STATE OF RHODE ISLAND SUPERIOR COURT
PROVIDENCE, S.C.

RHODE ISLAND PATIENT ADVOCACY COALITION, INC; RHODE ISLAND ACADEMY OF PHYSICIAN ASSISTANTS, INC., and PETER NUNES, SR.,
Plaintiffs

v. **P.C. NO. 2012-**

MICHAEL FINE, MD, Individually and in his capacity as DIRECTOR OF THE RHODE ISLAND DEPARTMENT OF HEALTH, and THE RHODE ISLAND DEPARTMENT OF HEALTH,
Defendants

COMPLAINT

I. Introductory Statement

1. This is a civil action by two organizations, and an individual who was recently denied an application for registration as a Medical Marijuana Program participant, against the Director of the Rhode Island Department of Health, who administers the statutory program and denied Mr. Nunes' application among many other recent applications. The complaint alleges that for the past six years the defendant accepted written certifications from licensed Rhode Island Registered Nurse Practitioners and licensed Rhode Island Physician Assistants, as well as licensed Rhode Island physicians, and then abruptly altered its practice in the summer of 2012, denying applications or renewals certified by nurse practitioners and physician assistants. The complaint asserts that this significant and detrimental change

in policy was decreed with absolutely no notice and comment rule-making procedure under the Administrative Procedure Act and also that the new policy is substantively violative of the Edward O. Hawkins and Thomas C. Slater Medical Marijuana Act, Rhode Island General Laws Sections 21-28.6-1 et seq (hereafter "The Act"). The complaint seeks declaratory and injunctive relief, on both the procedural and substantive issues.

II. Jurisdiction

2. This Court has jurisdiction over the September 5, 2012, denial of the Peter Nunes application by the Department of Health pursuant to Rhode Island General Laws Section 42-35-15 of the Administrative Procedures Act (APA). This Court also has jurisdiction over the request for declaratory relief pursuant to Section 42-35-7 (declaratory judgment on validity or applicability of rules).

III. The Parties

3. Plaintiff Rhode Island Patient Advocacy Coalition, Inc. (RIPAC) is a nonprofit 501(c)(3) Rhode Island corporation composed of medical marijuana patients, caregivers, doctors, advocacy groups and others interested in medical marijuana. It promotes advocacy, education, research, and policy development regarding the implementation of the Act.
4. Plaintiff Rhode Island Academy of Physician Assistants (RIAPA) is a 501(c)(3) not for profit Rhode Island corporation whose mission is to provide the membership of the Academy with a forum for issues that relate

to the role of the physician assistant in Rhode Island. It organizes panels and forums concerning the delivery and quality of health care services.

5. Plaintiff Peter Nunes, Sr. (Nunes) is a 50 year old resident of Bristol, Rhode Island, with a history of acute and chronic neck and back pain, determined by the Social Security Administration Office of Disability Adjudication to be fully disabled after a career as a truck driver, with the back and neck pain exacerbated by a 2012 motor vehicle accident in which he was rear-ended at a red light. Nunes, currently taking prescription pain medication with negative side effects and also potentially addictive, applied for participation in the Rhode Island Medical Marijuana program and was denied on September 5, 2012, as more fully explained below.
6. Defendant Michael Fine, M.D. (the Director) is Director of the Rhode Island Department of Health (RIDOH) and in that capacity is charged with the administration of that agency's statutory duties.
7. Defendant Rhode Island Department of Health (RIDOH) is an "agency" as defined at Rhode Island General Laws Section 42-35-1(1)(APA). It is joined as a defendant pursuant to Section 42-35-7 on declaratory relief ("the agency shall be made a party to the action.").

IV. Factual Background

8. Plaintiffs incorporate paragraphs 1-7, supra.
9. In 2005, the Rhode Island General Assembly (hereafter "Legislature") first passed the Edward O. Hawkins and Thomas C. Slater Medical Marijuana Act, codified at Section 21-28.6-1 et seq.

10. The Legislature made the following findings, among a series of findings:

    Section 21-28.6-2 (1):

    Modern medical research has discovered beneficial uses for marijuana in treating or alleviating pain, nausea and other symptoms associated with certain debilitating medical conditions, as found by the National Academy of Sciences' Institute of Medicine in March 1999.

    Section 21-28.6-2(5):

    State law should make a distinction between the medical and nonmedical use of marijuana. Hence, the purpose of this chapter is to protect patients with debilitating medical conditions, and their physicians and primary caregivers, from arrest and prosecution, criminal and other penalties, and property forfeiture if such patients engage in the medical use of marijuana.

