GEORGIA BOARD OF PHARMACY
Low THC Committee
2 Peachtree St., N.W., 5th Floor
Atlanta, GA 30303
February 15, 2023
8:00 a.m.

The following Committee members were present:
Cecil Cordle, Chair
Michael Brinson
Dean Stone

Board members present:
Michael Azzolin

Staff present:
Eric Lacefield, Executive Director
Michael Karnbach, Deputy Director, GDNA
Alec Mathis, Special Agent, GDNA
Max Changus, Senior Asst Attorney General
Kimberly Emm, Assistant Attorney General
Clint Joiner, Attorney
Brandi Howell, Business Support Analyst I

Visitors:
Reid Stone, Botanical Sciences
Gary Long
Brian Dalton
Becca Hallum, GHA
Zina Knaeler, Botanical Sciences
Kaitlyn Moreland, Janus Rx
Freyanna Magee

Open Session

Mr. Cordle established that a quorum was present and called the meeting to order at 8:00 a.m.

Mr. Cordle welcomed the visitors.

Mr. Cordle reminded the Committee of what its objective is and as members of the Board of Pharmacy that everything they do is with protecting the public in mind. He stated that in regards to the Low THC Committee it should not write rules that are more restrictive for the pharmacy business than the retail side of the dispensaries. He added that the goal is to try and keep a fair playing field, but also keep an open access to as many citizens of Georgia as possible.

Approval of Minutes
Mr. Stone made a motion to approve the February 1, 2023, Conference Call minutes. Mr. Brinson seconded, and the Committee voted unanimously in favor of the motion.

Low THC Discussion
Mr. Cordle stated that he appreciated Mr. Joiner's hard work on the draft rules provided. He further stated that drafts have been provided regarding the subset license the Committee previously discussed regarding retail pharmacies that will need to have the subset license in order to bring low THC into their stores. Mr. Cordle explained that is the framework of what the Committee wants to discuss today.

Mr. Stone commended Mr. Joiner on the job well done on the draft rules. He stated that one item previously discussed by the Committee was allowing for the dispensing of the product from inside a retail

pharmacy or offsite in a controlled way, but the Committee agreed on moving forward with what had been put together at that point by following the retail rules, and suggested having discussion about having a separate location or site outside the pharmacy at a later time.

Mr. Stone discussed the draft provided by Mr. Joiner. He stated that Rule 480-XX-.0G(1)(d) states that "Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business." He stated that if the retail pharmacy license is required prior to having a low THC license, he suggested striking this section of the draft because the retail license is required to start with.

Mr. Stone continued by discussing the draft referencing the Medical Cannabis Commission rules on the dispensaries and part of that incorporation into the retail side of it. Mr. Stone stated that he personally feels pharmacists are best at helping patients managing their diseases. He further stated that low THC is considered a drug and the pharmacist would be the best person to help the patient. He added that he wants to ensure that pharmacists are not being hindered from assisting those patients when there is a different set of rules for dispensaries.

Mr. Brinson commented that he has an issue with the statute requiring a pharmacist to review the Prescription Drug Monitoring Program ("PDMP") and not requiring anyone else to do it. He stated that he understands pharmacists are at a higher level, but feels it puts pharmacists on an uneven playing field. Mr. Brinson continued by stating that there are no guidelines as to what the pharmacist should be looking for when reviewing the PDMP.

Mr. Brinson expressed his concerns regarding the cost of low THC oil. He asked what will be the cost from the suppliers to the retail pharmacies as opposed to the dispensing clinics. He stated that another concern is about supply. He further stated that there is nothing written stating any distributor or grower must supply any product to a retail operation.

Mr. Brinson discussed sales and use tax O.C.G.A. § 16-12-226. He inquired as to what is a sales and use tax as there is no definition. He asked if the sales and use tax was just for retail pharmacies or was it also for all dispensaries. He stated that clarification is needed.

Mr. Cordle responded by stating that he believed most of Mr. Brinson's concerns are in the statute, and they are valid concerns; however, he was unsure as to what the Board could do regarding those matters. Mr. Brinson agreed.

Mr. Joiner discussed Mr. Stone's suggestion of striking the language in Rule 480-XX-.0G(1)(d) that states, "Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business." Mr. Joiner explained that the statute requires the license be non-transferable so that language cannot be removed. He stated that O.C.G.A. § 16-12-206(a)(1) states in part "…the State Board of Pharmacy shall be authorized to develop an annual, nontransferable specialty dispensing license…" Mr. Changus commented that the Committee should say that the license is not transferrable, which would be in line with the statute. He added that the idea of null and voiding these licenses is always a bit of a concern because there is property interest there. He stated that the subset license has to follow the pharmacy and does not get to exist on its own.

