NEVADA STATE BOARD OF MEDICAL EXAMINERS

1105 Terminal Way, Suite 301 Reno, NV 89502-2144

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Board President

Edward O. Cousineau, J.D. Executive Director



* * * M I N U T E S * * *

OPEN SESSION R100-17 SUBCOMMITTEE MEETING

Held in the Conference Room at the Offices of the Nevada State Board of Medical Examiners/Nevada State Board of Dental Examiners 6010 S. Rainbow Boulevard, Building A, Suite 1, Las Vegas, Nevada 89118

and videoconferenced to

the Conference Room at the Offices of the Nevada State Board of Medical Examiners 1105 Terminal Way, Suite 301, Reno, Nevada 89502

WEDNESDAY, MARCH 21, 2018 - 2:00 P.M.

Subcommittee Members Present at Board Office in Las Vegas

Victor M. Muro, M.D., Chair Daniel Burkhead, M.D. Michael C. Edwards, M.D., FACS Senator Joseph P. Hardy, M.D. Rudy Manthei, D.O. Rupesh Parikh, M.D. Robert Pretzlaff, M.D. Faisal Suba, M.D.

Subcommittee Members Present at Board Office in Reno

Paul Edwards, J.D. Catherine O'Mara, J.D. Michael Salas, M.D. Dave Wuest, R.Ph.

Subcommittee Members Absent

Wayne Hardwick, M.D.
Karen Massey, MHA, FACMPE, CPMSM
Ms. April Mastroluca
Crane Pomerantz, J.D.
Ms. Karen Rubel
Erin Russell, Ph.D.

Staff/Others Present at Board Office in Las Vegas None

Staff/Others Present at Board Office in Reno

Edward O. Cousineau, J.D., Executive Director Jasmine K. Mehta, J.D., Deputy Executive Director Laurie L. Munson, Chief of Administration and Information Systems Brenda Riviera, Finance Assistant Henna Rasul, J.D., Senior Deputy Attorney General

Agenda Item 1
CALL TO ORDER AND ANNOUNCEMENTS
Roll Call/Quorum

The meeting was called to order by Dr. Muro at 2:04 p.m.

Ms. Mehta took roll call of the Subcommittee members. Subcommittee members not present were Michael C. Edwards, M.D., FACS, Wayne Hardwick, M.D., Karen Massey, MHA, FACMPE, CPMSM, Ms. April Mastroluca, Crane Pomerantz, J.D., Ms. Karen Rubel and Erin Russell, Ph.D. Ms. Mehta announced there was a quorum. Mr. Pomerantz and Dr. Russell arrived shortly thereafter.

Agenda Item 2 PUBLIC COMMENT

Dr. Muro asked whether there was anyone in attendance who would like to present public comment.

James G. Marx, M.D. stated he had been practicing in Las Vegas for over 25 years, and explained that his office is receiving three to five calls a day from patients who are being abandoned by their current practitioners. With minimal investigation, they have found virtually all these patients to be legitimate patients, most of whom are not receiving high doses of medication, by any stretch of the imagination. He said we have a crisis coming, as we cannot accommodate all the patients who are calling. There is one very legitimate interventional pain practice that is sending his office all their higher and even modest dose pain patients because they do not want to drug administer and write prescriptions for them. He said he suspects that many of these patients will use whatever means necessary to get medication, and he is afraid some will go to the illegal market. He thinks we have some really serious unintended consequences coming from this legislation.

Agenda Item 3 APPROVA<u>L OF MINUTES</u>

- March 14, 2018 Subcommittee Meeting - Open Session

Senator Hardy moved that the Board approve the Minutes of the March 14, 2018 Subcommittee Meeting – Open Session. Dr. Burkhead seconded the motion, and it passed unanimously.

Agenda Item 4

CONSIDERATION OF CHANGE TO MEETING SCHEDULE

Dr. Muro referred the Subcommittee to the calendar which had been provided. He explained there was a need to change the meeting schedule due to the Board of Medical Examiners office move and attendance at the Federation of State Medical Boards Annual Meeting by Medical Board members.

