



**STATE OF  
OHIO**  
BOARD OF PHARMACY



**OFFICIAL MINUTES OF THE AUGUST 23, 2019  
MEETING OF THE STATE OF OHIO BOARD OF PHARMACY, HEALTH CLAIMS REVIEW  
COMMITTEE**

**10:03 a.m.** The Health Claims Review Committee convened in room 1914, 19<sup>th</sup> Floor, Vern Riffe Center for Government & the Arts, 77 South High Street, Columbus, Ohio, with the following committee members present:

Kathy Burns, MS, APRN-CNS, AGCNS-BC, Bridget Protus, PharmD, MLIS, BCGP, CDP, Krissy Reinstatler, PharmD, BCPP, Jan Scaglione, M.T., PharmD, D.ABAT, GERALYN Waters, PharmD, BCPS, and Harrison Weed, MD.

Stephanie Abel, PharmD, BCPS, **Absent**

Also present were Erin Reed, *Director of Medical Marijuana*, Christopher H. Logsdon, *Manager of the Medical Marijuana*, and Stephen Wilson, *Medical Marijuana Licensee Liaison*

Ms. Reed opened the meeting by thanking members for the willingness to serve on the Health Claims Committee. Ms. Reed briefly addressed the history of the program and then reviewed the charge of the committee. Ms. Reed also introduced Ms. Protus as the committee chairperson.

Members and attendees then introduced themselves, their professional backgrounds, and their relevant interests in the program.

**10:16 a.m.** Ms. Protus took the roll call; noting a quorum of the members were present, she opened the committee meeting to consider regular business. After addressing rules of conduct and attendee participation, Ms. Protus asked staff to present the first agenda item: Committee Orientation.

*Material Reviewed: Committee Orientation - Slide presentation*

**10:20 a.m.** Ms. Reed began by identifying Mr. Wilson as the primary point of contact for marketing and advertising matters. Ms. Reed then began her presentation. The following subjects were presented:

1. A review of the origins of the Medical Marijuana program in the State of Ohio and H.B. 523, which created the program.
2. A review of the role and responsibilities of the three agencies responsible for regulating the Ohio Medical Marijuana Control Program: the Ohio Department of Commerce, the Ohio State Medical Board, and the Ohio Board of Pharmacy.
3. The Ohio Medical Marijuana Control Program guiding principles.
4. Applying for a license to dispense medical marijuana in Ohio, the process involved in issuing a certificate of operation to dispense, and the license renewal process.
5. The key timelines and dates for implementing the Ohio Medical Marijuana Control Program.
6. Forms and methods of administration authorized.
7. Prohibited forms and methods of administration.
8. Determination of 90-day supply of products dispensed and the difference between tier I and tier II products.
9. Product identification process in the seed-to-sale system and naming conventions.



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Members of the committee asked questions throughout the presentation and Ms. Reed addressed each question raised.

Ms. Reed then continued with the presentation by reviewing the licensing process. The following subjects were reviewed:

1. The license distribution and the Request for Application (RFA) processes.
2. The allocation of licenses guiding principles and statutory requirements.
3. A review of the current distribution map

Members of the committee asked questions throughout the presentation and Ms. Reed addressed each question raised.

Mr. Logsdon followed Ms. Reed's presentation. Mr. Logsdon reviewed the patient and caregiver registration process and the current active registration numbers. The following material was reviewed:

1. The physician certificate to recommend process, including determination of qualifying condition, registry in the Medical Marijuana Registry, and the notification of registration to the patient.
2. A review of the total number of current physicians authorize to recommend medical marijuana.
3. The patient registration process, registration fee payment, and use of the patient registration card to obtain medical marijuana at a licensed dispensary.
4. A breakdown of patient recommendations by registration status and diagnosis types.

**11:29 a.m.** The Committee took a break.

**11:42 a.m.** The Committee returned to public session.

Mr. Wilson followed Mr. Logsdon. Mr. Wilson reviewed the advertising and marketing process, including a review of standardized responses for health claims submissions. The following information was reviewed:

1. Prohibitions on advertisements for medical marijuana that address safety and efficacy without substantive evidence and clinical data.
2. Health Claims Review Committee process
3. Categories of health claims
4. 16 examples of health claims and standardized responses.

Mr. Wilson address member questions throughout his presentation. A question concerning testing for terpenes was addressed by Ms. King, Director of Strategic Initiatives for the Ohio Department of Commerce, Medical Marijuana Control Program, who was present in the audience.

Last, Mr. Logsdon reviewed provisions of Ohio Sunshine law, and Ohio Ethics law. The following areas were addressed:

1. Open meetings requirements.
2. Violations of the Open Meeting Act, including "Round Robin" prohibitions.
3. Public records requirements, including the definition of a public record and form, media, and content.
4. Ohio Ethics statute references for conflict of interest, unlawful interest in a public contract, and soliciting or receiving improper compensation.



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**1:00 p.m.** The Committee took a break.

**1:09 p.m.** The Committee returned to public session.

**1:09 p.m.** Review of Advertising and Marketing Health Claims. Ms. Protus asked the staff to present the health claim submission for item 1342 v3 Clubhouse Dispensary.

