

GEORGIA BOARD OF PHARMACY
Low THC Committee Conference Call
2 Peachtree St., N.W., 6th Floor
Atlanta, GA 30303
December 19, 2022
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:

Blair Curless

Open Session

Mr. Cordle established that a quorum was present and called the meeting to order at 1:01 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 explained that pursuant to O.C.G.A. § 16-12-206, the Georgia Board of Pharmacy has been directed to develop an annual, nontransferable specialty dispensing license for Georgia independent pharmacies to dispense low THC oil and products to registered patients and to adopt rules pertaining to the dispensing of low THC oil and products.

Mr. Cordle continued by stating that the Georgia Access to Medical Cannabis Commission (“Commission”) released public notice for proposed rules which will be reviewed by the Committee and the Board.

The Committee discussed draft rules pertaining to a low THC oil specialty dispensing license. Mr. Cordle read the following:

Rule 480-6-.03

- (1) An independent pharmacy holding an active pharmacy license in this state pursuant to Rule 480-6-.01 shall be eligible to obtain one Low THC Oil Specialty a Dispensing Pharmacy License provided that:
 - a. The licensee shall dispense Low THC oil and products at the same location as the licensed independent pharmacy or in a separate establishment located outside the boundaries of the Georgia licensed pharmacy provided however that the separate establishment shall not be located beyond 1 mile of the Georgia licensed pharmacy and the separate establishment shall dispense only Low THC oil and products and shall not dispense dangerous drugs or other controlled substances; and

- b. The low THC oil specialty dispensing pharmacy shall not be operated in any location within 1,000 foot radius of a public or private school, an elderly care of education program as defined in O.C.G.A. 20-1A-2; or a church, synagogue, or other public place of religious worship, in existence prior to the date of licensure of such licensee by the Georgia Board of Pharmacy.

Mr. Cordle stated that it was important to note that the pharmacy holder would have to have an active license in Georgia.

Mr. Cordle stated there was information in the Commission rules he believes the Board should draw from. He stated that O.C.G.A. § 16-12-215(a) states in part, "...Notwithstanding the provisions of this subsection, local governments may, via use of existing zoning powers otherwise provided by law, allow dispensing licensees only to locate in places other than those provided in this subsection so long as such modification is needed to allow retail outlets to be established to service registered patients residing within such local jurisdiction..." Mr. Cordle stated that this would allow the local jurisdiction to meet some needs because in some of the areas of needs our pharmacies are downtown within some of these restrictions. He added that the needs of the town are met by those businesses and places of worship are inside the city limits.

Mr. Stone commented that it is important that the patients can be serviced. He stated that in rural areas, one cannot go in any small pharmacy and not be close to a church or post office because of where it is located. He added that a pharmacy that has that specialty license can be located within a mile from the pharmacy to be able to meet the need of the patient. Mr. Stone stated that he was interested in hearing Mr. Joiner's and Mr. Changus' thoughts on the matter.

Mr. Changus stated that he believes the idea behind the other facility somehow connected to the pharmacy is designed to address some of the concerns about the federal status of marijuana. He further stated that he thinks that language was included to address what he thinks is a legitimate concern. He continued by stating that he did not know if the General Assembly intended that a pharmacy, in order to be able to do this, would have to establish a separate location for the provision of these substances. Mr. Changus stated that he thinks the idea is the licensure scheme allows the Board of Pharmacy to issue licenses and allows the Commission to issue dispensing licenses to class I and class II facilities that are identified in the statute. He added that it seems to be cumbersome in terms of someone looking to engage in the dispensing of low THC oil and products. He stated that addressing that concern, whether or not that is something the Board feels it needs to stick with, is a reasonable question at this point.

Mr. Joiner stated that O.C.G.A. § 16-12-215(a) reads in part, "...Notwithstanding the provisions of this subsection, local governments may, via use of existing zoning powers otherwise provided by law, allow dispensing licensees only to locate in places other than those provided in this subsection..." He further stated that as such, it would be within the 1000 foot envelope. Mr. Joiner added that there is a local solution for the problem, but one would have to go through a zoning board to do that. Mr. Brinson commented that the zoning board could grant a waiver.