Questions and concerns were discussed by Deputy Director Karnbach. He stated that the Committee keeps referring to a retail pharmacy, but his assumption was this was open to any license type. He inquired if this was for strictly retail only. Mr. Cordle responded by stating that the Committee decided the pharmacy would need to hold an active retail license in order to apply for the specialty license. He explained that is why the draft refers back to the retail pharmacy rules and why there is not language about refrigerators, sinks, or square footage because the pharmacy has to meet those standards under the

primary license. Deputy Karnbach stated there are many hospitals, especially children's hospitals. Mr. Brinson responded by stating that there was language regarding hospitals in the first draft, but it was stricken. Mr. Joiner stated that the discussion at the last meeting was that a hospital pharmacy that also had a retail pharmacy could have a dispensary permit under the retail license.

Deputy Director Karnbach inquired if the intent of the 150 square feet is that it is shared space. He asked if the retail pharmacy has 150 square feet, an additional 150 square feet would not be required. The Committee agreed. He inquired if the same applied to refrigerators and equipment, for example, that it is all shared. The Committee agreed. Mr. Joiner stated that a line was added to the new draft regarding the retail pharmacy prescription department being a shared space with the underlying low THC dispensing license.

Deputy Director Karnbach stated that if GDNA receives a complaint and has to conduct an investigation, what are the Board's expectations of the pharmacist in that role. He inquired if the pharmacist is required to check the product like a prescription, and should the pharmacist be checking the label. Mr. Stone responded by stating that he envisions low THC being treated like another drug in the retail department. He stated that the pharmacist would have to review, check for interactions, and check it to the best of his/her ability. Deputy Director Karnbach responded by stating that GDNA requests the rule be clear so the pharmacist knows what his/her expectations are. He continued by stating that when talking about a prescription medication the rule requires the pharmacist to check every prescription, including the contents and the label. He stated that does not apply to medications that are considered over-the-counter. Mr. Stone stated he understood Deputy Director Karnbach's point because there really is not a prescription as the patient will have a letter from the physician or a card. Mr. Lacefield added that it is a pre-packaged product that cannot be tampered with. Deputy Director Karnbach agreed and asked if the pharmacist would be obligated to check that product before it leaves the pharmacy or is the pharmacist authorizing the technician or cashier to sell it. Mr. Stone stated that he had that same concern. He further stated that it is really not a prescription and if the pharmacist is working it, there needs to be a way to track it. He added that he would lean more to treating it like a Sudafed product, for example. He stated that the Committee would have to add that in the rule to address that. Deputy Director Karnbach stated that it would make it easier if the Board were to receive a complaint and could rely on specifics as to what should have occurred. Mr. Stone stated that with dispensaries not having a pharmacist, that is why he stated the product should be treated like Sudafed. He added that his goal is to have pharmacists help patients and be involved in the process. Mr. Joiner commented that the draft is one step further than that. He stated that as far as storage and record keeping the direction is to treat low THC oil as a dangerous drug. He added that in regards to records of dispensing, receiving the product, storage, etc., the product would be treated as though it was a dangerous drug. Mr. Joiner stated that section .0J of the rule discusses how the product can be dispensed.

Deputy Director Karnbach discussed label requirements. He stated that if low THC is to be treated like Sudafed and GDNA does an inspection and sees the pharmacist is not checking the label, he asked would that be considered a violation. He stated the rules need to be as clear as possible so there is no ambiguity. Mr. Stone commented that his initial thought was to treat the product as a dangerous drug.

Mr. Cordle inquired if the following language from section (4) of draft Rule 480-XX-.0J Requirements for Dispensing Low THC Products came from the Commission's rules:

(4) All Low THC Products dispensed shall be labeled by the Low THC Pharmacy Dispensary with the following information: (351-6-.06(3))
  (a) Date the Low THC Product is dispensed to the patient; (351-6-.06(3)(a))
  (b) Patient identification information: (351-6-.06(3)(b))
    1. Patient's first and last name; (351-6-.06(3)(b)(iii))
    2. Patient's date of birth; (351-6-.06(3)(b)(iv))

3. Patient's unique patient registry serial number; (351-6-.06(3)(b)(ii))
4. Patient's caregiver's first and last name and unique patient registry serial number, if applicable. (351-6-.06(3)(b)(v))

