DHHS Therapeutic Cannabis Medical Oversight Board Meeting
July 17, 2019, DHHS Offices, 29 Hazen Drive
Meeting Minutes

Members Present: Jonathan Ballard, Virginia Brack, Heather Brown, David Conway, Jerry Knirk, Molly Rossignol, Seddon Savage, Dennis Thapa, Lisa Withrow

Members Absent: Bert Fichman, Richard Morse, Cornel Stanciu

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

Meeting convened at 5:35 p.m.

Minutes from June 5, 2019 were approved. Motion: Knirk; second: Rossignol; all approve.

Board Membership Update

Dr. Ballard announced that Commissioner Meyers appointed:

- Heather Brown to serve as qualifying patient member
- Virginia Brack to serve as member representing the pediatrics field

Dr. Ballard announced that Gil Fanciullo, clinical representative from an alternative treatment center, has resigned from the Board, and that this position is now vacant.

Introductions were made around the table.

Legislative Update

Relevant current legislation was reviewed by Michael Holt:

- Qualifying conditions bills have not changed status; still retained in Committee pending action of this Board, including:
    - HB 366, adding opioid addiction, misuse, and abuse
    - SB 175, adding insomnia, anxiety, Lyme
- SB 175, removing all qualifying conditions for therapeutic cannabis, was re-referred
- HB 350, adding physician assistants to list of certifying providers, was passed effective 8/20/19
- SB 88, removing requirement for photos on ID cards and 3-month provider patient relationship was vetoed by the Governor
- HB 174, adding a fifth ATC license, inexpedient to legislate
- HB 335, relative to therapeutic cannabis dispensary locations, authorizes second dispensary locations for the current ATCs located in Regions 1 and 2, passed effective 9/8/19:
    - SB 388 from 2018 session authorized second dispensary locations for ATCs in Regions 3 and 4. A satellite dispensary opened in Conway on July 6 (Region 4); and a satellite dispensary is expected to open in Keene (Region 3) in the fall
    - Brings the total number of authorized dispensaries in New Hampshire to 8 dispensaries, operated under 4 licenses
    - Patients are not required to register separately at a satellite dispensary location; they are allowed to go to both locations
- SB 145, relative to the organization of the ATCs, would allow ATCs to become for-profit entities, was vetoed by the Governor
- SB 33, allowing the release of TCP data to researcher, passed effective 8/17/19
- HB 364, allowing home cultivation of cannabis by caregivers and patients, is still pending Governor action

The Therapeutic Cannabis Program had a legislative performance audit conducted by the Legislative Budget Assistant. The audit findings, and the Department's responses, were approved by the NH Fiscal Committee in June 2019. The Department concurred with all the findings. The Department's audit responses included the intention of re-introducing a change proposed by SB 88 (see above), which was removed by the Senate committee, which would extend the duration of a provider's written certification for up to 3 years (currently a written certification is effective for one year). The Department asked for the board's input on such a change.

- Arguments for extending the current annual certification for up to 3 years at the certifying provider's discretion:
    - Decrease barriers to access the program by easing the financial and administrative burden for patients to reapply every year
    - Reduce the volume of renewal applications received by the Department
    - Level the monthly peaks and troughs of renewal applications received
- Arguments against extending the duration of the written certification:
    - There are no clinical standards for follow-up regarding cannabis use
    - Providers may see patients less frequently than clinically appropriate to assess response to cannabis use and to reinforce risks and benefits of cannabis use
- Further discussion:
    - Could we extend certification to every 3 years but mandate at least annual visits?
        - For which other drugs do we mandate how often providers see patients?
            - Opioids
            - Other drugs with REMs?
        - Good medical practice shouldn't be legislated
    - Many agreed reassessment at least annually or more often was important
    - Some agreed that removing barriers to access the program was a good idea
    - One suggested a compromise of a 2-year certification
    - One said that most patients want a longer certification for chronic conditions
    - Diversion is a potential risk and clinicians hear from other patients that some are diverting
    - Online recertification might be possible to reduce administrative burden

<u>Qualifying Medical Condition Discussion</u>

Dr. Ballard updated the Board on guidance from the Attorney General's office:

- Board members can share materials with the whole board via email but cannot discuss those materials except at public meetings
- Board subcommittees can share materials via email with other subcommittee members, or the whole board, but cannot discuss those materials except at public meetings:
    - It was recommended that subcommittee members share materials via email with the entire board rather than subcommittee members only
    - All subcommittee meetings must be open to public and are subject to all the formal meeting rules of the full board

Public hearing requirement was discussed:

- State law requires that prior to the board making a recommendation on adding or removing a qualifying condition that the board hold a public hearing to solicit public input
- There was discussion of whether the next meeting should be a public hearing on the conditions currently being considered (opioid use disorder, anxiety, insomnia)
- As there is need for clarification of the timing, how to announce, where to meet and when, required rulemaking, and the legal mandate for such a hearing considering that the conditions currently being discussed are the subject of active legislation, it was decided to defer this decision

Discussion about a draft "criteria for inclusion" as an indication for therapeutic cannabis which had been circulated:

- There was some disagreement on the details of the criteria as stated, but some agreement that the principles raised by each point were important for discussion
- It was suggested that instead of using the draft as hard and fast criteria, these might serve as discussion points for considering the various proposed therapeutic indications

Proposed indications from the legislature for therapeutic cannabis were discussed:

- It was agreed that this session would be for initial discussion of the topics without decisions, formal proposals, or votes

Opioid Use Disorder. Three team members each provided comments followed by discussion.

