



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

**Doubletree Hilton Orlando Airport
5555 Hazeltine National Drive
Orlando, Florida
(407) 235-1189**

August 25, 2017

Meeting Report

Meeting called to order by Dr. Rosenberg at 8 a.m.
Roll was called by Ms. Kemp.

Members Present:

Steven Rosenberg, M.D., Chair
Nicholas Romanello, Esq., Consumer Member
Joel Rose, D.O.
Sandra Schwemmer, D.O., Vice-Chair
Michelle Mendez, D.O.

Members Absent:

Zachariah P. Zachariah, M.D. (Excused)
James W. Orr, Jr., M.D. (Excused)

Staff Present:

Claudia Kemp, J.D., Executive Director
Edward Tellechea, Board Counsel
Donna McNulty, Board Counsel
Nancy Murphy, Certified Paralegal
Kama Monroe, Executive Director
Carol Taylor, Program Operations Administrator

Others Present:

Court Reporter:

American Court Reporting
3213 Hargill Drive
Orlando, Florida 32806
Phone: (850) 241-0058
Phone: (407) 896-1813

Introductory Remarks:

Ms. Kemp identified the name of the committee and the purpose for which the committee was meeting. Additionally, she provided introductory procedural remarks.

Public Comments:

Dr. Rosenberg stated that there were no speaker cards submitted. He then inquired if any members of the audience wished to make public comment. There was no response.

Ms. McNulty identified non-committee members of the Board of Osteopathic Medicine that were in the audience. They included: Ms. Janson, Ms. Jackson and Dr. Hayden.

64B8ER17-1 (64B8-9.018)/64B15ER17-1(64B15-14.013):

(a) Informed Consent Form Discussion

Dr. Rosenberg stated the next item for consideration was the Informed Consent Form and various modifications that had been made. He inquired if any members of the committee had anything they wished to say. Mr. Tellechea was recognized.

Mr. Tellechea suggested shortening the title of the consent form to “Medical Marijuana Consent Form.” He opined that the title was overly large and did not believe it needed to be identified as belonging to the Board of Medicine or the Board of Osteopathic Medicine. He suggested “Medical Marijuana Consent Form” or either “Florida Medical Marijuana Consent Form.”

Dr. Rosenberg opined the shorter the better and noted he didn’t believe the title needed to say Florida. He noted other states might choose to plagiarize Florida’s but that is their issues. He suggested the name be, “Medical Marijuana Consent Form.”

Following discussion:

Motion by, Dr. Schwemmer to name the consent form the, “Medical Marijuana Consent Form.”

Seconded by, Mr. Romanello.

The motion passed unanimously.

Dr. Rosenberg opened the floor for any additional comments and/or suggestions. There were none.

Dr. Rosenberg stated it was appropriate for a motion to accept the revised informed consent form as presented on IViewer page 399.

Following discussion:

Motion by, Dr. Rose to approve the form. Seconded by, Dr. Mendez.

Motion passed unanimously.

Mr. Romanello commented on motion, that there were some technical and typographical non-substantive tweaks that had been discussed that would need to be made to the form. He added subject to those tweaks he approved the motion.

Ms. McNulty asked that the corrections be noted for the record.

Mr. Tellechea noted that obviously there would be footers, etc. that required correction. He inquired of Ms. Kemp whether the form would be sent to the graphics unit to “pretty up.”

Ms. McNulty noted it would have a better layout.

Ms. Kemp confirmed that once approved the form will be sent to the graphic design unit for formatting.

Mr. Tellechea stated that the motion would be to substantively approve the form with the amendment to the title that was voted on earlier in this meeting.

Dr. Rosenberg noted that the committee voted on the above and it passed; therefore, another motion is not needed.

(b) Documentation of Comparable Conditions Form Discussion

Dr. Rosenberg noted the next item on the agenda is the Documentation of Comparable Conditions Form.

Ms. Kemp identified the form as a form for physicians to provide the required documentation if a patient is diagnosed with a medical condition of the same kind or class or comparable to those conditions that are listed in Section 381.986(2) (a-j). Currently the documentation must be mailed into the Department, as there is no data system. Software is being developed, as well as, a data receiving system. The documentation will subsequently be submitted electronically.

