling experienced growers to do things that were not good for the plant. It degrades the quality of the medicine and with the highest prices in the nation by about [three times,] it ultimately forces people to use the street or to import marijuana from other states[,] so they can affordably get relief. There are a lot of issues with the program. [Cannabis] should … be tested [not only] for cannabinoids and chemicals but [also] for mite infestation, powdery mildew, improper drying[,] and curing. [The commenter has] purchased improperly grown and prematurely picked marijuana from more than one ATC. Only two [existing] ATCs [in the State] are producing [medical-quality] cannabis … There is no regulation on what type of nutrients can be used to grow marijuana in ATCs. Naturally based nutrients [versus] synthetic nutrients can make a big difference in the medicinal value of a plant. [Department ATC]

inspectors … are overlooking a lot of important things to ensure patients are getting a medical quality product. [The commenter has] seen [medicinal marijuana dispensed] with powdery mildew, [the] use [of] the lowest quality nutrients … [and the dispensing of] leaves and trim [that have been rubbed] through a screen[, sold] as 'shake' when supply was very low in 2015 [and] 2016." (7)

136. COMMENT: A commenter states, "a few of the current dispensaries truly have their hearts in the right place even though they are independent businesses and not everyone would agree. The ones that don't care about patients are churning out some of the unhealthiest, inconsistent, and [low-grade] cannabis to their patients. It isn't fair to limit a [patient's] relief by … geographical location. Some of that medication is being used to care for sick children. Is the [State] really [all right] with testing it once a year? Would [State leaders] have faith in a medication for their children that is … tested once a year? Surely not. [The State needs] to back us up when it comes to having consistent, quality, clean medication for [patients]. We cannot let greed shove compassion out of the way when it comes to this program. Though times have changed when it comes to the demographic of the patient community and illnesses … some of the sickest patients in the [State are] part of this program." (10)

137. COMMENT: A commenter states, "Many [dispensaries] in [the State] aren't caring for their cannabis properly[,] which affects the quality of the medicine. Some are even using pesticides and washing the cannabis, which still leaves traces of the pesticides that patients are taking in when they use their cannabis." (13)

138. COMMENT: A commenter states that two existing "ATCs are the only [ATCs] growing [medical-grade] cannabis[. The] other dispensaries are lying about test results,

have their plants turning brown, have insane daily purchase limits, and just terrible service and medicine. Some dispensaries don't even have handicap ramps!!!" (20)

139. COMMENT: A commenter states that although the Department's 2018 request for applications for new ATCs requires "quality assurance, quality control, and testing protocols, and proposed legislation includes a reference to marijuana testing facilities licensed to analyze and certify the safety and potency of marijuana, the [rulemaking proposal] does not address product quality control testing and release requirements … Every batch or lot of medicinal marijuana or marijuana products [that] is cultivated, processed, and packaged for distribution by an ATC in the State … should be fully tested and meet predetermined specifications [following] validated methods … consistent with the manufacture and distribution of any other … prescription or over-the-counter [medicine]. [Quality control] testing of each batch [and] lot of product provides assurance that the products are pure and free from contamination[,] potent[,] and meet the stated label claim.

While [existing] ATCs [in the State] may have the capacity to perform limited testing, especially regarding contaminants (microbiological, residual solvents, pesticides, and heavy metals), this does not constitute formal release testing. In-house testing for screening or research purposes can be very informative to the [cultivator] and [processer] when growing new cultivars or formulating new products. However, for the [purpose] of product release to distribute to patients, a [third-party], independent [testing] facility is required. Currently, 24 of the 30 states with medical cannabis programs require product testing prior to release to a dispensary and in each case the

testing must be performed by an independent, accredited licensed testing facility within the [State].

[The Department should] add a subchapter [requiring] independent testing laboratories [to obtain State registration or licensing,] to achieve full accreditation by an impartial organization [that] is a signatory to the International Laboratory Accreditation Cooperation [and establish] minimum testing requirements for potency and purity … in line with current thinking and consistent with other [states'] programs. Many good examples of both regulations and guidances[,] which are … available from other states like Maryland, California, Nevada, and Pennsylvania[,] would provide a [starting point] for New Jersey." (30)

140. COMMENT: A commenter states, "Testing and tracking are among the most quickly evolving areas of concern for cannabis regulation nationwide … and … have also been the source of unwanted market distortions and other unwanted situations … New Jersey will have the benefits of cutting-edge best practices in developing its cannabis testing program." (32)

141. COMMENT: A commenter states, "Marijuana cannot be called organic, no matter how environmentally friendly the cultivation practices used to grow it, because the term is [Federally] regulated, and the [United States Department of Agriculture (USDA)] does not recognize cannabis as a legitimate agricultural crop. New Jersey would have to setup its own certification or look to third[-]party organizations that [follow USDA standards." The commenter states that there is "a high demand for [cannabidiol (CBD)] products. [Because a CBD plant is] derived [from hemp], it has a long flowering time and is difficult to incorporate into timely production schedules. CBD isolates can be

sourced from reputable, out-of-[S]tate wholesale providers in compliance with the [United States] Farm Bill. Obtaining these isolates at the earliest convenience will help patients tremendously [and assist] in dispensary revenues of non-psychoactive cannabinoids. Along with obtaining CBD isolates, the industry should adopt a strong … quality control procedure for obtaining and utilizing these CBD isolates." (40)

142. COMMENT: A commenter states that the Department should amend N.J.A.C. 8:64-13.4 to establish "'patient-focused certification' … to bring national standards to every aspect of [State medicinal marijuana activities] (testing, etc.) through [quality assurance] audits using the industry's best technical experts. The commenter provides a link to a website describing a "third-party certification program for the medical cannabis industry" which appears to be akin to an accreditation program. (31 and 49)