11. Of significance in this litigation, the definition given the term "practitioner" by the Legislature is the following:

    Section 21-28.6-3(8):

    "Practitioner" means a person who is licensed with authority to prescribe drugs pursuant to chapter 37 of title 5 or a physician licensed with authority to prescribe drugs in Massachusetts or Connecticut.

12. An applicant for medical marijuana must submit, among other things, a written certification that is signed by a practitioner and states the specified chronic or debilitating disease or medical condition that qualifies under the Act. Section 21-28.6-3(14).

13. The written certification is only to be made "in the course of a bona fide practitioner-patient relationship after the practitioner has completed a full assessment of the qualifying patient's medical history." Section 21-28.6-3(14).
14. Shortly after enacting the Act, the Legislature also passed what is known as the "global signature" act, Rhode Island General Laws Section 5-34-42, which states that whenever any general law requires the "signature, certification, stamp, verification, affidavit or endorsement by a physician," it "shall be deemed to include" the signature, etc., by a registered nurse practitioner. P.L. 2006, ch. 130, Sec. 1; P.L. 2006, ch. 156, Sec. 1.
15. In addition, at the same time, the Legislature amended the statute on physician assistants, Section 5-54-8(a), adding the same alternative signature language for physician assistants whenever any law or regulation requires a signature by a physician.
16. Registered nurse practitioners have "prescriptive privileges" pursuant to Rhode Island General Laws Section 5-34-39.
17. Physician assistants have "prescriptive privileges" pursuant to Rhode Island General Laws Section 5-54-8(c). Physicians, physician assistants, and registered nurse practitioners do not "prescribe" marijuana for medical purposes; rather they certify that a patient has a disease or illness that qualifies as a debilitating illness under the Act.

18. Beginning in 2006 and continuing for six years, DOH accepted certifications under the Medical Marijuana Act, signed by registered nurse practitioners or by physician assistants, in addition to those signed by physicians.
19. The official DOH application forms for participation in the program all included express authorization for both the Physician Assistant and Registered Nurse Practitioner, licensed in Rhode Island, to qualify as a "practitioner." See attached six pages of DOH forms, all of which were utilized by the agency until late summer of 2012. Exhibit A.
20. Many applicants, including Peter Nunes in June of 2012, submitted paperwork to DOH, on DOH forms, utilizing certifications signed by RNPs or PAs, and for a period of six years such applications were approved, assuming all other criteria were met.
21. Peter Nunes' application, submitted June 21, 2012, met all required criteria. It was signed by an RNP who had previously signed such certifications for other patients and had them accepted.
22. The Act, at Section 21-28-6.9 (b), states that if DOH fails to issue a registration card within thirty-five days of its submission, the registration "card shall be deemed granted."
23. DOH took no action on plaintiff Nunes' application following its June 21st submission. On September 5, 2012, DOH issued the attached denial notice, based solely on the fact that the application was signed by a "licensed nurse practitioner or licensed physician assistant."

24. The denial letter was issued seventy-six days after the submission of the Nunes application. See two-page denial, issued by DOH to Nunes on September 5, 2012, attached as Exhibit B.
25. DOH had already accepted and deposited the payment that Mr. Nunes had sent in with his application. The Department invited him to apply for a refund.
26. Mr. Nunes, like many medical marijuana applicants and patients, had difficulty finding the requisite "practitioner-patient relationship" with a physician and had such a relationship with his RNP. Just by way of example, veterans whose physicians work at the VA cannot obtain such certifications from a federally-employed physician due to differing policies on this subject between the state and federal governments.
27. Mr. Nunes cannot afford a clinic fee to try to start over and establish a practitioner-patient relationship with a new physician. Such a fee would not be covered by his medical insurance. Furthermore, establishing such a practitioner-patient relationship could take some time.
28. Plaintiff Nunes is currently taking prescription pain medication, which has negative side-effects. He would like to reduce or eliminate such medication by utilizing the potential benefits of the medical marijuana program. Plaintiff organizations suffer ongoing harm to themselves and their affiliated patients or members through denials of applications, disruptions of consistency for patients, uncertainties regarding permissible employment duties for each physician assistant and registered nurse practitioner, and the

prospect of arrest and detention and criminal prosecution of patients or applicants improperly denied their cards.

29. The DOH policy of expressly allowing RNPs and PAs to sign the certifications, which continued for six years, was a practice or procedure or statement of general applicability and therefore a "rule" under Section 42-35-1(8) of the APA.

30. The revised DOH policy of barring RNPs and PAs from signing the certifications is a practice or procedure or statement of general applicability and therefore a "rule" under Section 42-35-1(8) of the APA.