Ms. Mehta explained there were two dates the Subcommittee previously voted on which were up in the air – April 25 and May 9. Board members and some of the Subcommittee members would be traveling to the FSMB conference on April 25 and the proposal was to move that date to April 18. The Board's Reno office will not be available, but Ms. O'Mara has offered to allow the Subcommittee to use her Reno office location. She said we are still trying to determine if we can video conference, but we can certainly teleconference. When the Subcommittee voted on the May 9 date, staff had not had a chance to check with the Dental Board, and the room in Las Vegas will be occupied in on that date. The proposal is to move the meeting to May 2. That will still allow the Subcommittee plenty of time to get its recommendations to the Board of Medical Examiners in time for its June Board meeting.

Discussion ensued regarding the newly proposed dates.

Dr. Muro explained the Subcommittee may not need to hold all of the meetings, but should schedule them up in the event it does.

Dr. Burkhead moved that the Subcommittee have upcoming meetings on April 11, April 18 and May 2, 2018. Dr. Manthei seconded the motion, and it passed unanimously.

Ms. Mehta clarified that the meeting time would remain the same, from 2:00 p.m. to 4:30 p.m.

Dr Muro further clarified that meetings would be held on April 11, April 18 and May 2, as necessary.

Agenda Item 5

COLLECTION OF MEMBER INPUT AND CONSIDERATION OF RECOMMENDATIONS REGARDING PROPOSED REGULATION R100-17 AND PROPOSED RECOMMENDATIONS TO CLARIFY IMPLEMENTATION OF ASSEMBLY BILL 474 (2017)

Dr. Muro said he thought the Subcommittee left off at the screening, evaluations and assessments in different environments, and that Subcommittee members were going to try to get information from some of the psychiatry people.

Ms. O'Mara stated she had reached out to the Nevada Psychiatric Association, and they provided some feedback. She said their feedback in general was that the screening tools available on the SAMHSA website were generally accepted, so they didn't have a different list from what the Subcommittee had been discussing in the past. She said Ms. Mehta had provided the Subcommittee members with the SAMHSA screening tools in hard copy for this meeting, and those have been marked by the Nevada Psychiatric Association as being valid.

Ms. Mehta explained the handout provided has the SAMHSA website address at the bottom and you can click on any of those tools that are embedded as hyperlinks on that page and the actual patient questionnaires will come up.

Senator Hardy said he didn't see the DEX Depression Scale, the PHQ-2 or the PHQ-4.

Ms. Mehta said the PHQ-2 and PHQ-9 are on there, but she thinks they are under the Providence Center Medical Screening Form and the Mental Health Screening Form. One of those two links actually incorporates the PHQ-2 questions, but they are not listed separately on the website page.

Ms. O'Mara added the Nevada Psychiatric Association also referenced the PHQ-9, which Senator Hardy referenced in the last meeting, so they agree with Senator Hardy that it is an appropriate test. She said she thinks it is essentially covered in the SAMHSA list, but it may not be explicit. She said she wanted to revisit the idea of having a list in general. Having spoken with different provider groups in the last week, she thinks the criteria that it be nationally recognized and peer reviewed should be enough. The SAMHSA and Prescribe 365 gives some samples, and she doesn't think the Subcommittee wants to inadvertently narrow the field and endorse some over others. If people find tests that are nationally recognized and peer reviewed, that is what the law requires, so with the SAMHSA documents and Prescribe 365, she would be inclined not to try further narrow or define any other tests.

Dr. Muro said he thought the previous discussion was centered more around whether the mental health assessment was separate from the substance abuse assessment, and thought the Subcommittee decided those two are different. There are a lot of nationally recognized and peer reviewed and validated tools out there that meet the standard and how individual environments put them into their workflow is up to them to decide.

Discussion ensued regarding the tools available for assessing mental health and performing the substance abuse assessment, and that there may be some that are nationally recognized and peer reviewed that incorporate the mental health assessment into the risk assessment.

Dr. Suba said the Subcommittee should make it as simple as possible for the providers. Dr. Pretzlaff agreed.

Further discussion ensued regarding the mental health assessment and the tools available to make that assessment, maintaining the integrity of the tools as they were designed and developed, and communicating to practitioners what is acceptable.

Dr. Parikh moved that a mental health assessment incorporate, at a bare minimum, the PHQ-2.