143. COMMENT: A commenter states, "one of the most important public health and consumer protection measures [that states with well-regulated medical cannabis markets adopt] are standards for laboratory testing of cannabis products. This is particularly relevant for cannabis concentrates, as low levels of pesticides or heavy metals in the starting material can be distilled to dangerous levels. Additionally, depending on the extraction and refinement methods used, residual solvents such as butane and propane may persist in the concentrates, posing potential risks to patients. Finally, the THC potency of cannabis concentrates can cover a broad range — as much as an order of magnitude — and it is essential that patients have access to accurate potency data in order to make informed decisions about their health. Because the nature and concentrations of contaminants and cannabinoid compounds may change throughout the various manufacturing processes to which they are subjected … testing

[should] be conducted on finished manufactured products, rather than only raw material inputs. While manufacturers should be encouraged to test their products at intermediate stages of production, to mandate such testing would likely create a heavy financial burden which will be absorbed by patients." The commenter provides a citation to another state's "robust testing rules and procedures" as an exemplar of a model to be followed. (47)

RESPONSE TO COMMENTS 134 THROUGH 143: Existing N.J.A.C. 8:64-13.4, proposed for readoption, requires the Department to test samples of ATCs medicinal marijuana products for quality control and to ensure the safety of qualifying patients. As several commenters note, allowing third-party laboratories to assist with this testing could be a viable option for ensuring that the Department's testing capacity keeps pace with an expanding market. The Commissioner stated in the EO 6 Report at 7, "With the anticipated addition of ATCs and the influx of new patients, the Department is researching the feasibility of using external laboratories to provide the required testing, with the Department acting as a secondary testing source. The Department will continue to explore whether there are sufficient external laboratory resources qualified to supplement the testing capacity of our current State laboratory." The Department continues to research this issue, and, depending on the result of its findings as to the feasibility of delegating the required testing to external laboratories, as described above, the Department would promulgate an appropriate rulemaking, informed by its research findings, to authorize this activity.

Recodified N.J.A.C. 8:64-10.9 would continue to authorize ATCs to label medicinal marijuana as "organic if the registered dispensary is certified as being in

compliance with the United States Department of Agriculture (USDA) certification requirements applying to organic products." However, a commenter correctly notes that the USDA does not recognize medicinal marijuana as a product eligible for organic certification due to it being a Schedule 1 Controlled Substance. The rule does not require ATCs to obtain organic certification but makes available the opportunity to ATCs to label their products as organic if the Federal government recognizes medicinal marijuana as a crop eligible for organic certification in the future. The Department notes optimistically that the Agriculture Improvement Act of 2018 (2018 Farm Bill) at § 10113 directs the USDA to issue regulations and guidance to implement a program for the commercial production of industrial hemp in the United States, which is likely to include direction on organic growing requirements. This could facilitate a rapid transition to the establishment of organic certification of medicinal marijuana upon Federal action to legalize marijuana. The Department continues to consult with the New Jersey Department of Agriculture to assess the potential for State-level organic certification of medicinal marijuana.

Recodified amended N.J.A.C. 8:64-10.7 would continue to require ATCs to process and package medicinal marijuana "in a safe and sanitary manner to protect registered qualifying patients from adulterated marijuana" and to ensure that "proper sanitation" is maintained and that the product is "free of mold, rot or other fungus or bacterial diseases." Recodified N.J.A.C. 8:64-10.8 would continue to prohibit ATCs from applying pesticides in the cultivation of medicinal marijuana. Persons with knowledge of ATC activity that contravenes these standards should report this information directly to the Division of Medicinal Marijuana, so that the Division can

investigate. The Department would promptly investigate all allegations of an ATC's use of pesticides and improper practices in the cultivation and processing of medicinal marijuana, and/or an ATC's dispensing of medicinal marijuana that has mite infestation, powdery mildew, or other contaminants.

Based on the foregoing, the Department will make no change upon adoption in response to the comments.

ATC Home Delivery (N.J.A.C. 8:64-10.12)

144. COMMENT: A commenter states, "delivery" [sic]. (2)

145. COMMENT: A commenter "agrees with the statement in the EO 6 [Report] that New Jersey can implement a delivery model that 'would ensure timely and accurate delivery of product to patients, driver safety, and compliance with applicable State law.' [The commenter] hoped [that the notice of proposal would address] permitting delivery … and [encourages] the Department … to permit it in the future. Some patients are simply unable to drive, and public transportation may not be a viable option depending on their health and location. Continually having to pick up medicine may put a strain on that person's caregivers, or the patient may not have a caregiver available who can pass the statutorily required background check. Allowing delivery would increase patient access. In addition, it would alleviate privacy concerns for some patients and caregivers. A person who walks into a drug store could be buying a soda or a magazine, but if [patients] or [caregivers walk] into a dispensary, it is apparent to observers that they [have] or a close loved one [has] a serious illness, which they may not want to discuss. Delivery allows [patients] to keep their health information private.

[Delivery] is an option in the illegal market, so legal, regulated businesses should also be permitted to provide that service. Regulating delivery also improves public safety, because the regulator can implement common sense precautions, such as requiring the delivery person to verify that the person requesting medical cannabis is an actively registered patient." (5)

146. COMMENT: A commenter states, "[for] patients to avail themselves fully of [medicinal marijuana], the [Department] needs to permit home delivery … The prohibition of home delivery [at] N.J.A.C. 8:64-10.12 assumes that patients either … are well enough to leave home and travel to acquire their medication or … know someone who can serve as a primary caregiver who will secure … patients' medicine. Patients with limited mobility or limited access to transportation are constrained to purchase product from the closest ATC and not necessarily the best ATC for such patients." (8)

147. COMMENT: A commenter states, "to have a cohesive, fully-functioning, and well-regulated [medicinal] marijuana ecosystem [in the State,] the [Department] should … amend [N.J.A.C.] 8:64-10.12, which … prohibits [ATCs] from delivering [medicinal] marijuana to the home of a registered qualifying patient or caregiver. By neglecting to facilitate a legal, regulated [medicinal] marijuana delivery system, the [Department allows] a significant hardship in the current marketplace to continue to exist that can present a significant barrier to access for very ill patients, especially those who do not have [caregivers]." The commenter suggests several standards that a rule authorizing home delivery should contain, and states that by "implementing a home delivery model for [medicinal] marijuana that [contains the suggested standards], the [Department

would] take a significant step to address the access concerns that have been raised by [medicinal] marijuana patients since the … program began in 2011." (11 and 23)

