

PUBLIC NOTICE

HEALTH

THE COMMISSIONER

MEDICINAL MARIJUANA PROGRAM

Notice of Action on Petition for Rulemaking

Revision of N.J.A.C. 8:64 Medicinal Marijuana Program Rules

Petitioner: Ken Wolski, RN, MPA, Executive Director, Coalition for Medical Marijuana—
New Jersey, Inc., Trenton, NJ.

Take notice that on October 16, 2014, the Department of Health (Department) received a petition for rulemaking from Ken Wolski, RN, MPA, Executive Director of the Coalition for Medical Marijuana—New Jersey, Inc., of Trenton, New Jersey. See 46 N.J.R. 2378(a) (December 1, 2014). The petitioner requests that the Department make certain amendments to N.J.A.C. 8:64, the Medicinal Marijuana Program Rules.

N.J.A.C. 8:64 implements the New Jersey Compassionate Use Medical Marijuana Act (Act), N.J.S.A. 24:6I-1 et seq.

In accordance with N.J.S.A. 52:14B-4 and N.J.A.C. 1:30-4.2(a)3, the Commissioner having duly considered the petition pursuant to law, the Department responds to the petition as follows.

REQUEST 1: The petitioner requests that the Department eliminate the \$200.00 fee required in N.J.A.C. 8:64-2.1(f) for all volunteer caregivers.

RESPONSE: N.J.S.A. 24:6I-4 requires the Department to impose a fee for caregiver registration. Pursuant to N.J.A.C. 8:64-2.2(f)1, the Department imposes no caregiver registration fee for the caregiver of a minor patient. Pursuant to N.J.S.A.

24:6I-11, the Medicinal Marijuana Program applies all fees it collects toward offsetting program administrative costs.

Caregiver registration is valid for two years. Therefore, the \$200.00 biennial fee for caregiver registration at N.J.A.C. 8:64-2.1(f) totals \$100.00 per year.

N.J.A.C. 8:64-2.1(c)1 establishes a reduced biennial fee of \$20.00 for registration of patients and caregivers who are eligible to receive benefits under one of the following programs: Medicaid, the Supplemental Nutrition Assistance Program, New Jersey Temporary Disability Insurance, Supplemental Security Income, or Social Security Disability. As registration is valid for two years, this makes the reduced registration fee only \$10.00 annually. Approximately 47 percent, that is, nearly half, of all patients and caregivers that the Department registered in 2013 registered under the reduced fee. 2013 Annual Report of the Medicinal Marijuana Program, New Jersey Department of Health (February 2014) at 3, available at http://www.state.nj.us/health/medicalmarijuana/documents/annual_report.pdf.

Among states and districts that authorize medicinal marijuana and impose caregiver registration fees (separate from qualifying patient registration fees), the fee the Department assesses is generally consistent with, and, in some cases, lower than, the fees that those states impose. See, for example, Arizona (\$200.00 annually; no income-based reduced fee available), A.A.A. R9-17-102; Delaware (\$125.00 annually; income-based reduced fee available), DEL. MEDICAL MARIJUANA CODE §7.5.2.1.7; District of Columbia (\$100.00 annually; \$25.00 income-based reduced fee available), D.C. MUN. REGS. TIT. 22-C §1300 (2014); Illinois (\$25.00 annually), 77 ILL. ADM. CODE §946.210; Maine (\$300.00 per qualifying patient served, up to five patients, for a total potential

annual fee of \$1,500), 10-144 CODE ME. R. CH. 122 §7.3; Montana (\$50.00 annually), MONT. ADMIN. REG. §37107.117; New Hampshire (\$50.00 annually), N.H. CODE ADMIN R. HE-C §401.14 (2014); Rhode Island (\$200.00 biennially or \$25.00 income-based reduced fee biennially), R23-1-17-FEE; and Vermont (\$50.00 annually), CVR 28-000-003 §7.3.

Based on the foregoing, the Department will take no action in response to the petitioner's request that the Department eliminate the \$200.00 biennial fee for caregiver registration at N.J.A.C. 8:64-2.1(f).

REQUEST 2. The petitioner requests that the Department eliminate the sales tax on medical marijuana.

