NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,

RULE 480-52-.02 LOW THC PRODUCTS: INSPECTION, RETENTION OF RECORDS AND SECURITY, AND NOTICE OF PUBLIC HEARING

TO ALL INTERESTED PERSONS AND PARTIES:

Notice is hereby given that pursuant to the authority set forth below, the Georgia State Board of Pharmacy (hereinafter "Board") proposes adoption of new Georgia Board of Pharmacy Rules, Rule 480-52-.02 LOW THC PRODUCTS: INSPECTION, RETENTION OF RECORDS AND SECURITY (hereinafter "proposed amendments").

This notice, together with an exact copy of the proposed amendments and a synopsis of the proposed amendments, is being forwarded to all persons who have requested, in writing, that they be placed on an interested parties list. A copy of this notice, an exact copy of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments may be reviewed during normal business hours of 8:00 a.m. to 5:00 p.m. Monday through Friday, except official State holidays, at the Department of Community Health at 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. These documents will also be available for review on the Georgia State Board of Pharmacy's web page at www.gbp.georgia.gov.

A public hearing is scheduled to begin at 9:00 AM on June 14, 2023 at University of Georgia College of Pharmacy, 250 West Green Street, Athens, Georgia 30602 to provide the public an opportunity to comment upon and provide input into the proposed amendments. At the public hearing, anyone may present data, make a statement, comment or offer a viewpoint or argument whether orally or in writing. Lengthy statements or statements of a considerable technical or economic nature, as well as previously recorded messages, must be submitted for the official record. Oral statements should be concise and will be limited to 5 minutes per person. Additional comments should be presented in writing. Written comments are welcome. To ensure their consideration, written comments must be received prior to June 7, 2023. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. You may email your comments to elacefield@dch.ga.gov.

The proposed amendments will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:00 AM on June 14, 2023 at University of Georgia College of Pharmacy, 250 West Green Street, Athens, Georgia 30602. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed amendments pursuant to authority contained in O.C.G.A. §§ 16-12-206, 26-4-28, and 26-4-110.

At its meeting on March 8, 2023, the Board voted that the formulation and adoption of these rule amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed amendments cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22.

Also, at its meeting on March 8, 2023, the Board voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A. § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of this chapter will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

For further information, contact the Board office at 404-651-8000.

This notice is given in compliance with O.C.G.A. §50-13-4.

Eric R. Lacefield

Executive Director

Georgia Board of Pharmacy

SYNOPSIS OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-52-.02 LOW THC PRODUCTS: INSPECTION, RETENTION OF RECORDS AND SECURITY

Purpose: To carry out the directive of the General Assembly in O.C.G.A. § 16-12-

206, directing the Georgia State Board of Pharmacy to develop a licensure scheme and guidelines for the appropriate dispensing of low THC oil to

qualified patients.

Main Features: Specification of appropriate storage and security for Low THC Products

and records attendant thereto, and GDNA inspection.

TEXT OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-52-.02 LOW THC PRODUCTS: INSPECTION, RETENTION OF RECORDS AND SECURITY

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

Text of the proposed rule is attached hereto.

Rule 480-52-.02 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.
 - (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.
 - (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.
- (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.
- (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.
- (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.
 - (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.
 - (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
- (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.