148. COMMENT: A commenter states, "N.J.A.C. 8:64-10.12 … prohibits the delivery of medicinal marijuana. [Home] delivery should be available to debilitated patients who have trouble getting to an ATC and may not have a caregiver who is able to get them their medicine. This would also help create additional jobs in the [State]." (12)

149. COMMENT: A commenter states that the Department should "permit [ATCs] to deliver [medicinal] marijuana to the private [homes] of … registered qualifying [patients]," and notes that patients who qualify "for the Medicare home health benefit are, by definition, home-bound, thus limiting their ability to travel to [an] ATC to pick up … medication. Home health and hospice agency policies prohibit their [employees] transporting of patient narcotic medications. Family caregivers are already burdened with caregiving tasks. Allowing [an] ATC to deliver … medication would free up time for the caregivers to spend with their loved ones and/or catch up on missed sleep. [The commenter,] thus[, encourages] the Department to permit home delivery of [medicinal] marijuana, and to require that such deliveries be made in unmarked cars, to avoid alerting neighbors to the presence of marijuana in patient's homes." (16)

150. COMMENT: Commenters state, "[Dispensaries] should be allowed to deliver meds to patients." (29 and 48) A commenter states, "Patients should be able to have [their] medicine delivered while waiting for [their] plants to grow!" (29)

151. COMMENT: A commenter states, "the prohibition on home delivery is egregious. There are many patients who are either homebound or it is extremely hard for them to leave their homes. It can be extremely hard to get around with musculoskeletal

disorders. Now that New Jersey has allowed chronic pain of musculoskeletal origins as an approved condition it is guaranteed that there will be patients in need of a home delivery option due to their limited mobility. It is only fair and just in keeping with the new inclusiveness of the program to allow all who would benefit from [medicinal] marijuana to have a safe and reliable way to obtain their medicine. Home delivery for [medicinal] marijuana is not a new concept. About half of [medicinal] marijuana purchases in … California were obtained through home delivery services. While … a person with limited or no mobility has the option to have a caregiver … there are some patients who do not have anybody [to] appoint as [a] caregiver. [If] not given the opportunity for home delivery[, those patients] might not be able to participate in the program at all." (31)

152. COMMENT: A commenter states, "delivery is a fundamental, compassionate component of patient accessibility, particularly with those patients suffering impaired ambulatory function. The importance of delivery increases when the number of ATC dispensaries are limited to the degree as is currently the case in New Jersey. Delivery is also a real feature of the illegal market supply chain. Reducing the prevalence of illegal market cannabis will be materially assisted by a regulated delivery capacity … ATCs with a dispensary endorsement should also be permitted to deliver, or subcontract with a licensed entity, to deliver on their behalf to patients. Many severely ill patients are unable to travel for medical cannabis and permitting delivery would significantly advance patient access for those who are seriously ill and/or live in remote locations." (32)

153. COMMENT: A commenter states that the Department “should determine the eligibility for a patient to receive home delivery based on physical ability to leave his [or] her home or place of residency[, for] example, if a patient is severely handicapped or qualifies for [State] transportation services due to incapacity. A dispensary would [home-deliver] only to prequalified patients.” (40)

154. COMMENT: A commenter states, “[home] delivery as allowed in the original bill [should] be added.” (45)

155. COMMENT: A commenter states, “[cannabis] delivery ensures that homebound patients and patients without access to transportation have access to their medicine[,] especially in jurisdictions where there is insufficient density of retailers to ensure access. Medical cannabis delivery facilities can be set up at a much faster pace than storefronts, helping [to] ensure [that] patients … have access to points of retail while the medical cannabis program continues to expand. [The commenter] commends the Department … for including delivery [in] the [EO] 6 Report [by] specifically mentioning, ‘home delivery would provide an added value to MMP patients; and the Department is undertaking a deliberate and thorough review of home delivery, with the goal of removing the prohibition on home delivery …’ While the proposed … rules [would make] significant strides in incorporating the recommendations made in the [EO] 6 [Report], the prohibition on home delivery still remains. As noted by the Department, delivery would provide an added value to medical cannabis patients. With over 100 patients being added to the program since the release of the [EO] 6 [Report], the program is quickly serving more patients with mobility issues [(citation omitted)]. On top of helping homebound patients, medical cannabis delivery is key for serving those with

little to no access to public or private transportation. For example, [patients] living in Jersey City[,] where almost 40 [percent] of residents do not own a vehicle, would need to spend approximately [two] hours round trip to go to their nearest dispensary [(citations omitted)]. [Patients] will [either] not have access to their medicine or … be forced to deal with illegal market operators.

Delivery not only ensures that homebound and patients without access to reliable transportation have access to their medicine, it also helps create a satisfactory amount of legal points of access to product and faster start up times. [Delivery-only retailers] (DORs) have been critical in California to [ensuring and allowing] city officials to create sufficient retail density [and access] while appeasing residents who are still reluctant to see cannabis storefronts in their town. Currently, there are 24 New Jersey towns with some sort of ban on legal cannabis sales [(citation omitted)]. With only [six] towns hosting existing ATCs, providing an option to host a delivery site allows a more palatable option for communities that have not dealt with cannabis facilities before.

Delivery services also have a much shorter start up [time than do brick-and-mortar] retail [facilities]. With such an increase in patients, dispensaries are beginning to struggle with demand. With such a large expansion, the Department must ensure that patients have access to product. Although the Department will be issuing new licenses for medical cannabis dispensaries, dispensaries take an incredible amount of time to open. New Jersey's sixth ATC finally opened its doors [seven] years after originally gaining Department … approval [(citation omitted)].