(c) Name, address, and license number of the Low THC Pharmacy Dispensary; (351-6-.06(3)(b)(i))
(d) Directions for use of the Low THC Product; and (351-6-.06(3)(c))
(e) Any cautionary statement or symbols required. (351-6-.06(3)(d))

Mr. Joiner responded affirmatively. Mr. Stone commented that he was under the impression that the pharmacist had to check the label based on the language. Mr. Joiner responded by stating that the draft states what the label is supposed to have on it, but it does not say the pharmacist has to check it. Deputy Director Karnbach commented that the law requires the pharmacist to check every prescription; however, he stated that low THC is not a prescription. He asked if language could be added to the rule one way or the other so that it is clear. Mr. Joiner responded by stating that any ambiguity should be removed.

Discussion was held by Deputy Director Karnbach regarding the statute requiring the pharmacist to check the label. Deputy Director Karnbach added that interactions, drug utilization review, etc., are proponents of a prescription check and label accuracy. He stated that there are three pieces for a prescription that a pharmacist is obligated to check for by law. Mr. Changus commented that the pharmacist is checking to see if there are interactions with other drugs, and what experience is there in terms of how it interacts with other drugs, etc. He added that part of the check seems inapplicable. Deputy Director Karnbach responded by stating that the pharmacist is not going to be able to open the package to check since it is pre-packaged. He stated that the concept seems to be to put a label on the product that is produced. He continued by stating that if it is the Board's intention to have the pharmacist check the accuracy of the label, GDNA was good with that. Mr. Changus responded by stating that he did not know if one could ask for any more than that. He stated that there are other aspects of storage and understanding what amounts can be distributed. He further stated, as indicated in the rule, making sure the registry number matches up with the card. Mr. Cordle commented that it is ultimately the responsibility of the license holder to make sure it is accurate.

Deputy Director Karnbach stated that if this were to be treated as a dangerous drug, he assumed this would be a technician function. He stated that when GDNA conducts its inspection and the pharmacy has the low THC section quarantined off, is that a function the Board intends to classify as a technician function. Mr. Stone responded by stating that the Committee has not addressed that much because the dispensaries will have staff that are not technicians. Deputy Director Karnbach stated that would depend on the setting. He added that the cashier is separate and does not perform technician functions. Mr. Stone stated that he personally thinks for the setting the Committee has outlined now, it would be a technician function. He added that the Committee has to be flexible as this is a new area and the rule may need to be changed when needed. Mr. Cordle commented that the language leads to it being a technician function. Mr. Stone agreed and stated that the rules allude to working in a retail pharmacy that would be a technician function unless the Committee specified otherwise.

Mr. Changus inquired as to who would be conducting the PDMP check because ordinarily there are not PDMP checks for pharmacists when dispensing. He stated that the pharmacist has to upload what is being dispensed but they are not doing checks. Deputy Director Karnbach responded by stating that the pharmacist is not required to do anything but submit to it. Mr. Stone commented that the law states the pharmacist shall review for low THC. Mr. Changus stated that if the card is presented by the patient and they are looking for this to be dispensed, it seems the pharmacist would need to be involved in that step. Mr. Brinson asked if this information was going to be on the PDMP. Mr. Stone stated it was not. He added that he thinks it is to help the pharmacist review and monitor as they treat the patient as dosages

change. He stated that is his interpretation of it. He further stated that it helps him make a better decision about how to treat the patient.

Mr. Changus commented that a bill dropped the day prior to amend O.C.G.A. § 16-12-206 to change the phrasing of low THC to medical marijuana. He stated that O.C.G.A. § 16-12-206 requires the Board to develop a license and rules. He further stated that section (b) states that such rules shall include but not be limited to:
(1) Standards, procedures, and protocols for the effective use of low THC oil and products as authorized by state law and related rules and regulations;
(2) Standards, procedures, and protocols for the dispensing of low THC oil and products by a pharmacy with a dispensing license and by retail dispensing licensees and for the utilization of a tracking system;
(3) Procedures and protocols to provide that no low THC oil or products may be sold to or transferred to a location outside of this state;
(4) The establishment of standards, procedures, and protocols for determining the amount of usable low THC oil and products that is necessary to constitute an adequate supply for registered patients in this state to ensure uninterrupted availability for a period of one month, including amounts for topical treatments;
(5) The establishment of standards, procedures, and protocols to ensure that all low THC oil and products dispensed are consistently pharmaceutical grade;

Mr. Changus stated that if the product comes prepackaged, he does not see any ability for the pharmacist to do anything with it. He added that there will be some holes in this and the Board should maintain its focus on what it is required to do and try to answer the questions to the best of their ability. He stated that the Board needs to remember that it is charged with protecting the safety and welfare of the citizens of Georgia.