*Material Reviewed: (1) Clubhouse dispensary health claim submission with pin cite referenced support documents; and (2) Summary of Clubhouse dispensary health claims submissions and location of pin cites.*

Mr. Wilson reviewed a document containing a summary of the health claims, the supporting references, and the pin cites filed by Clubhouse Dispensary. Additionally, all members were provided a copy of the submission and the references provided by the Clubhouse Dispensary. Members reviewed and discussed each claim. Following discussion, the following recommendations were read:

### **1342 v3 Clubhouse Dispensary Health Claims Committee Recommendations**

#### **Key**

- Remove = ~~words stricken~~
- Add = underline
- Replace entire statement with suggested language
- Status/Recommended Language – applies to all references in the Health Claim

| Health Claim | Location of Claim in the Advertising Material                         | Status / Recommended Language                                                                                                                                                                                                                                                                                                                                                     |
|--------------|-----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.A          | 2 <sup>nd</sup> column, 3 <sup>rd</sup> row, 3 <sup>rd</sup> sentence | "Cannabinoids are lipophilic. This means they combine with or dissolve in lipids or fats to travel through your bloodstream."                                                                                                                                                                                                                                                     |
| 2.A          | 5 <sup>th</sup> column, 3 <sup>rd</sup> row, entire block             | "Edibles could be beneficial if used correctly. Patients that have more persistent, chronic ailments typically feel more relief with edibles. This is due to the anti-inflammatory properties linked to your CB2 receptors within your immune and central nervous system. Edibles could help provide long lasting relief with no irritation to your lungs or respiratory system." |
| 3.A          | 4 <sup>th</sup> column, 3 <sup>rd</sup> row, entire block             | "Products such as edibles, capsules and tinctures could provide hours of relief to a patient from just a single dose. In most cases, these products are also                                                                                                                                                                                                                      |



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|     |                                                                                                                                                                                                                                                       |                                                           |                                                                                                                                                                                                                                                                                                                                                |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     | offered in high doses of CBD and low doses of THC. This means these products could be consumed and provide hours of relief for minor aches and pains with minimal psychoactive effects."                                                              |                                                           | patient from just a single dose. In most cases, these products <del>are also</del> <b>Products</b> are also offered in high doses of CBD and low doses of THC. This means these products could be consumed and provide hours of relief for minor aches and pains with <b>may have</b> minimal psychoactive <del>effects</del> <b>effect</b> ." |
| 4.A | "Topicals have the potential to provide hours of relief for minor aches and pains."                                                                                                                                                                   | Claim not included in the advertising submission          | "Topicals have the potential to provide hours of relief for minor aches and pains."                                                                                                                                                                                                                                                            |
| 5.A | "While vaporizing has been proven to be less dangerous for the respiratory system than smoking, a lot of patients don't want to risk it. Patients with ailments affecting the respiratory system should choose a different method of administration." | 5 <sup>th</sup> column, 4 <sup>th</sup> row, entire block | "While vaporizing has been proven to be less dangerous for the respiratory system than smoking, a lot of patients don't want to risk it. Patients with ailments affecting the respiratory system should choose <b>consider</b> a different method of administration."                                                                          |

**The Committee also identified the following health claims that will require remediation:**

|     | Health Claim                                                                                                         | Location of Claim in the Advertising Material             | Status / Recommended Language                                                                                                                                                                                                          |
|-----|----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.B | With the use topicals, there is no need risk irritation to your lungs or respiratory system.                         | 4 <sup>th</sup> column, 2 <sup>nd</sup> row, entire block | Statement may not be made without substantial evidence or clinical data. Statement may be modified as follows: Talk to your recommending physicians about whether topicals can be used to treat symptoms of your qualifying condition. |
| 2.B | Depending on your metabolism and the dose consumed, oral forms of administration could last anywhere from 4-8 hours. | 3 <sup>rd</sup> column, 3 <sup>rd</sup> row, entire block | Depending on your metabolism and the dose consumed, oral forms of administration could last anywhere from 4-8 hour, <b>or longer</b> .                                                                                                 |
| 3.B | Keep in mind, the faster the effects of a product are felt, the faster the effects will                              | 3 <sup>rd</sup> column, 4 <sup>th</sup> row, entire block | "Keep in mind, the faster the effects of a product are felt, the faster the effects will wear                                                                                                                                          |



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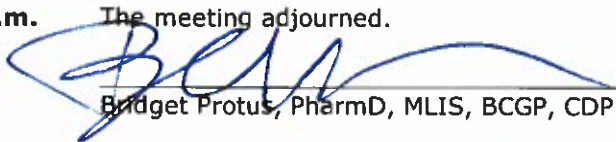
|     |                                                                                                                                                                                                                                  |                                               |                                                                                                                                                                                                                                                               |
|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     | wear off. Depending on the dose, patients typically feel the effects of vaporizing for 2-3 hours.                                                                                                                                |                                               | off <u>inhalation results in faster onset</u> . Depending on the dose, patients typically feel the effects of vaporizing for 2-3 hours."                                                                                                                      |
| 4.B | While vaporizing is less dangerous for the respiratory system than smoking, a lot of patients don't want to risk it. Patients with ailments affecting the respiratory system should choose a different method of administration. | 5th column, 4 <sup>th</sup> row, entire block | "While <del>vaporizing is less dangerous for the respiratory system than smoking, a lot of patients don't want to risk it.</del> Patients with ailments affecting the respiratory system should choose <u>consider</u> a different method of administration." |

The Committee also recommends that patches be removed from the category of topical administration and a distinct patch category created. Additionally, the Committee recommended that the Board consider issuing a warning on the dangers of vaping.

**R-2020-001** Dr. Weed moved to approve the recommendations as read. Ms. Watters seconded the motion. Discussion: None. Motion carried: 6- Yes, 0- No.

**R-2020-002** Ms. Watters moved to adjourn. Dr. Weed seconded the motion. Discussion: None. Motion carried: Aye - 6/ Nay - 0.

**2:40 p.m.** The meeting adjourned.

  
Bridget Protus, PharmD, MLIS, BCGP, CDP

Date: 12/30/2019