Conversely, [the commenter] understands the Department's desire to ensure monitoring and security of the cannabis supply chain. Towards that end, the

Department should consider adopting the requirement for retailers to be able to real-time GPS track their drivers as well as require drivers to be able to produce a real-time manifest of the cannabis products in the vehicle, as both California and Oregon have done. Such a requirement would provide an added layer of security and assurance for delivery accountability.

[The] Department [should lift] the prohibition on medical cannabis delivery and create a separate ATC endorsement for delivery. These operators would be subject to the same rules as storefront dispensaries, they simply would not allow walk-in customer purchases. [This] approach [would enhance] consumer access and [allow] a safer, healthier cannabis marketplace." The commenter provides suggested rule text and an article "on the utility of delivery and regulatory lessons from other states." (4)

156. COMMENT: A commenter states that the continued "prohibition on home delivery … is unacceptable and must be eliminated and home delivery expressly permitted." (31 and 49)

RESPONSE TO COMMENTS 144 THROUGH 156: The Commissioner states, in the EO 6 Report at 7, that the "Department is currently working with external stakeholders to review delivery models that would ensure timely and accurate delivery of product to patients, driver safety, and compliance with applicable State law. We recognize that home delivery would provide an added value to MMP patients; and the Department is undertaking a deliberate and thorough review of home delivery, with the goal of removing the prohibition on home delivery." The Department's review with respect to this issue is ongoing and incomplete. The Department anticipates that the issue most critical to implementing home delivery would be ensuring the safety of qualified patients,

their caregivers, and ATC employees. The Department continues to research this issue, and, depending on the result of its findings as to the feasibility of establishing a Statewide home delivery framework that ensures participant security, the Department would promulgate appropriate rulemaking, informed by its research findings, to authorize this activity.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

ATC and Physician Education of, and Disclosures to, Patients; Physician Continuing Education (N.J.A.C. 8:64-2.5, 11.1, and 11.2)

157. COMMENT: A commenter states, "The proposed rule to require ATCs to provide educational material to patients is very important. It would be beneficial for people with MS to have printed information dispensed with [medicinal] marijuana that outlines safety concerns and warnings. The information should be similar to information that is provided with pharmaceutical prescriptions, outlining potential side effects and safety concerns. This detailed information would encourage a dialogue between the person with MS and his or her healthcare provider, which the [commenter] supports." (6)

158. COMMENT: A commenter states that many standards in N.J.A.C. 8:64, as proposed for readoption with amendments, repeals, and a new rule, "are based on inaccurate data, like [N.J.A.C. 8:64-]2.5(a)9[, which requires physicians to] educate [patients] 'on the lack of scientific consensus for the use of medical marijuana, its sedative properties, and the risk of addiction.' While we might all agree that there is lack of scientific consensus regarding almost everything, those who have studied

cannabis know of its amazing therapeutic properties [and] that the 'risk of addiction' is nearly negligible and certainly not in the commonly accepted definition of 'addictive.' Frankly, if I were a new patient who thought I might benefit and was told that by my doctor, I would want no part of it. Further, cannabis is not a sedative. It is effective on so many and varied ailments as it works with our own bodies' endocannabinoid system." (24)

159. COMMENT: The commenter states that the Act at N.J.S.A. 26:6I-2 "stands in direct contradiction to [the] unwarranted requirement" at N.J.A.C. 8:64-2.5(a)9 that physicians make certain disclosures to patients to whom they recommend the use of medicinal marijuana. The commenter states, "[marijuana] is an extremely safe substance that has extensive medicinal benefits [and] no physically addictive properties[,] only psychologically addictive ones. Legal substances that are physically addictive include prescription pain medications, alcohol, benzodiazepines, and nicotine. It is … completely physically impossible to fatally overdose on marijuana. There is … a plethora of scientific evidence that proves marijuana's medicinal benefits. The only reason there is not even more scientific evidence is due to the [Federal] government's abhorrent continued classification of marijuana as a [Schedule 1] substance[,] thus[,] making it extremely hard to conduct studies showing proof of marijuana's medicinal benefits." (31)

160. COMMENT: A commenter states, "cannabis has been proven to be valuable medicine for much human suffering. For many conditions, no other medicine is nearly as effective. Moreover, there is NO medicine available, including [ibuprofen], aspirin, and [over-the-counter] cough medications, [which is] as safe and not susceptible to

abuse. When the Department [of Law and Public Safety] held hearings on where cannabis should be scheduled, if at all, the [commenter] submitted a brief[, which the commenter submits with the comment,] demonstrating that cannabis has none of the attributes of a controlled dangerous substance …. The [rules] should not contain false propaganda. Cannabis is not addictive. About [nine percent] of patients who cease using have some very mild negative feelings. There may not be another medicine that has such a small and mild negative sensation from withdrawal." (41)

161. COMMENT: A commenter states that education of health care providers in medicinal cannabis "should be more widely available" and notes that "the [EO] 6 [Report] calls for the development of [a health care provider education program]. This step would simultaneously accomplish a number of important things, including: expanding physician participation through raising confidence in recommending, increasing physician competence in recommending, [broadening] the patient base due to more recommenders, and [improving the] integration of cannabis into an overall patient wellness plan. However, to task the Review Panel with creating a program from the ground up is [time-consuming], inefficient[,] and unnecessary when there are already quality organizations with experience in this arena."