Dr. Muro said the motion was that for the mental health assessment, a PHQ-2 would be acceptable, and it is up to the physicians to decide whether there is another tool that is more

appropriate, as long as it meets the criteria of a nationally recognized, peer reviewed tool and is used as intended.

Dr. Burkhead stated that at the last meeting, Mr. Wuest mentioned that any tool that is used must incorporate at least one question about depression, and the PHQ-2 would meet that; however, as to Ms. O'Mara's point, the Subcommittee may not want to include any specific tests.

Discussion ensued regarding the motion.

Dr. Manthei seconded the motion.

Ms. O'Mara asked that the motion be restated.

Dr. Parikh restated his motion as follows: that any mental status exam incorporate, at a bare minimum, the PHQ-2, or such, from a list of five different examples that are on the SAMHSA website, in its intended form, without modification, as part of the minimum status exam.

Dr. Burkhead said that use of the term "mini mental status exam" could be misconstrued, and suggested altering the term to "mental health assessment."

Ms. O'Mara encouraged the Subcommittee not to set a bare minimum because the law already sets the bare minimum, which is it has to be nationally recognized and it has to be peer reviewed. If another test comes out that may be different from the PHQ-2, the Subcommittee, in effect, would have set a standard that may raise questions if someone deviates from it. She suggested removing the bare minimum language.

Discussion ensued regarding the motion.

Dr. Parikh accepted the amendment to exclude the bare minimum wording.

Dr. Edwards joined the meeting at 2:32 p.m.

Discussion ensued regarding what 'documentation' means with respect to the mental health assessment and risk assessment, and whether language requiring documentation of the assessment should be included the proposed regulation.

James G. Marx. M.D. stated that public comment was not requested when the agenda item was announced, and that he would like make a public comment.

Ms. Rasul stated that public comment is only required to be taken as agendized, which is at the beginning of the meeting and at the end of the meeting, as designated on the agenda.

Further discussion ensued regarding documentation of the mental health assessment and whether language should be added requiring it be documented.

Dr. Parikh restated his motion as follows: For purposes of the mental health assessment requirements in Section 54(l)(d), practitioners can use resources provided by the SAMHSA website and Prescribe365.gov, including, but not limited to, the PHQ-2, PHQ-9, Kessler K10 and others.

- Ms. O'Mara requested the following be added to the motion: "or any other risk assessment tool that is nationally recognized and peer reviewed."
- Dr. Parikh accepted the amendment. Dr. Edwards seconded the motion, it passed unanimously.
- Ms. O'Mara said she thought what the Subcommittee just did was vote to make recommendations to the Board of Medical Examiners regarding the mental health assessment, and asked whether that was correct.
- Ms. Mehta explained the process was that the recommendation is to the Board of Medical Examiners to make a recommendation to the Board of Pharmacy to put in a regulation.
- Mr. Wuest stated the Board of Pharmacy has already watched what this Subcommittee has done and the partnership is working out well. Anything that comes from the Subcommittee in the future will at least be considered by the Board of Pharmacy, so the Subcommittee's voice will be heard.
- Ms. Mehta referenced the proposed regulation from the Board of Pharmacy, which had been provided to the Subcommittee, and stated it incorporates the prescription medication agreement, as discussed at the last Subcommittee meeting. She read Section 2, Subsection 4: "For the purpose of section 56 of AB 474 (2017), a 'prescription agreement' may be shared by all practitioners with access to a common database that allows the practitioner to view and act upon the prescription medication agreement."
- Mr. W'uest said it would be helpful to the Board of Pharmacy to know whether the new language in the proposed regulation meets the expectations of the Subcommittee. The consensus was that it does.
- Dr. Muro read Subsections 1 through 6 of the proposed regulation and asked for comments after reading each subsection. There were no comments with regard to these subsections.
- Dr. Muro read Subsection 7: "Ongoing treatment means the same medication for the same diagnosis. This does not prohibit a prescriber from prescribing a different medication, increasing the dosage on the same medication or replacing lost or stolen or destroyed medications."
- Dr. Parikh said he had a concern regarding a comment Dr. Havins made at a seminar last weekend, that if you are covering for somebody, under the law, you are not allowed to write the same prescription.
- Mr. Wuest stated the law does not say that, and explained that the change in this section was an attempt to clarify that, realizing we cannot go against the law and we must follow the law. Nowhere in section 60 does it say you can't prescribe the same medicine. He understands that it might be interpreted that way, but that was not the intent of the law.
 - Discussion ensued regarding interpretation of the requirements under Subsection 7.
- Mr. Wuest stated the law clearly contemplates that physicians cover for each other. The only time you don't have to check the PMP is when you are covering for someone, so clearly the law intended that providers would cover for one another.