Dr. Mendez commented that she understood that the need for the form was to standardize the information that was being provided to the Department. She noted that the form as created does not appear to be able to solve the problem of the data collection in the first place. She enquired whether there was any method by which to modify the form to say “do not send attachments.”

Ms. Kemp noted she had spoken with Mr. Tellechea regarding this matter. She noted that when she sees the word documentation, she thinks of attachments, journal articles, or some sort of supporting documentation. She further noted that very soon with regular rule making, and the development that is going on at the Department with the office of medical marijuana use, and the boards, all of this will be able to be submitted electronically and the attachments will be uploaded so that everything that goes to the coalition will be electronic.

Ms. McNulty stated that the statute requires documentation be submitted.

Dr. Mendez acknowledged awareness of the statutes but noted that this did not appear to solve the problem as the Department will receive copies of patient paper charts, as well as, formatted EMRs from various vendors. Dr. Mendez noted that this will not help the Department collect any data.

Ms. Kemp stated that it is problematic now, but noted we need to have a format. The Department has currently received approximately seven or eight, which, were received in all kind of various formats. The information was not complete and it did not include the statutory requirements. Ms. Kemp noted that this form provides physicians a format.

Dr. Mendez acknowledged that this would provide a guideline on what to submit.

Dr. Rosenberg enquired what the purpose was. He asked whether the idea was to go into a period of rulemaking, if a pattern of specific conditions that meet these criteria are identified.

Mr. Tellechea noted that the Board does not have the authority to add these different conditions to the list that is in the constitutional amendment or in the statute. Mr. Tellechea opined that maybe a recommendation might go to the legislature to add them statutorily.

Ms. Kemp added that because the committee has agreed to serve as the panel review, they would have the opportunity to review that data and make recommendations.

Dr. Mendez asked if the meaning of the word “review” is clear. She noted there is concern about the word “review” in the medical community because it can have a lot of different distinct meanings. The concern in the community is that this review is not data gathering, but is to determine whether treatment will be approved.

Dr. Mendez stated concern is that someone will inform Dr. Smith, Dr. Jones that this is not approved, this condition is not approved.

Dr. Mendez opined that the reason three pages of e-mails were received regarding this matter is because there is a misunderstanding that treatment will be denied because the documentation is not good enough.

Ms. Kemp stated that the Board is not going to be refusing. This information will be immediately transferred to the coalition, but noted that some of the information may go into a larger data base. The review panel will be receiving sets of data that will allow the panel to look at what is happening and that is what recommendations to the legislature and the governor will be based upon. Ms. Kemp identified a form that was provided by Moffitt for consideration. Moffitt would like additional information included on the form. The form from Moffitt; however, would be for consideration during general rulemaking. Review of the form would have to be completed to determine whether the information is under the authority of the board to include in their form and whether it is statutorily allowed.

Dr. Mendez then noted a concern regarding de-identified (confidential patient information) information.

Dr. Mendez identified different things that physicians consider de-identified information. She noted that without specific instructions of what information not to include, the Department will receive a medical record that includes identified information.

Mr. Tellechea noted that this has already happened.

Ms. Kemp noted that this is all about the efficacy of why the condition falls under that provision. The form specifically states: do not provide patient confidential information. Ms. Kemp noted that on some level, physicians are counted on to know the meaning.

Dr. Mendez noted she would like to see in parenthesis, (such as, name, date of birth, social security number).

Dr. Rosenberg agreed that confidential means different things. He stated that HIV may be something you wanted to include in that but you would not want to include any patient identifying information. He opined that it should be clear that confidential means different things to different individuals but the important thing is, that the physician not include any patient identifying information, no social security number, patient's name, etc.

Dr. Mendez suggested a parenthetical comment, no name, date of birth, social security number.

Also suggested were no patient identifiers and not to provide patient identification information.

Dr. Mendez acquiesced and noted or words to that effect, if it is clear confidential means a method in which to identify who the patient is.

Mr. Tellechea enquired the committee's opinion regarding the term "documentation supporting qualified physician's opinion." He further asked if this would cause confusion.

