EXECUTIVE ORDER 6 REPORT

Issued by Acting Commissioner Shereef Elnahal, M.D., M.B.A.

March 23, 2018

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EXECUTIVE SUMMARY[1]

Governor Murphy issued Executive Order No. 6 (2018) (EO 6) directing the New Jersey Department of Health[2] (Department) to undertake a review of all aspects of New Jersey's Medical Marijuana Program (MMP), with a focus on ways to expand access to marijuana for medical purposes. These include, but are not limited to, a review of the current rules for operations and siting of dispensaries and cultivation facilities; conditions for participating physicians in the program; the current list of debilitating medical conditions for which medical marijuana may be authorized pursuant to N.J.S.A. 24:6I-3; physician flexibility to make determinations about qualifying conditions; methods by which patients and caregivers obtain product; forms for medical marijuana to be ingested, taking into consideration the needs for different methods for different patients; and other aspects of the MMP within the Department discretion that hinder or fail to effectively achieve the statutory objective of ensuring safe access to medical marijuana for all patients in need.

The Department of Health, after consultation with stakeholders and the Alternate Treatment Center (ATC) operators, presents the following action items and recommendations to improve and expand patient access to medicinal marijuana.[3]

DEPARTMENT ACTION ITEMS

EXPANSION OF AUTHORIZED DEBILITATING MEDICAL CONDITIONS

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.

A final agency decision was issued on March 22, 2018 to accept the Panel's recommendations to effectuate the addition of these debilitating conditions.

DEVELOPMENT OF PATIENT, CAREGIVER, AND PHYSICIAN MOBILE ACCESS PORTAL

The Department recognizes the need to provide a more convenient technology experience for patients, caregivers, and physicians. *The Department will develop and implement a comprehensive updated program portal, which will include the ability to securely upload documents and submit payments using a smartphone or tablet, with a target implementation date of Spring 2019.*

In an interim measure, Department IT staff have been able to provide access via mobile device to the current registry and payment processing system. This access will go live in Spring 2018 and provide expanded patient access to the registry.

REGULATORY ACTION ITEMS

REDUCE REGISTRATION FEES

The Department plans to revise N.J.A.C. 8:64-2.1(1)(c) to reduce registration fees. Currently, the fee for issuance or renewal of an MMP registry identification card is $200, with a reduced card fee of $20 for those receiving

[1] The recommendations made in this Executive Summary are presented in tabular form in Attachment A, Executive Summary Matrix, attached to this report.

[2] Executive Order 6 also directed the Board of Medical Examiners to conduct the same review; however, the Board has advised that its recommendations will be provided under separate cover.

[3] Please note that the Department may consider additional programmatic changes through the regulatory process, which is subject to public comment pursuant to N.J.A.C. 1:30-5.4.

certain forms of public assistance.[4] *The Department will expand the reduced card fee to senior citizens and military veterans,[5] and continue the reduced card fee for those receiving public assistance. Additionally, the Department will reduce the registration fee for all other qualifying patients and caregivers to $100 for the issuance or renewal of a registry identification card, which is valid for a two-year period.*

In advance of the formal rulemaking process, the Department will begin charging these reduced registration fees to qualifying patients to alleviate the financial burden on patients.

PERMIT SATELLITE ATC LOCATIONS

The Department plans to amend N.J.A.C. 8:64-7.9 to permit current ATCs to dispense at satellite locations and permit more than one cultivation site per ATC with Department approval. Additional sites will be subject to all applicable laws, rules and local ordinances. *The goal of eliminating the prohibition on satellite sites is to allow for increase in supply of, and access to, product for qualifying patients.*

In advance of the formal rulemaking process, the Department will consider waivers of* N.J.A.C. 8:64-7.9 *from ATCs on a case-by-case basis.

ELIMINATE THE PHYSICIAN REGISTRY

The Department plans to eliminate N.J.A.C. 8:64-2.4 and revise associated rules, which requires physicians interested in providing care to MMP patients to first register with the Department. In turn, these physicians were listed on the Department's public website in a physician registry for patient convenience. *The Department's elimination of the physician registry will permit any New Jersey physician in good standing and in possession of an active controlled dangerous substances registration issued by the State Division of Consumer Affairs to authorize medicinal marijuana for their qualifying patients. The Department recognizes that not every physician eligible to authorize medicinal marijuana will choose to do so; therefore, the Department will continue to publish a list of physicians who are interested in providing care to qualifying MMP patients. These physician listings will be done on an optional basis as a convenience to patients.*

In advance of the formal rulemaking process, the Department will begin the transition in Spring 2018 to eliminate the current physician registry procedure. This will allow program and IT staff to begin the review and potential reengineering of business processes to streamline the experience for patients, physicians, and program once the new portal is up and running. The portal would be rolled out in a series of modules next year.

STREAMLINE PROCESS FOR ADDITION OF DEBILITATING CONDITIONS

The Department plans to revise N.J.A.C. 8:64-5.2 and -5.3, which created a petition process and review panel to make recommendations for the approval of additional debilitating medical conditions. The Medicinal Marijuana Review Panel serves a vital role in the review and recommendation of additional debilitating medical conditions. *The Panel will continue to serve the Department in an advisory capacity; however, the Department will streamline the petition and panel process by removing the requirement in N.J.A.C. 8:64-5.3 that petitions for the addition of debilitating conditions be referred to the Medicinal Marijuana Review Panel. This will allow for the Commissioner to add debilitating conditions in extraordinary circumstances without a lengthy review process. These proposed*

[4] Qualifying patients who receive New Jersey Medicaid, food stamps, temporary disability insurance (TDI), or Federal Supplemental Security Income (SSI) or Social Security Disability (SSD) benefits are eligible for the reduced fee.

[5] The U.S. Department of Veterans Affairs revised its policy with respect to medical marijuana in late 2017. The policy urges government physicians to "discuss with the Veteran marijuana use, due to its clinical relevance to patient care, and discuss marijuana use with any Veterans requesting information about marijuana." The full policy can be found on the VA website at https://www.publichealth.va.gov/marijuana.asp. In addition, states such as Massachusetts have implemented fee waivers for veterans and other states with medicinal marijuana programs have reduced registration fees for veterans.

revisions will eliminate bureaucratic barriers for patients in need whose illnesses are not included in the current list of debilitating conditions already covered by the program.

ALLOW TWO CAREGIVERS PER PATIENT

The Department plans to revise N.J.A.C. 8:64-1.2 and associated rules to allow designation of a second primary caregiver who will be subject to the same requirements as the primary caregiver. *This revision will 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.