Mr. Stone commented that this is something that is new for the Board. He stated that there are classes one can take regarding low THC. He continued by stating that there will be a limited number of suppliers that will be licensed. He added that the Board will need to move the best way it can and be able to adjust when necessary.

Mr. Lacefield inquired if there were any other changes to the draft that needed to be made in order to address GDNA's concerns. Deputy Director Karnbach commented that GDNA can refer to the minutes as long as it is documented what the Board's intent is.

Mr. Lacefield discussed the changes that the Committee recommended bringing to the full Board for consideration. He stated that the language in section (1)(d) of Rule 480-XX-.0G would be amended to state, "Low THC Pharmacy Dispensary licenses shall be non-transferrable." Mr. Joiner added that the draft would be amended to state that the pharmacist is required to check the label before dispensing.

Mr. Stone made a motion to refer the suggested recommendations to the full Board for consideration. Mr. Brinson seconded. Discussion was held by Mr. Azzolin who stated that the thought that comes to his mind is when a patient is admitted to a hospital, can the physician prescribe low THC upon admission and can the pharmacy in that hospital house the product and distribute it. He stated that he was just thinking about what that pharmacist and physician would do when a patient shows up and needs that medication. Mr. Brinson responded by stating that the Committee will have to come up with provisions for that, but it is dealing with the retail side today, but can discuss that matter with the full Board. There being no further discussion, the motion passed unanimously. The following are the recommendations to present to the full Board:

480-XX-.0A Definitions

(X) **"Low THC Product"** shall mean low THC oil delivered through an oil, tincture, transdermal patch, lotion, or capsule, except as prohibited by O.C.G.A. § 16-12-234, but not including any food products infused with low THC oil, including, but not limited to, cookies, candies, or edibles. (**O.C.G.A. § 16-12-200(15)**)

(X) **"Low THC Pharmacy Dispensary"** shall mean a retail pharmacy, previously licensed by the Georgia Board of Pharmacy, which has obtained a permit Low THC Pharmacy Dispensary license. (**Drafted**)

(X) **"Low THC oil"** shall mean an oil that contains an amount of cannabidiol and not more than 5 percent by weight of tetrahydrocannabinol, tetrahydrocannabinolic acid, or a combination of tetrahydrocannabinol and tetrahydrocannabinolic acid which does not contain plant material exhibiting the external morphological features of the plant of the genus Cannabis. Such term shall not mean products approved by the federal Food and Drug Administration under Section 505 of the federal Food, Drug, and Cosmetic Act. (**O.C.G.A. § 16-12-190**)

(X) **"Registered Patient"** shall mean

(X) **"Direct supervision"** shall mean that a pharmacist is physically present, providing care at the address listed on the pharmacy license, and is in the prescription department, consultation room, vaccination room, or areas where over-the-counter drugs, devices, or durable medical equipment are displayed. The supervising pharmacist is professionally responsible and accountable for all activities performed by authorized pharmacy personnel and is available to provide assistance and direction to authorized pharmacy personnel. This shall not require a pharmacist to maintain a direct line of sight to authorized pharmacy personnel. The supervising pharmacist shall provide a final check of prepared products and document final checks before any prescription drug is dispensed. (**480-10-.02(1)(a)**)

(X) **"Pharmacy care"** shall mean those services related to the interpretation, evaluation, or dispensing of prescription drug orders, the participation in drug and device selection, drug administration, and drug regimen reviews, and the provision of patient counseling related thereto. (**480-10-.02(1)(b)**)

(X) **"Preparation"** shall mean the functions of preparing a prescription to be dispensed, including product selection, data entry into a pharmacy dispensing system, and any other functions required to have the prescription ready to be verified, checked, and dispensed by a pharmacist or pharmacy intern working under the direct supervision of a pharmacist. (**480-10-.02(1)(c)**)

(X) **"Pharmacy"** shall mean all areas of a facility when the prescription department is not closed or locked separately from the facility or only the area of the prescription department in those facilities where the prescription department is locked and separated. (**480-10-.02(1)(d)**)