The commenter states that N.J.A.C. 8:64-2.5(a)9, which requires physicians to educate patients "'on the lack of scientific consensus for the use of medical marijuana, its sedative properties, and the risk of addiction' … is contrary to broadly accepted science[. There] has … never been a death from consumption of cannabis[. There] are no cannabinoid receptors in the brainstem so it is … physically impossible. Cannabis is shown to be less addictive than even caffeine, let alone alcohol, tobacco, [selective

serotonin reuptake inhibitors], or prescription opioids. Scare tactics have no place in a doctor-patient relationship." (42)

162. COMMENT: A commenter notes that the EO 6 Report states, "the Department is exploring the creation of an education program for all physicians, with focus on the endocannabinoid system (ECS)." The commenter states, "[t]here are already a number of educational programs on the ECS that are approved for [continuing medical education] credits for physicians. The Department should adopt one of these programs immediately … and require mandatory ECS education for all physicians in New Jersey who have prescription privileges as a condition of continued licensure in the [State]. A great many more people in New Jersey are going to be using marijuana in the near future and it is incumbent upon prescribers to be familiar with how marijuana works in conjunction with traditional therapies in controlling and managing health problems."

The commenter states that the required physician disclosure at N.J.A.C. 8:64-2.5(a)9 is an "unwarranted requirement" and a "disingenuous assertion" that "stands in direct contradiction" to the Act at N.J.S.A. 26:6I-2." The commenter states, "there has never been a single fatality from the use of marijuana. It is impossible to fatally overdose on marijuana. [The] risk of addiction [is not] a major concern with marijuana. After stopping, less than 10 percent of users experience noticeable withdrawal symptoms even after heavy, long-term use of marijuana. These withdrawal symptoms, when noticed, are typically mild and include irritability and sleep disturbance. There are no serious withdrawal symptoms like those noted with alcohol (delirium tremens, seizures, death); heroin (flu-like symptoms); or nicotine (intense craving). The addiction potential for marijuana is about equivalent to that of caffeine. [There] is no lack of

scientific consensus on the existence of the ECS, its role, and its importance in managing diseases, medical conditions[,] and symptoms, at least among those who study the issue. What lack of consensus there is for the use of [medicinal] marijuana is a direct result of the [Federal] government's refusal to allow any large-scale clinical trials of marijuana. While there have been successful, small scale clinical trials of marijuana, the [Federal] government continues to obstruct research into the benefits of medical marijuana. Thus, physicians in New Jersey are required to make a political statement about marijuana without a thorough explanation of why a lack of scientific consensus on medical marijuana exists. One might also argue that now, with 30 of 50 states having [medicinal] marijuana programs, there is indeed a consensus, scientific as well as popular, on the use and benefits of [medicinal] marijuana." (31 and 49)

RESPONSE TO COMMENTS 157 THROUGH 162: EO 6 at § 1c requires the Department to examine the "conditions for participating physicians in the program to ensure that any such requirements are not needlessly onerous." In accordance with this mandate, the Department continues to review the requirements applicable to physician participation, certification, education, and enrollment with a view toward the reduction of unnecessary barriers to physicians' willingness and ability to recommend to their patients the use of medicinal marijuana as a viable treatment option. The EO 6 Report, particularly at 12-16 and 20, contains the Commissioners findings and recommendations for improvement with respect to some but not all the concerns the commenters raise. The Department concurs with the commenters' assertion that some of the requirements may impose unnecessary barriers to access and participation and upon the conclusion of the review described above, will develop a rulemaking that

facilitates greater physician participation within the limits of the Department's statutory obligations, practical administrative capacities, and security responsibilities.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

ATC Standards for Patient Self-Assessment (N.J.A.C. 8:64-11.4)

163. COMMENT: A commenter states, "to ensure standardization, the Department should provide the standards and specifically a questionnaire," regarding the requirement that, "ATCs … develop standards for documenting patient self-assessment." (31 and 49)

RESPONSE: As stated above in response to previous comments, pursuant to the mandate of EO 6 at § 1a that the Department review its rules at N.J.A.C. 8:64 to determine how the Department could ease ATC operational obligations, the Department concurs with the commenter that the establishment of a standardized form of patient self-assessment could assist ATCs in fulfilling their obligations pursuant to existing N.J.A.C. 8:64-11.4, proposed for readoption. The Department is including the commenter's suggestion among the issues the Department is reviewing pursuant to EO 6. The Department will consider the suggestion in consultation with members of the regulated community and persons with expertise to evaluate the appropriateness of standardizing this form without impeding ATCs' autonomy to customize their processes based on their internal expertise and understanding of their clients' needs. Upon the conclusion of this review, including consideration of the consensus of the regulated community, the Department will develop a rulemaking, as appropriate, to implement its

findings with respect to the appropriateness of and need for a standardized form of patient self-assessment.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

ATC Marketing and Advertising (N.J.A.C. 8:64-12.1)

164. COMMENT: A commenter states that the Department should authorize ATCs "to market [their brands] through promotions, marketing[,] and branding cannabis products for sale to other dispensaries within the [State, and] to sell … accessories such as hats, T-shirts, reusable bags[,] and other branded items as accessories or paraphernalia." (40)

RESPONSE: The Department disagrees with the commenter's suggestion that it should revise existing N.J.A.C. 8:64-12, proposed for readoption, to delete the first sentence of subsection (f). Marijuana remains a controlled substance that is illegal under Federal law. The initial decision to certify the use of medicinal marijuana to address a patient's debilitating medical condition is a serious matter that is to be made within the context of a "bona fide physician-patient relationship," N.J.S.A. 24:6I-3, which ought not be influenced by an ATC's dissemination of novelty items. If a person is a qualifying patient, the second sentence of subsection (f) would continue to permit ATCs to distribute promotional products to qualifying patients and their primary caregivers. The Department declines to allow ATCs to expand their marketing to persons who are neither qualifying patients nor their caregivers. Moreover, ATCs cannot engage in sales transactions with persons who are neither qualifying patients nor their caregivers,

because existing N.J.A.C. 8:64-9.7(b)12, proposed for readoption with amendment, prohibits ATCs from allowing persons to be on ATC premises, "who are not on-duty personnel of the ATC and who are not ATC registrants engaging in authorized ATC-dispensary activity."

Based on the foregoing, the Department will make no change on adoption in response to the comment.