CREATE SEPARATE ENDORSEMENTS FOR ATC PERMITS

The Department plans to revise N.J.A.C. 8:64-7.1 and associated rules to create an endorsement system within the ATC permitting process. These endorsements would allow ATCs to engage in one or more of the following activities related to the provision of usable marijuana to qualifying patients: 1) cultivation and harvesting usable marijuana; 2) manufacturing and processing usable marijuana (including the manufacturing of edible products); and 3) dispensing of usable marijuana. The Department envisions that existing ATCs would receive some combination of production, cultivation, and dispensing endorsements under this new system, which will be set forth in regulation. *Once approved through regulation, this endorsement system would permit an increase in the available supply of, and access to, usable marijuana to mitigate patient supply issues and promote a more diverse workforce and industry dedicated to the provision of medicinal marijuana. It is anticipated that this separate endorsement system will be utilized in a future Request for Applications to solicit applicants for ATC permits.*

ELIMINATE 10% THC LIMIT

The Department plans to repeal N.J.A.C. 8:64-10.7(c) to remove the 10% THC limit for product sold. The 10% THC limit was implemented at MMP inception 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.[6] *Upon further evaluation, the Department will eliminate the THC limit to allow for more effective treatment of the debilitating medical conditions covered under the State's program.*

ELIMINATE PSYCHIATRIST EVALUATION FOR MINORS

The Department plans to revise N.J.A.C. 8:64-2.5 to remove the requirement for "written confirmation from a physician trained in the care of pediatric patients and from a psychiatrist" for a physician to authorize the use of medicinal marijuana for a minor. In the event that physicians need to seek consultation from another provider, this can be done in the regular course of care. *This requirement creates an artificial barrier to care, as there should be parity in the treatment of patients, regardless of age.*

STATUTORY RECOMMENDATIONS

While amendments to statute are beyond the Department's authority, the following provisions of the Compassionate Use Medical Marijuana Act (Act or CUMMA) restrict the ability to expand safe access to medical

[6] The study entitled "A Review of Medical Cannabis Studies Linked to Chemical Compositions and Dosages for Qualifying Medical Conditions" can be found at http://www.health.state.mn.us/topics/cannabis/practitioners/dosagesandcompositions2017.pdf

marijuana for all patients in need. The Department recommends working with the Legislature to propose the following statutory changes.

ALLOW EDIBLES FOR ALL PATIENTS

N.J.S.A. 24:6I-7(a) restricts use of edible products to qualifying patients who are minors; however, this product type should be permissible for all patients. The ingestion of medicinal marijuana is healthier for patients than smoking. *While some manufactured products such as topicals and lozenges are available for adults, patients with dexterity issues or who have difficulty following dosage instructions would benefit from the use of edibles.*

ALLOW PATIENT TO REGISTER AT MORE THAN ONE ATC

N.J.S.A. 24:6I-10(d) states that patients "shall be registered to purchase usable marijuana from only one ATC at a given time." This limits patient access to product. *The Department recommends that the statute be amended to allow patients to obtain product from any State ATC dispensary.*

ALLOW USE OF MARIJUANA AS A FIRST-LINE TREATMENT

N.J.S.A. 24:6I-3 stipulates that "seizure disorder, including epilepsy; intractable skeletal muscular spasticity; post-traumatic stress disorder; or glaucoma" must be "resistant to conventional medical therapy" to be considered a debilitating medical condition. *The Department recommends that this caveat be deleted to permit the use of medicinal marijuana as a first-line treatment, rather than a last resort, for these conditions.*

PERMIT UNLIMITED SUPPLY FOR PATIENTS RECEIVING HOSPICE CARE

As N.J.S.A. 24:6I-10(a) establishes a two-ounce limit that may be authorized by physicians in a 30-day period, this limit may be restrictive for those receiving hospice care in the final stages of life. Research in *The Journal of Pain* indicates that the use of medicinal marijuana is associated with improvements in pain, function, and quality of life.[7] To effectively provide symptom and pain control, the maximum monthly product limit should be eliminated. *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."*[8]

INCREASE MAXIMUM MONTHLY PRODUCT LIMIT

N.J.S.A. 24:6I-10(a) establishes a two-ounce limit that may be authorized by physicians in a 30-day period. Physicians should have the discretion to authorize more than two ounces. *To that end, 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.*

REMOVAL OF NON-PROFIT REQUIREMENT FOR ORIGINAL ATCs

N.J.S.A. 24:6I-7(a) currently establishes that the first two alternative treatment centers issued a permit in each region shall be nonprofit entities, and centers subsequently issued permits may be nonprofit or for-profit entities. This subsection further defines the requirements of an ATC with respect to the lifecycle of supplying usable

[7] This research study, *Cannabis for the Management of Pain: Assessment of Safety Study (COMPASS)*, is in Volume 16, Issue 12 of the Journal of Pain (December 2015). The article can be found at http://www.jpain.org/article/S1526-5900(15)00837-8/fulltext.

[8] N.J.S.A. 24:6I-2(e).

marijuana to qualifying patients. *The Department recommends removal of the non-profit requirement for the original alternate treatment centers to create parity among all centers.*

ADDITIONAL CONSIDERATIONS

In addition to the recommendations and action items presented above, the Department is exploring the following areas to continue the expansion of patient access and elimination of bureaucratic barriers:

HOME DELIVERY

The Act provides that an ATC is "authorized to acquire a reasonable initial and ongoing inventory, as determined by the department, of marijuana seeds or seedlings and paraphernalia, possess, cultivate, plant, grow, harvest, process, display, manufacture, *deliver*, *transfer*, *transport*, distribute, supply, sell, or dispense marijuana, or related supplies to qualifying patients or their primary caregivers who are registered with the department." N.J.S.A. 24:6I-7(a). However, the rules currently prohibit home delivery of product to patients or caregivers. N.J.A.C. 8:64-10.12.

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.

PERMITTING EXTERNAL LABORATORIES TO CONDUCT QUALITY CONTROL TESTING

N.J.A.C. 8:64-13.4 currently requires that the Department conduct testing of samples for product quality control to ensure the safety of registered qualifying patients. 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.

DEVELOPMENT OF PROVIDER EDUCATION PROGRAM AND DOSING GUIDELINES

With the expansion of authorized debilitating conditions, the Department recognizes the need to provide education and guidance to providers. To that end, the Department is exploring the creation of an education program for all physicians, with focus on the endocannabinoid system.

The Department plans to leverage the expertise of the Medicinal Marijuana Review Panel to oversee the curriculum development for this program. This education program will serve to create best practices for the safe and effective administration of medicinal marijuana to the expanded universe of qualifying patients.

In conjunction with the provider education program, there is also a need to develop standardized dosing and administrative protocols for medicinal marijuana products, including information on expected effects, side effects, and adverse effects. In addition to the provider education component above, 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 Medicinal Marijuana Program 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.

ELIMINATION OF SALES TAX ON MEDICINAL MARIJUANA

Bulletin TB-68 issued on November 30, 2012 by the New Jersey Division of Taxation 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.

Given the Governor's instruction through the promulgation of Executive Order 6 to expand access and eliminate bureaucratic barriers, the Department of Health will work with the Department of the Treasury to expand the sales tax exemption for retail sales of medicinal marijuana through the issuance of revised technical guidance.

DEPARTMENT REVIEW OF ATC PERMITTING AND BACKGROUND CHECK PROCESS

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.***

NEW JERSEY COMPASSIONATE USE MEDICAL MARIJUANA ACT

P.L. 2009, c. 307, approved January 18, 2010, and codified at N.J.S.A. 24:6I-1 *et seq*., is the New Jersey Compassionate Use Medical Marijuana Act (the Act). The Act is the enabling authority for the New Jersey MMP. P.L. 2013, c. 160, effective September 10, 2013, amended various sections of the Act, such as providing that alternative treatment centers (ATCs) shall not be limited in the number of strains of medical marijuana cultivated;[9] that ATCs are allowed to cultivate and dispense medical marijuana in dried form, oral lozenges, topical formulations, or edible form as well as any other form as authorized by the Commissioner; that the edible form shall include tablets, capsules, drops or syrups and any other form as authorized by the Commissioner; and that the edible form[10] shall be available only to qualifying patients who are minors. P.L. 2016, c. 53, effective September 14, 2016, expanded the definition of "debilitating medical condition" to include Post-Traumatic Stress Disorder and to permit individuals who suffer from Post-Traumatic Stress Disorder to qualify to obtain and use marijuana for medicinal purposes.

