

Board of Medicine and Osteopathic Medicine's Joint Committee on Medical Marijuana Meeting

July 14, 2017

MEETING MINUTES

Meet-Me Number: 1-888-670-3525 Participation Code: 125 528 7056

Roll Call 10:09 am

Members Present:

Steven P. Rosenberg, MD
Zachariah P. Zachariah, MD
Nicholas Romanello, Esquire, Consumer Member
Joel Rose, DO
Sandra Schwemmer, DO
Michelle Mendez, DO

Staff Present:

Others Present:

Members Absent:

Seela Ramesh, MD

Claudia Kemp, JD, Executive Director American Court Reporting Edward Tellechea, Esq., Board Counsel Suzette Bragg

Donna McNulty, Esq., Board Counsel 421 Old Magnolia Road Nancy Murphy, Certified Paralegal Crawfordville, Florida, 32327

Crystal Sanford, CPM, Program Operations Administrator

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Brad Dalton, Public Information Officer

Ms. Kemp called the meeting to order. She advised the Committee would be working on specific provisions of SB8-A passed during the 2017 Special Legislative Session and related to the medical use of marijuana. She explained the Committee would not be taking final action at this meeting and another meeting has been set up on August 3, 2017 at the Board of Medicine Meeting at which time the Committee will take public comments. The Committee will then make recommendations to the respective Boards to approve.

Ms. Kemp stated SB8-A was approved by the Governor on June 23, 2017 and grants the Boards authority to begin emergency rulemaking to implement section 381.986, Florida Statutes. Ms. Kemp further stated the law requires qualified physicians to:

- Obtain the voluntary and informed written consent of each patient for medical use of marijuana (this is one of several requirements that must be met for qualified physicians to issue a physician certification).
- Qualified physicians must obtain this written consent each time they issue a physician certification for a patient.
- They must use a standardized consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine.

She said the committee was tasked with developing a consent form so the law could be implemented and qualified physicians could begin complying with the requirements for issuing a physician certification to a qualified patient.

Ms. Kemp advised the Committee the first order of business was to elect a Chair and Vice Chair.

A motion was made, seconded and carried unanimously to elect Dr. Rosenberg as a temporary Chair until the August 3, 2017 meeting.

A motion was made, seconded and carried unanimously to table electing the Vice Chair until the August 3, 2017 meeting.

Ms. Kemp introduced the draft consent form provided in the agenda materials.

A motion was made, seconded and carried unanimously to use the draft consent form as a starting point then each paragraph will be discussed.

Dr. Mendez requested clarification about the emergency rulemaking process.

Mr. Tellechea explained the Committee would review and approve the proposed consent form and disciplinary guidelines. He said the Committee will meet again on August 3, 2017 at the Board of Medicine Meeting to take public comment, then the recommendation of the Committee goes to both Boards for approval. He said once both Boards have approved the consent form and disciplinary guidelines, the emergency rule can be adopted.

- Dr. Mendez asked when the Legislature has asked the rule be in place.
- Mr. Tellechea, the Boards need to initiate rulemaking by January 1, 2018.
- Mr. Romanello joined the call.

Review of the Consent Agreement:

Lucy Gee, Director of Medical Quality Assurance asked to address the Committee regarding the patient identification card. She said in a meeting with the Legislators, they pointed out a concern about a patient's care giver carrying the identification card. She said they asked the Committee to consider adding a care giver.

- Dr. Rosenberg said that was reasonable to add.
- Dr. Mendez clarified it should be qualified care giver.
- Mr. Tellechea read language from the law about the qualified caregiver:

Caregiver must be in immediate possession of his or her medical marijuana use registry identification card at all times when in possession of marijuana or a marijuana delivery device and must present his or her medical marijuana use registry identification card upon the request of a law enforcement officer.

Paragraph A

Dr. Mendez stated she had issues with the term "in public".

Dr. Rosenberg agreed and language is needed to include transportation from dispensary to the patient's home.

Dr. Mendez suggested removing "in public" and changing it to "in possession of".

Dr. Schwemmer agreed.

Dr. Rosenberg stated that change was reasonable.

A motion was made, seconded and carried unanimously to approved paragraph A of the consent form as amended.

The patient or caregiver must have in his or her possession at all times his or her medical marijuana user identification card.

Paragraph B

Dr. Rosenberg stated he approved the language but wanted "ie" and everything in the parenthesis be removed.

When under the influence and/or possession of marijuana, the patient or caregiver must have in his or her possession at all times his or her medical marijuana user identification card.

A motion was made, seconded and carried unanimously to remove everything in parenthesis from paragraph B.

Paragraph C

Ms. Kemp advised the Legislators had issues with the language in this paragraph, "current state of research". She explained the language includes comparable conditions or in the same class. She said it was not specific.

