DHHS Therapeutic Cannabis Medical Oversight Board Meeting
October 9, 2019, DHHS Offices, 29 Hazen Drive
Meeting Minutes

Members Present: Jonathan Ballard, Virginia Brack, Heather Brown, David Conway, Jerry Knirk, Richard Morse, Molly Rossignol, Seddon Savage, Cornel Stanciu, Lisa Withrow

Members Absent: Bert Fichman, Dennis Thapa

DHHS Staff: Michael Holt, DHHS Program Administrator; Patricia Tilley, DPHS Deputy Director

Meeting convened at 5:39 p.m.

Opening Remarks

Knirk provided a legislative update

- House HHS&EA subcommittee will meet on 10/16 (and the following week if needed) to discuss retained bills
- He will present the Board's recommendations at that meeting, as well as amendments to HB 466 and HB 361 as appropriate, based on the Board's recommendations.
- Specific legislative action based on the Board's recommendations cannot be guaranteed.
- He asked that any recommendations consider whether the qualifying medical condition would be a stand-alone condition, a condition that requires a qualifying symptom, or a symptom that requires a qualifying diagnosis.
- He asked that the Board consider, as part of any recommendation, whether the draft recommendation report could be provided to the legislative subcommittee.

Ballard provided other opening remarks

- He will provide the Board's recommendations to the Commissioner of HHS.
- He offered the possibility of Board members drafting "minority reports" if desired and appropriate.

Qualifying Condition Discussion, Recommendation, and Vote

Insomnia

- Morse presented draft report, with a recommendation to add insomnia as a qualifying medical condition for therapeutic cannabis. The recommendation included certain caveats, detailed in the report.
    - Most available literature does not measure sleep as a primary outcome, but a secondary one.
    - Evidence is mixed; difficult to study; difficult to interpret.
        - Many types of insomnia, many causes of insomnia
        - Many types of cannabinoid products

- It was asked whether the condition should be a specific diagnosis of “insomnia” or the more general and common “sleep disorder” condition. It was clarified that HB 366 used the term “moderate to severe insomnia.”
- Discussion of potential reasons why cannabis may not be indicated for insomnia:
    - There were concerns expressed:
        - Long-term effects
        - Withdrawal mediated insomnia
        - Studies that show students who use cannabis sleep poorly.
    - The limitations and side effects of current product were noted and impressions based both on studies and on testimonials, suggested cannabis may be better tolerated.
    - A number of exclusion or caveats were suggested:
        - Age of use
        - Short term use.
    - It was pointed out that this group has the option to define best practices for provider certification. It was discussed whether this might be done in the context of this discussion, or later, but the point was not settled.
    - Reminder that the Board should be careful not to hold cannabis to a higher standard than other medications
- Discussion whether this should be a stand-alone condition or a qualifying symptom associated with a qualifying diagnosis.
    - After discussion, Board generally agreed that it should be a qualifying symptom associated with a condition/diagnosis.
- Motion
    - Morse: Motion to recommend approval of insomnia as a qualifying medical condition for therapeutic cannabis, specifying that it should be a qualifying symptom, and not a stand-alone condition. Motion included recommendation to submit draft report to House HHS&EA subcommittee for consideration.
    - Rossingnol seconded.
    - Vote: 9 for; 1 opposed (Brown).
    - Motion approved.
- Motion
    - Knirk: Motion to recommend approval of insomnia as a qualifying medical condition for therapeutic cannabis, specifying that it should be a stand-alone condition, and not a qualifying symptom tied to a diagnosis/condition.
    - Brown seconded
    - Knirk withdraws motion after discussion that the qualifying condition/diagnosis could be virtually anything that caused the insomnia, and that primary insomnia is a rare condition.

Anxiety

- Stanciu presented draft report, with a recommendation not to add anxiety as a qualifying medical condition for therapeutic cannabis.

    - There are many different types of anxiety and many cannabinoid products making interpretation of the available literature difficult.
    - Studies of cannabis in healthy volunteers were reviewed. In aggregate, they found:
        - There is a curve with THC where low dose improves anxiety symptoms, but at higher doses it increases anxiety, especially in adolescents, where suicidalities increase.
        - There is 70% comorbidity with depression.
    - With CBD pretreatment for social/performance anxiety disorder, there is improvement in symptoms acutely.
    - With chronic administration of CBD and THC, anxiety is worsened.
    - Anxiety is a normal part of life. Diagnosis of anxiety disorder should be made by someone qualified to make a good diagnosis.
    - Suicidal tendencies must be recognized and intervened.
    - If used along with standard treatment modalities, there can be interactions with SSRIs and others medications.
    - Impossible with all the uncertainties to know where in the algorithm cannabis would fall.
- Discussion on whether adding any restrictions on which providers, including qualifications specialties, and certifications, could certify patients for anxiety would change the recommendation.
    - Stanciu would still not be in favor of recommending adding the condition with this restriction.
- Discussion on the effect of cannabis on the manifestation of schizophrenia.
- Motion
    - Stanciu: Motion to not recommend the addition of anxiety as a qualifying medical condition for therapeutic cannabis.
    - Knirk seconded
    - Vote: 8 for; 2 opposed (Brown and Withrow)
    - Motion approved.

