

Report & Recommendations to the New Mexico Secretary of Health

From the Medical Advisory Board to the Medical Cannabis Program

From a Public Hearing on Friday 30 October 2015 at the Harold Runnels Building Auditorium, 1190 St. Francis Drive, Santa Fe NM

Report prepared by Steven Jenison, M.D., Chair, for the Medical Advisory Board.

A public hearing of the Medical Advisory Board to the New Mexico Medical Cannabis Program was held in the Harold Runnels Building Auditorium at 1190 St. Francis Drive in Santa Fe NM from 10:00 AM to 12:00 PM on Friday 30 October 2015.

A. Introductory Comments, Introduction of Board Members, Approval of Agenda

Dr. Steven Jenison, Chair, called the meeting to order at 10:05 AM.

Board members present:

1. Laura Brown, MD, Family Medicine
2. Rachel Goodman, MD, Obstetrics/Gynecology
3. Steven Jenison, MD, Infectious Diseases (Chair)
4. William Johnson, M.D., Psychiatry
5. Jeffrey Nelson, MD, Neurology
6. Bélyn Schwartz, MD, Physical Medicine & Rehabilitation
7. Mitchell Simson, MD, Internal Medicine

Member excused:

1. Timothy Lopez, MD, Oncology

Dr. Jenison welcomed the new member of the Medical Advisory Board, Dr. Rachel Goodman, who was appointed recently to the Board by Secretary Ward upon nomination by the New Mexico Medical Society. Dr. Goodman is an Obstetrician / Gynecologist who practices in Española.

Present representing the Department of Health:

1. Kenneth Groggel, Director, Medical Cannabis Program
2. Andrea Sundberg, Program Coordinator, Medical Cannabis Program
3. Chris Woodward, JD, Office of General Counsel

Not present from the Department of Health:

1. Dr. Steven Rosenberg, Medical Director, Medical Cannabis Program
2. Dr. Maureen Small, Medical Director, Medical Cannabis Program

The Public Hearing Agenda was reviewed and approved.

B. Actions of the Secretary of Health on the Recommendations of the Medical Advisory Board from the Public Hearing on 1 May 2015

The last public hearing of the Medical Advisory Board was held on 1 May 2015. At that hearing, Dr. William Johnson, Member of the Medical Advisory Board, introduced a proposal to expand the eligible condition of "hospice care" to include "palliative care". The Board voted 6 to 0 (in favor: Brown, Jenison, Johnson, Lopez, Nelson, Schwartz) to recommend this change to the Secretary.

On 6 July 2015, Health Secretary Retta Ward issued a Final Decision regarding the Advisory Board Report and Recommendations:

*"The Medical Cannabis Advisory Board recommended that the treatment "palliative care" be added to the list of qualifying medical conditions and treatments approved for enrollment in the program. **I am not adopting this recommendation.**"*

Secretary Ward's Final Decision is attached to this report.

In addition, Secretary Ward acknowledged the recommendations of the Medical Advisory Board regarding proposed changes to the Rule governing the Patient Registry (7.34.3 NMAC) that would 1) remove the requirement that a certifying clinician attest that standard treatments had been tried and failed; 2) the requirement for subspecialist certification for severe chronic pain and inflammatory arthritis; and, 3) the requirement that the application for enrollment under post-traumatic stress disorder (PTSD) include a diagnosis by a psychiatrist, psychiatric nurse practitioner or prescribing psychologist.

From Secretary Ward's Final Decision:

"All of these requests relate to recent litigation involving a challenge to the Department's medical cannabis patient rule. Based on that litigation, the Department will be removing the 'standard treatments' attestation requirement, and the specialist certification and/or diagnosis requirements concerning Department-approved conditions. The Department has already implemented these changes to its practice and modified medical cannabis program application forms accordingly; and the Department intends to formally adopt the changes in Department rule when next the medical cannabis rules are amended."

The Medical Cannabis Program has submitted to the Medical Advisory Board a draft of proposed rule changes in anticipation of this public hearing. The Medical Advisory

Board considered those proposed rule changes and voted to approve them, as discussed later in this report.

C. Medical Cannabis Program Update

Mr. Kenneth Groggel, Director of the Medical Cannabis Program, presented an update of the status of the Medical Cannabis Program. The report is included as an attachment.

At the time of the public hearing, there were 18,628 patients actively enrolled in the Medical Cannabis Program. In the month of October 2015, 1242 new patients were enrolled and 1060 patients were re-enrolled. Mr. Groggel suggested that the increased rate of enrollment during the months since the last public hearing in May 2015 may be due to the changes in enrollment policies described above.

Secretary Ward recently approved 12 applications for new non-profit medical cannabis producer licenses.