REGULATIONS GOVERNING THE MEDICINAL MARIJUANA PROGRAM

DEPARTMENT OF HEALTH

The Department rules governing the MMP are set forth at N.J.A.C. 8:64-1 *et seq.* The rules establish the process by which qualifying patients, their physicians, and their primary caregivers register with the Department to avail themselves of the Act's protections against civil and criminal sanction. The Department rules also establish procedures for the permitting, establishment, and operation of ATCs to cultivate and dispense medicinal marijuana and related supplies.

The Department originally proposed rules for the MMP on November 15, 2010.[11] Thereafter, the Legislature passed a concurrent resolution stating that certain rules were inconsistent with the intent of the Act. *S. Res.* 130, 214th Leg. (N.J. 2010) and *Assemb. Res.* 151, 214th Leg (N.J. 2010). *See also* 43 N.J.R. 340(a) (Feb. 22, 2011). The concurrent resolution directed the Department to amend or withdraw portions of rules that the Legislature identified as non-conforming, within thirty days. More specifically, the concurrent resolution identified as non-conforming the imposed limitation on debilitating conditions treatable by medicinal marijuana, the separation of ATC activities for cultivation and distribution of marijuana, and the limit imposed on the level of delta-9-tetrahydrocannabinol (THC) contained in marijuana products sold.

On February 22, 2011, the Department proposed modified rules.[12] The new rules differed from the rules proposed at 42 N.J.R. 2668(a) by providing for 6 alternative treatment centers (ATCs) that cultivate and dispense medicinal marijuana, combining the separate application processes for cultivating and dispensing permits into one application for an ATC permit; prohibiting ATC satellite dispensing locations; prohibiting home delivery;[13] and only requiring that the medical conditions originally named in the Act be resistant to conventional medical therapy in order to qualify as debilitating medical conditions for purposes of a patient obtaining a registry identification

[9] Although the Department rules currently limit the number of strains of medical marijuana to three that an ATC may cultivate, N.J.A.C. 8:64-10.7(a), that provision will be repealed and has not been enforced by the Department as of the law being amended in 2013.

[10] Oral lozenges are not classified as "edible form" and are available to both qualifying adult and minor patients.

[11] 42 N.J.R. 2668(a).

[12] 43 N.J.R. 340(a).

[13] As explained in the Department's Notice of Adoption, effective December 19, 2011, a bi-partisan agreement between Governor Chris Christie and Assemblyman Reed Gusciora, one of the primary sponsors of the Act, eliminated home delivery as part of an effort to reach a compromise to implement the MMP. The Notice of Adoption also explained that experience with the program would determine whether home delivery is needed in the future.

card. A second concurrent resolution, *S. Res.* 151, 214th Leg (N.J. 2011) was introduced on April 11, 2011, which reaffirmed those proposed rules found to deviate from the Act's intent. However, the Legislature never adopted that resolution. The MMP rules were finalized and adopted on November 23, 2011, effective December 19, 2011.[14] The Department rules are scheduled to expire on December 19, 2018.

Notably, the Department MMP rules include a provision enabling the Department to waive requirements regarding the operations of the ATC if necessary to achieve the purpose of the Act and to provide access to patients who would otherwise qualify for the use of medicinal marijuana, so long as such waiver does not create a danger to the public health, safety or welfare. N.J.A.C. 8:64-7.11.

MEDICINAL MARIJUANA PROGRAM REVIEW

The Department undertook a review of the MMP as directed by Executive Order No. 6, mindful of the limits of its respective authority under the Act. Accordingly, this report includes recommendations of what can be done to responsibly expand access to marijuana for medical purposes by way of operations and regulatory changes. The report also highlights areas where legislative change would be necessary to lift restrictions or expand the MMP.

AN EVALUATION OF THE CURRENT RULES REGULATING THE OPERATIONS AND SITING OF DISPENSARIES AND CULTIVATION FACILITIES, PARTICULARLY FOCUSING ON WHETHER THE RULES SHOULD BE REVISED TO REMOVE OBSTRUCTIONS TO EXPANSION

The Act addresses the operations and siting of ATCs. Specifically, the Act states that "[t]he department shall accept applications from entities for permits to operate as [ATCs], and may charge a reasonable fee for the issuance of a permit . . . 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. The first two centers issued a permit in each region shall be nonprofit entities, and centers subsequently issued permits may be nonprofit or for-profit entities." N.J.S.A. 24:6I-7.

Siting of ATCs is impacted by a regulatory prohibition on satellite locations. That is, N.J.A.C. 8:64-7.9(a) provides that **"**[t]he Department shall not authorize or permit dispensing operations at any satellite locations. However, an ATC, as approved by the Department, may cultivate marijuana at a location separate from the location where the ATC shall dispense the marijuana, but both locations shall be within the same region."

To address the current regulatory limits to ATC expansion, the Department respectfully submits the following regulatory action item:

REGULATORY ACTION ITEM: PERMIT SATELLITE ATC LOCATIONS

The Department plans to amend N.J.A.C. 8:64-7.9 to permit current ATCs to dispense at satellite locations and permit more than one cultivation site per ATC with Department approval. Additional sites will be subject to all applicable laws, rules and local ordinances. *The goal of eliminating the prohibition on satellite sites is to allow for increase in supply of, and access to, product for qualifying patients.*

In advance of the formal rulemaking process, the Department will consider waivers of* N.J.A.C. 8:64-7.9 *on a case-by-case basis.

[14] 43 N.J.R. 3335(a), effective Dec. 19, 2011.

Notably, siting of ATCs is subject to local ordinance. As set forth in the rules, a political subdivision of this State is not prohibited from limiting the number of ATCs that may operate in the political subdivision or from enacting reasonable local ordinances applicable to ATCs. N.J.A.C. 8:64-7.9(b).

A REVIEW OF THE CURRENT PROCESS FOR OBTAINING A LICENSE TO OPERATE A MEDICAL MARIJUANA DISPENSARY, INCLUDING RECOMMENDATIONS TO EXPEDITE THAT PROCESS

The Act outlines the process for obtaining a license to operate a medical marijuana dispensary. Specifically, the Act provides that the "department shall accept applications from entities for permits to operate as alternative treatment centers, and may charge a reasonable fee for the issuance of a permit." N.J.S.A. 24:6I-7(a). It is the Department's statutory charge 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. The Act further provides that the first two centers issued a permit in each region shall be nonprofit entities, and centers subsequently issued permits may be nonprofit or for-profit entities. N.J.S.A. 24:6I-7(a). Applicants for authorization as nonprofit ATCs shall be subject to all applicable State laws governing nonprofit entities, but need not be recognized as a 501(c)(3) organization by the federal Internal Revenue Service. Ibid.

As to the application process for operating an ATC, the Department has broad authority to require that an applicant provide such information as the department determines to be necessary pursuant to regulations. N.J.S.A. 24:6I-7(b). The Act directs the Commissioner to require each applicant seeking a permit to operate as an ATC to undergo a criminal history record background check. Owners, directors, officers, and employees of an ATC are subject to criminal background checks. N.J.S.A. 24:6I-7(d)(1). The Commissioner shall not approve an applicant for a permit to operate, or authorization to be employed at, an ATC if the criminal history record background information of the applicant reveals a disqualifying conviction under the Act. However, disqualifying convictions are subject to a clear and convincing showing of rehabilitation under certain enumerated factors. N.J.S.A. 24:6I-7(d)(6). Notably, the Commissioner has authority to offer provisional authority for employees of ATCs for a period of three months with an attestation that the individual has not been convicted of any disqualifying conviction. N.J.S.A. 24:6I-7(d)(5). Overall, the Department has broad authority to issue a permit to operate an ATC consistent with the purposes of the Act.[15]

The Department discharged its statutory duty to promulgate rules that created the ATC application process. Pursuant to N.J.A.C. 8:64-6.1, "the Department may periodically announce a request for applications for the award of an ATC" and the Department shall announce a request for such applications by publication in the New Jersey Register. The rule further provides for the contents of the Notice, such as eligibility criteria, evaluation criteria, weights for the criteria, applications materials, deadlines, etc. N.J.A.C. 8:64-6.1(a)-(c).

