GEORGIA BOARD OF PHARMACY

Low THC Committee Conference Call 2 Peachtree St., N.W., 6th Floor Atlanta, GA 30303 February 1, 2023 1:00 p.m.

The following Committee members were present:

Cecil Cordle, Chair Michael Brinson Dean Stone **Staff present:**

Eric Lacefield, Executive Director Dennis Troughton, Director, GDNA Max Changus, Senior Asst Attorney General

Clint Joiner, Attorney

Brandi Howell, Business Support Analyst I

Visitors:

Becca Hallum, Georgia Hospital Association

Open Session

Mr. Cordle established that a quorum was present and called the meeting to order at 1:02 p.m.

Mr. Lacefield asked the visitors on the call to send an email via the "Contact Us" portal on the website if he/she would like his/her name reflected as being in attendance in the minutes.

Low THC Discussion

Mr. Cordle thanked Mr. Joiner for the materials he pulled together and sent to the Committee to review. He stated that the purpose of the call is for the Committee to discuss responsibilities and the licensure process for low THC dispensaries.

Mr. Cordle explained that the law requires the Board to develop an annual, nontransferable specialty license for pharmacies to dispense low THC products. He stated that the Committee would like to move forward with the specialty license being under the retail pharmacy license. He further stated that a pharmacy would need to hold an active retail license to be eligible for the specialty dispensing license. Mr. Cordle stated that there would be a separate application for the specialty license. He added that one of the requirements for a specialty license is the pharmacy would be ineligible to purchase any prescription medications, dangerous drugs, or controlled substances under this license. He stated that defining part of that license is the location of where THC can be dispensed and should be made accessible to as many patients as possible. He further stated that the product would be allowed to be contained in the pharmacy if the business decides to do that, but it has to be licensed as a retail pharmacy.

Mr. Cordle stated that the Committee should consider rules for pharmacies that want to dispense the product at a separate location or offsite. He further stated that the product would have to be secure and the Committee would need to define what "secure" is.

Mr. Stone commented that the Board is charged with protecting the public. He stated that the Board must be diligent with creating rules regarding this matter. He further stated that he understands that the rules could be amended, if needed, but it would be best to not create rules that would be stricter than what the Georgia Access to Medical Cannabis Commission ("Commission") has laid out for the dispensaries. Mr. Stone explained that there would be a retail pharmacy permit and a subset license. He stated that the

license number of the subset license would reference that permit number of the parent pharmacy. He continued by stating that if a regular retail pharmacy wants to keep the product inside the four walls of the pharmacy, it can, but if the pharmacy wants to have a site outside of the pharmacy, that would be restricted because that license would not allow them to buy any other products other than low THC. The pharmacy would have to follow all security measures where they can operate that dispensing pharmacy outside their regular/parent pharmacy permit. Mr. Stone stated that he does agree that could be an option, but thinks it would require two different sets of rules. Mr. Cordle stated that if the product is in the retail pharmacy, the rules for storage are already there.

Mr. Changus commented that it is hard to envision exactly how the General Assembly was looking for this to roll out. However, he stated that O.C.G.A. § 16-12-206(a)(1) reads in part, "Upon request by a licensed pharmacy in this state, the State Board of Pharmacy shall be authorized to develop an annual, nontransferable specialty dispensing license for an independent pharmacy with a registered office located within this state to dispense low THC oil and products to registered patients..." Mr. Changus stated that this does seem to envision the pharmacy itself having a role to play. He further stated that he thinks that is why the General Assembly was looking for pharmacies to be involved in the dispensing of low THC because they have knowledge and understanding of registered patients as well. He added that it seems like it should be integrated into the practice of pharmacy as carried out by those licensed pharmacies.

Mr. Cordle stated that if that was the General Assembly's intent, he would like for them to require a pharmacist at every dispensary that is licensed. Mr. Cordle continued by stating that there was not any language regarding what responsibility a pharmacy owner would have in the dispensing process.

Mr. Stone agreed with Mr. Cordle. He stated that this is a great opportunity to help the patients in this state and feels pharmacists should be involved in the process. He discussed keeping low THC products in a secure location and having the personnel to oversee that process and dispensing the product. He stated that the Board should allow for the dispensing of the product from either inside a retail pharmacy or offsite.

Mr. Cordle agreed and stated that he feels that gives the retail license the option to decide whether dispensing low THC fits their business model. He stated that there has been discussion about how insurance companies and DEA would feel about this. He stated that if the Board were to allow for the dispensing of the product from inside a retail pharmacy or offsite in a controlled way, the pharmacy can decide which way fits their business model the best.

Mr. Brinson commented that the Board has the authority to allow for a licensed pharmacy to obtain a separate license and integrate that into the store. He asked Director Troughton if the pharmacy created a separate space inside the building where the product could be dispensed and kept secure, would that satisfy DEA regulations or an insurance company's concerns about a separate location. Director Troughton responded by stating that the Board creates the rules and GDNA would enforce those rules as the Board sees fit. He commented that whether or not a separate space inside or outside was allowed would be a question for Mr. Joiner or Mr. Changus. He continued by stating that the way he originally interpreted it was being in the pharmacy. He stated that whether the pharmacy is a chain pharmacy or large independent store, the pharmacy is not the whole building. Director Troughton stated that when the Board issues a pharmacy license, it is licensing that pharmacy space only, not the entire building. He further stated that if the license allows the pharmacy to open up a separate space inside or down the street makes no difference. He added that once the location is determined whether it is in the pharmacy or if it is an extension of the pharmacy, GDNA can adapt to that without any issues.