Dr. Mendez affirmed that it would.

Mr. Tellechea enquired what the committee suggested in lieu of documentation.

Dr. Mendez stated to say exactly what you want.

Dr. Rose asked what the statute states.

It was clarified that the statute states what is on the form.

Mr. Tellechea clarified that the documentation desired is the documentation that supports the opinion that the condition is comparable or in the same class to those listed in the constitutional amendment.

Discussion ensued as to what type of documentation is wanted. It was clarified that supporting documentation could consist of various types of information.

Dr. Rose noted a need to review what the committee's role will be.

Dr. Mendez noted that these are questions she foresees staff receiving.

Ms. Kemp agreed that these are questions that will be encountered but noted that something needs to be set in place that provides a format. She noted that this will be a fillable PDF on the web. She noted that there has been a good discussion as to what a physician would consider as supporting documentation.

Dr. Mendez noted a need for precedent.

Ms. McNulty reminded the committee that at this stage this is an Emergency Rule. At this point it is important to put something in place and review as time moves along. It can be refined when working on non-emergency rule.

Ms. Kemp noted that the boards are not performing a quality review. Review to determine exactly what is being received is important, but whether it is complete or of quality is not something the board office will be doing.

Dr. Mendez asked for clarification that precedent is not important at this point.

Multiple parties noted that the committee will not be approving these forms.

Much discussion ensued regarding possible scenarios that might arise. The role of the panel was also discussed, as well as, how to have information disseminated.

It was clarified that confidential information does not fall under the umbrella of identification.

The committee agreed to clarify the meaning of the word “confidential” on the form.

Following discussion:

Motion by Dr. Mendez, to change the Documentation of Comparable Conditions form to include the language “Do not provide patient identifying information” Seconded by, Mr. Romanello.

Motion passed unanimously.

Following discussion:

Motion by, Dr. Schwemmer change the title to “Documentation Required Under Section 381.986(4)(b), Florida Statutes.” Seconded by, Dr. Mendez.

Motion passed unanimously.

Mr. Tellechea noted the need to amend the draft rule language that incorporates the forms by reference, as amended as the titles have been amended by the forms.

Ms. McNulty also noted the language would read: “which is hereby incorporated by reference and available from the board’s website at “blank”, blank being the website address. She noted that the rule cannot be moved until she has the website.

Mr. Tellechea clarified the websites would be the respective board websites. The names of the forms will be changed to “Medical Marijuana Consent Form” and “Documentation Required Under Section 381.986(4)(b), Florida Statutes.”

Ms. Kemp noted that the steps above are in a holding pattern until approved and the sites are developed.

At this point, Ms. McNulty noted that Dr. Bellingar, Board of Osteopathic Medicine non-committee board member was in the audience, observing and listening to the proceedings.

Conversation then reverted back to the “Documentation Required Under Section 381.986(4)(b), Florida Statutes” form. Mr. Tellechea inquired of the chair, regarding the Documentation form, if there would be any value to defining documentation as “medical or scientific data supporting the physician opinion.”

Discussion ensued regarding the matter.

Following discussion:

Motion by, Dr. Mendez to amend paragraph 2 of the Documentation Required Under Section 381.986(4)(b), Florida Statutes form to state: documentation (clinical, medical or scientific data).

Seconded by, Mr. Romanello.

Motion passed unanimously.

Discussion then reverted back to the rule draft language.

Following discussion:

Motion by, Mr. Romanello to approve the rule draft language as amended in the discussion.

Seconded by, Dr. Mendez.

Motion passed unanimously.

New Business

There was no new business.

Old Business

Motion by, Dr. Schwemmer to approve the August 3, 2017, committee meeting minutes.

Dr. Mendez commented that she was referred to as both Dr. Mendez and Ms. Mendez in the minutes and asked that they be corrected to reference her as Dr. Mendez throughout.

Dr. Schwemmer modified the motion to approve the August 3, 2017, committee meeting minutes with Dr. Mendez being referred to as Dr. Mendez throughout.

Seconded by, Mr. Romanello.

Motion passed unanimously.

The meeting adjourned at 8:41 a.m.