RESPONSE: The Department neither imposes nor collects a medicinal marijuana sales tax. The New Jersey Division of Taxation has jurisdiction to determine the taxability of any activity or substance. For additional information on this issue, see Technical Bulletin TB-68 (November 30, 2012), issued by the Regulatory Services Branch of the Division of Taxation, New Jersey Department of the Treasury, available at <http://www.state.nj.us/treasury/taxation/pdf/pubs/tb/tb68.pdf>.

Based on the foregoing, the Department will take no action on the petitioner's request that the Department eliminate the sales tax on medicinal marijuana.

REQUEST 3. The petitioner requests that the Department delete the requirement at N.J.A.C. 8:64-2.4 that physicians register with the Department to be eligible to submit a certification pursuant to N.J.A.C. 8:64-2.5.

RESPONSE: The Department based the Medicinal Marijuana Program (MMP) on a medical model. The Department requires physicians to register in order to account for

and monitor the certifications issued to registered patients. Such monitoring is critical to DOH's role to implement the MMP and ensure the safety of public health. Further, the physician registration does not impose a fee nor does it require extensive information from the certifying physicians. The registration requirement places a minimal burden on physicians.

The MMP maintains an online search engine through which potential patients can identify physicians who are amenable and willing to consider recommending the use of medicinal marijuana as a therapeutic measure, by geographic location and specialty. This is comparable to the provider registries that health care insurance plans make available to their insureds to assist them in identifying physicians and other health care providers that accept the insureds' insurance plans.

As with the majority of professional decisions, a physician is free to choose whether to register with the MMP. To date, more than 360 physicians have chosen to register with the MMP, providing most registered qualifying patients a number of physicians whom they may consult concerning medicinal marijuana and who may be recommended by a treating physician within the ambit of a bona fide physician-patient relationship as defined at N.J.A.C. 8:64-1.2.

The Department is not persuaded by petitioner's suggestion that more physicians would recommend medicinal marijuana for their patients but for the requirement that they register with the MMP. Anecdotal evidence to the contrary exists. See, for example, the statement in a newspaper article of the Executive Director of the Medical Society of New Jersey, discounting the assertion that physicians are reluctant to enroll with the MMP:

“Larry Downs, executive director for the Medical Society of New Jersey, said he found the lack of doctor involvement a ‘convenient excuse’ for the program’s struggles. ‘If dispensary owners have overestimated the market, then that is not the concern of the medical field,’ Downs said. ‘If doctors believe it is a legitimate therapy, being published on a website is not going to stop them,’ he added. ‘A lot of doctors do not believe it is a good therapy and that it does not meet standards of efficacy and safety.’”

Livio, S., “NJ medical marijuana program struggling, with worries growing over few doctors, patients enrolled,” The Star-Ledger (June 15, 2014) available at http://www.nj.com/politics/index.ssf/2014/06/medical_marijuana_programs_slow_enrollment_worries.html.

Based on the foregoing, the Department will take no action on the petitioner’s request that the Department eliminate the physician registration requirement at N.J.A.C. 8:64-2.4.

REQUEST 4. The petitioner requests that the Department delete the “course requirement in pain management in order for licensed physicians to recommend medical marijuana.”

RESPONSE: As part of the process to register with the MMP, physicians complete a Physician Registry and Attending Physician Statement that asks them to indicate that they have taken a course in addiction medicine and pain management. Methodologies for prescribing otherwise illegal addictive substances (that is, substances

on Schedule 1 of the Controlled Substances Act, 21 U.S.C. §§ 801 et seq.) as part of pain management are not generally part of a standard medical education. Moreover, unlike other drugs that physicians regularly prescribe, guidance from package inserts (also known as a prescription drug product inserts or professional labeling) approved by the Food and Drug Administration or from the Physicians' Desk Reference[®] is unavailable to inform physicians about the risks (such as addiction) and palliative benefits associated with marijuana use. Therefore, it is reasonable to require physicians who elect to recommend medicinal marijuana for their patients to have at minimum some knowledge in this topic as a condition of participation in the medicinal marijuana program.

Based on the foregoing, the Department will take no action on the petitioner's request that the Department eliminate the requirement that registering physicians indicate that they have taken a course in addiction medicine and pain management.

REQUEST 5. The petitioner requests that the Department delete N.J.A.C. 8:64-2.5(a)6, which requires physicians to identify the diagnosis of persons applying to register with the MMP as qualifying patients.