ATC Financial Audit (N.J.A.C. 8:64-13.8)

165. COMMENT: A commenter states that the Department should require each ATC to submit "an annual financial audit … performed by a [State-]licensed accounting firm [by] no later than June [first] of the following year, and [to respond to] follow up questions … after that [date, because it is burdensome for ATCs to undergo two] audits at the same time." (40)

RESPONSE: Existing N.J.A.C. 8:64-13.8, proposed for readoption with amendment, authorizes the Department at paragraph (b)2, "within its sole discretion, [to] periodically require the audit of an ATC's financial records by an independent certified public accountant approved by the Department." The Department has yet to require an ATC to submit an audit pursuant to this authority. However, the New Jersey Department of Health Division of Medicinal Marijuana Biennial Report, (April 1, 2019), available at https://www.nj.gov/health/medicalmarijuana/, at 12, in the discussion of ATC revenue, states that "to better assess the relationship between price and revenue, the Department may consider requiring audits of ATCs under N.J.A.C. 8:64-13.8 for the next biennial report."

The commenter's reference to the submission of two audits is unclear. It is possible the commenter is suggesting that the Department might exercise its authority pursuant to N.J.A.C. 8:64-13.8(b)2 to require ATCs to submit audits for periods other than the fiscal year that the entity selects for accounting purposes. Absent extraordinary circumstances, the Department does not anticipate requiring ATCs to submit audits for date ranges that are different than the fiscal year periods the ATC designates for accounting purposes.

If the Department were to require an ATC to submit an audit, the Department would not impose a limit on the period during which it could inquire of that ATC as to information presented in the audit as the Department's obligation to ensure compliance with the Act and rules, and to "monitor, oversee, and investigate all activities performed by an ATC," pursuant to N.J.S.A. 24:6I-7.i(2), is ongoing over the lifespan of an ATC. Moreover, an ATC has a continuing obligation to correct or clarify information that it submits to the Department that is inaccurate or unclear.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

ATC Sales Tax

166. COMMENT: A commenter states, "medicine should be tax free like other medicines" [sic]. (2)

167. COMMENT: Commenters state, "get rid of the [sales] tax on medical cannabis!" (29 and 48)

RESPONSE TO COMMENTS 166 and 167: Existing N.J.A.C. 8:64, as proposed for readoption with amendments, repeals, and a new rule, has not, and would not, impose a tax on medicinal marijuana sales. The Division of Taxation, of the New Jersey Department of the Treasury, determines the taxability of State sales transactions. In the EO 6 Report at 8, the Commissioner notes that the Division of Taxation's Regulatory Services Branch Technical Bulletin TB-68 (November 30, 2012), "directs that '[r]etail sales of medical marijuana are subject to tax,' citing N.J.S.A. 54:32B-3(a), which authorizes the imposition of sales tax for retail sales. This guidance was issued despite previous Taxation guidance in Bulletin TB-63(R), issued February 16, 2010, which exempts 'drugs sold pursuant to a doctor's prescription' from the imposition of sales tax. TB-63(R) defines 'drug' as 'a compound, substance or preparation, and any component of a compound, substance or preparation, other than food and food ingredients, dietary supplements or alcoholic beverages, that is: (1) Recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, and supplement to any of them; or (2) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or (3) Intended to affect the structure or any function of the body.['] Given this definition, marijuana could certainly be classified as a drug for sales tax purposes. If the distinguishing factor is the semantic difference between 'prescribing' a drug versus the dispensing of medicinal marijuana pursuant to a physician's 'authorization,' the intent of physicians in both instances is the same: to provide relief to those suffering from debilitating medical conditions." Consistent with the recommendations of the EO 6 Report at 8, the

Department remains committed to working with other State agencies and the Legislature to reduce and ultimately eliminate the sales tax in the future.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

ATC Other Matters

168. COMMENT: A commenter states that the Department should review the existing rules at N.J.A.C. 8:64 “to eliminate unnecessary, stigmatizing, costly[,] and burdensome provisions relating to labeling and advertising requirements, security[,] and recordkeeping protocols, and pesticide and cultivation methodologies.” (32)

RESPONSE: As described in the response to previous comments, the Department is engaged in ongoing review of N.J.A.C. 8:64 pursuant to EO 6 and anticipates developing rulemaking upon the conclusion of that review to implement its findings. Consistent with the commenter’s suggestion, this review would include analysis to determine if N.J.A.C. 8:64 contains rules that are “unnecessary, stigmatizing, costly[,] and burdensome.”

Based on the foregoing, the Department will make no change on adoption in response to the comment.

Police, Court, and Children’s Services Awareness and Education; Equity to Address Marijuana Enforcement Disparity; Legality of Marijuana

169. COMMENT: A commenter states that the Department “needs to educate other [State] agencies about [medicinal marijuana in New Jersey] and the rights of patients

thereunder. The Department of Children and Families must understand that a parent's mere participation [as a qualifying patient using medicinal marijuana] program does not endanger a child's welfare. New Jersey courts must understand that a parent's status as [a qualifying] patient cannot be used against such parent in determining custody of children." (8)

170. COMMENT: A commenter states that the establishment of additional debilitating conditions means that "the program is now not just for the sickest of the sick and dying, [thereby adding] thousands of [able-bodied] people who are intelligently choosing their medication without the addition of any education, uniformity, or protections for those who suffer from these illnesses while also holding employment, being guardians of minor … children, or even [patients] choosing to take a vacation within their own [State]. Law enforcement is NOT informed on how to handle interactions with patients, for the most part. Child Services and Probation are still able to 'use their discretion' in matters where the [adult] is a qualified [medicinal] marijuana patient. While … change at the Federal [level] is crucial in some cases, just two weeks ago a patient was beaten up when stopped by plainclothes officers as he was walking in a shore town following all recommendations related to location, proximity of restricted medicating areas, and labeling on his medication. If that [patient] was not part of this program, he would not have been beaten up because he would not have been using marijuana. What is the message we are sending to the [patient] community when we open the door out of compassion[,] but we enact no protections[,] so [patients] are treated as common criminals or worse? If this is to be considered medication, how can we hold [one's] criminal past against them in a medical conversation? [We] must take into

consideration the current and incoming [patient community resulting from the recognition of additional qualifying debilitating conditions]. These people are not dying as [were] a lot of the [patient] base from the past. They have professional lives, active homes and families." (10)