On or about January 13, 2011, the Department posted a Request for Applications (RFA) for ATC permits on its website and required that completed applications be filed by February 14, 2011. The applicant eligibility section of the RFA stated that applicants must be non-profit entities organized under the laws of the State of New Jersey because no more than six permits for ATCs would be issued at the outset. Moreover, in response to several inquiries about the RFA, the Department, on its Frequently Asked Questions (FAQ) webpage, reiterated that only non-profit applicants may apply. The Department's decision to initially limit the number of ATC permits

[15] Under the Act, the Department may suspend or revoke a permit to operate as an alternative treatment center for cause, which shall be subject to review by the Appellate Division of the Superior Court. N.J.S.A. 24:6I-7(e). There are no express penalty provisions in the Act to ensure compliance with law and regulation. This is problematic insofar as it risks availability of product to patients if the Department's only enforcement option is the extreme measure of suspending or revoking a permit of operation to address ATC non-compliance.

to six was part of a bi-partisan agreement reached between Governor Christie and the Assembly sponsor of the Act in early December 2010.

By February 14, 2011, 21 separate entities had submitted 35 applications for ATC permits. After evaluating the applications based on criteria in the RFA, the Department awarded six permits to non-profit entities: two permits in the north region, two in the central region, and two in the south region. The Department's determination to award no more than the statutorily prescribed minimum number of ATCs, and to decline to accept applications from for-profit entities at the outset, was upheld on appeal by the New Jersey Superior Court, Appellate Division. See Natural Medical, Inc. v. New Jersey Dep't of Health & Sr. Servs., 428 N.J. Super. 259 (App. Div. 2012).

The Department respectfully submits the following regulatory action item and statutory recommendation to expand patient access:

REGULATORY ACTION ITEM: CREATE SEPARATE ENDORSEMENTS FOR ATC PERMITS

The Department plans to revise N.J.A.C. 8:64-7.1 and associated rules to create an endorsement system within the ATC permitting process. These endorsements would allow ATCs to engage in one or more of the following activities related to the provision of usable marijuana to qualifying patients: 1) cultivation and harvesting usable marijuana; 2) manufacturing and processing usable marijuana (including the manufacturing of edible products); and 3) dispensing of usable marijuana. The Department envisions that existing ATCs would receive some combination of production, cultivation, and dispensing endorsements under this new system, which will be set forth in regulation. *Once approved through regulation, this endorsement system would permit an increase in the available supply of, and access to, usable marijuana to mitigate patient supply issues and promote a more diverse workforce and industry dedicated to the provision of medicinal marijuana. It is anticipated that this separate endorsement system will be utilized in a future Request for Applications to solicit applicants for ATC permits.*

To further expand patient access and ensure adequate supply, the Department recommends an open application process for parties interested in applying for one or more of the endorsement types set forth above. It should be noted that all future endorsements would be on either a non-profit or for-profit basis. This may also result in the faster processing of applications for some entities, as previous delays were caused by the program's need to conduct significant due diligence to ensure applicant compliance with State non-profit laws.

STATUTORY RECOMMENDATION: REMOVAL OF NON-PROFIT REQUIREMENT FOR ORIGINAL ATCs

N.J.S.A. 24:6I-7(a) currently establishes that the first two alternative treatment centers issued a permit in each region shall be nonprofit entities, and centers subsequently issued permits may be nonprofit or for-profit entities. This subsection further defines the requirements of an ATC with respect to the lifecycle of supplying usable marijuana to qualifying patients. *The Department recommends removal of the non-profit requirement for the original alternate treatment centers to create parity among all centers.*

AN EXAMINATION OF CONDITIONS FOR PARTICIPATING PHYSICIANS IN THE PROGRAM TO ENSURE THAT ANY SUCH REQUIREMENTS ARE NOT NEEDLESSLY ONEROUS

Under the Act, "physician" is defined as "a person licensed to practice medicine and surgery pursuant to Title 45 of the Revised Statutes with whom the patient has a bona fide physician-patient relationship and who is the primary care physician, hospice physician, or physician responsible for the ongoing treatment of a patient's debilitating medical condition, provided, however, that such ongoing treatment shall not be limited to the provision of authorization for a patient to use medical marijuana or consultation solely for that purpose." N.J.S.A. 24:6I-3. The Act goes on to state that, to issue a certification authorizing use of medical marijuana to a qualifying patient, a physician shall be licensed and in good standing to practice in the State. N.J.S.A. 24:6I-5(a). A physician may not authorize through certification a patient who is a minor unless the custodial parent, guardian, or person

who has legal custody of the minor, consents in writing that the minor patient has that person's permission for the medical use of marijuana and that the person will control the acquisition and possession of the medical marijuana and any related paraphernalia from the alternative treatment center. N.J.S.A. 24:6I-5(b).

Regulations promulgated by the Board of Medical Examiners (BME)[16] set forth the requirements for physician participation in the MMP, including possession of an active controlled dangerous substances registration:

> (a) A physician shall provide a certification and written instructions for a patient for the medical use of marijuana only if:
>
> 1. The physician holds an active New Jersey license in good standing issued by the Board and possesses an active controlled dangerous substances registration issued by the Division of Consumer Affairs that is not subject to limitation; and
> 2. The physician has a bona fide physician-patient relationship with the patient.

N.J.A.C. 13:35-7A.3. A bona fide physician-patient relationship is defined in the BME Rules as:

> [A] relationship in which the physician has ongoing responsibility for the assessment, care and treatment of a patient's debilitating medical condition, consistent with the requirements of N.J.A.C. 13:35-7A.5. For purposes of this definition, "ongoing responsibility" means:
>
> 1. The physician-patient relationship has existed for at least one year;
> 2. The physician has seen and/or assessed the patient for the debilitating medical condition on at least four visits; or
> 3. The physician assumes responsibility for providing management and care of the patient's debilitating medical condition after conducting a comprehensive medical history and physical examination, including a personal review of the patient's medical record maintained by other treating physicians reflecting the patient's reaction and response to conventional medical therapies.

N.J.A.C. 13:35-7A.2; see also N.J.S.A. 24:6I-3 ("Bona fide physician-patient relationship" means a relationship in which the physician has ongoing responsibility for the assessment, care and treatment of a patient's debilitating medical condition."); N.J.A.C. 8:64-1.2 ("Bona fide physician-patient relationship" means a relationship in which the physician has ongoing responsibility for the assessment, care and treatment of a patient's debilitating medical condition consistent with the requirements of the Act and N.J.A.C. 13:35-7A.").

Physicians and alternative treatment centers are required to transmit information to ensure the confidentiality of patient information in compliance with all Federal and State laws, rules and regulations, including the Federal Health Insurance Portability and Accountability Act of 1996, PL 104-191. N.J.A.C. 13:45A-33.5(c).

While there are 523 MMP-approved physicians throughout the State (as of February 15, 2018), only **79%** are actively writing patient statements and treating patients. Since March 2017, the program has gained 9,292 patients, or an average of 774 per month. As of February 15, 2018, there are **17,806** patients with active registry cards. Patients currently may ask their primary physician to register with the MMP or they may locate a participating physician on the website by county and/or medical specialty.