(X) **"Prescription Department"** shall mean an area set aside for the preparation and dispensing of prescription drugs and Low THC Products. In a facility offering other departments and types of merchandise not requiring a pharmacist to be open for business, this term shall apply only to the area in which prescriptions are prepared and dispensed. (**480-10-.02(1)(e)**)

(X) **"Vaccination room"** is an area adjacent to the pharmacy where vaccinations are administered. (**480-10-.02(1)(f)**)

(X) **"Consultation room"** is an area adjacent to the pharmacy where patient or customer consultations are done, and more in-depth pharmacy care may be provided. (**480-10-.02(1)(g)**)

(X) **"Board"** shall mean the Georgia Board of Pharmacy. (**480-10-.20(1)(a)**)

(X) **"Immediate notification"** shall mean written notification sent within twenty-four hours of the event. (**480-10-.20(1)(b)**)

(X) **"Significant adverse drug reaction"** shall mean any reaction which requires any medical treatment beyond a consultation between Pharmacist/patient, Pharmacist/Prescriber, patient/prescriber or Pharmacist/patient/Prescriber; and (**480-10-.20(1)(c)**)

(X) **"Written notification"** shall mean in writing and sent by statutory overnight delivery or by email. (**480-10-.20(1)(d)**)

(X) **"Predicate Retail License"** shall mean the presently active Retail Pharmacy license, previously issued by the Georgia Board of Pharmacy, to the applicant for, or licensee of a Low THC Pharmacy Dispensary license.

(X) **"Predicate Retail Licensee"** shall mean the entity licensed by the Georgia Board of Pharmacy as a Retail Pharmacy and attendant to whose licensure a Low THC Pharmacy Dispensary license has been applied for or obtained.

480-XX-.0B Low THC Products: Inspection, Retention of Records and Security

(1) Every licensed pharmacy, possessing or having possessed any Low THC Product, within a period of two years, and/or possessing any record related to the same, shall exercise diligent care in protecting such Low THC Products and/or records related to the same from loss or theft. (**480-10-.01(1)**)

(a) Records relative to Low THC Products required to be maintained in compliance with this rule shall be those records which would be required to be kept relative to a Dangerous Drug by O.C.G.A. T. Ch. 16-13. All records relative to Low THC Products shall be kept, secured, and safeguarded in the same manner as similar records relating to Dangerous Drugs. (**Drafted**)

(b) Every licensed Low THC Pharmacy Dispensary shall ensure that all Low THC Products are purchased from and/or returned to firms holding a current permit issued by the Georgia Access to Medical Cannabis Commission ("Commission"). This requirement can be met by a pharmacy maintaining a copy of such firms' current Commission permit. (**480-10-.01(1)(a)**)

(2) All Low THC Products shall be kept in the prescription department, accessible only to an authorized person, except where contained in a collection receptacle compliant with state and federal law and regulation. (**480-10-.01(2)**)

(3) The Georgia Drugs and Narcotics Agency ("GDNA") shall have the authority to conduct inspections of any place or premises used by any such licensed Low THC Pharmacy Dispensary in relation to such Low THC Products and/or any records pertaining to their acquisition, dispensing, disposal, or loss. (**480-10-.01(3)**)

(4) The GDNA shall have the authority to examine, copy, or remove all such records, and to examine, copy, remove, or inventory all such Low THC Products. (**480-10-.01(4)**)

(a) It shall be the responsibility of such person possessing such Low THC Products and/or records to make the same available for such inspection, copying, examination, or inventorying by said GDNA. (**480-10-.01(4)(a)**)

(b) At the conclusion of an inspection, the GDNA personnel examining said Low THC Products and/or records shall have the responsibility of providing to such Low THC Pharmacy Dispensary a copy of an inspection report on which any deficiencies or violations are listed along with any recommendations, if any, concerning the satisfactory storage, keeping, handling and security of Low THC Products. (**480-10-.01(4)(b)**)

(5) Any person possessing Low THC Products and/or records may request that such an inspection be made, and upon receipt of such written request, the GDNA Director shall make, or cause to be made, without reasonable delay, an inspection in compliance with said request. (**480-10-.01(5)**)

Rule 480-XX-.0C Prescription Department, Requirement, Supervision, Hours Closed

(1) The physical spatial bounds of a Low THC Pharmacy Dispensary shall be the same as and co-terminus with, the same such space occupied by the Predicate Retail Licensee, and the activities of the Low THC Pharmacy Dispensary shall be conducted therein. That area or areas designated as the "Prescription Department" pursuant to Rule 480-10-.02(2), for the Predicate Retail Licensee shall constitute the same such area for the Low THC Pharmacy Dispensary and the activities of the Low THC Pharmacy Dispensary may be conducted therein. (**Drafted**)