Opioid Use Disorder

- Savage presented a draft report on cannabis and opioid use disorder, which included a potential path towards recommending the approval of opioid use disorder as a qualifying condition for therapeutic cannabis.
- Discussion on elements of the potential path to recommend approval.
- Discussion of supporting trials of CBD for OUD
- Rossignol presented comments on a draft report for cannabis and opioid use disorder in the context of Savage's presentation:
    - She would support waivered physicians using CBD as an adjunct to MAT.
    - She noted that probably a third of her patients on MAT also use cannabis and many do just fine, but noted it was impossible to know if CBD is helping or potentially limiting them in some way.

    - The literature simply is not adequate to support OUD as an indication.
    - Stanciu concurred and agreed with the lack of evidence.
- Motion
    - Savage: Motion as follows:
        1. **That OUD <u>not</u> be an indication for therapeutic cannabis certification** through the current general therapeutic cannabis certification process;
        2. That certification of OUD for therapeutic cannabis:
            - **<u>May be provided</u> as an adjunct in the context of evidence-based MAT** by a DATA 2001 waivered clinician who is prescribing or authorizing the individual's MAT; <u>OR</u>
            - **<u>May be provided</u> by an ABAM, APA or ACGME certified addiction medicine or addiction psychiatry physician**, with or without other MAT treatment;
        3. In order for a patient to be certified for therapeutic cannabis for OUD, that patient must have an associated symptom or either cravings or withdrawal (based on recommendation by Rossingnol); <u>AND</u>
        4. That such treatment **must be treated as a clinical trial**. To that end
            - The certifying clinician and/or patient must complete and submit a quarterly data sheet (TBD) to DHHS;
            - Tracking/analysis of data must be performed; and
            - Policy for approving OUD as qualifying medical condition for therapeutic cannabis may be changed based on clinical trial findings and on evolving scientific literature.
    - Knirk seconded.
    - Vote: 4 for (Brown, Knirk, Morse, Withrow); 6 opposed (Ballard, Brack, Conway, Rossignol, Savage, and Stanciu)
    - Motion failed.

<u>Tick-Borne Illness</u>

- Withrow presented draft report, with a recommendation to add tick-borne illnesses as a qualifying medical condition for therapeutic cannabis. The recommendation was for this condition to be a stand-alone condition.
    - Recommendation based on the experiences of patients and providers (clinical experience) and not on available medical literature.
- Discussion on the lack of medical literature related to cannabis and tick-borne illnesses, and the reliance on only clinical practice evidence as the basis of the recommendation.
- Discussion noted due respect for patient experience and observational data but concern was expressed about lack of objective evidence and specific studies.
- It was noted that many of the symptoms that patients' experience with tick-borne illnesses may be covered under current conditions and symptoms listed in law.
- Discussion of tick-borne illness symptoms vs. acute disease state, for which cannabis is not indicated.
- Motion

    - Withrow. Motion to recommend approval of tick-borne illness, manifesting in a chronic state and accompanied by any related symptom, as a qualifying condition for therapeutic cannabis.
    - Brown seconded.
    - Vote: 2 for; 8 opposed (Ballard, Brack, Conway, Knirk, Morse, Rossignol, Savage, and Stanciu)
    - Motion failed.

Qualifying Condition Discussion, Reports

- Discussion on whether anyone wanted to produce a minority report on any of the conditions voted on.
- Discussion on whether draft reports may be distributed to House HHS&EA subcommittee for consideration.
- Motion
    - Knirk. Motion to submit draft reports on insomnia and anxiety to legislative committee.
    - Ballard seconded
    - Vote: 9 for; 1 opposed (Brown)
    - Motion approved.

Meeting Adjourned
7:50 p.m.

Note. Agenda items marked "time permitting" were not addressed at the meeting, including: Review/Approve minutes from 9/4/19 meeting; DHHS Update; and Public Comments.