[16] The Department is including BME rules for reference; however, recommendations to revise regulations to expand patient access and eliminate bureaucratic barriers are limited to those within the Department's purview.

All registered physicians are listed on the MMP website. The website currently features "Find a Doctor" through which patients can search on the internet by specialty, name or city for a physician participating in the MMP. The link can be found at http://www.nj.gov/health/medicalmarijuana/patients/find-doctor/.

To address the current requirements imposed on participating physicians, the Department respectfully submits the following departmental and regulatory action items and statutory recommendation:

DEPARTMENT ACTION ITEM: DEVELOPMENT OF PATIENT, CAREGIVER, AND PHYSICIAN MOBILE ACCESS PORTAL

The Department recognizes the need to provide a more convenient technology experience for patients, caregivers, and physicians. *The Department will develop and implement a comprehensive updated program portal, which will include the ability to securely upload documents and submit payments using a smartphone or tablet, with a target implementation date of Spring 2019.*

In an interim measure, Department IT staff have been able to provide access via mobile device to the current registry and payment processing system. This access will go live in Spring 2018 and provide expanded patient access to the registry.

REGULATORY ACTION ITEM: ELIMINATE THE PHYSICIAN REGISTRY

The Department plans to eliminate N.J.A.C. 8:64-2.4, which requires physicians interested in providing care to MMP patients to first register with the Department. In turn, these physicians were listed on the Department's public website in a physician registry for patient convenience. *The Department's elimination of the physician registry will permit any New Jersey doctor meeting the requirements in* N.J.A.C. 8:64-2.5 *to authorize medicinal marijuana for their patients meeting the program requirements. The Department recognizes that not every physician eligible to authorize medicinal marijuana will choose to do so; therefore, the Department will continue to publish a list of physicians who are interested in providing care to qualifying MMP patients. These physician listings will be done on an optional basis as a convenience to patients.*

In advance of the formal rulemaking process, the Department will begin the transition in Spring 2018 to eliminate the current physician registry procedure. This will allow program and IT staff to begin the review and potential reengineering of business processes to streamline the experience for patients, physicians, and program once the new portal is up and running. The portal would be rolled out in a series of modules next year.

REGULATORY ACTION ITEM: ELIMINATE PSYCHIATRIST EVALUATION FOR MINORS

The Department plans to revise N.J.A.C. 8:64-2.5 to remove the requirement for "written confirmation from a physician trained in the care of pediatric patients and from a psychiatrist" for a physician to authorize the use of medicinal marijuana for a minor. In the event that physicians need to seek consultation from another provider, this can be done in the regular course of care. *This requirement creates an artificial barrier to care, as there should be parity in the treatment of patients, regardless of age.*

AN ANALYSIS OF THE CURRENT LIST OF DEBILITATING MEDICAL CONDITIONS FOR WHICH MEDICAL MARIJUANA MAY BE AUTHORIZED PURSUANT TO N.J.S.A. 24:61-3, AND A RECOMMENDATION AS TO WHETHER DOCTORS SHOULD BE GIVEN FLEXIBILITY TO MAKE THESE DETERMINATIONS ON THEIR OWN

The Act and rules define "debilitating medical condition" as follows:

1) one of the following conditions, if resistant to conventional medical therapy: seizure disorder, including epilepsy; intractable skeletal muscular spasticity; or glaucoma;

2) one of the following conditions, if severe or chronic pain, severe nausea or vomiting, cachexia, or wasting syndrome results from the condition or treatment thereof: positive status for human immunodeficiency virus, acquired immune deficiency syndrome, or cancer;
3) amyotrophic lateral sclerosis, multiple sclerosis, terminal cancer, muscular dystrophy, or inflammatory bowel disease, including Crohn's disease;
4) terminal illness, if the physician has determined a prognosis of less than 12 months of life; or
5) any other medical condition or its treatment that is approved by the department by regulation.

N.J.S.A. 24:6I-3; N.J.A.C. 8:64-1.2. The Department rules also set forth a petition and panel review process by which additional debilitating medical conditions may be added for purposes of patient participation in the MMP. In summary, the Department publishes notice that it will be accepting petitions; the Commissioner appoints a medical review panel (Panel)[17] to make recommendations to the Commissioner for approval or denial of those petitions; the Panel makes an initial recommendation to the Commissioner; the Panel's recommendation is posted for a 60-day public comment period and subject to a public hearing; the Panel determines whether, based on public input, any changes should be made before making its final recommendation to the Commissioner; and the Commissioner renders a final agency determination as to whether to grant or deny the petition. N.J.A.C. 8:64-5.1 through -5.4.

In February 2016, then-Commissioner Cathleen D. Bennett appointed individuals to serve on the Panel[18] for a term of three years. Thereafter, the Department published a notice in the New Jersey Register that it would be accepting petitions for additional conditions to be added to the MMP.[19] The Department reviewed petitions for completeness according to rules and then submitted forty-five petitions to the Panel for review. The Panel evaluated each petition and grouped them according to seven categories. On July 21, 2017, the Panel submitted its Initial Recommendation to the Commissioner. The Panel recommended that the Commissioner grant the petitions listed under five of the seven categories: chronic pain related to musculoskeletal disorders, migraine, anxiety, chronic pain of visceral origin, and Tourette's Syndrome. The Panel recommended that Commissioner deny petitions listed under the two remaining categories of Asthma and Chronic Fatigue. Following public comment and a public hearing, the Panel adopted its Initial Recommendation unchanged as its Final Recommendation to Commissioner on October 25, 2017.[20] The Commissioner has reviewed and concurs with the Final Recommendation of the Panel.

To move forward on the addition of the identified debilitating conditions, the Department respectfully submits the following action item:

[17] "Review panel" means a panel of health care professionals appointed by the Commissioner to review petitions and make recommendations for identification and approval of additional debilitating medical conditions. N.J.A.C. 8:64-1.2. The Panel shall consist of not more than 15 health care professionals, among whom shall be the President of the Board of Medical Examiners or the President's designee and other physicians as well as non-physicians who are knowledgeable about the condition as to which the petition seeks approval. Each physician appointed to the review panel shall be nationally board-certified in his or her area of specialty. At least three physicians appointed to the review panel shall have expertise in pain and symptom management. A majority of the panel shall be physicians. N.J.A.C. 8:64-5.2(b); (c).

[18] The Panel is made up of the following individuals: Alex Bekker, M.D., Ph.D.– Chairperson; Cheryl Kennedy, M.D.- Vice Chairperson; Mary Bridgeman, Pharm. D.; Mary Johansen, Ph. D., NE-BC, R.N.; Petros Levounis, M.D., M.A.; Jessica Scerbo, M.D.; and Stephanie Zarus, Pharm. D.

[19] 48 N.J.R. 1395(a).

[20] The Panel's Initial/Final Recommendation is available at: http://www.nj.gov/health/medicalmarijuana/documents/Initial%20Recommendation%20Letter.pdf.

DEPARTMENT ACTION ITEM: EXPANSION OF AUTHORIZED DEBILITATING MEDICAL CONDITIONS

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.

A final agency decision was issued on March 22, 2018 to accept the Panel's recommendations to effectuate the addition of these debilitating conditions.