171. COMMENT: A commenter states, "The lack of law enforcement training makes medical marijuana patients [targets] for wrongful arrest and seizure of [their medicinal marijuana]. No law enforcement has known anything about [the Act] or about possession or public usage or anything at all[,] resulting in wrongful arrests, seizures of medicine, [harassment], and more … There should be mandatory training for police and more places for patients to use in public safely and legally. We are sick, we are targeted by police … while suffering and this must end. It is not a privilege to have a debilitating illness when you are treated like a drug addict while in complete compliance with [the Act]. This must end or there will [be] wrongful [arrests] and patient [protests] until we are treated fairly and we don't have to teach law enforcement the law!!!!!!! Enough bullying already." (20)

172. COMMENT: A commenter states that the proposed rulemaking lacks "any meaningful attempt to create an equity program that would address the disparate impact of marijuana enforcement on communities of color[, does not] address the disparate impact of marijuana prohibition on communities of color[, and] does not include anything specific to individuals harmed by marijuana prohibition." (5)

RESPONSE TO COMMENTS 169, 170, 171, AND 172: Both the Act and the rules proposed for readoption with amendments, repeals, and a new rule, at N.J.A.C. 8:64 are silent on the impact of a qualifying patient's use of medicinal marijuana on that

person's fitness to parent. Nonetheless, the Act establishes that medicinal marijuana is a valid and legal medical treatment for persons who have debilitating medical conditions.

The Department is without authority to mandate education of law enforcement personnel or the DCF on the legality of medicinal marijuana, or to take a position on a qualifying patient's parental fitness, which is necessarily a matter for the DCF's exercise of expertise as applied on a case-by-case basis. The Department, however, is open to the establishment of partnerships with other Executive Branch agencies and the Judiciary to share expertise and the experiences of qualified patients. For example, the Department has provided training to Drug Court and Worker's Compensation judges, and staff of the Division of Mental Health and Addiction Services within the Department of Human Services.

The Department recognizes that the establishment of additional protections for patients, such as workplace and tenant protections, would support their ability to use medicinal marijuana without unwarranted interference, the same as one would use a prescription medication. However, the Department is without statutory authority or jurisdiction to establish these protections through rulemaking.

The Department disagrees with a commenter's assertion that the rules proposed for readoption and the proposed amendments, repeals, and new rule, would make no effort toward the achievement of equity with respect to communities of color and persons harmed by the disparate impact of marijuana prohibition. Proposed new N.J.A.C. 8:64-6.2(e)6 would require an ATC permit selection committee to consider an applicant's "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," and proposed new N.J.A.C. 8:64-7.1(b)2xii and xiii would require ATC permit applicants to demonstrate evidence "of community engagement or participation in the ATC's operations through ownership, management, and local hiring plans, and support of community organizations" and evidence of "minority, women, and veteran participation in ATC operations through ownership, management, and local hiring plans." Moreover, with respect to "individuals harmed by marijuana prohibition," existing N.J.A.C. 8:64-7.2, proposed for readoption, would continue to allow persons with disqualifying convictions to serve as officers, directors, board members, and employees of ATCs, upon demonstrating evidence of their rehabilitation to the Commissioner.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

Clinical Research (N.J.A.C. 8:64-11.2)

173. COMMENT: A commenter "supports advancing research to better understand the benefits and potential risks of marijuana and its derivatives as a treatment for MS. Therefore, the proposed rule requiring ATCs to contact registered qualifying patients and their primary caregivers with information concerning ongoing peer-reviewed clinical studies related to the use of medicinal marijuana is an important bridge between research and practice." (6)

174. COMMENT: "[It] would be prudent for [the State that is] known as the Medicine Chest of the World … to establish an … Institutional Review Board [(IRB) comprising

physicians, ethicists, ordinary citizens, etc.,] so that [researchers] can present research ideas … to obtain funding to conduct [clinical trials]. This IRB … can be funded with the monies from the [legal sale] of [cannabis] in [the State]. Not only will the [cannabis industry be good for [the State] financially[, the State] can also be good for the [cannabis industry because it is] a very scientific state [that] is uniquely situated to bring [cannabis] to the [next level] and sustain it 100 years into the future. That future is [scientific research] and conducting [clinical trials]. [The State has] the brain-power. This just needs to be funded [without] Federal [money]. There are great minds … in [the State] who are ready and experienced to conduct very [high-level] research. [Let's] not let this opportunity … slip by us. [The State has] the [technological] brainpower [and] infrastructure … to accomplish great innovations in the [cannabis technology space, which is another] opportunity [that] we don't want to slip by. Funding is needed for both of these areas in the [cannabis industry]." (25)

175. COMMENT: A commenter states that the Department should promulgate rules that "broaden permissions for research activities beyond ATCs. The selection of products available on the modern medical cannabis [market] is evolving rapidly, with much of the underlying intellectual property being licensed across state lines. Given the heterogeneity of cannabis plants and extracts … it [is] vitally important for the protection of … public health that companies be given explicit permission to conduct necessary safety research. Federal law currently provides no legal path for companies to conduct such research; it is[,] therefore[,] vital that states now developing their medical cannabis regulations address this regulatory gap [(citations omitted)]. New Jersey is home to some of the top research universities in the country. In the interest of advancing the

safety and science of medical cannabis … the [rules should allow] scientific investigation of cannabis under the supervision of the [State]. [The commenter provides a citation to another state's law] to enable public and private research of cannabis [(citation omitted)]." (47)

RESPONSE TO COMMENTS 173, 174, AND175: The Department acknowledges the commenters' support of existing N.J.A.C. 8:64-11.2(c), proposed for readoption, which establishes a mechanism by which ATCs can "contact registered qualifying patients and their primary caregivers with information concerning ongoing peer reviewed clinical studies related to the use of marijuana." N.J.A.C. 8:64-11.2 would continue to have no impact on "permissions for research activities beyond ATCs."