Ms. Mehta added if you go back to Section 51, the definition of "initial prescription," from which a lot of these requirements key off, the second sentence in that definition says the term does not include any act concerning an ongoing prescription that is issued by a practitioner to continue a course of treatment for a new or existing patient of the practitioner.

Mr. Edwards said the intent when they added that sentence was to facilitate the ability for covering physicians or to allow the passing of a patient from one practitioner to another without having to start over. Section 51 allows for coverage and Section 60(b) does not prohibit it.

Discussion ensued regarding possibly recommending a change to the language in subsection 7 to clarify the intent of the law regarding the ability for a covering physician to prescribe the same medicine to a patient.

Mr. Wuest explained that when the Board of Pharmacy proposed the regulation, the intent was not to deviate from Section 60, but give the practitioners room to use the same medication at times when, looking strictly at the numbers in the PMP the patient should still have medicine but he or she doesn't, and the doctor makes that determination. If the Subcommittee wants to say that a different prescriber can prescribe the same medication, the Board of Pharmacy could do that in a different regulation that is not tied to Section 60. They could tie it to Section 51 and say that one doctor can prescribe the same medication as another.

Ms. O'Mara suggested one way to clarify it might be to add the following language to the wording in Subsection 7: "ongoing treatment means the same medication for the same diagnosis for the same time period."

Discussion ensued regarding the time element with regard to refilling prescriptions.

Dr. Wuest said his intention, as the Deputy of the Board of Pharmacy, was not to pull the regulatory language back. It is already at the LCB, and if it is pulled back to fix what he thinks is a minor issue with Subsection 7, then the Board of Pharmacy will not be able to move forward with all the other items because they would be back to the public workshop stage and would have to reset the clock. He said he did not want to suppress the conversation, but from the Board of Pharmacy's perspective, unless the Subcommittee says it is an emergency, this would be round two of regulations that the Board of Pharmacy would propose.

Further discussion ensued regarding a potential change to the wording of Subsection 7.

Ms. O'Mara said if her proposed additional language would be deemed to be a substantive change, she would not want to draw back the regulation.

Further discussion ensued regarding a potential change to the language of Subsection 7.

Dr. Burkhead suggested adding a Subsection 8 to the proposed regulation that says something along the lines of, "Section 51 and Section 60 do not prohibit a different practitioner from providing a prescription for controlled substances if working on behalf of the prior practitioner," which would clarify the call situation.

Mr. Wuest said that his takeaway is that nothing in AB474 prohibits one practitioner from writing the same medication for a patient as another practitioner, if appropriate, and he thinks they will do another run of regulations through the Board of Pharmacy when this Subcommittee finishes its process and they receive input from all the boards.

Mr. Wuest said he looked at the FAQs, which had been approved by all the boards, and an FAQ on this could also be added to the list so as boards receive questions, they could refer individuals there for clarification.

Senator Hardy asked for confirmation that the Board of Pharmacy is not going to turn in a provider for being on call and writing a prescription to continue the course of treatment with the same medicine at the same dose, or increasing the dose if the provider feels like so doing, nor is the Board of Medical Examiners going to call that a violation and count every time the doctor does that as a separate violation causing him to lose his license after five times.

Mr. Wuest said the law doesn't prohibit what Senator Hardy was saying, so the Board of Pharmacy would have no grounds to look at that and say there has been a violation of law.

Dr. Muro explained that determining whether a violation has occurred is part of the due process whenever a complaint is brought before the Board of Medical Examiners, so five complaints do not equate to five violations and five events also do not equate to five violations. Unfortunately, there is a lot of misinformation that is being disseminated out there that has practitioners scared.