D. Hearing of the Petition to Add New Conditions to the List of Diagnoses Eligible for Enrollment in the Medical Cannabis Program

A Petition was received from a member of the public to add "Attention Deficit Hyperactivity Disorder / Attention Deficit Disorder" (ADHD/ADD) to the list of conditions eligible for enrollment in the New Mexico Medical Cannabis Program. The petition is attached to this report.

The Petitioner was present at the public hearing and was offered the opportunity to present the petition either in public session or in executive session. The Petitioner declined to provide oral testimony and indicated that the written petition would suffice. The subject matter of the Petition appeared in the Public Notice of the Medical Advisory Board public hearing that was

published in the Albuquerque Journal on 27 September 2015. The Notice included information on the procedure for submitting written testimony and requesting the opportunity to present oral technical testimony. No submissions were received by the Department prior to the deadline for submitting technical evidence.

The Medical Advisory Board conducted a medical literature search in anticipation of the public hearing and reviewed the following articles that related to ADHD/ADD and cannabis:

- 1) Aharonovich E et al., Concurrent cannabis use during treatment for comorbid ADHD and cocaine dependence: effects on outcome. *American Journal of Drug & Alcohol Abuse* **32** (4) 629 - 635, 2006.
- 2) Bidwell LC et al., Childhood and current ADHD symptom dimensions are associated with more severe cannabis outcomes in college students. *Drug & Alcohol Dependency* **135**: 88 – 94, 2014.
- 3) Hadland SE et al., Medical marijuana: review of the science and implications for developmental-behavioral pediatric practice. *Journal of Developmental & Behavioral Pediatrics* **36** (2): 115 – 123, 2015.
- 4) Kollins SH et al., An exploratory study of the combined effects of orally administered methylphenidate and delta-9-tetrahydrocannabinol (THC) on cardiovascular function, subjective effects, and performance in healthy adults. *Journal of Substance Abuse Treatment* **48**: 96 – 103, 2015.
- 5) Loflin M et al., Subtypes of attention deficit-hyperactivity disorder (ADHD) and cannabis use. *Substance Use & Misuse* **49**: 427 – 434, 2014.

- 6) Marwaha S et al., Adult attention deficit hyperactivity symptoms and psychosis: epidemiological evidence from a population survey in England. *Psychiatry Research* **229**: 49 – 56, 2015.
- 7) Newman E et al., Go/NoGo task performance predicts cortical thickness in the caudal inferior frontal gyrus in young adults with and without ADHD. *Brain Imaging & Behavior* doi: 10.1007/s11682-015-9453-x, 24 September 2015.
- 8) Rasmussen J et al., ADHD and cannabis use in young adults examined using fMRI of a Go/NoGo task. *Brain Imaging & Behavior* doi: 10.1007/s11682-015-9438-9, 21 October 2015.
- 9) Roberts W et al., Identifying the facets of impulsivity that explain the relation between ADHD symptoms and substance use in a nonclinical sample. *Addictive Behaviors* **39**: 1272 – 1277, 2014.
- 10) Strohbeck-Kuehner P et al., Cannabis improves symptoms of ADHD. *Cannabinoids* **3** (1): 1 – 3, 2008.

Dr. Johnson reviewed the clinical aspects of ADHD/ADD and his experience as a Child & Adolescent Psychiatrist with patients with the diagnosis, including his experience with ADHD patients who use cannabis. He discussed the literature cited above, pointing out that it was mostly descriptive in defining the associations between ADHD/ADD and cannabis use and the neurophysiological basis for the role of cannabinoid receptors in the brain in ADHD/ADD. There are data that suggest that patients with ADHD self-medicate with cannabis mainly to alleviate the symptoms of impulsivity associated with ADHD. Aside from one or a few case reports, there is no clinical data regarding the therapeutic effects of, or adverse events associated

with, medical cannabis in the treatment of ADHD/ADD. Dr. Johnson noted concerns regarding a study that suggested that adolescent use of cannabis was associated with IQ declines (Meier MH et al., Persistent cannabis users show neuropsychological decline from childhood to midlife. *PNAS* **109**: E2657 – E2664, 2012), although the findings of this study have been disputed. There are also persistent concerns about the possible association between adolescent cannabis use and earlier onset of psychosis, although this also remains highly controversial. Because most ADHD patients are children and adolescents, these concerns are relevant.

Dr. Brown suggested that in future consideration might be given to inclusion of the diagnosis of ADD in adults in order to avoid the concerns associated with child and adolescent use of cannabis.

Dr. Jenison pointed out that it is difficult to draw conclusions about the potential role of medical cannabis in the treatment of any condition based upon studies that examine cannabis use in the context of self-medication or illicit substance use. He noted that the only condition that is currently eligible for enrollment in the New Mexico Medical Cannabis Program that is likely to enroll a significant number of children is epilepsy, where the use of cannabidiol preparations have resulted in improvements in mental functioning by decreasing seizure activity.