In fact, the Department's most recent request for applications for permits to operate ATCs included among the selection criteria an applicant's ability "to produce and maintain appropriate research data," and required applicants to submit evidence of their "commitment to research" relating to medicinal marijuana. See Application Part B at 16-17, July 2018 request for applications for permits to operate ATCs, available at https://www.nj.gov/health/medicalmarijuana/alt-treatment-centers/applications.shtml.

The Department plans to continue its efforts to collaborate with New Jersey's research and higher education institutions to identify opportunities for clinical research regarding medicinal marijuana. Some of these institutions receive Federal funding, which can cause their administrators to be reluctant to engage in activities that might jeopardize that funding, such as maintaining medicinal marijuana on the premises to conduct medicinal marijuana research, as possession of marijuana is illegal under Federal law.

However, a commenter is incorrect in stating that there is “no legal path” under Federal law for entities to conduct medicinal marijuana research. Researchers can obtain funding and cannabis to conduct research through the National Institute on Drug Abuse (NIDA). https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research. The University of Mississippi, pursuant to a Federal contract, grows the cannabis that the NIDA makes available for research. https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research/information-marijuana-farm-contract.

The Commissioner recognizes the need for medicinal marijuana clinical research in the EO 6 Report, in stating at 20, “there is … a need to develop standardized dosing and administrative protocols for medicinal marijuana products, including information on expected effects, side effects, and adverse effects. [The] Department will charge the Medicinal Marijuana Review Panel, in an advisory role, to oversee the study of the efficacy of medicinal marijuana in treating New Jersey [qualifying] patients. This research will inform dosing and administration protocols to create best practices and improve health outcomes for qualifying patients. The Department believes that this refocusing of the Medicinal Marijuana Review Panel will make the best use of the expertise that the Panel provides to create best practices to inform health care providers and improve health outcomes for qualifying patients.”

The Department maintains IRB services through Rowan University. See https://research.rowan.edu/officeofresearch/compliance/irb/njdoh/index.html. Therefore, the Department’s establishment of an additional IRB, as one commenter suggests, is unnecessary.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

Summary of Agency-Initiated Changes:

1. The Department is making non-substantial changes on adoption at N.J.A.C. 8:64-6.2 and 10.7 to correct grammatical errors.

2. The proposed definition of the new term, “reduced-fee eligible,” at N.J.A.C. 8:64-2.1, does not specifically identify, at paragraph 2, persons who are beneficiaries or recipients of NJ FamilyCare as being reduced-fee eligible, although it specifically identifies New Jersey Medicaid beneficiaries and recipients as being reduced-fee eligible. The Department understands NJ FamilyCare to be part of New Jersey Medicaid. To avoid potential ambiguity by the omission of a specific reference to NJ FamilyCare, the Department will make a change on adoption to the definition of the term “reduced-fee eligible” to specifically include NJ FamilyCare beneficiaries and recipients as being reduced-fee eligible.

3. The Department is making a non-substantial change on adoption to add “opioid use disorder,” within the definition of the term, “debilitating medical condition” at N.J.A.C. 8:64-1.2, provided the patient is concurrently adherent to “medication-assisted therapy.” This would reflect the Commissioner’s approval of that condition as a debilitating medical condition in the RFAD, which became effective on January 23, 2019, pursuant to N.J.S.A. 24:6I-3 and N.J.A.C. 8:64-1.2 and 8:64-5. The terms “opioid use disorder” and “medication-assisted therapy” would have the meanings that the Substance Abuse and Mental Health Services Administration within the United States

Department of Health and Human Services assigns to those terms at 42 CFR Part 8 – Medication Assisted Treatment of Opioid Use Disorders.

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 readopted 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 readopted 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 (October 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 explained 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.

Full text of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 8:64.

Full text of the adopted amendments and new rule follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

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:

…

"Debilitating medical condition" means:

1.-4. (No change from proposal.)

5. Opioid use disorder, provided the qualifying patient is participating in, and compliant with, medication-assisted treatment for the opioid use disorder;

Recodify existing 4.-5. as ***6.-7.*** (No change in text.)

…

"Medication-assisted treatment" means "Medication-Assisted Treatment (MAT)" as 42 CFR Part 8 – Medication Assisted Treatment of Opioid Use Disorders, defines that term, particularly at § 8.2, as amended and supplemented.

…

["Original ATC" means one of the first six ATCs to which the Department issued a permit pursuant the Act.]

...

"Reduced-fee eligible" means a person is:

1. (No change from proposal.)

2. A beneficiary or recipient of:

i. (No change from proposal.)

ii. NJ FamilyCare;

Recodify proposed ii.-v. as ***iii.-vi.*** (No change in text from proposal.)

…

[“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.]

...

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

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

1.-5. (No change.)

6. 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

7. (No change.)

(b)-(f) (No change from proposal.)

8:64-2.4 Physician *[registration]* ***enrollment***

(a)-(b) (No change from proposal.)

8:64-6.2 Criteria for identifying alternative treatment centers

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

1.-5. (No change from proposal.)

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

7.-8. (No change from proposal.)

(b) (No change.)

8:64-10.7 Processing and packaging of marijuana

(a)-(b) (No change from proposal.)

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

1.-2. (No change from proposal.)

3. Be in a closed container that holds no more than 1/4 ounce and ***is*** sealed, so that the package cannot be opened, and the contents consumed, without the seal being broken.

(d)-(e) (No change from proposal.)

(f) The ATC shall submit the label to the Division for approval and *[record]* ***recording***.

1. The Division shall provide a copy of the label to authorized employees of State agencies or local law enforcement agencies, as necessary ***for these agencies*** to perform their official duties.

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.-4. (No change from proposal.)

(b) (No change from proposal.)