Ms. Mehta described the process the Board of Medical Examiners follows when an informal complaint is received.

Senator Hardy said he thought what Ms. Mehta was saying was that the Board of Medical Examiners does not need to do "anything else because we already have the tools that have been working have worked, and we don't actually need to do anything else in our regulation to give us more power to do anything."

Mr Cousineau said he thought Senator Hardy was correct in his statement and that is one thing that is very important for people to understand. The Board of Medical Examiners did not need AB474 to enforce violations addressed in AB474, either prior to January 1 or subsequent. What is important, though, is the Board is statutorily charged with adopting a regulation to address violations as they relate to prescribing improprieties.

Mr. Cousineau said that R100-17 was in the working phase and nothing had been finalized. The initial language of the regulation was vetted through the Board of Medical Examiners in September 2017, but he was confident that whatever recommendation is proposed by this Subcommittee as appropriate language the Board should consider to start the regulatory adoption process anew will not be similar to what was initially proposed.

Mr. Cousineau explained it was the Subcommittee's charge to propose language that would meet the minimum requirements under AB474, and it would take the Board's approval to amend R100-17 or withdraw it and begin anew with the language recommended by this Subcommittee. He said he thought it would make more sense to withdraw R100-17. He said his biggest concern is the perception out there that this regulation is already reality, and it is not, and that needs to be dispelled.

Senator Hardy moved to withdraw R100-17 and put into place the language that the Subcommittee comes up with in its subsequent meetings, which includes the CME that is required by law.

Mr. Cousineau clarified that CME is the minimum requirement, but there could be more, and the credit hours of the CME is something that needs to be addressed.

Senator Hardy said that was included in his motion.

Discussion ensued regarding a potential recommendation to the Board of Medical Examiners that it withdraw R100-17 and potential proposed language to replace it.

Dr. Burkhead read the language that had been proposed by the Dental Board to address this issue.

Discussion ensued regarding the Dental Board's proposed language and whether the Board of Medical Examiners could use similar language in its regulation.

Ms. Mehta suggested that since there was a motion pending to withdraw R100-17, the Subcommittee could act on that motion and then consider proposed language at the next meeting on April 11 that incorporates the concept Dr. Burkhead has provided from the Dental Board.

Dr. Parikh seconded Senator Hardy's motion.

A vote was taken on the motion, and it passed unanimously.

Dr. Edwards asked whether any of the other boards had come up with language that the Subcommittee could also review.

Ms. Mehta and Ms. O'Mara said they would work together to come up with some proposed language.

Dr. Edwards said it was important to get the word out to the providers that the boards have worked together on this.

Ms. Mehta said that based on her recollection, she didn't believe the discussion on ongoing treatment had been concluded.

Discussion ensued regarding adding the language proposed by Ms. O'Mara regarding the time element.

Mr. Wuest recommended that the Subcommittee recommend the change be made during a second round of regulations. He said the Subcommittee did not have the authority to pull the regulation because it was already in process. The Pharmacy Board could attempt to add it at the public hearing if it is deemed not to be a substantive change, but if the LCB says it is a substantive change, the clock would be reset on the regulation. From his perspective, they need to move the regulation forward because there are so many good things in it that people are waiting for.

Ms. O Mara moved that the Subcommittee make a recommendation to the Board of Medical Examiners to ask the Board of Pharmacy to move the current regulation forward as it is now and to flag the clarification on the time period for the next round, if there is one. Dr. Manthei seconded the motion.

Discussion ensued regarding the motion.

A vote was taken on the motion, and it passed unanimously.

Ms. Mehta stated at the last meeting, the Subcommittee discussed Section 54(1)(d) of AB474, which is the mental health and risk assessments, and Section 55(1)(a), which is just the risk assessment, so chronologically, the Subcommittee would move on to Section 54(2), which is the informed written consent and what it must contain. She said there is a form on the Prescribe 365 website that basically encapsulates this language and asked if there were any questions regarding what it must contain.

Dr. Burkhead asked for clarification regarding Section 54(2)(a), with respect to whether there needs to be a separate informed consent for each specific controlled substance the patient is being provided or whether one informed consent could list multiple controlled substances. For example, the risks and benefits of a Hydrocodone prescription are virtually identical to the risks and benefits of an Oxycodone prescription, and some patients may need one versus the other for side-effect purposes.