Mr. Tellechea said a list of conditions could be in the rule, but would require the Boards to update the rule every time new conditions needs to be added. He said this is a problematic area of the rule and suggested leaving the language generic.

Dr. Rosenberg suggested removing the work "current".

Ms. Kemp reminded the Committee, the term "current" was in law.

Mr. Tellechea stated this is practical from the Board's standpoint but not for the practicing physician.

Dr. Mendez agreed and suggested using "evidence based research".

Mr. Tellechea asked the members if they currently had to include current research with any of their consent forms.

The members denied attaching current research to their consent forms.

Mr. Tellechea said the Board is being asked to put something in rule that is not normally included in a rule.

Ms. Kemp read suggested language to the Committee to consider.

Dr. Mendez asked if the physician will know what research is the correct research.

Dr. Rosenberg asked if an emergency rule could be challenged.
Mr. Tellechea confirmed the emergency rule could be challenged.
Dr. Rosenberg stated he liked Ms. Kemp's suggested language.
Ms. McNulty asked if it would be appropriate to use the NSA Report in the rule.
Dr. Schwemmer suggested "Dr has provided me with information on research ".
Dr. Rosenberg said he wanted to avoid determining what information is accurate and current.
Dr. Rose suggested removing "current research" and replacing it with the language being discussed.
Dr. Rosenberg said this language is a good starting point and suggested removing "current" and replacing it with Dr. Schwemmer's suggested language. He suggested adding "for the use of medical marijuana for my qualified condition".
Dr. Rose suggested removing the first sentence of this paragraph.
Ms. Kemp said Ms. Gee's suggested language is removing the first sentence and replacing it with, "The efficacy of marijuana is not fully understood. The doctor has provided me with information on research on the use of medical marijuana for my qualified condition."
A motion was made, seconded and carried unanimously to approved the language as amended.
The efficacy of marijuana is not fully understood. The doctor has provided me with information on research on the use of medical marijuana for my qualified condition.
Paragraph D Dr. Rose said the language "I will contact my doctor" several times and asked if it could just be said once at the end.
Mr. Romanello stated from a risk standpoint, it would be better to have the patient acknowledge each paragraph individually.
Dr. Schwemmer suggested the patient call an addiction treatment facility.
Dr. Mendez said the consent form is a contract between the physician and the patient and wanted to add language, "ordering physician Dr".
Ms. Kemp suggested using Dr. with a blank behind it so the patient and doctor can fill in the appropriate person to be called.
Dr. Schwemmer, building on Ms. Kemp's suggested language, said "I will contact my ordering physician."
Ms. Kemp says this may imply it is the same person and said that is why she suggested adding a place to fill in the physician's name. Dr. Mendez suggested it read "contact ordering physician, name of physician."

Ms. Kemp reminded the members the form is a consent between a qualifying physician and a qualifying patient.

Mr. Romanello suggested leaving the physician's name blank because the ordering physician may want the patient to contact another specialist.

Dr. Rosenberg said the physician that ordered the medical marijuana should be notified there is an addiction and he/she should make the referral.

Mr. Romanello said the law uses the term "ordering physician".

Mr. Tellechea said his staff would draft the appropriate language.

Dr. Rosenberg suggested the language read, "I should contact Dr. _____certifying physician."

A motion was made, seconded and carried unanimously to approve the amended language.

Individuals may develop a tolerance to, dependency, and/or addiction to, marijuana. I
understand that if I require increasingly higher doses to achieve the same benefit or if I think
that I may be developing a dependency on marijuana, I should contact Dr.
(name of ordering physician).

Paragraph E

Dr. Schwemmer suggested removing "heavy machinery".

Ms. McNulty pointed out the law uses that term.

Dr. Rosenberg suggested using different language than "heavy machinery" such as "I should not participate in activities which could be a danger to myself or others while using medical marijuana."

Dr. Mendez liked Dr. Rosenberg's suggested language.

Dr. Schwemmer liked the suggested language and stated there are all kinds of tools that people could injure themselves on and they cannot all be listed in the rule.

Ms. McNulty suggested adding "medical" wherever "marijuana" is written to be consistent.

A motion was made, seconded and carried with one opposed to approve the language as amended.

The potential side effects of medical marijuana use.

The potential effect that medical marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly. I should not participate in activities which could be dangerous to myself or other while using medical marijuana.

Paragraph F

A motion was made to approve the language as written. There was no second to the motion.

Dr. Mendez disagreed and said there are other conditions that have impact and should be included in the rule, such as sex hormones.