RESPONSE: As a condition of the Department's registration of a person with the MMP registry and issuance to that person of a registry identification card, N.J.S.A. 24:6I-4 requires the Department to verify that the person is a qualifying patient, that is, a person in a bona fide physician-patient relationship. In turn, to verify the existence of a bona fide physician-patient relationship, the Department must verify, among other matters, that the person has a debilitating medical condition. To verify that the person has a debilitating medical condition, N.J.A.C. 8:64-2.5(a)6 and 7 require physicians to

identify the patient's diagnosis and to indicate that the diagnosed condition is a debilitating medical condition within the meaning of the Act.

Petitioner asserts that disclosure of patient's diagnosis to the Department requires physicians to violate "Federal law protecting [patients'] rights to privacy." The Department disagrees. The implementing regulations of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (Aug. 21, 1996) establish exemptions authorizing health care providers to make the disclosures N.J.A.C. 8:64-2.5 requires. See, for example, 45 CFR § 164.512(b) (authorizing disclosures of protected health information to public health authorities to carry out their public health functions) and 45 CFR § 164.512(f) (authorizing disclosures to law enforcement officials when required by law).

The Department notes that the rules of the State Board of Medical Examiners (Board) also require physicians, as a condition of their continued licensure in good standing and as part of the Board's physician oversight role, to disclose potentially individually identifiable health information of qualifying patients to that Board. See N.J.A.C. 13:35-7A.6, which requires physicians to "comply with all requests for information from the Division of Consumer Affairs concerning the issuance of certifications and written instructions for the medical use of marijuana."

Based on the foregoing, the Department will take no action on the petitioner's request that the Department eliminate N.J.A.C. 8:64-2.5(a)6.

REQUEST 6. The petitioner requests that the Department delete N.J.A.C. 8:64-2.5(a)9.

RESPONSE: N.J.A.C. 8:64-2.5(a)9 requires physicians to explain “the potential risks and benefits of the medical use of marijuana” and to document the explanation in the patient’s medical record. This requirement is consistent with N.J.A.C. 13:35-7A.5(f)5, by which the State Board of Medical Examiners requires physicians recommending medicinal marijuana to “keep accurate and complete records that include: ... Evidence of informed consent. In obtaining informed consent, the physician shall advise the patient about the lack of scientific consensus for the medical use of marijuana, its sedative properties and the risks for addiction.”

N.J.A.C. 8:64-2.5(a)9 is also consistent with N.J.S.A. 24:6I-5, which requires physicians to explain to the parents of a minor child for whom a physician is recommending medicinal marijuana the potential risks and benefits thereof and to document this explanation in the minor patient’s medical record.

Petitioner asserts that the statement to which N.J.A.C. 8:64-2.5(a)9i requires physicians to certify is inconsistent with the Legislative findings and declarations at N.J.S.A. 24:6I-2. The Department disagrees. As the required certification states, “a lack of scientific consensus concerning the use of medicinal marijuana” exists, particularly with respect to matters such as dosages, frequency of dosages, delivery routes and methods, the most suitable strains for the treatment of specific conditions, and which cannabinoid compounds affect which areas of the body. As this is an accurate statement, it is appropriate that physicians tell this to their patients, as part of physicians’ general responsibility in recommending any treatment to enable patients to make informed decisions and give informed consent.

Furthermore, it is important for the safety of patients, and the public generally, that physicians warn patients of marijuana's known sedative properties to make patients aware of potential dangers associated with operating machinery, or engaging in other activities that require alertness, following marijuana use. See, for example, Salomonsen-Sautel, Stacy et al., "Trends in fatal motor vehicle crashes before and after marijuana commercialization in Colorado," Drug and Alcohol Dependence, 2014 July 1;140:137-44, doi: 10.1016/j.drugalcdep.2014.04.008, Epub 2014 April 23, erratum in: Drug and Alcohol Dependence, 2014 September 1;142:360; available at <http://www.ncbi.nlm.nih.gov/pubmed/24831752>, in which researchers examined data from the National Highway Traffic Safety Administration's Fatality Analysis Reporting System for the period from 1994 to 2011, and observed an increase in the number of marijuana-positive drivers involved in fatal motor vehicle crashes in Colorado since the commercialization of medical marijuana in the middle of 2009. See also, "The prevalence of cannabis-involved driving in California," Drug and Alcohol Dependence, 2012 June 1; 123 (1-3):105-9. doi: 10.1016/j.drugalcdep.2011.10.023, Epub 2011 November 17; available at <http://www.ncbi.nlm.nih.gov/pubmed/22101027> (confirming findings that cannabis users do not perceive cannabis to impair driving ability and finding that drivers with medical cannabis permits were considerably more likely than were nonpermit holders to test positive for Delta-9-tetrahydrocannabinol (THC) (the active ingredient in cannabis), which has been shown to affect areas of the brain that control the body's movement, balance, coordination, sensations, and judgment rates, and the presence of which in blood has been associated with an increased risk for crash compared to drug-free controls).