(2) The pharmacist in charge of the Low THC Pharmacy Dispensary shall be the same pharmacist who is designated pharmacist in charge for the Predicate Retail Licensee, and in operation of the Low THC Pharmacy Dispensary shall be subject to Rule 480-10-.02(3). (**Drafted**)

(3) A licensed pharmacist shall be present and on duty in a Low THC Pharmacy for the same time and in the same manner as required for operation of the Predicate Retail Licensee. (**Drafted**)

Rule 480-XX-.0D Location of Low THC Products

(1) All Low THC Products shall be stored within the prescription department of the Predicate Retail Licensee possessing such drugs or devices; and (**480-10-.03(1)**)
   (a) In complying with this Rule, all Low THC Products shall, at minimum, be stored and secured in the same manner required for dangerous drugs (legend drugs) by Board Rule 480-10-.03. (**Drafted**)

(2) All Low THC Products shall be kept from the public in a secure manner. (**480-10-.03(2)**)

Rule 480-XX-.0E Sufficient Space in Prescription Department

There shall be provided within the prescription department of each Low THC Pharmacy Dispensary sufficient shelf, drawer, counter or cabinet space for the neat and orderly storage of all Low THC Products, equipment, publications and other items kept therein. Low THC Products may be stored apart from or together with other dangerous drugs stored in the prescription department. (**480-10-.04**)

Rule 480-XX-.0F Refrigeration

There shall be provided within each prescription department adequate facilities for the proper storage of Low THC Products which require refrigeration, and such Low THC Products shall be stored therein in such manner as to preserve their therapeutic activity. (**480-10-.05**)

Rule 480-XX-.0G Licensure, Applications, and Display of License and Renewal Certificate

(1) Licensure and Applications
   (a) Every Low THC Pharmacy Dispensary must be licensed by the Board in accordance with the laws and regulations of this State. The term "Low THC Pharmacy Dispensary" shall have the meaning ascribed in Board Rule 480-XX-.0A. (**Drafted**)
   (b) All Low THC Pharmacy Dispensary licensees shall renew this license annually by June 30th with the Georgia State Board of Pharmacy; pharmacy dispensary licenses shall be issued only to those pharmacies who comply with this rule. (**480-10-.06(b), modified to accord with O.C.G.A. § 16-12-206(a)(1)**)
   (c) Low THC Pharmacy Dispensary licenses shall be issued only to those licensed retail pharmacies who meet the following requirements: (**480-10-.06(1)(c)**)
      1. Submission of an application with the following information: (**480-10-.06(1)(c)(1)**)
         i. The name, full business address, telephone number, and current Georgia Board of Pharmacy license number of the licensee; (**480-10-.06(1)(c)(1)(i)**)
         ii. All trade or business names used by the licensee; (**480-10-.06(1)(c)(1)(ii)**)
         iii. Address, telephone number, and the name of the Pharmacist in Charge; (**480-10-.06(1)(c)(1)(iii)**)
         iv. The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship); (**480-10-.06(1)(c)(1)(iv)**)
         v. The name(s) of the owner and/or operator of the licensee, including: (**480-10-.06(1)(c)(1)(v)**)
            (I) If a person, the name of the person; (**480-10-.06(1)(c)(1)(v)(I)**)
            (II) If a partnership, the name of the partnership and the name of each partner; (**480-10-.06(1)(c)(1)(v)(II)**)
            (III) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity; or (**480-10-.06(1)(c)(1)(v)(III)**)

(IV) If a corporation, the corporate name, the name and title of each corporate officer and director, the state of incorporation; and the name of the parent company, if any. (**480-10-.06(1)(c)(1)(v)(IV)**)

vii. Documentation of one of the following:

(I) Written certification from the applicant that the applicant's operation of a Low THC Pharmacy Dispensary at the proposed location would comply with the location restrictions imposed by O.C.G.A. § 16-12-215(a); or (**Drafted**)

(II) Certified copy of an Order from the local zoning authority permitting the applicant to operate a Low THC Pharmacy Dispensary in the proposed location, as provided by O.C.G.A. § 16-12-215(a). (**Drafted**)

