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Devon L. Graf, Director  
Office of Legal & Regulatory Compliance  
Office of the Commissioner  
New Jersey Department of Health & Senior Services  
P.O. Box 360  
Trenton, NJ 08625-0360  
*Via Hand Delivery*

**Re: PRN 2011-054; Medicinal Marijuana Program Rules, Re-Proposed New Rules: N.J.A.C. 8:64; 43 N.J.R. 340 (Feb. 22, 2011)**

**Dear Director Graf:**

The Medical Society of New Jersey (MSNJ) appreciates the opportunity to comment on the New Jersey Department of Health & Senior Services' (the Department's) re-proposed rules governing the medicinal marijuana program. MSNJ represents approximately 8,000 physicians in the state of New Jersey and was active in the development of the originally proposed regulations to establish a *medical model* for the compassionate use of medical marijuana under limited circumstances.

We commented on the originally proposed rules by letter dated January 13, 2011. We support the Department's program, but continue to have a concern expressed in those comments. In fact, the re-proposed rules require us to reiterate one of our primary concerns.

**Debilitating Medical Conditions:**

MSNJ believes that medicinal marijuana should only be available to patients with the specified debilitating conditions and findings, memorialized in a physician certification, that the patient's diagnosis is a debilitating medical condition specified by statute **and that the patient has not responded to conventional medical treatment as defined by evidence-based algorithms of care and may benefit from the use of medicinal marijuana.** (See originally proposed N.J.A.C. 8:64-2.5 at 42 N.J.R. 2676 requiring such a finding memorialized in a certification from a physician in a *bona fide* relationship with the patient.) In other words, the use of medicinal marijuana should be a treatment modality of last resort. Significantly, the re-proposed rules do not require such a finding or that it be memorialized in the physician certification. (Compare N.J.A.C. 8:64-2.5 at 42 N.J.R. 2676, to N.J.A.C. 8:64-2.5 at 43 N.J.R. 348.)

MSNJ did not take a position on the enabling legislation because our official policy calls for more research on the efficacy of smoked marijuana through the National Cancer Institute and other academic and research institutions. We continue to have concerns about the lack of scientifically based dosage guidance and efficacy studies. This is one reason that we believe that there should be a medical finding that the patient has not responded to conventional medical treatment. It is simply clinically appropriate to first try tested medications with proven efficacy before resorting to treatments that lack scientifically based dosage guidance and efficacy studies.

It is noteworthy that the law, as originally passed, required that seizure disorder, including epilepsy, intractable skeletal muscular spasticity, or glaucoma, be **resistant** to conventional medical therapy to be classified as a “debilitating medical condition” and, therefore, appropriate conditions for treatment under the medicinal marijuana program. C.24:61-3. Both sets of rulemaking expanded upon the specified conditions to allow either resistance to **or intolerance** to conventional medical therapy. MSNJ believes that “intolerance to conventional medical therapy” should not be merely subjective, but rather must be critically evaluated by the *bona fide* treating physician as to whether, for example, it is merely temporal in nature or a typical short-term side-effect.

The re-proposed rules, like the originally proposed ones, require at least two annual reports before the review panel may consider and approve additional debilitating medical conditions. We supported this hiatus and the establishment of a review panel, comprised primarily of physicians, to allow time for the Department to evaluate the strengths and weaknesses of the program. We appreciate that the Department has maintained both of these requirements in the re-proposal.

#### **Nomenclature:**

MSNJ suggests that the Department reconsider the nomenclature used for the “Medical Advisory Board” and the “Review Panel.” The “Medical Advisory Board” is proposed to be comprised of five members, three of whom are licensed healthcare professionals one of whom shall be a physician. The Medical Advisory Board is charged with advising the alternative treatment centers (ATCs) (by definition, the ATC includes the permitted ATCs, plant cultivation & dispensaries) on all aspects of the business.

The “Review Panel” is composed of not more than 15 healthcare professionals and the majority of its members must be physicians. MSNJ supported the majority physician composition of the Review Panel. The Review Panel is specifically responsible for vetting additional qualifying debilitating medical conditions. To avoid confusion in the general public and the regulated community the Department should consider whether the nomenclature for these two entities is correct. We believe that the work of the Review Panel will be **primarily medical** in nature whereas the Medical Advisory Board is charged with advising on more **general business** issues.

**Criminal Enforcement:**

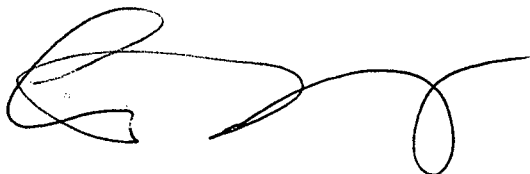
While the State's proposed rules grant immunity from prosecution for those involved in New Jersey's medicinal marijuana program, there is no corollary immunity from federal prosecution. Indeed, the Federal Government has recently enforced against individuals, including at least one physician, in states that also have medicinal marijuana programs. We note that the Department of Justice (DOJ) has specifically reserved the right to enforce against individuals who use a state's medicinal marijuana program as a shield to conduct unlawful activity.

We are confident that the Department and the Governor's law enforcement staff carefully crafted a medicinal program that would pass muster under the DOJ guidelines on enforcement. To ensure the continuing integrity of the medicinal marijuana program, and to protect patients and physicians who may become involved in the program as a modality treatment of last resort, we urge the Department to continue to test both the program design and implementation against the DOJ enforcement guidelines.

**Support for a Medical Model:**

We will continue to support the Department's efforts to implement a medical model for the compassionate use of marijuana. Please accept these comments in the spirit of ensuring that the program meets the statutory intent, maintains program integrity, and allows the compassionate use of marijuana for patients whose conditions meet all of the requirements of the program.

Respectfully submitted,



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General Counsel  
Medical Society of New Jersey