In sum, it is important that patients are fully informed of the unknown and scientifically known potential side effects, just as with any other medication they may use or treatment they may undergo.

Based on the foregoing, the Department will take no action in response to petitioner's request that it delete N.J.A.C. 8:64-2.5(a)9 and particularly N.J.A.C. 8:64-2.5(a)9i.

REQUEST 7. The petitioner requests that the Department add post-traumatic stress disorder (PTSD) to the list of debilitating medical conditions.

RESPONSE: The Department will take no action on the petitioner's request that the Department add PTSD to the definition of "debilitating medical conditions" at N.J.A.C. 8:64-1.2, because the request does not comply with N.J.A.C. 8:64-5.1. N.J.A.C. 8:64-5.1 establishes the procedure by which the Department will accept petitions to add conditions to the definition of debilitating medical conditions.

Based on the foregoing, the Department will take no action on the petitioner's request that the Department add PTSD to the definition of "debilitating medical conditions" at N.J.A.C. 8:64-1.2.

REQUEST 8. The petitioner requests that the Department eliminate "the requirement in N.J.A.C. 8:64-[2.5(b)] for parents to seek the approval of three licensed physicians in order to obtain medical marijuana for their child."

RESPONSE: The petitioner overstates the regulatory burden. N.J.A.C. 8:64-2.5(b) requires written confirmation from a psychiatrist as to the therapeutic or palliative benefit of medicinal marijuana use to the child, in addition to a certification pursuant to N.J.A.C. 8:64-2.5(a) from a child's treating physician. Only if the treating physician is

not “trained in the care of pediatric patients” does N.J.A.C. 8:64-2.5(b) require written confirmation as to the therapeutic or palliative benefit of medicinal marijuana use to the child from an additional physician who is trained in the care of pediatric patients. The additional physician need not be a pediatric psychiatrist, as the commenter erroneously suggests.

Moreover, the available scientific research continues to indicate that marijuana use can have a particularly deleterious effect on minors’ developing brains, and that the earlier use begins, the greater, and potentially more irreversible, the harm. See, for example, Volkow; Lisdahl, K. et al., “Dare to delay? The impacts of adolescent alcohol and marijuana use onset on cognition, brains structure and function,” Frontiers in Psychiatry, 2013 July 1; 4:53. doi: 10.3389/fpsy.2013.00053. eCollection 2013, available at <http://www.ncbi.nlm.nih.gov/pubmed/23847550> (finding that adolescents and emerging adults who use marijuana regularly “tend to show inferior cognitive skills compared to teens that abstain or use lightly” or compared to individuals who begin use in adulthood, and that heavy use among adolescents may disrupt brain function, especially psychomotor speed, executive functioning, emotional control and learning and memory, which persists even after periods of abstinence); and Meier, M., et al. (August 27, 2012) “Persistent cannabis users show neuropsychological decline from childhood to midlife,” Proceedings of the National Academy of Sciences, U.S.A. 109, E2657-E2664.10.1073/pnas.1206820109, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3479587/> (finding an association between adolescent-onset cannabis use and decline in intelligence quotient).

Therefore, because of the particular impact of marijuana use on minor's brains and psychosocial development, it is a reasonable exercise of the Department's rulemaking authority to require recommending physicians to coordinate a minor's care with a psychiatrist and thus add the additional safeguard of psychiatric review as a condition of registering a minor as a qualifying patient. The Department anticipates that a psychiatrist, in consultation with a minor's treating physician, will evaluate and weigh the potential harm against the potential benefit to a particular child, taking into consideration the severity of the minor's underlying condition and prognosis for recovery. An ancillary benefit of this consultation may be to assist parents in understanding how best to monitor the use of medicinal marijuana by their children.

Based on the foregoing, the Department will take no action on the petitioner's request that the Department delete N.J.A.C. 8:64-2.5(b).