Director Troughton commented that from what he understood a pharmacy could dispense low THC if it obtained the additional license. He inquired where it states in the law that the pharmacy could get a place down the street and call it "Dennis' Professional Pharmacy in Kennesaw Low THC", for example. Mr. Changus responded by stating that the zoning issue about where these licenses can be issued in any restriction seems to be is a separate matter. He continued by stating that there may be some relief on where these places can be housed. 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 a license can be issued through that pharmacy. He further stated that he does not see how that is necessarily contemplated in the statute itself. He added that he thought the idea of having this other annex is to prevent it from being mixed in with the pharmacy itself given the concerns about federal restrictions.

The Committee discussed reporting through the PDMP. Director Troughton stated that it does not make sense that he is a pharmacy and can open up a dispensary down the street. He stated that it seems like they are saying that you can have this in the pharmacy, but if you are a dispensary you cannot dispense anything else. He further stated that as far as a pharmacy, now you are getting this specialty license so you can bring that product into your pharmacy and sell it. He explained that there is a pharmacist who is required to dispense the product and a pharmacist that is required to check the PDMP. Director Troughton stated that is where he is getting confused and seems like it is opening a third category. Mr. Stone responded by stating that he has not read where the pharmacist has to report since this is not prescriptions, but rather it is a letter from physician being brought to the pharmacy by the patient to be dispensed.

Director Troughton discussed O.C.G.A. § 16-12-230(b), which states: “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.” Director Troughton stated that the language states “shall”. He further stated that this language tells him if he has a pharmacy license dispensing low THC, he shall look at the PDMP to review what else the patient receives. Mr. Brinson commented that this was not true for the dispensaries that are on the other side that do not have to do that. He stated that one of the issues he has is that the Board is being held to a different set of rules than the dispensaries. He further stated that all playing fields should be level. Director Troughton stated that, to the point he was making, he is not debating what the legislature says. He added that it is his job is to work through the enforcement side so he can better assist the Board.

Discussion was held regarding needing to hold a current pharmacy license in order to obtain a specialty dispensing license.

Mr. Lacefield inquired if the independent pharmacy or licensed pharmacy is merely a prerequisite for being able to get licensed and is not location specific, or is it at the location the licensed pharmacy. Mr. Changus responded by stating that the statute says, “upon request by a licensed pharmacy”, which means one has to have a licensed pharmacy established in some sense to make application. He added that the statute also says in part, “...the State Board of Pharmacy shall be authorized to develop an annual, nontransferable specialty dispensing license for an independent pharmacy...” Mr. Changus stated that “independent pharmacy” is a term of art in the world of pharmacy and is not a chain pharmacy. He further stated that in reading the statute, one would think it was contemplated they would be setting up an additional pharmacy like a dispensary. He added that he was unsure if the intent was to allow a pharmacy to establish another pharmacy down the road to dispense this one product. Mr. Changus stated the physical location would need to be established and it would need to be staffed appropriately for it to be a pharmacy.

Mr. Lacefield inquired if that would be an operational decision for that particular pharmacy. Director Troughton responded by stating if they have a valid pharmacy license and want to obtain a low THC dispensing license, he does not see anything wrong with that from an enforcement standpoint. He added that GDNA would inspect it like it normally would. He continued by stating that they would have to have the pharmacy license in that same spot with the low THC and would fall under the same guidelines as a

pharmacy, plus low Thc. Director Troughton stated that it seemed like the part about not dispensing for anything else was meant for the dispensaries.

Mr. Stone stated that he feels the pharmacists are positioned to assist patients for this because he considers this a medication designed to help patients. He further stated that he does not want to put restrictions on pharmacists and pharmacies trying to meet a need for the public. He continued by stating that he does not see this as pharmacist having to be there all the time as he believes patients can be seen by appointment. He added that he thinks the operations of this will be different. Mr. Stone discussed this being a separate license type that falls under different requirements and it not necessarily be ran like a regular retail pharmacy where the pharmacist has to be there all day long and be available personally right there.

Mr. Brinson agreed it has to be a specialty license or a separate type of license all together. He stated that the way the law reads is it has to be a separate establishment.

Mr. Cordle agreed that it has to be a specialty license. He asked does it tie into being a separate location or not. He stated that he thinks the Committee agrees that it would rather not have that component of it being one mile down the road. Mr. Stone agreed and stated that he could see potential issues with that part as it would be hard to maintain and identify that.