- Dr. Rose agreed.
- Mr. Romanello said he would defer to the physicians on the Committee.
- Dr. Mendez suggested using "production" instead of "levels".
- Mr. Tellechea asked if patients will understand it is not a good thing that medical marijuana could affect a patient's production of hormones.
- Ms. Kemp suggested adding "but not limited to" and leave out the other hormones.
- Dr. Rose suggested changing it to read "could affect the production of hormones that could lead to adverse effects".
- Ms. Kemp suggested adding that language by "immune system" in the language.
- Dr. Rosenberg agreed it should be moved up in the paragraph.
- Dr. Schwemmer said she liked the term "sex hormones".
- Dr. Mendez said she believes using "sex hormones" would leave the discussion open so the patient and physician can discuss the matter further.
- Dr. Rose liked the second paragraph under section f, but suggested changing it to say "while consuming alcohol, it is not recommended."

A motion was made, seconded and carried unanimously to approve the language as amended during discussion.

Potential side effects from the use of marijuana include, but are not limited to, the following: dizziness, anxiety, confusion, sedation, low blood pressure, impairment of short term memory, euphoria, difficulty in completing complex tasks, suppression of the body's immune system, may affect the production of sex hormones that lead to adverse effects, inability to concentrate, impaired motor skills, paranoia, psychotic symptoms, general apathy, depression and/or restlessness. Medical Marijuana may exacerbate schizophrenia in persons predisposed to that disorder. In addition, the use of marijuana may cause me to talk or eat in excess, alter my perception of time and space and impair my judgment. Many medical authorities claim that use of medical marijuana, especially by persons younger than 25, can result in long-term problems with attention, memory, learning, a tendency to drug abuse, and schizophrenia.

_____ I understand that using marijuana while consuming alcohol is not recommended.

Additional side effects may become present when using both alcohol and medical marijuana.

Paragraph G

Ms. Kemp said the language in the first sentence is elsewhere in the rule.

- Dr. Rosenberg suggested deleting the first paragraph.
- Dr. Rose pointed to the paragraph that says there are 587 drugs that are known to interact with cannabis. He suggested using the term "hundreds" instead of 587.
- Dr. Rosenberg said or use "numerous".
- Dr. Schwemmer suggested "many".

Discussion also followed to include " marijuana and not all drug interactions are known."
A motion was made, seconded and carried unanimously to approve the language as amended by discussion.
Signs of withdrawal can include: Feelings of depression, sadness, irritability, insomnia, restlessness, agitation, loss of appetite, trouble concentrating, sleep disturbances and unusual tiredness.
Symptoms of marijuana overdose include, but are not limited to, nausea, vomiting, hacking cough, disturbances in heart rhythms, numbness in the hands, feet, arms or legs, anxiety attacks and incapacitation. If I experience these symptoms, I agree to contact Dr. immediately or go to the nearest emergency room. (no change)
Numerous drugs are known to interact with marijuana and not all drug interactions are known. Some mixtures of medications can lead to serious and even fatal consequences. I agree to follow the directions of Dr regarding the use of prescription and non-prescription medication. I will advise any other of my treating physician(s) of my use of medical marijuana.
Dr. Schwemmer expressed concern regarding the paragraph about low birth rates as it was currently written.
Dr. Rose suggested using "I have advised the patient to ".
Dr. Rosenberg suggested removing the last sentence altogether.
Ms. McNulty said the physician should be notified in case he/she wants to change the treatment plan.
Dr. Rosenberg suggested "I will advise Dr if I become pregnant or try to become pregnant ".
Dr. Schwemmer said those two go together, but the outlier is breastfeeding. She suggested leaving as is or breaking that portion of out of the language.
Dr. Rosenberg said he liked either way but wants the Gynecologists to weigh in on this section at the August 3, 2017 meeting. He directed Ms. Sanford to invite them to the next meeting.
A motion was made, seconded and carried unanimously to adopt the amended language. I understand that medical marijuana may have serious risks and may cause low birthweight or abnormalities in babies. I will advise Dr if I become pregnant or try to get pregnant, or breastfeed.
Paragraph H Mr. Romanello left the conference call.
A motion was made, seconded and carried unanimously to approve paragraph h, as written.
Mr. Tellechea introduced the proposed language for both Board's disciplinary guidelines. He reminded the Committee the guidelines are used for Recommended Orders, Informal Hearings, Licensure Hearings and Determination of Waiver cases.

Dr. Mendez said the guidelines look reasonable.

A motion was made, seconded and carried unanimously to approve the disciplinary guidelines as written.

Ms. Kemp asked if the Committee needed to approve the rules separately since there were two sets of disciplinary guidelines, one for each Board.

Ms. McNulty said no because the two rules are identical.

Ms. Kemp advised staff would be changing the name of the Committee to the Joint Boards of Medicine and Osteopathic Medicine Medical Marijuana Committee.

The Committee agreed.

The meeting adjourned at 11:42 am.