Discussion ensued regarding whether it would be allowed under the law to attach a list of multiple medications to one informed consent.

Mr. Wuest said he thinks the intent of the law was that the patient understand what medication he or she is getting and what the potential risks and benefits of that medication are, and clarified that this requirement only applies to medications for pain. He said it should be left up to the individual practitioner to decide how he or she wants to inform the patient, as his or her setting would dictate that

Further discussion ensued regarding whether a list of multiple medications could be attached to one informed consent.

Dr. Burkhead asked whether the Subcommittee needed to make a recommendation for a regulation from the Board of Pharmacy to clarify that an informed consent could include a list of multiple medications, considering the law itself states "the controlled substance," which seems to preclude a list the way it reads.

Mr. Wuest said he didn't think the Board of Pharmacy necessarily needed to do a regulation. He said he didn't think the Subcommittee was changing the law by saying this could be done by a list or singularly, but if the Subcommittee is concerned about this, it would make sense to make the recommendation for a regulation. He said he hadn't received any questions about this.

Discussion ensued regarding whether the informed consent could be tied to the course of treatment and not a specific drug.

Dr. Muro asked whether a list of potential medications that were appropriately discussed at the time the informed consent was obtained would satisfy this requirement.

Mr. Wuest stated that for the Board of Pharmacy and its staff, it would suffice.

Further discussion ensued regarding whether attaching a list of medications to an informed consent would be acceptable under the law.

Discussion ensued regarding the informed consent and how it applies to a covering physician.

Mr. Edwards stated if it is a covering physician who is continuing a course of treatment, that is not an initial prescription, and this applies only to initial prescriptions.

Dr. Pretzlaff said he thought the Subcommittee should possibly come up with a recommendation to the Board that it allow a list of certain medicines that are appropriate for the condition being treated to be included in one informed consent form.

Ms. O'Mara recommended that discussion be tabled until the next meeting to allow the Subcommittee members time to think about it and decide whether it is necessary to do that.

Dr. Muro said that would be what the Subcommittee would open with at the next meeting.

Agenda Item 6 PUBLIC COMMENT

Dr. Muro asked whether there was anyone in attendance who would like to present public comment.

James G. Marx, M.D. said he wanted to commend the Subcommittee on its progress. He said he had been looking at opioid prescribing agreements for close to 30 years and had yet to see one that listed every possible drug, and to address Mr. Wuest's comment that patients don't know what opioids are, he would disagree. By the time they get to him anyway, they all know what opioids are. If you claim that patients are ignorant, does that mean you have to list every trade name or drug? For example, you could put down Hydrocodone, but do you have to put down Norco, Vicodin, Lortab? The same thing is true for other drugs. You really cannot list every possible drug and trade name for every drug. He said he thinks informed consent is not a piece of paper, it is a process, an educational process, and once you tell a patient he or she is going to be getting a class of drug that includes things he or she may be familiar with, but may also include other drugs he or she may not be familiar with, that should be sufficient. He said we have created a situation that is becoming really daunting for the average primary care doctor, and he firmly believes that most of pain management should be done at the primary care level, not at the pain management level. That is way too heavy-handed, and we have created a situation that is really too foreboding and too difficult for the average prescriber to deal with. He thinks you would want to make this as simple as possible and make these prescribers comfortable so that they can do this because they have a much better opportunity to assess a patient's mental health, and when we push these people off to other prescribers who may have very limited time to do this, he thinks we are doing the patient a big disservice. He said the objective of this legislation was to prevent overdoses, and so far he hasn't heard anything that would prevent an overdose, so he thinks we need to get back on track, figure out what the legislative intent was, and then make regulations that address that, although he doesn't think there is anything in the statute that addresses overdoses. He said he wanted to commend the Subcommittee members, but he thought they needed to look at the informed consent in a different light because they were making it way too complicated.

Agenda Item 7 ADJOURNMENT

Dr. Burkhead moved to adjourn the meeting. Dr. Pretzlaff seconded the motion, and it passed unanimously. Dr. Muro adjourned the meeting at 4:28 p.m.