- First
    - It was noted that CB1 and Mu opioid receptors are co-located and interactive throughout the nervous system and there is a huge emerging pre-clinical literature on their interactions
    - 30-40% of patients on OUD treatment in one clinician's practice also use cannabis (not necessarily registered therapeutic cannabis patients)
    - Should not discharge people from MAT programs for using cannabis; counterproductive to treating the disease of addiction
    - CBD is often the active component
    - Use, misuse, and addiction are different entities; need to parse these with respect to the legislative request
- Second
    - Difficult to identify studies for opioid use disorders. Clinical perspectives important too
    - Reports success in getting several patients off methadone using cannabis
    - Noted a colleague has developed a protocol for using cannabis to treat OUD and/or decrease analgesic opioids for pain
    - Observes great value in many patients in reducing or eliminating opioids both in context of pain and addiction
        - It was commented that real change should be measurable and measured. We need data beyond anecdote
- Third
    - A bibliography of human studies relevant to opioids and cannabis was circulated, divided into OUD specific, pain specific, and epidemiologic associations between indicators of cannabis use/harm and state cannabis policy changes
    - It was noted that OUD and pain treatment studies seemed more or less evenly divided between those that showed positive effects of cannabis in terms of outcomes or

reduction in opioid use and those that showed negative effects in terms of clinical outcomes or increased opioid use
    - The one human RCT of cannabinoids for OUD found that CBD alone indicated CBD significantly reduced cue related craving and anxiety in abstinent heroin users
    - It was suggested that perhaps this board should support off label use of pharmaceutical CBD and/or recommendation of OTC CBD for OUD:
        - The inconsistent nature of OTC CBD was noted
        - Alternatively, perhaps persons with OUD could be certified for CBD only
        - It was noted that THC may have a role as well; this is not clear
    - An opinion was offered that all pharmacologic treatment of OUD with a rewarding substance (THC or whole plant cannabis) should be provided/certified only by a trained addiction specialist with commitment to follow the patient closely and to revise treatment as indicated
- Discussion
    - It was noted that Massachusetts and other states have not affirmed OUD as an indication for cannabis use, but other states have. NH may be a pilot program if it approved OUD
        - There was speculation that states may stop affirming new indications once cannabis is legalized (as in Massachusetts) since it is then available for any adult use
    - There was some support expressed for cannabis certification for OUD (if approved as an indication) being managed by an addiction specialist or possibly x-waivered physicians who have at least a minimum of training in management of SUDs
        - It was noted that in pain medicine people, providers sometimes just take patients with aberrant opioid-related behaviors off opioids, provide them certification for cannabis and wish them well. Referring them to an addiction provider for certification in this context of opioid misuse would be more clinically appropriate.

Anxiety

- Reviewer reported some limited and mixed evidence that cannabis can:
    - Reduce anxiety
    - Increase anxiety
- There was discussion of terpenes, chemicals associated with scent of botanicals and implicated as modulators of cannabinoid actions
- One clinician reported clinical experience seeing a large reduction in anxiety in patients using cannabis
    - Stated that patients with history of anxiety should use low THC products
- It was noted that first line treatment for anxiety should be biobehavioral, eg CBT, exercise, mindfulness other non-medication interventions prior to meds
- Review of Cornel Stanciu's and Mary Brunette's systematic review of cannabis and cannabinoids for anxiety, which has been submitted for publication, was recommended prior to the group making a recommendation

Insomnia

- Insomnia Is a co-occurring diagnosis in most pain states

- Pain, nausea, and sleep are the top three conditions for which patients report use of cannabis
- One review reports overall increase in sleep quality:
    - Sleep latency reduced by more than an hour
    - THC versus CBD:
        - THC decreases latency
        - CBD helps with nightmares
        - High CBD may be helpful with OSA
- National Academy of Science did find moderate efficacy for sleep
- Some literature suggests that long-term sleep is disrupted by chronic cannabis use
- One clinician noted that sleep is the first thing that seems to improve when patients use cannabis for another target symptom. Another person stated that it is helpful for chronic pain and sleep
- It was noted that THC interferes with dreaming and for some people that is good because dreams can be disturbing
- One study was noted of combat veterans with PTSD and anxiety that found that THC an hour before bedtime decreases REM sleep and increase deep sleep phase

Public Comment

Keenan Blum, administrator of Prime ATC:

- Offered his help, happy to provide a perspective from the clinical side. Can arrange patients for board to speak with
- Mentioned that Dr. Corey Burchman is Prime ATC's medical board member
- Was asked how many certifying providers engage with the ATCs and whether they provide guidance on cannabis choices. Responded:
    - Prime sees about 1000 patients monthly; has 3248 registered patients
    - 30 providers have given direct instructions to the ATC
    - About 50% of patients report verbal instructions from their providers
    - Observes that most patients see their doctors regularly; believes this is important

Meeting Dates

An additional board meeting was scheduled for Wednesday, October 9th, 5:30 to 7:30 p.m.

Meeting adjourned at 7:40 p.m.

Next meeting Wednesday, September 4th, 5:30-7:30 pm, 29 Hazen Drive, Room 312.