The Department respectfully submits the following regulatory action item and statutory recommendation to provide additional flexibility:

REGULATORY ACTION ITEM: STREAMLINE PROCESS FOR ADDITION OF DEBILITATING CONDITIONS

The Department plans to revise N.J.A.C. 8:64-5.2 and -5.3, which created a petition process and review panel to make recommendations for the approval of additional debilitating medical conditions. The Medicinal Marijuana Review Panel serves a vital role in the review and recommendation of additional debilitating medical conditions. *The Panel will continue to serve the Department in an advisory capacity; however, the Department will streamline the petition and panel process by removing the requirement in N.J.A.C. 8:64-5.3 that petitions for the addition of debilitating conditions be referred to the Medicinal Marijuana Review Panel. This will allow for the Commissioner to add debilitating conditions in extraordinary circumstances without a lengthy review process. These proposed revisions will eliminate bureaucratic barriers for patients in need whose illnesses are not included in the current list of debilitating conditions already covered by the program.*

STATUTORY RECOMMENDATION: ALLOW USE OF MARIJUANA AS A FIRST-LINE TREATMENT

N.J.S.A. 24:6I-3 stipulates that "seizure disorder, including epilepsy; intractable skeletal muscular spasticity; post-traumatic stress disorder; or glaucoma" must be "resistant to conventional medical therapy" to be considered a debilitating medical condition. *The Department recommends that this caveat be deleted to permit the use of medicinal marijuana as a first-line treatment, rather than a last resort, for these conditions.*

AN ASSESSMENT OF THE METHODS THROUGH WHICH PATIENTS OR THEIR PRIMARY CAREGIVERS ARE OBTAINING MEDICAL MARIJUANA AND A RECOMMENDATION OF WHETHER RULES SHOULD BE AMENDED TO APPROVE ADDITIONAL METHODS THAT COULD FACILITATE PATIENT ACCESS

PATIENT AND PRIMARY CAREGIVER REGISTRATION.

The Act provides that the Department shall establish a registry of qualifying patients and their primary caregivers who shall be issued a registry identification card that is valid for two years. N.J.S.A. 24:6I-4(a). The Act provides a 30-day timeframe for approval or denial of a completed application, and a 5-day timeframe from approval to issue or renewal of the registration card. N.J.S.A. 24:6I-4(b). Primary caregivers must undergo a background check. N.J.S.A. 24:6I-4(c)(1). The Act also provides that primary caregivers may not serve in that capacity for more than one qualifying patient. N.J.S.A. 24:6I-3.

By rule, the patient and primary caregiver MMP registration fee is $200.00 for two years. N.J.A.C. 8:64-2.1(c). Patients and caregivers that receive New Jersey Medicaid, Supplemental Nutrition Assistance Program (SNAP) benefits, New Jersey Temporary Disability Insurance benefits, Supplemental Security Income (SSI) benefits or Social Security Disability (SSD) benefits, receive a reduced registration fee of $20.00. N.J.A.C. 8:64-2.1(c)(1). Approximately 18% percent of registered patients and caregivers receive the reduced application fee of $20.00.

In addition to the development of the mobile access portal previously discussed, the Department respectfully submits the following regulatory action items to facilitate the patient registration experience to reduce costs and ensure continuity of care:

REGULATORY ACTION ITEM: REDUCE REGISTRATION FEES

The Department plans to revise N.J.A.C. 8:64-2.1(1)(c) to reduce registration fees. Currently, the fee for issuance or renewal of an MMP registry identification card is $200, with a reduced card fee of $20 for those receiving certain forms of public assistance.[21] *The Department will expand the reduced card fee to senior citizens and military veterans,*[22] *and continue the reduced card fee for those receiving public assistance. Additionally, the Department will reduce the registration fee for all other qualifying patients and caregivers to $100 for the issuance or renewal of a registry identification card, which is valid for a two-year period.*

In advance of the formal rulemaking process, the Department will begin charging reduced registration fees to qualifying patients to alleviate the financial burden on patients.

REGULATORY ACTION ITEM: ALLOW TWO CAREGIVERS PER PATIENT

The Department plans to revise N.J.A.C. 8:64-1.2 and associated provisions to include a second "primary caregiver," who will be subject to the same requirements as the primary caregiver.[23] *This revision will 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.

MEDICAL MARIJUANA DISPENSING

The Act limits the quantity of product that a patient can obtain in a 30-day period. Specifically, a physician shall provide written instructions for a registered qualifying patient or his caregiver to present to an ATC concerning the total amount of usable marijuana that a patient may be dispensed, in weight, in a 30-day period, which amount shall not exceed two ounces. N.J.S.A. 24:6I-10(a). A physician may issue multiple written instructions at one time authorizing the patient to receive a total of up to a 90-day supply, subject to certain conditions. N.J.S.A. 24:6I-10(b).

The rules provide that the maximum THC[24] content of any sold product shall not exceed 10 percent. N.J.A.C. 8:64-10.7.

The Department respectfully submits the following regulatory action item and statutory recommendations with respect to expanding patient access with respect to product dispensing:

REGULATORY ACTION ITEM: ELIMINATE 10% THC LIMIT

The Department plans to repeal N.J.A.C. 8:64-10.7(c) to remove the 10% THC limit for product sold. The 10% THC limit was implemented at MMP inception 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

[21] Qualifying patients who receive New Jersey Medicaid, food stamps, temporary disability insurance (TDI), or Federal Supplemental Security Income (SSI) or Social Security Disability (SSD) benefits are eligible for the reduced fee.

[22] The U.S. Department of Veterans Affairs revised its policy with respect to medical marijuana in late 2017. The policy urges government physicians to "discuss with the Veteran marijuana use, due to its clinical relevance to patient care, and discuss marijuana use with any Veterans requesting information about marijuana." The full policy can be found on the VA website at https://www.publichealth.va.gov/marijuana.asp. In addition, states such as Massachusetts have implemented fee waivers for veterans and other states with medicinal marijuana programs have reduced registration fees for veterans.

[23] The Act prohibits a primary caregiver from serving more than one patient at a time but it does not prohibit multiple primary caregivers for one patient.

[24] THC, or delta-9-tetrahydrocannabinol, is the principal psychoactive constituent of cannabis.

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. *Upon further evaluation, the Department will eliminate the THC limit to allow for more effective treatment of the debilitating medical conditions covered under the State's program.*

STATUTORY RECOMMENDATION: PERMIT UNLIMITED SUPPLY FOR PATIENTS RECEIVING HOSPICE CARE

As N.J.S.A. 24:6I-10(a) establishes a two-ounce limit that may be authorized by physicians in a 30-day period, this limit may be restrictive for those receiving hospice care in the final stages of life. Research in *The Journal of Pain* indicates that the use of medicinal marijuana is associated with improvements in pain, function, and quality of life.[25] To effectively provide symptom and pain control, the maximum monthly product limit should be eliminated. *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."*[26]

STATUTORY RECOMMENDATION: INCREASE MAXIMUM MONTHLY PRODUCT LIMIT

N.J.S.A. 24:6I-10(a) establishes a two-ounce limit that may be authorized by physicians in a 30-day period. Physicians should have the discretion to authorize more than two ounces. *To that end, 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.*

STATUTORY RECOMMENDATION: ALLOW PATIENTS TO REGISTER AT MORE THAN ONE ATC

N.J.S.A. 24:6I-10(d) stipulates that patients "shall be registered to purchase usable marijuana from only one ATC at a given time." This limits patient access to product. *The Department recommends that the statute be amended to allow patients to obtain product from any State ATC dispensary.*

A REVIEW OF REGULATIONS THAT GOVERN THE FORMS IN WHICH MEDICAL MARIJUANA CAN BE INGESTED, TAKING INTO CONSIDERATION THE NEEDS FOR DIFFERENT METHODS FOR DIFFERENT PATIENTS

As noted above, the Act was amended in 2013 to expand the permissible forms of medicinal marijuana. The Act currently provides that an ATC may package and directly dispense marijuana to qualifying patients in dried form, oral lozenges, topical formulations, or edible form, or any other form as authorized by the Commissioner. Edible form shall include tablets, capsules, drops or syrups and any other form as authorized by the Commissioner. Notably, the Act limits availability of edible forms to qualifying patients who are minors. N.J.S.A. 24:6I-7(a).