Mr. Brinson commented that, by law an independent pharmacy can dispense low THC products in their store if they choose. Director Troughton affirmed that with the proper licensing, that is correct. He stated

that he was pointing out that in some stores the whole space or building is not considered the pharmacy, only the prescription department is licensed. He stated that it is up to the Board to decide whether licensure is appropriate, and GDNA can enforce without any issues.

Mr. Cordle stated that, to Director Troughton's point, it needs to be clearly identified as a dispensary if it is outside the pharmacy. Mr. Stone commented that the product should also be kept secure exactly like in a pharmacy.

Mr. Cordle commented that if it is outside the retail space and identified, he does not see where a pharmacist would be required to be onsite if a dispensary was open. Director Troughton responded by stating that O.C.G.A. § 16-12-230(b) reads: "A pharmacist who dispenses low THC oil or products shall seek and review information on a registered patient from the prescription drug monitoring program data base established pursuant to Code Section 16-13-57 prior to dispensing low THC oil or products to the registered patient."

Discussion was held regarding reviewing the Prescription Drug Monitoring Program ("PDMP"). Mr. Brinson inquired as to whether or not the pharmacist was looking for interactions that may occur. He expressed his concerns as to why it has to be done as there is no criteria established regarding what a pharmacist is supposed to look for when reviewing the PDMP.

Mr. Stone stated that in reviewing the statute, it does not require a pharmacist to report to the PDMP. He added that it states, "shall seek and review". He further stated that the pharmacist is making sure there are no interactions and should be knowledgeable about what strains the patient is using and dosages.

The Committee discussed creating a subset license with a different designation and matching it up with the parent pharmacy. Mr. Lacefield stated that there is an ability to issue a specialty license with its own designation that is attached to the underlying pharmacy at the same location. He further stated that he did not know if that is something that could be done for an offsite location. He explained that he gave Mr. Joiner direction on drafting rules with the impression that Committee was moving towards having the specialty license linked to the retail pharmacy, along with including the product in the inventory, treating it like it is a dangerous drug in the inventory at that location and following the rules required for a retail pharmacy. However, Mr. Lacefield stated that it sounds like the Committee is talking about that scenario, plus the scenario of allowing the pharmacy to have a specialty license outside the walls of pharmacy that would not have licensed pharmacy personnel in that adjacent/offsite location, which would require separate rules. He added that staff could draft rules for what the Committee desired, but requested staff be provided with specific direction on what the committee wanted.

Mr. Joiner stated that in the law and rules when there is a separate location, a separate license is required. He further stated it would be two distinct rules from a drafting perspective. He explained the first rule would cover the instance where the dispensary is inside of a retail pharmacy and the second rule would cover the dispensary being a separate stand alone. He stated that because of the different situations those are in, different rules would be required. Mr. Cordle agreed and stated the Committee originally talked about having the dispensary inside with the other dangerous drugs; however, in speaking with other people regarding this matter, Mr. Cordle stated that there are concerns about how to be compliant with the legalities of this product, how does one protect themselves as a retailer if he/she wants to dispense this product from inside the store. Additionally, he stated there is concern about the questions it may raise from insurance providers or the DEA who may have a different view on low THC than Georgia. Mr. Cordle stated the Committee wants to provide two distinct and separate pathways and let the licensee decide which one is best for his/her business model.

Mr. Changus commented that O.C.G.A. § 16-12-230(b) seems to indicate that it is intended to have a pharmacist involved. He inquired if there is a separate location, would that location be staffed by a pharmacist there just to handle the product and would that be enough to run a separate location. He continued by stating that the law states that a licensed pharmacy may apply for a dispensing license to provide this product. Mr. Changus stated that this does not open it up to anyone to apply, it states the pharmacy may apply and as such it seems like it should be tied to the pharmacy. He added that the less it looks associated to the pharmacy, would seem as though the intent of the General Assembly was not being followed.

The Committee discussed the draft prepared by Mr. Joiner. Mr. Cordle stated that he and Mr. Stone could further review the draft and make adjustments where necessary. He further stated that he felt the dispensary rules should be similar to the retail rules.

Mr. Stone discussed moving forward with what the Committee has put together at this point by following the retail rules, and suggested having discussion having a separate location or site outside the pharmacy at a later time. Mr. Changus responded by stating that having the specialty license tied to the pharmacy in the pharmacy is what he thinks was intended by the General Assembly. He stated that as the Committee moves forward with this, it can make adjustments as it sees fits.

After further discussion, the Committee agreed to create a subset license that would be linked to a retail pharmacy license, but that subset license would be ineligible to purchase any products other than low THC.

Mr. Cordle inquired if this matter could be brought before the Board at its February 15th meeting. Mr. Lacefield responded by stating that the rules still need to be refined. He added that staff can refer to the retail rules for most of the requirements; however, there are some sections that will need additional language with regard to records, requirements of dispensing, etc. He stated that much of that has been spelled out in the Commission's rules and the Committee could borrow from that language.

Mr. Joiner stated the Committee has made a lot of progress and he should be able to prepare a draft quickly, but feels the Committee should have an additional meeting. The Committee agreed to meet in person at the DCH office on February 15, 2023, at 8:00 a.m.

Approval of Minutes

Mr. Stone made a motion to approve the December 19, 2022, Conference Call minutes. Mr. Brinson seconded, and the Committee voted unanimously in favor of the motion.

There being no further business to come before the Committee, the meeting was adjourned at 2:11 p.m.

The next scheduled meeting of the Low THC Committee of the Georgia Board of Pharmacy will be held on Wednesday, February 15, 2023, at 8:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 5th Floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Support Analyst I Minutes edited by Eric R. Lacefield, Executive Director