2. Payment of an application fee. Application fees shall not be refundable. (**480-10-.06(1)(c)(2)**)

3. Filing a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license. (**480-10-.06(1)(c)(3)**)

(d) Low THC Pharmacy Dispensary licenses shall be nontransferrable. (**480-10-.06(1)(c) the second one**)

(e) Low THC Pharmacy Dispensary licenses are 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, of the same year, the license shall lapse and shall not be renewed except by application for a new license. (**480-10-.06(1)(d) modified to accord with O.C.G.A. 16-12-206(a)(1)**)

(f) Changes in any information in this rule shall be submitted to the Board prior to such change. (**480-10-.06(1)(e)**)

(g) The Board will consider the following factors in determining eligibility for licensure of applicants in charge of the facility and the applicant licensee who are applying for a Low THC Pharmacy Dispensary license: (**480-10-.06(1)(f)**)

1. Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances; (**480-10-.06(1)(f)(1)**)

2. Any felony convictions of the applicant under Federal, State, or local laws; (**480-10-.06(1)(f)(2)**)

3. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution; (**480-10-.06(1)(f)(3)**)

4. Suspension or revocation by Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant; (**480-10-.06(1)(f)(4)**)

5. Compliance with licensing requirements under previously granted licenses; (**480-10-.06(1)(f)(5)**)

6. Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained by the licensee pharmacy and by a Low THC Pharmacy Dispensary; (**480-10-.06(1)(f)(6)**)

7. The disciplinary history of the Predicate Retail Licensee, if any; and (**Drafted**)

8. Other factors or qualifications the Board considers relevant to and consistent with the public health and safety. (**480-10-.06(1)(f)(7)**)

(h) The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public. (**480-10-.06(1)(g)**)

(2) The Low THC Pharmacy Dispensary wall certificate issued by the Georgia State Board of Pharmacy (Board), along with the current renewal license of each full-time Pharmacist employed at the Low THC Pharmacy Dispensary, as well as any letter(s) from the Board which have granted a licensee any exception(s) and/or exemption(s) from this, or any other rule, shall be displayed in the same manner as that required by Rule 480-10-.06 for the Predicate Retail Licensee; (**480-10-.06(2 & 3)**)

(3) No pharmacist or intern/extern shall display his or her license in any Low THC Pharmacy Dispensary where he or she is not employed or engaged in the practice of pharmacy and dispensing of Low THC Products, and shall not knowingly permit any other person to use his or her license for the purpose of misleading anyone to believe that such person is the holder or recipient of said license or intern certificate. (**480-10-.06(4)**)

Rule 480-XX-.0H Sanitation

A Low THC Pharmacy Dispensary shall be operated in the same clean and sanitary manner as that required by Rule 480-10-.07 for the Predicate Retail Licensee. (**Drafted**)

Rule 480-XX-.0I Storage of Equipment

The required equipment of a Low THC Pharmacy Dispensary shall be cleaned and stored in the same manner as that required by Rule 480-10-.08 for the Predicate Retail Licensee. (**Drafted**)

Rule 480-XX-.0J Requirements for Dispensing Low THC Products

(1) Low THC Products shall only be dispensed by a Georgia Board of Pharmacy licensed Low THC Pharmacy Dispensary. (**O.C.G.A. §§ 16-12-206(a)(1) & 16-12-230(a)**)

(2) Low THC Pharmacy Dispensaries shall only dispense Low THC Products to Registered Patients and shall physically view and inspect the patient's identification and patient registry card, and shall verify the validity of the patient's registration, prior to dispensing Low THC Products. (**O.C.G.A. § 16-12-230(a) & Rule 351-6-.05(4)**)

(3) A pharmacist who dispenses Low THC Products shall seek and review information on a Registered Patient from the prescription drug monitoring program data base established pursuant to O.C.G.A. § 16-13-57 prior to dispensing Low THC Products to the Registered Patient. (**O.C.G.A. § 16-12-230(b)**)

(4) All Low THC Products dispensed shall be labeled by the Low THC Pharmacy Dispensary with the following information: (**351-6-.06(3)**)

- (a) Date the Low THC Product is dispensed to the patient; (**351-6-.06(3)(a)**)
- (b) Patient identification information: (**351-6-.06(3)(b)**)
  1. Patient's first and last name; (**351-6-.06(3)(b)(iii)**)
  2. Patient's date of birth; (**351-6-.06(3)(b)(iv)**)
  3. Patient's unique patient registry serial number; (**351-6-.06(3)(b)(ii)**)
  4. Patient's caregiver's first and last name and unique patient registry serial number, if applicable. (**351-6-.06(3)(b)(v)**)
- (c) Name, address, and license number of the Low THC Pharmacy Dispensary; (**351-6-.06(3)(b)(i)**)
- (d) Directions for use of the Low THC Product; and (**351-6-.06(3)(c)**)
- (e) Any cautionary statement or symbols required. (**351-6-.06(3)(d)**)

(5) Prior to dispensing any Low THC Product, a Georgia licensed pharmacist shall review the drug label to ensure compliance with Rule 480-XX-.0J(4) (**Drafted**).