The Department rules provide that an ATC shall package or dispense marijuana in:

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

[25] This research study, *Cannabis for the Management of Pain: Assessment of Safety Study (COMPASS)*, is in Volume 16, Issue 12 of the Journal of Pain (December 2015). The article can be found at http://www.jpain.org/article/S1526-5900(15)00837-8/fulltext.

[26] N.J.S.A. 24:6I-2(e).

N.J.A.C. 8:64-10.8(e). Although the Department rules do not yet reflect the Act's 2013 amendments as to "edible form," the Department has allowed the manufacturing and dispensing by ATCs of product in all forms as permitted by law. There are currently two ATCs that provide manufactured products to qualifying patients. It should be noted that the Department does not mandate that ATCs provide marijuana in topical or edible formulations, as it is an individual business decision made by each ATC. In fact, the Department issued standards governing the manufacturing of lozenges, topical formulations and edible form products by ATCs in March 2015. The standards were issued to help ensure that ATCs provide patients with products that are of acceptable and consistent in strength, quality, and purity. In addition, the standards sought to ensure the safety of ATC employees working in the manufacturing process.

In summary, the Department allows all forms of medical marijuana permitted by law and ATCs make their own business decisions as to production of dried product, oral lozenges, topical formulations, or edible forms.

Although the Executive Order charges the Department with a review of the regulations governing the forms of medical marijuana available for patients, the Department is constrained by the current statutory restriction on the availability of edible forms of marijuana for adult patients. To that end, the Department respectfully submits the following statutory recommendation with respect to expanding patient access to all forms of medical marijuana:

STATUTORY RECOMMENDATION: ALLOW EDIBLES FOR ALL PATIENTS

N.J.S.A. 24:6I-7(a) restricts use of edible products to qualifying patients who are minors; however, this product type should be permissible for all patients. The ingestion of medicinal marijuana is healthier for patients than smoking. *While some manufactured products such as topicals and lozenges are allowed for adults, patients with dexterity issues or who have difficulty following dosage instructions would benefit from the use of edibles.*

ADDITIONAL CONSIDERATIONS

In addition to the recommendations and action items presented above, the Department is exploring the following areas to continue the expansion of patient access and elimination of bureaucratic barriers:

HOME DELIVERY

The Act provides that an ATC is "authorized to acquire a reasonable initial and ongoing inventory, as determined by the department, of marijuana seeds or seedlings and paraphernalia, possess, cultivate, plant, grow, harvest, process, display, manufacture, *deliver*, *transfer*, *transport*, distribute, supply, sell, or dispense marijuana, or related supplies to qualifying patients or their primary caregivers who are registered with the department." N.J.S.A. 24:6I-7(a). However, the rules currently prohibit home delivery of product to patients or caregivers. N.J.A.C. 8:64-10.12.

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.

PERMITTING EXTERNAL LABORATORIES TO CONDUCT QUALITY CONTROL TESTING

N.J.A.C. 8:64-13.4 currently requires that the Department conduct testing of samples for product quality control to ensure the safety of registered qualifying patients. 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 current testing capacity of our State laboratory.

DEVELOPMENT OF PROVIDER EDUCATION PROGRAM AND DOSING GUIDELINES

With the expansion of authorized debilitating conditions, the Department recognizes the need to provide education and guidance to providers. To that end, the Department is exploring the creation of an education program for all physicians, with focus on the endocannabinoid system.

The Department plans to leverage the expertise of the Medicinal Marijuana Review Panel to oversee the curriculum development for this program. This education program will serve to create best practices for the safe and effective administration of medicinal marijuana to the expanded universe of qualifying patients.

In conjunction with the provider education program, there is also a need to develop standardized dosing and administrative protocols for medicinal marijuana products, including information on expected effects, side effects, and adverse effects. In addition to the provider education component above, 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 Medicinal Marijuana Program 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.

ELIMINATION OF SALES TAX ON MEDICINAL MARIJUANA

Bulletin TB-68 issued on November 30, 2012 by the New Jersey Division of Taxation 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.

Given the Governor's instruction through the promulgation of Executive Order 6 to expand access and eliminate bureaucratic barriers, the Department of Health will work with the Department of the Treasury to expand the sales tax exemption for retail sales of medicinal marijuana through the issuance of revised technical guidance.

DEPARTMENT REVIEW OF ATC PERMITTING AND BACKGROUND CHECK PROCESS

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.

CONCLUSION

The Department of Health respectfully submits this report pursuant to Executive Order No. 6 (2018).

ATTACHMENTS

Executive Summary Matrix

Executive Order 6

Attachment A: Executive Summary Matrix

	Item Description	Estimated Timeframe for Implementation *	Operational Actions	Regulatory Actions	Statutory Actions
PATIENT PERSPECTIVE	**Expand debilitating conditions as recommended by Medicinal Marijuana Review Panel**	March 27, 2018	Final Agency Decision adding new conditions was issued.	Propose to revise N.J.A.C. 8:64-1.2 to include these additional debilitating conditions.	
	Development of patient, caregiver, and physician mobile access portal	March 27, 2019	The Department will work to develop and/or procure an updated HIPAA-compliant comprehensive program portal with the ability to securely upload documents and submit payments. In an interim measure, Department IT staff have been able to provide mobile access to the current registry and payment processing system, which will go live in Spring 2018.		
	Reduce registration fees	March 27, 2018	In advance of rulemaking process, the Department will begin charging reduced registration fees to qualifying patients to alleviate the financial burden on patients.	Propose to revise N.J.A.C. 8:64-2.1(1)(c) to expand the reduced card fee to senior citizens and military veterans, and continue the reduced fee for those receiving public assistance. Additionally, the Department will reduce the registration fee for all qualifying patients and caregivers to $100 for the issuance or renewal of a registry identification card, which is valid for a two-year period.	
	Streamline process for addition of debilitating conditions	March 27, 2019		Propose to revise N.J.A.C. 8:64-5.2 and -5.3, which created a petition process and review panel to make recommendations for the approval of additional debilitating medical conditions.	
	Allow two caregivers per patient	March 27, 2018	In advance of formal rulemaking process, the Department will lift one-person limit on primary caregiver designation and allow two primary caregivers upon request.	Propose to revise N.J.A.C. 8:64-1.2 and associated rules to allow designation of a second primary caregiver who will be subject to the same requirements as the primary caregiver.	
	Eliminate 10% THC limit	March 27, 2019		Propose to repeal N.J.A.C. 8:64-10.7(c) to remove the 10% THC limit for product sold.	
	Allow edibles for all patients	Legislative Timeline		Rulemaking consistent with statutory amendments.	Recommend amending N.J.S.A. 24:6I-7(a) to expand availability of edible products to all qualifying patients, regardless of age.
	Allow patients to register at more than one ATC	Legislative Timeline		Rulemaking consistent with statutory amendments.	Recommend amending N.J.S.A. 24:6I-10(d) to expand patient access by allowing patients to be obtain product from any ATC.
	Permit unlimited supply of product for patients receiving hospice care	Legislative Timeline		Rulemaking consistent with statutory amendments.	Recommend amending N.J.S.A. 24:6I-10(a) to permit unlimited supply pf product to those receiving hospice care.
	Increase maximum monthly product limit	Legislative Timeline		Rulemaking consistent with statutory amendments.	Recommend amending N.J.S.A. 24:6I-10(a) to increase monthly product limit to 4 ounces and an associated revision to N.J.S.A. 24:6I-6 to ensure that MMP patients have adequate legal protection against criminal charges for possession.