Mr. Cordle stated that would be taken under advisement and the draft rule may need to be adjusted a bit. Mr. Joiner inquired if it was the Committee's decision to not have separate locations, but rather only allow dispensing through the pharmacy. Mr. Stone responded by stating that he thinks the Committee is saying if a pharmacy chooses to dispense low THC that is fine, but in order to do so a separate type of license would need to be obtained. Director Troughton commented that a new license type would be created. He added that the pharmacy would obtain two licenses, one for low THC license and the other being a specialty low THC dispensing license. He stated that one would not need to have a retail store. Director Troughton stated that GDNA would enforce the rules written for a THC license. He further stated that the Board would create rules as to when a licensed pharmacist has to be there.

Mr. Cordle read the remainder of the draft of Rule 480-6-.03:

- (2) Application for Low THC Oil specialty Dispensing Pharmacy License:
 - a. Applications must be filed with the Georgia State Board of Pharmacy located at the Department of Community Health, 2 Peachtree Street, 6th Floor, Atlanta, GA 30303, along with the required fee.
 - b. Application will be considered on the basis of the application filed and an approval letter received from the Director of the Georgia Drugs and Narcotics Agency certifying the pharmacy possesses the necessary facilities and equipment for a license.
 - c. The application fee shall NOT be refundable.
- (3) Every low THC oil specialty dispensing pharmacy shall be under the direct charge of a registered pharmacist whose name shall appear on the license. In the event such pharmacist whose name shall appear on said license shall no longer be in charge of a low THC oil specialty dispensing pharmacy, the Board shall be notified immediately, and shall be notified, at the same time, of the successor registered pharmacist.
- (4) Licenses shall not be transferable. Licenses become null and void upon the sale; or change of mode of operation of the business.
- (5) Licenses shall be renewed annually and expire on June 30th of each year and may be

renewed upon the payment of the required fee and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st, the license shall lapse and shall not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

Mr. Cordle discussed the proposed rules released by the Commission. He stated that Mr. Joiner has read through that information. He asked Mr. Joiner if he had any comments. Mr. Joiner discussed O.C.G.A. § 16-12-206(b)(4), which speaks to maintaining an adequate supply for registered patients for a period of one month. He stated that there was discussion about whether that was a logistical question of having to have enough inventory to supply patients for a month or if that was a dispensing question of being able to give the patient enough supply for a month. He added that the Commission seems to have answered that in proposed Rule 351-3-.02(6), which requires applicants to provide their procedures for how they will ensure a steady inventory of product and maintain an inventory management plan.

Mr. Brinson requested the Attorney General's viewpoint on pharmacies dispensing schedule I drugs. Mr. Changus responded by stating that, while he was not speaking for the Attorney General's office, this is the mandate from the General Assembly. He stated that the Attorney General's office was assisting the Board with meeting its mandate. He further stated that he would like the opportunity to review the statute again and how it should be read, along with the proposed rules from the Commission.

Mr. Joiner stated that there are a few places in the Commission's rules that speak to "consultation", "consultation rooms" or that "consultation to a patient does not constitute advertising". He inquired as to what "consultation" meant as it appears to be the practice of pharmacy. Mr. Changus responded that he would like some time to review the law and proposed rules before opining. He stated that the Board has an obligation to meet the request of the General Assembly, but there are some complicated factors involved.

Mr. Brinson commented that there needs to be a level playing field between pharmacies and dispensaries. He added that both need to have the same rules and regulations.

Mr. Cordle inquired if there were any public comments. Dr. April Hang was on the call and spoke to the Committee. Dr. Hang stated she is a pharmacist and independent owner. She added that she has been trying to get in touch with the Commission to make suggestions. In regards to the PDMP, she stated that a code could be added so THC oil does get reported to PDMP. She commented that she was interested in the application process.

In regard to the two larger licenses not wanting to share their product, she commented that she had been approached and was asked to provide them with all of her physician's contacts to they could market directly to those physicians. She added that she declined to do so.

Dr. Hang stated that it needs to be a level playing field. She continued by stating that pharmacists are important because of drug interactions. She discussed the importance of getting pharmacists recognized as providers and allowing them to register patients. She stated that the smaller licenses need to be awarded because the larger companies will try and keep patients to themselves. She inquired as to what guidelines the Board was following. Mr. Lacefield responded by stating that the Committee was referring to the proposed rules posted by the Commission. He added that the Commission will hold a public hearing to discuss the proposed rules on January 25, 2023. He stated that anyone interested in viewing the rules could find them on the Commission's website. Mr. Lacefield stated that a notice would be posted on the Board's website as to when the Low THC Committee meets again.

There being no further business to come before the Committee, the meeting was adjourned at 2:05 p.m.

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