Motion: Dr. William Johnson moved that the Medical Advisory Board recommend to the Secretary of Health that Attention Deficit Hyperactivity Disorder / Attention Deficit Disorder should NOT be added to the list of conditions eligible for enrollment in the New Mexico Medical Cannabis Program.

Voting in favor of the Motion: Brown, Goodman, Jenison, Johnson, Nelson, Simson, Schwartz

Voting against the Motion: none

Board Action: By a vote of 7 to 0, the Medical Advisory Board recommends that the Secretary of Health should deny the Petition and not add ADHD/ ADD to the list of conditions eligible for enrollment in the Medical Cannabis Program.

E. Recommendations for Changes to Rules Governing the Patient Registry (7.34.3 NMAC)

Pursuant to an Order of state District Court Judge David Thomson in the case of Carola Kieve, M.D. vs. New Mexico Department of Health and Medical Cannabis Advisory Board on 29 April 2015, the Department of Health changed certain policies regarding requirements for patient enrollment in the Medical Cannabis Program. The Medical Advisory Board has statutory responsibility to make recommendations to the Secretary of Health regarding rules governing the Patient Registry. In anticipation of this public hearing, the Department of Health drafted changes to the rule governing the Patient Registry, 7.34.3 NMAC, for consideration by the Medical Advisory Board. Those proposed rule changes are attached to this report.

In summary, the proposed rule changes would:

- Remove the requirement that a certifying clinician attest that standard treatments have been tried and have failed to provide adequate relief.
- Remove the requirement for a certification by a clinician with subspecialty credentials in pain management or a specialist with expertise in the disease process causing the pain for patients applying under the condition of severe chronic pain
- Remove the requirement for a certification by a board-certified

rheumatologist for patients applying under the condition of inflammatory arthritis

- Remove the requirement that the application of a patient applying under the condition of post-traumatic stress disorder (PTSD) must include a diagnosis by a psychiatrist, psychiatric nurse practitioner or prescribing psychologist.

The proposed rule changes also specify the information provided to the Department for Personal Production Licenses will be kept confidential.

Other rule changes governing non-profit cannabis producers were included in the draft but were not considered by the Medical Advisory Board because they are not within our purview.

Motion: Dr. Mitch Simson moved that the Medical Advisory Board recommend to the Secretary of Health changes in the rules governing the Patient Registry (7.34.3. NMAC) as submitted by the Medical Cannabis Program to the Medical Advisory Board for our consideration.

Voting in favor of the Motion: Brown, Goodman, Jenison, Johnson, Nelson, Simson, Schwartz

Voting against the Motion: none

Board Action: By a vote of 7 to 0, the Medical Advisory Board recommends that Secretary Ward propose rule changes governing the Patient Registry (7.34.3 NMAC) according to the draft developed by the Medical Cannabis Program.

The proposed rule changes must still be submitted for public hearing. The Department is currently unsure of the timeframe for those hearings.

F. Clarifying the Administrative Review Committee procedure (7.34.3.12 NMAC) versus the Appeal Process procedure (7.34.3.16 NMAC)

Dr. Jenison asked that Mr. Woodward and Program clarify the respective roles of the Administrative Review Committee process as defined in 7.34.3.12 NMAC and the Disciplinary Actions and Appeal process as defined in 7.34.3.16 NMAC.

Mr. Woodward stated that the Administrative Review Committee process was intended to review initial application denials and was not intended to have a role in summary suspensions (as currently stated in 7.34.3 NMAC). The Disciplinary Actions and Appeal Process was intended to hear and make decisions with regard to summary suspensions and revocations of patient enrollments.

Mr. Woodward agreed to examine the language in 7.34.3 NMAC and draft changes that more clearly differentiate the respective roles of these processes, and define what recourse is available to a potential enrollees who disagree with the decision of the Administrative Review Committee, in anticipation of upcoming promulgation of new rules.

G. Public Comment

Comments were taken from members of the public.

H. Adjournment & Next Public Hearing

The public hearing was adjourned at 12:00 PM. The next public hearing is tentatively scheduled for Friday 29 April 2016.

I. Attachments

1. Secretary of Health's "Final Decision Regarding Advisory Board Report and Recommendations of May 1, 2015", dated 7 July 2015.
2. Medical Cannabis Program Update report
3. Medical journal articles cited in the Medical Advisory Board's consideration of the Petition to add ADHD/ADD to the list of eligible conditions
4. Draft of Medical Cannabis Program rule changes submitted to the Medical Advisory Board by the Medical Cannabis Program for its consideration and recommendations