31. A registration card issued by DOH is a "license" within the meaning of Section 42-35-1(4).

32. The term "rule" under the APA includes the amendment of a prior rule. Section 42-35-1(8).

33. DOH engaged in absolutely no notice and comment procedures prior to the 2012 change in the rule. No compliance with Section 42-35-3 was even attempted, nor was Section 42-35-3.3 followed ("regulations affecting small business").

34. Director Fine had stated in writing that the "change" in the Department policy was "effective August 22, 2012". See letter of Dr. Michael D. Fine, August 22, 2012, attached at Exhibit C.

35. However, DOH applied the new policy to the Nunes application submitted on June 21, 2012.

36. The Legislature has not altered the definition of practitioner under the Act since it was first passed. In 2012, the Legislature revisited the Act with significant amendments regarding compassion centers. Yet it did not alter the definition of practitioner, despite six years of widespread use of RNP and PA certifications.

V. Legal Claims

Count 1
Administrative Procedure Act

37. Plaintiffs incorporate paragraphs 1-36, supra.

38. Defendants were required to follow the notice and comment rule-making procedures of the APA, Section 42-35-3 et seq., prior to simply announcing and implementing a rule-change.

39. Defendants failed to utilize any APA procedures and have acted contrary to law.

Count 2
Global Signature Statutes

40. Plaintiffs incorporate paragraphs 1-39, supra.

41. The Act's definition of practitioner, combined with Section 5-34-42 and Section 5-54-8(a) (global signature authority) make it clear that the Legislature intended the six-year practice of permitting certifications in Rhode Island by a physician or RNP or PA to be the correct practice by statute.

42. The Department's attempt to amend its rule in 2012 is an attempt to re-write the legislation.

43. The Department's new rule in 2012 is substantively contrary to the controlling statutes and is void.

Count 3
Retroactivity

44. Plaintiffs incorporate paragraphs 1-43, supra.

45. Defendant's practice of announcing an effective date of a new rule, of August 22, 2012, without notice and rule-making procedures, and then applying it retroactively to earlier applications, including the June 21, 2012, Nunes application, is violative of the APA, the Medical Marijuana Act, the Department's own procedures, and procedural due process protections guaranteed by the Rhode Island Constitution, Article I, Section 2.

Count 4
Due Process

46. Plaintiffs incorporate paragraphs 1-45, supra.

47. Both applicants and existing card-holders had a protected interest in the continuation of the eligibility of their PA or RPN to be able to certify under the medical marijuana program.

48. By altering the procedure and exposing patients, PAs and RPNs to inconvenience and in certain situations criminal liability, without any advance notice, comment period, or rule-making procedures, defendants have denied the plaintiffs their due process rights as guaranteed by the Rhode Island Constitution.

Count 5
Section 21-28.6-9
The 35-Day Rule

49. Plaintiffs incorporate paragraphs 1-48, supra.

50. Plaintiff Nunes and the organizational plaintiffs had justifiable reliance on the fact that an application shall be deemed granted if not acted upon within thirty-five days of its submission.

51. Defendants' failure to abide by this section of the Act, for example by denying the Nunes application seventy-six days after submission, violates the plaintiffs' rights guaranteed by Section 21-28.6-9(b).

Wherefore, plaintiffs request that this Court grant them:

a) Declaratory judgment that the defendants' actions and inactions are contrary to applicable law in each of the specific instances set forth in Counts 1-5, supra;

b) Preliminary and permanent injunctive relief requiring issuance of registration cards to plaintiff Nunes and others, as well as affiliated caregiver cards, whose applications are signed by an RPN or a PA, unless and until this Court approves an alternative result after adoption of a regulation following a notice and comment rule-making procedure which satisfies the APA, and which would then apply, if at all, to renewals and new applications;

c) Preliminary and permanent injunctive relief requiring issuance of registration cards to plaintiff Nunes and others, as well as affiliated caregiver cards, whose applications are signed by an RPN or a PA, unless and until the governing statute's definition of the term "practitioner" is amended or repealed by the Rhode Island Legislature, which amendments would then apply, if at all, to renewals and new applications;

d) Grant plaintiff Nunes and others affiliated with RIPAC registration cards pursuant to Section 21-28.6-9(b), due to the passage of 35 days from issuance of applications, wherever that subsection applies;

e) Grant costs and attorney's fees pursuant to the Equal Access to Justice Act;

f) Grant such other relief as the Court deems necessary or appropriate.

Respectfully submitted by:
Plaintiffs
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RHODE ISLAND ACADEMY OF PHYSICIAN ASSISTANTS, INC.,
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