Attachment A: Executive Summary Matrix

	Item Description	Estimated Timeframe for Implementation *	Operational Actions	Regulatory Actions	Statutory Actions
ATC PERSPECTIVE	**Permit satellite ATC locations**	March 27, 2018	In advance of rulemaking process, the Department will consider waivers of N.J.A.C. 8:64-7.9 on a case-by-case basis.	Propose to revise N.J.A.C. 8:64-7.9 to permit current ATCs to dispense at satellite locations and permit more than one cultivation site per ATC, with Department approval.	
	Create separate endorsements for ATC permits	March 27, 2019	The Department anticipates that this separate endorsement system will be utilized in a future Request for Applications to solicit applicants for ATC permits.	Propose to revise N.J.A.C. 8:64-7.1 and associated rules to create an endorsement system within the ATC permitting process. These endorsements would be broken down into the following activities: 1) cultivation and harvesting; 2) manufacturing and processing (including edible products); and 3) dispensing of usable marijuana.	
	Removal of non-profit requirement for original ATCs	Legislative Timeline		Rulemaking consistent with statutory amendments.	Recommend the revision of N.J.S.A. 24:6I-7(a) to remove non-profit requirement for original ATCs.
PHYSICIAN PERSPECTIVE	**Eliminate the physician registry**	March 27, 2019	In advance of the formal rulemaking process, the Department will begin the transition in Spring 2018 to eliminate the current physician registry procedure. This will allow program and IT staff to begin the review and potential reengineering of business processes to streamline the experience for patients, physicians, and program once the new portal is up and running. The portal would be rolled out in a series of modules next year. The Department will also create an optional public physician list for patient convenience.	Propose to amend N.J.A.C. 8:64-2.4, which requires physicians interested in providing care to MMP patients to register with the Department. This amendment will allow any New Jersey physician in good standing with an active CDS registration issued by the State Division of Consumer Affairs to authorize medicinal marijuana for their patients meeting the program requirements.	
	Eliminate psychiatrist evaluation for minors	March 27, 2019		Propose to revise N.J.A.C. 8:64-2.5 to remove the requirement for "written confirmation from a physician trained in the care of pediatric patients and from a psychiatrist" for a physician to authorize the use of medicinal marijuana for a minor.	
	Allow use of cannabis as a first-line treatment	Legislative Timeline		Rulemaking consistent with statutory amendments.	Recommend amending N.J.S.A. 24:6I-3 to remove stipulation that certain conditions be "resistant to conventional medical therapy" to be considered a debilitating medical condition.

* The estimated timeframe for implementation is given only for the operational and regulatory actions, which are within the direct control and purview of the Department and/or Board of Medical Examiners. Dates indicated in the cell represent the **earlier** estimated date of implementation or consideration where there is both operational and regulatory action items. Some operational actions may be taken by the Department in advance of a formal rulemaking process, as these actions are consistent with Executive Order No. 6 and will not reduce protections or increase regulatory burdens.

EXECUTIVE ORDER NO. 6

WHEREAS, it is beyond dispute that patients suffering from debilitating medical conditions deserve to live in dignity with as little suffering as possible; and

WHEREAS, medical decisions must be based on science and health, not ideology or social policy; and

WHEREAS, scientific studies demonstrate that the medical use of marijuana has proven to be an effective treatment for patients suffering from painful, debilitating, and often chronic medical conditions; and

WHEREAS, New Jersey amended its state law to allow for the authorized medical use of marijuana with the passage of the New Jersey Compassionate Use Medical Marijuana Act in 2010; and

WHEREAS, 29 states have recently allowed the use of marijuana for medical purposes; and

WHEREAS, even a Republican-controlled Congress has repeatedly renewed the Rohrabacher-Farr Amendment, prohibiting the U.S. Department of Justice from using funds to interfere with state medical marijuana laws; and

WHEREAS, implementation of the New Jersey Compassionate Use Medical Marijuana Act was a lengthy process marked by significant delays, resulting in far fewer patients being served by the program than anticipated when the law was enacted; and

WHEREAS, there are currently five medical marijuana alternative treatment centers (ATCs) in operation in New Jersey; and

WHEREAS, only one additional ATC has been able to obtain a permit and is scheduled to begin operations in the foreseeable future; and

WHEREAS, of New Jersey's nine million residents, only approximately 15,000 are able to participate in the State's medical marijuana program; and

WHEREAS, in contrast, the medical marijuana program in Michigan, a state with a similar population to New Jersey, currently serves over 218,000 patients, and the program in Arizona, a state with a smaller population than New Jersey, serves over 136,000 patients; and

WHEREAS, the need for medical marijuana in New Jersey currently far exceeds the supply that the existing licensed ATCs in operation are able to provide; and

WHEREAS, giving patients a greater opportunity to obtain medical marijuana in accordance with State law will ensure that they are receiving a product tailored to their medical needs, and make them less likely to turn to potentially more harmful and less medically appropriate drugs such as opioids, the use of which was declared a public health crisis in Executive Order No. 219 (2017); and

WHEREAS, one study conducted by researchers at the Johns Hopkins Bloomberg School of Public Health and the Philadelphia Veterans Affairs Medical Center found that the annual number of deaths from prescription drug overdose is 25 percent lower in states where medical marijuana is legal than in states where it is illegal; and

WHEREAS, my administration is committed to fulfilling the intent, promise, and potential of the New Jersey Compassionate Use Medical Marijuana Act by providing patients in New Jersey with a well-functioning and effectively administered medical marijuana program that best serves their medical needs;

NOW, THEREFORE, I, PHILIP D. MURPHY, Governor of the State of New Jersey, by virtue of the authority vested in me by the Constitution and by the Statutes of this State, do hereby ORDER and DIRECT:

1. The Department of Health (“Department”) and the Board of Medical Examiners (“Board”) shall 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. This review should include, but not be limited to:

a. An evaluation of the current rules regulating the operations and siting of dispensaries and cultivation facilities, particularly focusing on whether the rules should be revised to remove unwarranted obstructions to expansion;

b. A review of the current process for obtaining a license to operate a medical marijuana dispensary, including recommendations to expedite that process;

c. An examination of conditions for participating physicians in the program to ensure that any such requirements are not needlessly onerous;

d. An analysis of the current list of debilitating medical conditions for which medical marijuana may be authorized pursuant to N.J.S.A. 24:61-3, and a recommendation as to whether doctors should be given flexibility to make these determinations on their own;

e. An assessment of the methods through which patients or their primary caregivers are obtaining medical marijuana and a recommendation of whether rules should be amended to approve additional methods that could facilitate patient access;

f. A review of regulations that govern the forms in which medical marijuana can be ingested, taking into consideration the needs for different methods for different patients; and

g. Any other aspect of the program within the Department or the Board's discretion that hinders or fails to effectively achieve the statutory objective of ensuring safe access to medical marijuana for patients in need.

2. This review shall conclude within 60 days of this Order, at which time the Department and Board shall initiate the rulemaking process for appropriate regulatory reforms consistent with this Order.

3. This Order shall take effect immediately.

GIVEN, under my hand and seal this 23rd day of January, Two Thousand and Eighteen, and of the Independence of the United States, the Two Hundred and Forty-Second.

[seal]

/s/ Philip D. Murphy

Governor

Attest:

/s/ Matthew J. Platkin

Chief Counsel to the Governor