Rule 480-XX-.0K Outdated, Deteriorated Drugs

The Pharmacist in Charge of each Low THC Pharmacy Dispensary shall cause examination of the stock of the prescription department of that Pharmacy, by persons qualified to do so, and shall cause to be removed from stock all out-dated and deteriorated Low THC Products, and such shall be done at regular intervals of not more than six months duration, and under no circumstances will any Low THC Pharmacy Dispensary or Pharmacist permit any Low THC Product to be dispensed which bears a date of expiration which has been reached, or any Low THC Product which is in a deteriorated condition. (**480-10-.11**)

Rule 480-XX-.0L Minimum Equipment for Prescription Departments

(1) No Low THC Pharmacy Dispensary licensed in accordance with O.C.G.A. T. 16, Ch. 12, shall engage in the practice of dispensing Low THC Products unless it shall possess the following items: (**480-10-.12(1)**)
   (a) Copies of and/or computer or electronic access to current reference materials appropriate to Low THC Pharmacy Dispensary practice. These reference materials shall be authoritative on at least the topics of drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution. (**480-10-.12(1)(a)**)
   (b) The telephone number of a poison control center. This number shall be conspicuously posted within the prescription department. (**480-10-.12(1)(b)**)
   (c) Current copies of and/or computer or electronic access to the following: (**480-10-.12(1)(c)**)
      1. Georgia Pharmacy Practice Act, O.C.G.A. T. 26, Ch. 4; (**480-10-.12(1)(c)(1)**)
      2. Access to Medical Cannabis, O.C.G.A. T. 16, Ch. 12, Art. 9; (**Drafted**)
      3. Georgia Controlled Substances Act & Dangerous Drug Act, O.C.G.A. T. 16, Ch. 13; and (**480-10-.12(1)(c)(2)**)
      4. Official Rules of the Georgia State Board of Pharmacy. (**480-10-.12(1)(c)(3)**)
   (d) Adequate supply of Low THC Products most commonly prescribed (ONLY to be on hand after a permit has been issued by the Board). (**O.C.G.A. § 16-12-206(b)(4) and 480-10-.12(1)(g)**)

(2) The pharmacist-in-charge of a Low THC Pharmacy Dispensary may submit to the Georgia State Board of Pharmacy a typed request for a variance to these provisions relating to minimum equipment requirements. Stated reasons for application for variances must be included in submitted request. A variance may be granted by the Board only when, in the judgment of the Board, there are sound reasons for doing so which relate to the necessary or efficient delivery of health care. (**480-10-.12(2)**)
   (a) Any variance granted by the Board must be in writing. (**480-10-.12(2)(a)**)

Rule 480-XX-.0M Destruction of Low THC Products

(1) Low THC Products which are outdated or expired must be disposed of by return to the originating Georgia Access to Medical Cannabis Commission licensed producer. (**Rule 351-6-.09(2)(e)**)

Rule 480-XX-.0N Security System Approval

As set forth by O.C.G.A. § 16-12-206(b)(9), the Board may provide in its rules and regulations the manner in which the prescription department of a Low THC Pharmacy Dispensary may be secured. This requirement will be met in in the same manner described in Rule 480-10-.16 for the Predicate Retail Licensee.

Rule 480-XX-.0O Required Notifications to the Board

(1) A Low THC Pharmacy Dispensary shall be required to provide immediate notification to the Board of any event the occurrence of which the Predicate Retail Licensee would be required to immediately notify the Board pursuant to Rule 480-10-.20(2).

Rule 480-XX-.0P Purchase of Low THC Products by a Low THC Pharmacy Dispensary
All Low THC Pharmacy Dispensaries are required to purchase or receive Low THC Products from a firm licensed by the Georgia Access to Medical Cannabis Commission. (**480-10-.21, modified**)

There being no further business to come before the Committee, the meeting was adjourned at 8:40 a.m.

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